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Varnost pakirnih naprav - 2. del: Pakirni stroji za vlaganje v pripravljeno predoblikovano embalažo

Safety of packaging machines - Part 2: Packaging machines for pre-formed rigid containers

Sicherheit von Verpackungsmaschinen - Teil 2: Verpackungsmaschinen für vorgefertigte formstabile Packmittel

Sécurité des machines d'emballage - Partie 2: Machines d'emballage pour contenants rigides préformés

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Pakirni stroji

Packaging machinery

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Safety of packaging machines - Part 2: Packaging machines for pre-formed rigid containers

Sécurité des machines d'emballage - Partie 2: Machines
d'emballage pour contenants rigides préformés

Sicherheit von Verpackungsmaschinen - Teil 2:
Verpackungsmaschinen für vorgefertigte formstabile
Packmittel

This draft European Standard is submitted to CEN members for enquiry. It has been drawn up by the Technical Committee CEN/TC 146.

If this draft becomes a European Standard, CEN members are bound to comply with the CEN/CENELEC Internal Regulations which stipulate the conditions for giving this European Standard the status of a national standard without any alteration.

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EUROPEAN COMMITTEE FOR STANDARDIZATION
COMITÉ EUROPÉEN DE NORMALISATION
EUROPÄISCHES KOMITEE FÜR NORMUNG

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prEN 415-2:2022 (E)**European foreword**

This document (prEN 415-2:2022) has been prepared by Technical Committee CEN/TC 146 “Safety of packaging machines”, the secretariat of which is held by UNI.

This document is currently submitted to the CEN Enquiry.

This document will supersede EN 415-2:1999.

This document has been prepared under a Standardization Request given to CEN by the European Commission and the European Free Trade Association and supports essential requirements of EU Directive(s) / Regulation(s).

For relationship with EU Directive(s) / Regulation(s), see informative Annex ZA, which is an integral part of this document.

The following significant changes have been made:

- Packing and unpacking machines have been removed from the Scope;
- Description of hazards has been extended and the order of their presentation is hazard-based;
- Safety requirements have been rewritten so they are in line with EN 415-10:2014;
- Noise test code has been rewritten to be in line with EN 415-9:2009;
- Normative references have been changed to reflect the many changes that have been made to B1 and B2 standards.

EN 415, *Safety of packaging machines* consists of the following parts:

- *Part 1: Terminology and classification of packaging machines and associated equipment;*
- *Part 2: Pre-formed rigid container packaging machines;*
- *Part 4: Palletizers and depalletizers;*
- *Part 5: Wrapping machines;*
- *Part 6: Pallet wrapping machines;*
- *Part 7: Group and secondary packaging machines¹;*
- *Part 8: Strapping machines;*
- *Part 9: Noise measurement methods for packaging machines, packaging lines and auxiliary equipment, grade of accuracy 2 and 3;*
- *Part 10: General requirements.*

¹ EN 415-7:2006+A1:2008 is currently being revised with a new title: “Cartooning and Case-packing machines”.

Introduction

This document is of relevance, in particular, for the following stakeholder groups representing the market players with regard to machinery safety:

- machine manufacturers (small, medium and large enterprises);
- health and safety bodies (regulators, accident prevention organizations, market surveillance, etc.).

Others can be affected by the level of machinery safety achieved with the means of the document by the abovementioned stakeholder groups:

- machine users/employers (small, medium and large enterprises);
- machine users/employees (e.g. trade unions, organizations for people with special needs);
- service providers, e.g. for maintenance (small, medium and large enterprises).

The above-mentioned stakeholder groups have been given the possibility to participate at the drafting process of this document.

This document is a type-C standard as stated in EN ISO 12100:2010.

The machinery concerned and the extent to which hazards, hazardous situations or hazardous events are covered are indicated in the Scope of this document.

When requirements of this type-C standard are different from those which are stated in type-A or type-B standards, the requirements of this type-C standard take precedence over the requirements of the other standards for machines that have been designed and built according to the requirements of this type-C standard.

The full set of requirements for machines in the Scope of this document is composed by those given in this document in conjunction with the relevant requirements of EN 415-10:2014.

The Annex ZA of this document will not list the EHSR which are not relevant for these kinds of machines or are not covered for any other reason.

When an assembly of machinery or partly completed machinery (multi-functional machine) contains a function which is covered by another standard the risk assessment and measures for that function should comply with the relevant standard. In addition, the risks presented by the combination of functions or mechanisms – which is not covered by one of the standards - should be considered.

NOTE EN ISO 11161:2007 provides guidance for combinations of machines.

prEN 415-2:2022 (E)**1 Scope**

This document applies to the following machines and to machines which incorporate more than one function as listed below. The document also applies to partly completed machinery as far as conformity is claimed for certain essential health and safety requirements.

This document deals with the following machines handling rigid containers including:

- unscrambling machines;
- cap removing machines;
- cleaning machines;
- sanitizing machines;
- filling machines;
- capping, closing and sealing machines;
- closure securing machines;
- inspection machines;
- labelling machines;
- decorating machines;
- heating- and cooling machines for packed product, working at atmospheric pressure;
- sterilizing machines (others than heat treatment)

with one or more of the following functions: cleaning, sanitizing, pasteurizing, filling, labelling, closing, sealing or inspecting and handling pre-formed rigid containers including their closures.

This document also deals with equipment when it is part of a machine listed above:

- conveyors;
- vacuum or magnetic transfer conveyors;
- dispose or eject devices (pushers);
- keg stopping devices;
- keg lift and inverting machines;
- extraction or ventilation system or blowers;
- hoppers;
- rotary mechanisms;
- coding and marking equipment incorporated in a packaging machine;
- hot foil coders;

- laser coders;
- ink jet coders;
- emboss coders.

The individual machines are described in 3.2.

This document deals with safety requirements and their verification for machine design, construction and information applicable to installation, commissioning, operation, adjustment, maintenance, cleaning, dismantling of packaging machines for pre-formed rigid containers.

The extent to which hazards, hazardous situations and events are covered is indicated in Annex B.

NOTE The hazards on a specific machine can vary depending on its working principle; the type, size and mass of the product; the packaging material; auxiliary equipment attached to the machine and the environment in which the machine is used. If the machine presents hazards that are not covered by this document or EN 415-10, the manufacturer can assess these hazards and take measures by using the principles detailed in EN ISO 12100:2010.

Exclusions

This document is not applicable to the following machines:

- machines that were manufactured before the date of publication of this document by CEN;
- machines for cups or trays or tubs made of a foil of plastic, aluminium or paper, which are the subject of EN 415-3;
- aerosol filling and sealing machines;
- filling machines for gas;
- autoclaves; <https://standards.iteh.ai/catalog/standards/sist/cedc97ca-f210-4177-b570-11e43ac64887/osist-pren-415-2-2022>
- conveyors which link packaging machines but are not integrated in packaging machines or part of packaging machines;
- blow moulding machines;

NOTE See EN 422:2009:

- sleeve label removing machines.

This document does not consider the following hazards:

- the use of packaging machines in potentially explosive atmospheres not generated by the machine itself;
- hazards associated with packing explosives;
- hazards arising from ancillary equipment, which is not part of the machine, e.g. equipment for evacuating gases, for cooling or refrigeration, for the supply of steam, energy or product.

prEN 415-2:2022 (E)**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.

EN 415-1:2014, *Safety of packaging machines - Part 1: Terminology and classification of packaging machines and associated equipment*

EN 415-9:2009, *Safety of packaging machines - Part 9: Noise measurement methods for packaging machines, packaging lines and associated equipment, grade of accuracy 2 and 3*

EN 415-10:2014, *Safety of packaging machines - Part 10: General requirements*

EN 1005-2:2003+A1:2008, *Safety of machinery - Human physical performance - Part 2: Manual handling of machinery and component parts of machinery*

EN 1672-2:2020, *Food processing machinery - Basic concepts - Part 2: Hygiene and cleanability requirements*

EN 12198-1:2000+A1:2008, *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery - Part 1: General principles*

EN 60204-1:2018, *Safety of machinery - Electrical equipment of machines - Part 1: General requirements*

EN 60825-1:2014, *Safety of laser products - Part 1: Equipment classification and requirements*

EN 60825-4:2006², *Safety of laser products - Part 4: Laser guards*

EN 61310-3:2008, *Safety of machinery - Indication, marking and actuation - Part 3: Requirements for the location and operation of actuators*

EN ISO 4413:2010, *Hydraulic fluid power - General rules and safety requirements for systems and their components (ISO 4413:2010)*

EN ISO 4414:2010, *Pneumatic fluid power - General rules and safety requirements for systems and their components (ISO 4414:2010)*

EN ISO 7010:2020, *Graphical symbols - Safety colours and safety signs - Registered safety signs (ISO 7010:2019, Corrected version 2020-06)*

EN ISO 11204:2010, *Acoustics - Noise emitted by machinery and equipment - Determination of emission sound pressure levels at a work station and at other specified positions applying accurate environmental corrections (ISO 11204:2010)*

EN ISO 11553-1:2020, *Safety of machinery - Laser processing machines - Part 1: Laser safety requirements*

EN ISO 11688-1:2009, *Acoustics - Recommended practice for the design of low-noise machinery and equipment - Part 1: Planning (ISO/TR 11688-1:1995)*

² As impacted by EN 60825-4:2006/A1:2008 and EN 60825-4:2006/A2:2011.

EN ISO 11688-2:2000, *Acoustics - Recommended practice for the design of low-noise machinery and equipment - Part 2: Introduction to the physics of low-noise design (ISO/TR 11688-2:1998)*

EN ISO 12001:2009, *Acoustics - Noise emitted by machinery and equipment - Rules for the drafting and presentation of a noise test code (ISO 12001:1996)*

EN ISO 12100:2010, *Safety of machinery - General principles for design - Risk assessment and risk reduction (ISO 12100:2010)*

EN ISO 13732-1:2008, *Ergonomic of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 1: Hot surfaces (ISO 13732-1:2006)*

EN ISO 13732-3:2008, *Ergonomic of the thermal environment - Methods for the assessment of human responses to contact with surfaces - Part 3: Cold surfaces (ISO 13732-3:2005)*

EN ISO 13849-1:2015, *Safety of machinery – Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2015)*

EN ISO 13851:2019, *Safety of machinery - Two-hand control devices - Principles for design and selection (ISO 13851:2019)*

EN ISO 13854:2019, *Safety of machinery - Minimum gaps to avoid crushing of parts of the human body (ISO 13854:2017)*

EN ISO 13855:2010, *Safety of machinery - Positioning of safeguards with respect to the approach speeds of parts of the human body (ISO 13855:2010)*

EN ISO 14119:2013, *Safety of machinery - Interlocking devices associated with guards - Principles for design and selection (ISO 14119:2013)*

EN ISO 14120:2015, *Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards (ISO 14120:2015)*

EN ISO 14122-2:2016, *Safety of machinery - Permanent means of access to machinery - Part 2: Working platforms and walkways (ISO 14122-2:2016)*

EN ISO 14122-3:2016, *Safety of machinery - Permanent means of access to machinery - Part 3: Stairs, stepladders and guard-rails (ISO 14122-3:2016)*

EN ISO 20607:2019, *Safety of machinery - Instruction handbook - General drafting principles (ISO 20607:2019)*

ISO/TS 15066:2016, *Robots and robotic devices - Collaborative robots*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN 415-1:2014, EN 415-10:2014, EN ISO 12100:2010 and EN ISO 12001:2009 and the following apply.

Where definitions of this document differ from those in the standards listed above the definitions of this document have precedence over the definitions of those listed in the standards above for purposes of this document.

ISO and IEC maintain terminological databases for use in standardization at the following addresses:

— IEC Electropedia: available at <https://www.electropedia.org/>

— ISO Online browsing platform: available at <https://www.iso.org/obp>

prEN 415-2:2022 (E)**3.1 Definitions of terms****3.1.1****pre-formed rigid container**

rigid container that had been formed to its final shape before it is handled by the packaging machine

Note 1 to entry: Examples of preformed rigid containers are: bottles, cans, jars, pots, ampoules, vials or kegs, made of e.g. glass, metal, plastics, fibreboard, wood, ceramic material or composite materials

3.1.2**carousel**

rotating machine element which locates and transports containers through one or more processes in a packaging machine

3.1.3**counter pressure filling**

container filling where the container is presented to a filling nozzle and first filled with gas (usually carbon dioxide or nitrogen) under pressure, and the gas is then displaced by the product being filled

3.1.4**keg**

rigid container typically with a capacity between 5 l and 60 l, equipped with a fitting through which it can be filled, cleaned and emptied

3.1.5**cleaning**

removal of soils

Note 1 to entry: See EN 1672-2:2020.

3.1.6**soil**

any matter which can make food unsafe; including but not limited to product residues, micro-organisms, residual detergent, chemicals or disinfecting agents, except substances migrating (or released metallic ions) from food contact materials into the food

Note 1 to entry: See EN 1672-2:2020.

3.1.7**sanitizing**

physical or chemical germ reduction procedure to reduce germs on product, containers, closures or other packaging means to specified levels

Note 1 to entry: This germ reduction typically is performed with:

- liquid agents, e.g. peracetic acid or
- gaseous agents, e.g. H₂O₂ or
- radiation, e.g. ultraviolet rays or
- heat or
- a combination of some of these methods

Note 2 to entry: Examples are:

- immersion bath in the sterilizing agent with drying by means of germ-reduced hot air and/or UV light.
- dry germ reduction procedure and dilution of the sterilizing agent with germ-reduced water.

Note 3 to entry: These germ reduction procedures can be used for:

- packaging materials (bottles, cans, kegs, containers, closures).
- machine surfaces in the food industry, splash area.
- conveyor area of germ-reduced packaging.

3.1.7.1 disinfection

sanitizing process for inactivation of all pathogenic and product-damaging microbes to a level that complies with the respective hygiene requirements

3.1.7.2 sterilization

sanitizing process for destruction of microorganisms, including bacterial spores present in products or on the surfaces of materials and products

Note 1 to entry: In difference to disinfection, the target of the sterilization process is killing / deactivation of all microorganisms and spores.

3.1.7.3 pasteurizing

sanitizing process of heat treatment of packaged product to reduce the quantity of product-damaging microbes to an acceptable limit, in order to obtain a microbiological stable product within the chosen minimum shelf life <https://standards.iteh.ai/catalog/standards/sist/cedc97ca-f210-4177-b570-11e43ac64887/osist-pren-415-2-2022>

3.1.8 aseptic filling

filling of a germ reduced product in a germ reduced package with the aim of avoiding recontamination of the product

3.1.9 star wheel

star shaped component with pockets fitting to the shape of containers for spacing them whilst they are transported in a circular arc

3.1.10 air conveyor

machine or functional unit that conveys containers or components by the means of air flow along a guide rail

3.1.11 neck gripper conveyor

machine or functional unit which transports containers, usually plastic bottles, by the means of gripping devices fixed on a driven chain or belt

prEN 415-2:2022 (E)**3.1.12****walking beam conveyor**

machine or functional unit which transports containers step by step by a reciprocating motion of one or more bars

Note 1 to entry: Commonly used on in-line keg cleaning or filling machines. See also Figure B.22.

3.1.13**gripper chain conveyor**

machine or functional unit which transports containers or crates by friction applied laterally by parallel running chains fitted with rubber grippers

Note 1 to entry: Gripper chain conveyors typically are used to convey containers or to invert containers or to feed crate cleaning machines with high level in-feed or to invert containers or crates.

3.1.14**magnetic belt conveyor**

machine or functional unit which transports components or containers by applying magnetic force to increase the friction

3.1.15**cascaded pusher**

machine or functional unit which conveys crates or containers to different lanes using a row of pushers moving in a sequence

3.1.16**in-line machine**

generic configuration of machine in which processing operations on a container are performed whilst the container is transported through the machine in a straight line

Note 1 to entry: Spacing of containers usually is done by a screw or a star-wheel.

3.1.17**carousel type machine**

generic configuration of a machine in which processing operations on a container are performed whilst the container is transported through the machine in a circular path

Note 1 to entry: Machine parts transporting containers through a rotary type machine are treated as a functional unit (see B.3.9 and Figure B.13).

3.1.18**oscillating label magazine**

label magazine which oscillates from side to side during machine operation

3.1.19**multi-functional machine**

machine which combines several functional units which are arranged and controlled as an integral whole

Note 1 to entry: Examples of typical multi-functional machines are:

- filling – capping machines
- rinsing – filling – capping machines

- aseptic machines with sterilizing – filling- capping
- blowing moulding – filling – capping machine
- filling – capping – labelling machine

Note 2 to entry: Some functional units of multi-functional machines may be covered by other standards.

3.1.20

workstation

position defined by the manufacturer, in the vicinity of the machine, which is intended to be assumed by the operator

Note 1 to entry: A list of the usual workstations is given in A.2.

3.2 Description of machines in the scope of this document

3.2.1

bottle unscrambling machine

machine which accepts a bulk supply of randomly oriented bottles and dispenses the containers in a predetermined orientation

Note 1 to entry: Figure B.15 shows an example of a plastic bottle unscrambling machine.

3.2.2

cap removing machine

machine which removes a cap from a container

Note 1 to entry: Figure B.16 and Figure B.17 show examples of cap removing machines.

3.2.3

cleaning and sanitizing machines

3.2.3.1

bottle washing machine

machine which cleans the inside and outside of rigid containers, usually with water and detergent

Note 1 to entry: Can also remove labels.

Note 2 to entry: Figure B.18 shows an example of a bottle washing machine.

3.2.3.2

cleaning machine for kegs

machine in which kegs are sprayed inside or outside or dipped into different cleaning media

Note 1 to entry: Figure B.19, Figure B.20 and Figure B.21 show examples of a keg cleaning machines

3.2.3.3

crate washing machine

machine which cleans crates, usually with water and detergent

Note 1 to entry: This document deals with washing machines for crates for re-usable bottles or other rigid containers. The requirements can also be used for machines which clean crates used in the food industry which are similar in material and size.

Note 2 to entry: Figure B.24 shows an example of a crate washing machine.