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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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Foreword

This document (prEN 15593:2006) has been prepared by Technical Committee CEN/TC 261 “Packaging”, the secretariat of which is held by AFNOR.

This document is currently submitted to the CEN Enquiry.

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 along the packaging chain.

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

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 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 according to ISO 22000.

This European Standard does not purport to address the compulsory conformance 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 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 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 ISO 9001.

NOTE 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.

ISO 9000, *Quality management systems – Fundamentals and vocabulary*

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 9000 and ISO 22000 and the following apply.

3.1

contaminant

agent responsible for contamination. It can be classed as chemical, biological (including microbiological) or physical in nature.

- 3.2
contamination**
action of making impure or hazardous
- 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 wholesomeness, quality and safety of a product that might otherwise become hazardous or harmful
- 3.5
incident**
event that may potentially compromise the wholesomeness, quality or safety 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. 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 immediate return of all 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 or harm
- 3.12
specification**
explicit or detailed description of a material, product or service including hygiene aspects

4 Hygiene management system

4.1 Management responsibility

4.1.1 Top management of the organization shall define its hygiene policy, shall make public its commitment to develop and implement a hygiene management system, 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 European Standard.

4.1.2 Top management shall appoint a qualified person responsible for implementing and maintaining the hygiene management system.

4.1.3 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.

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

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

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

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

4.1.8 The organization shall have a comprehensive plan for cleaning and maintenance.

4.1.9 The requirements of this European Standard shall also apply to contractors and temporary personnel.

4.2 Control of documents

4.2.1 The organization shall have procedures for control of 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 initiated 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 would 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 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 for identification and tracing of all products. This shall cover every stage from receipt of incoming raw materials to delivery of product.

4.5.2 The effectiveness of the traceability system shall be demonstrated either by an audit of 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 for planning, conducting, and reporting results of audits and maintaining records shall be specified in a procedure.

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

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

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

4.7 Complaints 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. 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.

4.9 Outsourcing

4.9.1 The organization shall extend its hygiene management system to relevant outsourced processes. There shall be a written contract.

4.9.2 Outsourcing (sub-contracting) shall be, audited, evaluated, approved and monitored by the organization. Records shall be maintained.

4.10 Monitoring and measurement of product

4.10.1 The organization shall have in place procedures to verify that the product meets specified requirements.

4.10.2 Records of verification shall be maintained.

4.11 Human resources

4.11.1 The organization shall provide training in hygiene requirements for its personnel, and temporary and external staff to a level appropriate to the operations. The effectiveness of the training shall be monitored. Refresher training shall be organised and documented.

4.11.2 The organization shall have documented guidelines for injuries and diseases.

4.11.3 Training and its effectiveness shall be evaluated and recorded.

5 Hazard analysis and risk assessment

5.1 General

5.1.1 The organization shall apply hazard analysis and risk assessment to every stage from procurement to delivery of the product.

5.1.2 All persons carrying out hazard analysis and risk assessment shall be trained and have experience for their tasks.

5.1.3 Hazard analysis and risk assessment shall be based on the intended use of the product.

5.1.4 Hazard analysis and risk assessment shall comprise the following steps:

5.1.4.1 Establish a plan of process flows.

5.1.4.2 Identify and record all hazards for all production processes.

5.1.4.3 Evaluate the risk level of each hazard taking into consideration the likelihood of the occurrence and the severity of the outcome.

5.1.4.4 Where the risk may reach a level considered as unacceptable, the process shall be improved or the process point shall be monitored.

5.1.4.5 Define appropriate controls and measures to manage the identified hazards in written procedures.

5.1.4.6 Define which sub-clauses of clauses 6 to 8 of this European Standard cannot be applied to the organization. Use the hazard analysis and risk assessment process and document and justify their exclusion.

5.2 Procedures

5.2.1 Control measures and procedures defined in the hazard analysis and the risk assessment process shall be regularly reviewed, verified and validated.

5.2.2 A review of the hazard analysis and risk assessment process shall take place at least once a year or in case of any process changes.

6 Sources of contamination

6.1 Physical contaminants (foreign bodies)

6.1.1 Only essential non-production glass and brittle material shall be used in the production and storage areas. A written and documented control policy shall be in place for all non-production glass and brittle materials that are in use.

6.1.2 Light sources shall be protected by a shatter-proof cover or by some other effective means.

6.1.3 In production and storage areas, surfaces intended to contact the product shall be free from splinters and any other source of contamination. They should be suitable for easy and effective cleaning.

6.1.4 In production and storage areas, the use of loose fastenings (e.g. drawing pins and staples) shall not be allowed.

6.1.5 A formal procedure for the use of “sharps” shall be in place. No sharp objects or loose tools shall be left in any place and on surfaces where product contamination can occur. The use of snap-off blade knives shall be forbidden.

6.1.6 Whenever an incident occurs, the process of cleaning up or the maintenance shall be carried out under the control of a ‘designated’ person. Any contaminated product that cannot be effectively cleaned shall be discarded.

6.1.7 The non intended use of packaging materials and products shall not be allowed in production and storage areas.

6.1.8 Buildings, facilities and equipment shall be cleaned to remove dust, cobwebs, flakes and fragments (see also clause 6.5).

6.2 Chemical contaminants

6.2.1 Chemicals including cleaning materials and lubricants shall be controlled in order to prevent product contamination.

6.2.2 Cleaning agents shall be suitably identified and stored in designated areas. Chemicals that might cause organoleptic contamination shall not be used.

6.2.3 Lubricant intended to come in contact with direct food contact products shall be “food grade” type.

6.2.4 Uncontrolled leaks or the loss of lubricant shall be avoided.

6.2.5 Compressed air coming in contact with the product shall be suitably filtered.

6.3 Biological contaminants

6.3.1 Control measures shall be in place in the production and storage areas in order to prevent contamination from rodents, flying and crawling insects, birds and any other pests.

6.3.2 Pests shall be prevented from entering the premises.

6.3.3 All external doors shall be kept in good condition and closed when not in use.

6.3.4 Incoming and outgoing products, materials and vehicles shall be controlled.

6.3.5 A detailed pest control programme shall be in place.

6.3.6 A competent contracted company or an internal expert shall carry out pest control.

6.3.7 Flying insect control devices, baits and pesticides shall be used in such a way that they will not contaminate the product.

6.3.8 In the event of infestation of any kind of pest, immediate remedial action shall be undertaken.

6.3.9 Where appropriate, and as required for specific applications, microbiological checks may be conducted on equipment, surfaces and products.

6.4 Storage and distribution

6.4.1 Raw materials, packaging materials and products shall be protected from contamination (including uncharacteristic odour) during transport, storage and delivery.

6.4.2 Raw material, unfinished products and products transferred between premises shall be suitably protected.

6.4.3 Pallets shall be inspected before use. They shall be suitable for use with the intended products and clean, free from foreign bodies, uncharacteristic odours and pests. Pallets shall not contaminate raw materials, unfinished and finished products.

6.4.4 Transport vehicles shall be checked before loading and unloading. They shall be kept clean and free from foreign bodies, uncharacteristic odour and pests.

6.4.5 All the warehouses shall be controlled to prevent any possible cross-contamination.

6.4.6 Subcontracted warehouse facilities shall guarantee the same hygiene standard as the organization's own facilities.

6.5 Cleaning

6.5.1 Cleaning shall be carried out in accordance with scheduled plans.

6.5.2 Cleaning operations and auxiliary activities shall be carried out regularly in an effective way. They shall conform to the hygiene requirements applied in the specific area.

6.5.3 The equipment used for the cleaning operations shall be removed immediately after use and placed in a suitable storage area.

6.5.4 Cleaning of equipment shall not contaminate any part intended to come into contact with the product or its packaging.

6.5.5 The work stations in the production premises shall be kept tidy and checked regularly.

6.5.6 If cleaning activities are outsourced, the appointed company shall be competent and maintain documented procedures.

6.6 Maintenance

6.6.1 Maintenance programmes shall be systematically applied to minimize contamination of equipment.

6.6.2 A procedure shall be in place to demonstrate that any potential contaminant has been removed from machinery and equipment after maintenance work.

6.6.3 Maintenance personnel shall follow the prescribed hygiene procedures including wearing suitable clothing, hair covering, where appropriate, and observe all hygiene practices relating to their activities.

6.7 Scrap and waste handling

6.7.1 Containers for waste and for scrap shall be emptied at appropriate frequencies and kept in an adequate condition of cleanliness.

6.7.2 Production scrap intended for recovery and/or reuse shall be segregated and protected against contamination.

6.7.3 Waste shall be kept away from production and storage areas. Bins and containers for non-production waste shall be appropriately identified, emptied regularly and if necessary, provided with lids.

7 Factory requirements

7.1 External areas

7.1.1 All external areas belonging to the company and close to the premises shall be tidy and in good condition. Potential sources of contamination shall be minimised.

7.1.2 A clean and unobstructed area should be provided along the external walls of buildings used for production and storage.

7.1.3 External pathways should be suitably maintained to avoid contamination to raw materials, unfinished and finished products during transportation.

7.1.4 All the external openings for auxiliary devices and equipment shall be suitably protected.

7.1.5 When stored outside, all raw materials and products shall be protected from contamination.

7.1.6 External drainage systems shall be constructed to prevent the access of pests.

7.1.7 The organization shall have in place measures to prevent the access of non-authorized persons.

7.2 Buildings

7.2.1 Construction and layout shall permit adequate maintenance and cleaning.

7.2.2 In production and storage areas an appropriate gap along the walls shall be provided.

7.2.3 Protection against pest access shall be effective.

7.2.4 The organization shall provide appropriate and cleanable bins and containers for regular disposal of waste.

7.2.5 Surfaces of walls, partitions and floors shall permit appropriate cleaning.

7.2.6 To minimize the accumulation of dust and to prevent the possibility of condensation contaminating the product, ceilings and overhead fixtures should allow access for cleaning.

7.2.7 Windows, sills and doors shall be maintained and cleanable. They shall be properly fitted.

7.2.8 Other constructions such as stairs, steps, platforms, etc. shall be maintained and cleanable.

7.2.9 Adequate lighting shall be provided in all areas.

7.2.10 Where necessary, separate storage areas shall be available to prevent contamination of incoming materials, products, cleaning agents etc.

7.2.11 Windows in production and storage areas intended to be opened shall be equipped with screens

7.3 Equipment

7.3.1 All parts of equipment coming into contact with the products shall be maintained and cleaned.

7.3.2 Equipment shall be installed in order to allow adequate cleaning of the surrounding area.

- 7.3.3 All equipment shall be made of a material suitable for the intended use.
- 7.3.4 Fixtures, piping and ducts shall not cause condensation or leakage to fall on to the product.
- 7.3.5 “Temporary” engineering and modifications should be avoided and shall not become permanent.

7.4 Facilities

- 7.4.1 Facilities should be maintainable.
- 7.4.2 There shall be no possibility of cross-contamination or connection between potable and non-potable water supplies.
- 7.4.3 Designated areas shall be provided for storing cleaning equipment, utensils and work tools.
- 7.4.4 Adequate facilities for dressing, hand washing and hygienic drying shall be available.
- 7.4.5 Hand washing shall be encouraged by the provision of adequate advisory signs.
- 7.4.6 Sufficient toilet facilities shall be provided. Toilets shall not open directly into production and storage areas and shall be appropriately lit and ventilated. Toilets shall be equipped with hand washing facilities and should provide non-scented liquid soap and single-use towels. Waste bins shall be provided and should be lidded.
- 7.4.7 Hand washing or disinfecting facilities should be close to social areas.
- 7.4.8 Designated areas shall be provided for eating and drinking other than water. If smoking is allowed, a designated area for smoking isolated from production and storage areas shall be provided.
- 7.4.9 A suitable place shall be provided to store all food and drinks. Lidded bins shall be provided for any waste.
- 7.4.10 Facilities shall be provided for the storage of work clothes and personal belongings close to the production or storage areas.
- 7.4.11 Adequate means of natural or mechanical ventilation shall be provided in all production and storage areas to prevent excessive build up of condensation, odours and dust.
- 7.4.12 Mechanical ventilation systems should be designed and constructed so that they can be cleaned.
- 7.4.13 Containers for raw materials and auxiliary products should not be used for other purposes. Containers used for other purposes shall be marked.

8 Personnel

8.1 Access points and specific routes

- 8.1.1 The organization shall specify and control all entrances to the site and the access and routes to the production and storage areas.
- 8.1.2 The entry of unauthorized persons to the premises shall be prevented.
- 8.1.3 All personnel both internal and external including contractors likely to enter production and storage areas shall wash or disinfect their hands before working and whenever necessary.

8.2 Work clothes

8.2.1 The organization shall specify appropriate work clothes to be worn in the production and storage areas. They shall be available in sufficient number and shall not be worn outside the site.

8.2.2 Work clothes shall be suitably designed to prevent loose items contaminating the product.

8.2.3 Work clothes shall be worn in production and storage areas. Where appropriate, adequate covering of hair (including protection for beard and moustaches) shall be in place.

8.2.4 Work clothes shall be regularly cleaned or replaced. Suitable guidance shall be provided and monitored when a self-care system is in place.

8.3 Personal belongings

8.3.1 The organization shall have a policy to control personal belongings i.e. to prevent forbidden items being taken into production and storage areas.

8.3.2 Jewellery, wristwatches and visible piercings shall not be worn unless they are appropriately controlled to minimise contamination. The organization shall clearly define the type of jewellery allowed to be worn.

8.3.3 False nails shall be prohibited. Nail varnish should not be used.

8.4 Toilets and lockers

8.4.1 All sanitary facilities in the production and storage areas shall be kept clean.

8.4.2 After using toilets, hands shall be washed and dried. A non-scented liquid soap should be used. Any kind of waste, including paper towels and disposables, shall be put in the waste bin.

8.4.3 Clean and dirty clothing shall be segregated. Works clothes and personal clothing should not be stored in the same locker compartment. Other suitable storage facilities may also be used.

8.4.4 Lockers shall be kept clean. Nothing shall be put on top of lockers or on the floor.

8.4.5 When entering from the outside, locker rooms should be accessible without crossing production and storage areas.

8.5 Eating, drinking and use of tobacco and medicines

8.5.1 All food, drinks and medicines shall be stored in designated areas. Procedures shall be in place to control the use of medicines to minimise contamination.

8.5.2 Eating (including consuming confectionery, chewing gum or chewing tobacco), drinking other than water and smoking shall only be allowed in designated areas.

8.5.3 All such areas shall be kept clean. Appropriate and cleanable lidded bins and containers shall be used for disposal of waste.

8.5.4 Designated smoking areas shall be isolated from production and storage areas. Smoke shall not contaminate the product. Adequate containers for smokers' waste shall be provided.

8.5.5 Personnel shall wash or disinfect hands after eating, drinking (with the exception of drinking water) and smoking.

8.6 Injuries and diseases

8.6.1 Personnel shall follow documented guidelines for injuries and diseases.

8.6.2 All injuries including minor cuts shall be treated immediately and in an appropriate manner.

8.6.3 Dressings shall be changed at appropriate intervals. Self-adhesive plasters shall not contaminate the product. They shall be differentiated from the product (e.g. by colour).

8.7 Visitors

8.7.1 The organization shall specify hygiene rules for visitors. Where appropriate, protective clothing shall be worn.

8.7.2 Access to and pathways in production and storage areas shall be separated from materials and products to ensure that visitors cannot contaminate products.

8.7.3 Authorized personnel shall inform visitors about hygiene rules in the premises and accompany them in production and storage areas.

Bibliography

ISO 9001, *Quality management systems – Requirements*

EN 14182, *Packaging – Terminology – Basic terms and definitions*

EN ISO 14159, *Safety of machinery – Hygiene requirements for the design of machinery*