Form 36

DPC: 22/30426665 DC

BSI Group Headquarters

389 Chiswick High Road London W4 4AL

Tel: +44 (0)20 8996 9000
Fax: +44 (0)20 8996 7400
www.bsigroup.com

Date: 17 February 2022
Origin: European

Latest date for receipt of comments: 12 April 2022

Project No. 2020/02455

Responsible committee: MCE/3/3 Packaging machines

Interested committees:

Title: Draft BS EN 415-2 Safety of packaging machines. Part 2: Packaging machines for pre-formed rigid containers.

Please notify the secretary if you are aware of any keywords that might assist in classifying or identifying the standard or if the content of this standard

i) has any issues related to 3rd party IPR, patent or copyright
ii) affects other national standard(s)
iii) requires additional national guidance or information

WARNING: THIS IS A DRAFT AND MUST NOT BE REGARDED OR USED AS A BRITISH STANDARD. THIS DRAFT IS NOT CURRENT BEYOND 12 April 2022

This draft is issued to allow comments from interested parties; all comments will be given consideration prior to publication. No acknowledgement will normally be sent. **See overleaf for information on the submission of comments.**

No copying is allowed, in any form, without prior written permission from BSI except as permitted under the Copyright, Designs and Patent Act 1988 or for circulation within a nominating organization for briefing purposes. Electronic circulation is limited to dissemination by e-mail within such an organization by committee members.

Further copies of this draft may be purchased from BSI Shop http://shop.bsigroup.com or from BSI Customer Services, Tel: +44(0) 20 8996 9001 or email cservices@bsigroup.com. British, International and foreign standards are also available from BSI Customer Services.

Information on the co-operating organizations represented on the committees referenced above may be obtained from https://standardsdevelopment.bsigroup.com/.

Responsible Committee Secretary: Mr Christopher Brown (BSI)
Direct tel: 02089967441
E-mail: christopher.brown@bsigroup.com

AVA Documents Document Sharing Hub

Full document details: 22/30426665 DC

Introduction

This draft standard is based on national and international discussions. Your comments on this draft are invited and will assist in the preparation of the consequent standard.

For international standards, comments will be reviewed by the relevant UK national committee before sending the consensus UK vote and comments to the international committee, which will then decide appropriate action. If the international standard is approved, it is usual for the text to be published as a British Standard.

For national standards, comments will be reviewed by the relevant UK national committee and the resulting standards published as a British Standard.

UK Vote

Please indicate whether you consider the UK should submit a negative (with supporting technical reasons) or positive vote on this draft. Please indicate if you are aware of any reason why this draft standard should not be published as a British Standard.

Submission of Comments

- **Annotated drafts are not acceptable and will be rejected.**
- All comments should be submitted online at **https://standardsdevelopment.bsigroup.com/**. You will need to register in order to comment.

Template for comments and secretariat observations

Date: xx/xx/20xx	Document: ISO/DIS xxxx

1	2	(3)	4	5	(6)	7
MB	Clause No./ Subclause No./Annex **(e.g. 3.1)**	Paragraph/ Figure/Table/Note	**Type of comment**	**Commend (justification for change) by the MB**	**Proposed change by the MB**	**Secretariat observations on each comment submitted**
	3.1	Definition 1	ed	Definition is ambiguous and needs clarifying.	Amend to read '...so that the mains connector to which no connection...'	
	6.4	Paragraph 2	te	The use of the UV photometer as an alternative cannot be supported as serious problems have been encountered in its use in the UK.	Delete reference to UV photometer.	

Documents
Document Sharing Hub

Full document details: 22/30426665 DC

EUROPEAN STANDARD

NORME EUROPÉENNE

EUROPÄISCHE NORM

DRAFT
prEN 415-2

February 2022

ICS 55.200

Will supersede EN 415-2:1999

English Version

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.

This draft European Standard was established by CEN in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

CEN members are the national standards bodies of Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Iceland, Ireland, Italy, Latvia, Lithuania, Luxembourg, Malta, Netherlands, Norway, Poland, Portugal, Republic of North Macedonia, Romania, Serbia, Slovakia, Slovenia, Spain, Sweden, Switzerland, Turkey and United Kingdom.

Recipients of this draft are invited to submit, with their comments, notification of any relevant patent rights of which they are aware and to provide supporting documentation.

Warning : This document is not a European Standard. It is distributed for review and comments. It is subject to change without notice and shall not be referred to as a European Standard.



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

CEN-CENELEC Management Centre: Rue de la Science 23, B-1040 Brussels

© 2022 CEN All rights of exploitation in any form and by any means reserved worldwide for CEN national Members.

Ref. No. prEN 415-2:2022 E

Documents
Document Sharing Hub

Full document details: 22/30426665 DC

Contents

Page

European foreword ... 4
Introduction ... 5
1 Scope ... 6
2 Normative references ... 8
3 Terms and definitions ... 9
3.1 Definitions of terms ... 10
3.2 Description of machines in the scope of this document ... 13
4 Safety requirements and protective measures ... 16
4.1 General requirements ... 16
4.2 Risk reduction on equipment ... 26
4.3 Plastic bottle unscrambling machine ... 35
4.4 Machines for applying caps or removing packaging components or materials from containers ... 36
4.5 Cleaning machines ... 38
4.6 Filling machines ... 49
4.7 Sealing, seaming, crimping, flanging machine ... 52
4.8 Closure securing machine / cork wiring machine ... 53
4.9 Labelling and decorating machines ... 53
4.10 Heating or cooling machine for packed product working at atmospheric pressure (pasteurizer) ... 53
4.11 Inspection equipment ... 54
5 Verification of safety requirements and measures ... 55
5.1 General ... 55
5.2 Visual inspections with the machine stopped ... 55
5.3 Measurements with the machine stopped ... 55
5.4 Visual inspections with the machine running ... 56
5.5 Measurements with the machine running ... 56
5.6 Verification procedures ... 56
6 Information for use ... 60
6.1 General ... 60
6.2 Marking ... 60
6.3 Signals and warning signs ... 60
6.4 Instructions ... 61
Annex A (normative) Noise test code ... 64
A.1 General ... 64
A.2 Determination of emission sound pressure level at the workstation ... 64
A.3 Determination of the sound power level ... 66
A.4 Alternative method for very large machines ... 66
A.5 Operating conditions ... 66
A.6 Measurement ... 66
A.7 Information to be recorded ... 67
A.8 Information to be recorded ... 67
A.9 Declaration and verification of the noise emission values ... 67

AVA Documents
Document Sharing Hub
Full document details: 22/30426665 DC

Annex B (informative) List of significant hazards 68
B.1 General 68
B.2 Hazards that occur on most machines in the scope of this document 69
B.3 Components and equipment 72
B.4 Plastic bottle unscrambling machine 89
B.5 Machines for applying caps or removing packaging components or materials from containers 91
B.6 Cleaning machines 94
B.7 Filling machines 110
B.8 Sealing, seaming, crimping, flanging machine 115
B.9 Closure securing machine / cork wiring machine 118
B.10 Labelling and decorating machines 119
B.11 Heating or cooling machine for packed product working at atmospheric pressure (Pasteurizer) 122
B.12 Inspection machines 124
Annex ZA (informative) Relationship between this European Standard and the Essential Requirements of EU Directive 2006/42/EC 126
Bibliography 130

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

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 machines*[1];

— *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”.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

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.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

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;

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

— 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;

— 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.

AVA Documents Document Sharing Hub

Full document details: 22/30426665 DC

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 60825-4:2006[2], *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.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

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

Documents
Document Sharing Hub

Full document details: 22/30426665 DC

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. H_2O_2 or

— radiation, e.g. ultraviolet rays or

— heat or

— a combination of some of these methods

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

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

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

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

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 positions conveyed 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

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

— 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.

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

3.2.3.4
rinsing machine
machine which cleans the inside of a rigid container by injecting a liquid or gas into the inverted container

Note 1 to entry: Figure B.27 shows an example of a carousel type rinsing, filling and capping machine.

3.2.3.5
closure sanitizing machine
machine in which closures are fed through and treated with radiation or agents

Note 1 to entry: Agents can be water, clean air and ionized air. Vaporized agents (e.g. H_2O_2 or peracetic acid) can be applied for sanitation. There are also examples which transport the caps through a dipping bath.

Note 2 to entry: Figure B.25 and Figure B.26 show examples of a closure sanitizing machine.

3.2.4
filling machines
3.2.4.1
filling machines for bottles, jars or cans
machine in which bottles, jars or cans are filled with a product

Note 1 to entry: The filling machine is usually combined with a closing machine.

Note 2 to entry: Products are usually liquid or paste-like.

Note 3 to entry: Figure B.27 shows an example of a carousel type rinsing, filling and closing machine. Figure B.28 shows an example of an in-line filling machine.

3.2.4.2
Keg fill and seal machine
machine in which kegs are first filled with a product and then closed

Note 1 to entry: Figure B.20 shows an example of an in-line keg cleaning and filling machine. Figure B.23 shows an example of a semi-automatic keg cleaning and filling machine.

3.2.5
capping, closing and sealing machines
3.2.5.1
crown capping machine
closing machine which places a pre-formed metal or plastic (or combined) cap over the mouth of a rigid container, before crimping the edges of the cap to secure it to the container

3.2.5.2
plugging machine
closing machine which pushes a plug or cork into the mouth of a rigid container

Note 1 to entry: The plug can be made from plastic, cork, artificial cork, plastic covered glass, etc.

3.2.5.3
screw capping machine
closing machine which applies a threaded cap or lid to a rigid container

Note 1 to entry: The working principle is similar to a screw cap removing machine.

Note 2 to entry: Figure B.16 shows an example of capping machine.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

3.2.5.4
roll-on capping machine
closing machine which places a deformable closure over the mouth of a rigid container, before rolling the closure to form a thread and securing the closure to the container

3.2.5.5
foil sealing machine
machine which applies a reel fed foil or plastic cover to a rigid container, sealing it to the container by the application of heat

Note 1 to entry: The foil can be made of plastic, aluminium, etc. The sealing method can be e.g. ultrasonic, thermal or gluing.

Note 2 to entry: Often a cap is applied after foil sealing. The foil can also be part of the cap. In this case it is sealed by induction after the cap is applied.

3.2.5.6
can seaming machine
closing machine which places a pre-formed lid onto the mouth of a can and rolls their edges together to form a seam

Note 1 to entry: Figure B.30 shows an example of a can seaming mechanism.

3.2.6
closure securing machine
machine which places a securing element, e.g. wire-hood, cord, sleeve or fibre filament, over a bottle and the closure and then secures it e.g. by twisting (wire) or shrinking (capsule)

Note 1 to entry: Figure B.32 shows an example of a cork wiring machine.

3.2.7
labelling or decorating machine
machine which applies labels or tags onto containers

Note 1 to entry: Figure B.33, Figure B.34 and Figure B.35 show examples of labelling machines.

3.2.8
coding equipment
equipment to apply a code to a container or packaging component

Note 1 to entry: The code can also be a symbol. It can be applied in different ways (see 3.3.3 of EN 415-1:2014).

3.2.9
heating or cooling machine for packed product working at atmospheric pressure
heating machine/cooling machine that applies heat/cold to filled containers under controlled conditions while the containers are conveyed or in batch mode

Note 1 to entry: This includes pasteurizing machines. For hygiene risks on pasteurizers, EN 285:2015+A1:2021 might be helpful.

Note 2 to entry: Figure B.36 shows an example of a pasteurizer.

3.2.10
inspection machine
machine which inspects containers for some attribute

Note 1 to entry: Attributes can be e.g. size, wall thickness or cleanliness. The inspection can be done, e.g. by light, radiation, high frequency, camera systems.

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

4 Safety requirements and protective measures

4.1 General requirements

4.1.1 General

All machines in the scope of this document shall comply with the requirements of 4.1 to 4.11 of this document where the equivalent hazard exists.

All the machines in the scope of this document shall comply with the safety requirements and protective or risk reduction measures in 4.1 and the relevant machine specific measures in 4.2 to 4.11, where the equivalent hazard exists. In addition, machines shall comply with the relevant clauses of EN 415-10:2014 where they are specifically referenced in this document.

Where a machine has hazards, which are not described in Annex B, because they are not significant on a typical machine, the machine shall be designed according to relevant clauses of EN 415-10:2014. The requirements in 4.2 to 4.11 take precedence over those in 4.1, and the requirements of this document take precedence over those in EN 415-10:2014.

4.1.2 Inherently safe design

Inherently safe design measures shall be applied as far as possible to eliminate or reduce mechanical risks. For elimination of hazards, the pressure and force limits of ISO/TS 15066:2016 shall apply for contact of moving parts with human body.

4.1.3 Design of guards

Where inherently safe design measures are not practicable or not sufficient, access to hazardous moving parts shall be prevented by fixed and/or interlocking guards and/or ESPE (electro-sensitive protection equipment).

Where the guards comprise glove boxes, access to the gloves shall be safeguarded by interlocking guards if mechanical hazards are within the safety distances given in 5.2.1.3.2 and Table 1 of EN 415-10:2014. More specific requirements for safeguards for particular equipment and machines are contained in subclauses 4.2 to 4.11 of this document.

Guards shall be fixed or interlocked and comply with EN ISO 14120:2015, EN 415-10:2014, 5.2.1.3 and the additional requirements in 4.1.4 to 4.1.13 and 4.2 to 4.11 of this document.

Where access through a guard is foreseeable once per week or more often, this guard shall be interlocked.

Type 3 switches according to EN ISO 14119:2013, 3.18 shall not be used for interlocking of guards.

Where a machine has more than five interlocking guards or ESPE, or where these guards are not easy to reach, the control system shall signal which guard is open or is in a defective state.

Where guards are made of a transparent material and there is a risk of someone hitting the open transparent guard since visibility is reduced, the guard shall be marked or fitted with features which make the guard clearly visible when it is open.

If breaking of glass guards can lead to hazardous situations, e.g. undetected access to hazard zones, release of hazardous substances or ejecting of objects or contamination of product by shards, these guards shall be made from laminated safety glass.

On tanks or other containers which contain hazardous liquids where no mechanical hazards are present and no hazardous liquid is jetted or spilled, it is permissible to use movable lids without interlocking. These lids shall be provided with a closure which requires the use of a tool to open it and which remains open when fixings are not properly closed.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

Further requirements for guards which result from other than mechanical hazards are stated in the relevant clauses.

4.1.4 Reduction of mechanical risks

4.1.4.1 Reduction of risks from packaging material

When the process can lead to bursting of glass containers, resistant guards capable of retaining flying shards shall be used. The instructions shall detail the procedure, tools and personal protective equipment for removing shards from the machine.

4.1.4.2 Reduction of slip, trip or fall risks

5.2.2 of EN 415-10:2014 shall apply. Machine parts that are foreseeably used as steps, walkways or platforms shall comply with EN ISO 14122-2:2016 and EN ISO 14122-3:2016.

Where there is a combination of a falling risk and of possible access to moving parts, e.g. rotary mechanisms, from an elevated position, the requirements of 4.1.3 shall apply additionally to the requirements of this subclause.

4.1.4.3 Reduction of risks from loss of stability

5.2.3 of EN 415-10:2014 shall apply.

4.1.4.4 Reduction of risks from pneumatic or hydraulic equipment

5.4 of EN 415-10:2014 shall apply.

4.1.5 Reduction of electrical risks

5.5 and 5.6 of EN 415-10:2014 shall apply.

4.1.6 Reduction of thermal risks

5.7 and 5.20.7 of EN 415-10:2014 and the following shall apply.

External surfaces of the machine which exceed the temperature thresholds given in EN ISO 13732-1:2008 or EN ISO 13732-3:2008 and which can be touched unintentionally, e.g. while passing by the machine or during intervention, shall be isolated or guarded.

NOTE Unintentional contact to surfaces which exceed the thresholds only temporarily can be prevented by a deterring construction such as handrails.

The machine shall be designed to hold back splashes of hot liquid. Steam jets shall not be released to traffic ways or working places, e.g. by pressure relief valves.

Hot liquid shall be ducted in pipes or other protected parts of the machine frame. When unintended action can lead to the release of hot or cold fluid, this shall be prevented by, e.g. means that require two different movements to be opened. Their outlet opening shall be positioned no higher than 1 200 mm over access (foot) level and face downward.

Handles of machine parts or of piping shall be designed and mounted so that their temperature will be between 0 °C and 48 °C.

The instructions shall detail how to prevent burn or scalding injuries, e.g. during cleaning or interventions.

4.1.7 Reduction of risks from noise

For prevention of noise emission, the manufacturer shall follow the design principles given in EN ISO 11688-1:2009 and EN ISO 11688-2:2000 and in 5.8 of EN 415-10:2014.

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

Measures to reduce noise include:

— fitting valves for gas releases with silencers;

— using low noise nozzles that shall be adjusted so that only the intended objects will be hit;

— reducing noise transmission using surfaces made from noise damping material, e.g. of multi-layer sheet;

— avoiding acoustic vibrations by the fitment of reinforcements or noise reducing material to surfaces;

— isolation of vibration sources, e.g. by damping.

Where collision of rigid containers, e.g. bottles or cans, is a significant source of noise, one or more of the following requirements shall apply:

a) for the transport of containers or packaging components, low noise conveying systems like (magnetic) belt conveyers have precedence over those using compressed air or blowers;

b) where glass or metal containers are handled, contact surfaces such as guide rails, grippers or stopping devices shall be made from noise damping material, e.g. plastic;

c) minimizing the impact energy of the containers, e.g. by controlling the movement of all in-feed conveyors in order to avoid impact between containers by decreasing the transport speed of conveyors before the impact of bottles or by using a pusher and counter pusher with a soft start and stop, or reducing the dropping height of placement of containers

d) enclosing container impact areas in sound damping or sound retaining material;

e) preventing the generation of noise by the impact of a pusher on a container by reduction of the pushing speed to the minimum value that is necessary for the function;

f) use of noise reducing material or structures for the contact area of the pusher plate.

NOTE The criterion for assessing the efficiency of these measures is the actual noise emission values from the machine in relation to other machines of the same family and not the nature of the reduction measures themselves.

4.1.8 Reduction of risks from radiation

4.1.8.1 General

Where machines contain radiation sources or equipment that generates hazardous radiation, the design shall ensure that this radiation is contained, so that its effects on operators or persons in the vicinity of the machine are reduced to non-hazardous levels following 4.1.8.2.1 to 4.1.8.4 for the relevant types of radiation.

Where guards that block radiation have to be opened (e.g. for installation, adjustment or maintenance), compensatory safety measures shall be available in all phases of life cycle of the machine.

The manufacturer shall detail the protective measures in the instructions. This includes a description of energy disconnection and dissipation, use of personal protective equipment and measures against hazards for persons in the vicinity of the machine.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

4.1.8.2 Artificial optical radiation

4.1.8.2.1 Laser equipment

Laser equipment on packaging machines shall comply with EN 60825-1:2014.

The machine shall be designed so that the emission level of laser radiation outside the machine does not exceed the accessible emission level for class 1 lasers as specified in EN 60825-1:2014, Table 1.

Access to laser radiation higher than class 1 shall be prevented by guards. Those guards shall withstand the radiation of the laser according to EN 60825-4:2006[2].

The laser beam inside the machine shall be directed to the inner side or downward the machine.

The machine shall be marked according to Clause 6 of EN 60825-1:2014. The laser class of the integrated laser source if that is 3R, 3B or 4 shall be identifiable without opening guards.

Detailed information on the laser product (type, power, wavelength) and instructions for its safe use and maintenance shall be provided in the instructions.

For laser processing machines (e.g. for marking of products or cutting packaging material), EN ISO 11553-1:2020 also shall apply in addition to EN 60825-1:2014.

4.1.8.2.2 Ultraviolet (UV) radiation, LED and infrared light

Where ultraviolet (UV) radiation, LED or infrared light is used in a machine, e.g. for sterilization of containers or packaging materials, the machine shall be designed so that no light intensities higher than category 1 as defined in Clause 7 of EN 12198-1:2000+A1:2008 are emitted from the machine. This includes:

a) light-tight enclosures or guards;

b) where enclosures are not completely closed: light barriers or baffles blocking direct view to the light sources. Access with parts of the body to unblocked light shall be prevented by guards;

c) tinted glass to prevent glare by visible light.

Compounds of elastomer and plastics which can have contact with ultraviolet light shall be resistant against these influences.

Where the UV light causes thermal hazards, 4.1.6 and the following shall apply:

d) cooling and/or ventilation of the system;

e) to prevent overheating of material in case of a machine stop, the lamp shall be switched off or there shall be a shutter installed which blocks the heat.

If the UV-Lamp creates ozone, an extraction system according to 4.2.6 shall be provided which ensures that no ozone concentrations higher than 0,06 ml/m^3 (0,12 mg/m^3) can build up in areas accessible for the user.

The instructions shall warn of the risks and secondary risks (e.g. creation of hazardous substances like ozone) from those radiations and shall inform of protective measures. Where necessary, the instructions shall state the need of personal protective equipment including its specification.

NOTE Directive 2006/25/EC optical radiation gives limits to the emission those radiation sources.

4.1.8.3 Non-optical electromagnetic fields

Low frequency, radio frequency and micro-waves shall be contained using Faraday cages.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

Radiation emissions, e.g. from inspection devices, shall be no higher than given by category 1 as defined in Clause 7 of EN 12198-1:2000+A1:2008.

If the machine emits non-optical electromagnetic fields, the instructions shall state a warning that from those fields a hazard for workers with medical implants possibly exists.

If the machine contains strong permanent magnets the warning sign according to W006: "Warning for magnetic field" of EN ISO 7010:2020 shall be placed close by or on the magnets clearly visible also for inspection personnel.

NOTE Directive 2013/35/EU gives limits to the emission those radiation sources.

4.1.8.4 Ionizing radiation

Access to the area where ionizing radiation is present (e.g. the inspection area) shall be prevented by guards.

The emission of ionizing radiation of the machine shall be such that a person working at the machine as intended for 40 hours a week for 50 weeks a year is not exposed to an effective dose of more than 1 millisievert per calendar year

A status lamp shall display when X-Ray source is active. The machine shall be marked with W003 “Warning - Radioactive-material-or-ionizing-radiation” of EN ISO 7010:2020.

National laws and regulations should be observed.

NOTE Directive 2013/59/EURATOM gives limits to the emission of those radiation sources.

4.1.9 Reduction of chemical risks

4.1.9.1 General

Where guards are used to retain harmful substances, these guards shall comply with 4.1.3 and they shall be capable of retaining these substances.

Piping and components, e.g. seals, shall resist the foreseeable overpressure, temperature loads and substances used. Tools shall be necessary for dismantling of parts where hazardous substances can be released. Winged nuts shall not be used for fixing.

Valves or taps shall be provided for safe topping-up and taking samples of chemicals. Means to take samples shall be easily accessible. When unintended action can lead to the release of hazardous fluid this shall be prevented by e.g. means that require two different movements to be opened. Their outlet opening shall be positioned no higher than 1 200 mm over access (foot) level and face downward. The instructions shall detail the safe procedure for sample taking and specify the characteristics of necessary personal protective equipment.

The instructions shall inform of the cleaning and sterilization agents intended to be used and detail their safe use. The instructions shall indicate that any deviation from the intended cleaning substances or their mixing may lead to a hazardous situation (e.g. hypochlorite based bleaching agents and acids generate gaseous chlorine when mixed).

The instructions shall give detailed information on the kind and characteristics of personal protective equipment which is necessary for operations with chemical risk such as cleaning or entering machine parts that could be contaminated.

The instructions shall inform of the need of body and eye safety shower.

For hatches, 4.5.1.8.1 shall apply.

For windows, 4.5.1.8.2 shall apply

To prevent contamination of product, 5.3.2.8 and 5.3.2.9 of EN 1672-2:2020 shall apply.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

4.1.9.2 Pneumatic and hydraulic equipment

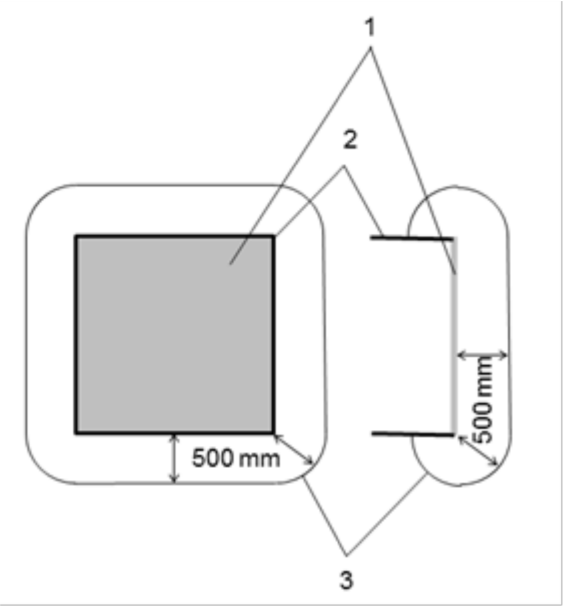
Where the machine is designed to pack foodstuffs, cosmetics, pharmaceuticals, or other products where contamination is a significant risk, the design shall ensure that hydraulic oil or pneumatic lubricating oil cannot come into contact with the product.

4.1.9.3 Cleaning or sanitizing

Machines using hazardous substances (for example hydrogen peroxide) to clean or sanitize machine parts, packaging materials or components shall be designed so that all foreseen interventions can be carried out safely and so that emissions of these substances from the machine to the work area around the machine are kept to a minimum.

The design and the control system shall ensure that hazardous concentrations of these substances do not build up outside the machine. The concentration shall be measured in a radial distance of 500 mm from the outer edges of every aperture where these substances are likely to be emitted, such as product exit or access doors, as shown in Figure 1.

NOTE 1 The permissible levels and the required measurement can vary depending on the substances and national legislation.



Key

1 plane of aperture
2 retaining guard or housing
3 measurement distance

Figure 1 — Measurement of substances schematic of measurement distance – front (left side of Figure) and side view (right side of Figure)

The seals and gaskets fitted to guard doors and other possible leakage points shall be made of materials that resist these substances being used. The design of the machine shall prevent contact of H_2O_2 or peracetic acid with lubricants. The machine design shall prevent the build-up of pressure from exothermic reactions of H_2O_2 or peracetic acid, e.g. by avoiding trapping of these substances within the pipework.

Movable guards shall be interlocked with guard locking devices to prevent access to areas of the machine that contain a hazardous concentration of these substances. The guard locking shall be

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

controlled either by automatic concentration measurement device or by time. Where time is used the time delay shall be determined for the worst-case conditions. A safe cut-off of the substance supply shall be used, e.g. using two controlled valves in combination with a pressure release.

If interventions are foreseen in an area while a hazardous concentration of these substances exists, suitable additional measures shall be provided, such as:

— fitting the machine with an extraction system complying with 4.2.6 to evacuate these substances;

— spraying the area with water to absorb these substances into water; or

— fitting the machine with glove boxes.

Where measures such as extraction or spraying systems are provided for the above purpose, these shall be dimensioned to function under the worst-case conditions and shall be interlocked to prevent access to the area if the extraction or spraying system is not functioning.

The supply system of these substances shall be designed to safely contain these substances. Pipe connections shall be used that can only be dismantled using tools. If it is foreseeable that these substances will be supplied from an external source (i.e. not from a container), the machine shall be fitted with an isolation valve that can be locked in the off position. For strainers, 4.1.9.4 shall apply.

Where airborne emissions of these substances occur, for example at discharge points, measures shall be provided to prevent the build-up of hazardous levels of the substance in the vicinity of the machine, such as:

— providing an extraction system complying with 4.2.6, e.g. tunnel guard with an aspiration system for residual cleaning agent as shown in Figure 2;

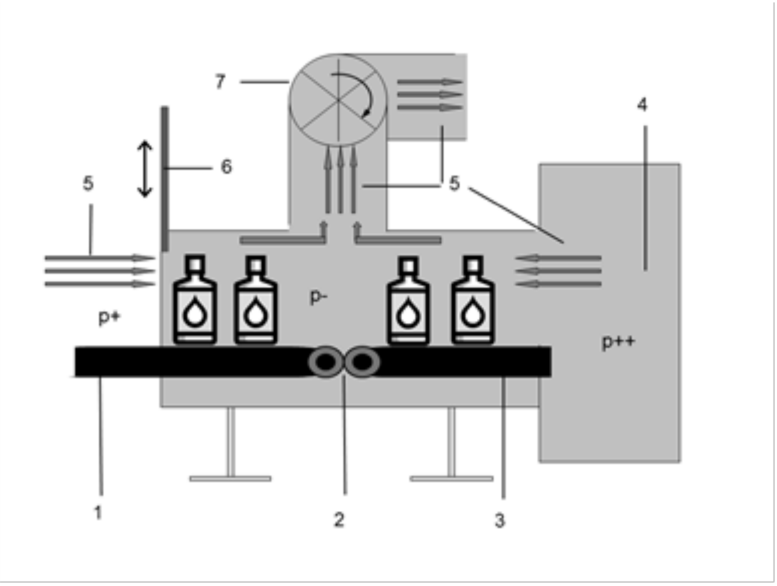
— providing automatic cleaning systems for conveyors that normally will be contaminated and reach out of the machine enclosure;

  In order to avoid carryover of the substances by the conveyors, the transfer from the discharge conveyor should be positioned within the machine or the discharge tunnel.

— ducting air streams to points where they can be connected to an extraction system;

— rinsing sterilizing substances from the outside of packages within the machine.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC



Key

1	outside conveyor	2	conveyor interruption (transfer point)
3	enclosed conveyor	4	area with hazardous substances
5	gas flow direction	6	movable/adjustable guard
7	fan	p++	highest pressure
p+	medium pressure	p-	lowest pressure

Figure 2 — Example of an extraction of hazardous substances at the container in-feed or discharge – sectional view

Valves or taps shall be provided for safe topping-up and taking samples of cleaning and sanitation solutions.

4.1.9.4 Requirements for cleaning in place, strainers and drainage

Strainers and removable parts, e.g. coupling bows or hoses which are foreseeably cleaned automatically by CIP and which have to be mounted or dismantled regularly, e.g. for cleaning the strainer, shall be located inside movable guards or the removable parts shall be interlocked with the CIP process.

This interlockings shall:

— swich off the pumps of the cleaning medium supply,

— close the valves of the cleaning medium supply.

— where necessary, release pressure safely from the system,

— where necessary, release hazardous media by a closed drainage.

Measures shall be taken to prevent overload of the valves and the connections in the case of emergency stop or safety stop. This can be reached, e.g. by the possibility of a slow shutdown of the process or a bypass.

If during a slow shutdown exposure to hazardous functions or substances is possible, interlocked guards shall be provided with guard locking.

AVA Documents Document Sharing Hub

Full document details: 22/30426665 DC

Strainer units shall be fitted with a form fit opening mechanism that forces the pulling out of the strainer from the pipe to prevent unexpected movement and liquid escape. The instructions shall inform of the correct use of this mechanism.

The design of the strainer shall ensure that residual cleaning medium is drained to a sink or containment while the strainer is extracted.

NOTE For example, a drilling in the strainer thread allows a targeted leakage of the cleaning liquid to a non-hazardous direction. With this method, operators are able to recognize when the strainer is filled with liquid.

Strainers and coupling bows shall be positioned from 0,5 m to 1,2 m over foot level.

Where parts have to be removed or installed to the machine manually before starting the cleaning process, the instructions shall inform of the need of a cold-water test in advance in order to identify leakages. The instructions shall describe how all liquids shall be drained safely.

4.1.10 Reduction of biological risks

Subclauses 5.10.1 and 5.10.2.1 and 5.12 of EN 415-10:2014 shall apply.

4.1.11 Reduction of ergonomic risks

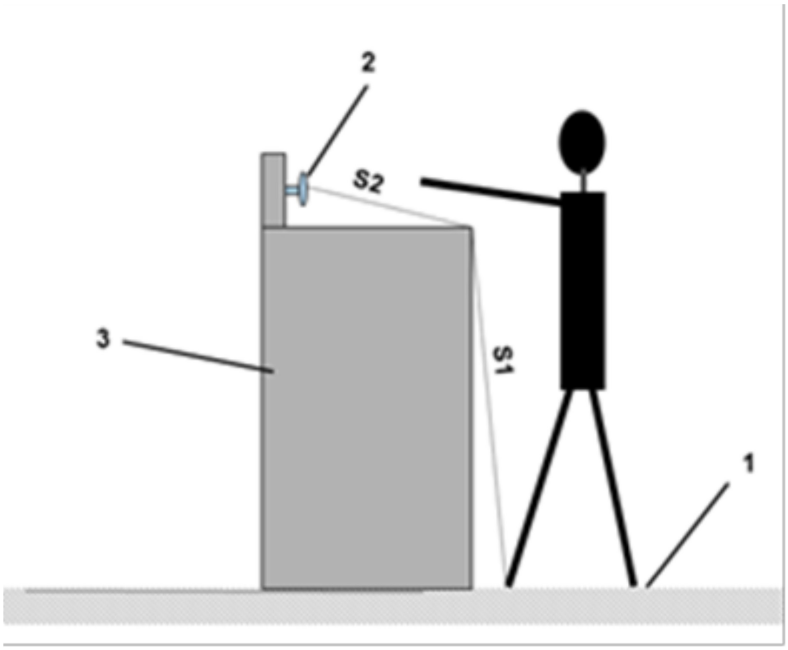
5.11 and 5.20.6.3 of EN 415-10:2014 and the following shall apply.

For calculation of the maximum object mass, the manufacturer shall choose M_{ref} from Table 1 of EN 1005-2:2003+A1:2008. The masses given in EN 415-10:2014 shall be regarded as M_{ref} according to EN 1005-2:2003+A1:2008.

All machine elements and operation panels, which will foreseeably be handled with personal protective equipment, and displays and control actuators shall be designed so that they can be used with the foreseeable personal protective equipment where it is needed.

For regular access, the shortest distance (tight string length), which is the sum of the distance from the operator's foot level to a deterring barrier, designated as S1 in Figure 3, and the distance from that deterring barrier to the access point, designated as "S2" in Figure 3, shall not exceed 1 800 mm. If this is not possible from floor level, the machine shall be provided with means of access to fulfil this requirement.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC



Key

1	foot level	2	access point (e.g. button)
3	machine frame or other barrier	S1	distance from foot level to a deterring barrier
S2	distance from the deterring barrier to the access point		

Figure 3 — Schematic for reach of access points

4.1.12 Prevention of unexpected start-up by another person

For machines which allow whole body access, 5.16.2 of EN 415-10:2014 shall apply. Where whole body access to the front and to the back of the machine is possible and the way to the front or back for checking the presence of persons is obstructed e. g. by conveyors or other barriers, one or more cameras or means of 5.16.2.3 a) and 5.16.2.3 c) of EN 415-10:2014 shall be provided.

4.1.13 Requirements for safety related control functions

4.1.13.1 Emergency stop

5.14.5 of EN 415-10:2014 shall apply with the following modifications:

A sufficient number of emergency stop actuators shall be provided in such a way that an operator shall not have to walk more than 5 m along the external guards or machine perimeter to reach an emergency stop actuator. Additionally, if the machine is likely to be part of a line of machines with possible access from several sides, the required number of emergency stop actuators shall be provided on both sides of the line.

4.1.13.2 Performance levels

Where there is no specific requirement in the subsequent Clauses, and where the respective function is present, the safety related control functions shall achieve the following minimum required performance levels (PL_r) as defined in EN ISO 13849-1:2015.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

Table 1 — Safety functions and related Performance Levels required PL_r

Safety function	PLr
safety related stop initiated by guard interlock or ESPE or hold-to run control for working with open guards	d
safety related stop initiated by an enabling device	d
safety related stop initiated by an extraction function	d
safety related stop initiated by a monitoring system, (when consequences of malfunction are serious or irreversible)	d
safety related stop initiated by a monitoring system (when consequences of malfunction are minor reversible health)	c
stopping hazardous functions by an access demand signal initiated on a guard locking system	d
prevention of unexpected start-up	d
emergency stop	c
emergency stop for hold-to run control for working with open guards	c

4.1.14 Devices for energy isolation

The machine shall be equipped with isolation devices for each type of potentially hazardous energy, readily accessible apart from hazard zones or hazardous situations. The isolation devices shall be clearly labelled, indicate the method of operation of the device, and be lockable in the off position.

The machine shall have the facility to release, or if this is not possible or practicable, to restrain or to contain any stored energy.

Pneumatic isolation valves shall comply with 5.2.8 of EN ISO 4414:2010, hydraulic isolation valves shall comply with 5.4.7.2.1 of EN ISO 4413:2010.

Devices for isolating of electrical energy sources shall be permanently accessible and selected from those listed in 5.3.2 of EN 60204-1:2018 and comply with 5.3.3 and 5.3.4 of that standard.

Devices for isolating electrical equipment shall be provided in accordance with 5.5 and 5.6 of EN 60204-1:2018.

The actuator of this supply disconnection device shall comply with EN 61310-3:2008.

4.2 Risk reduction on equipment

4.2.1 General

Where the following components or mechanisms are present on a machine in the scope of this document, they shall comply with the safety requirements and protective or risk reduction measures of this Clause.

4.2.2 Conveyors

4.2.2.1 General

5.20.4 of EN 415-10:2014 and the following Clauses apply.

4.2.2.2 Gripper chain conveyor

The manufacturer shall minimize the drawing-in and crushing risk between containers and the gripper chains by the following design measures:

AVA Documents Document Sharing Hub

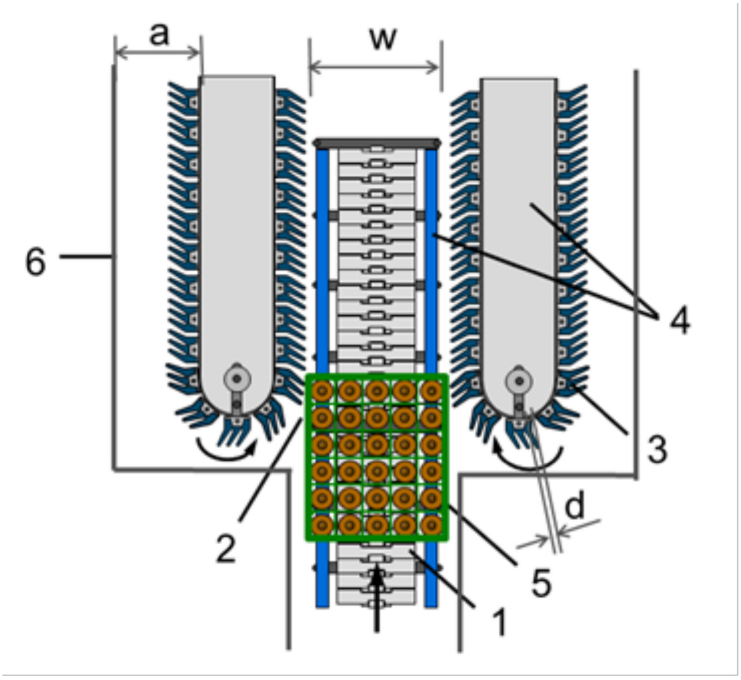
Full document details: 22/30426665 DC

The minimum adjustable gap (designated as "w" in Figure 4) between the parallel lateral grippers shall not be less than 70 mm. Where the conveyor is foreseen for non-deformable containers, the minimum length of the rubber grippers shall not be less than 40 mm.

At the deflection rollers the maximum gap (designated as "d" in Figure 4) between the solid parts of two gripper chains shall not exceed 5 mm.

Where one of these conditions cannot be fulfilled, the conveyor shall be safeguarded by guards with a tunnel guard according to 5.2.1.3.6 or 5.2.1.3.8 of EN 415-10:2014. The minimum distance between the tunnel guard and the grippers (designated as a in Figure 4) shall not be less than 100 mm where the drawing-in zone can be reached with hands only and not be less than 50 mm where the drawing-in zone can be reached with fingers only.

Where the gripper chain is not enclosed in the machine's safeguards, the manufacturer shall safeguard the gripper chains along their run by a top and bottom plates which cover the chain. The design of the safeguards shall comply with 5.2.1.2 of EN 415-10:2014.



Key

1	slat band conveyor	2	container transfer
3	gripper chain	4	machine frame
5	container	6	tunnel guard
a	distance between grippers and safeguard	d	distance between two gripper elements
w	distance between the parallel griper chains		

Figure 4 — Example of measures on a gripper chain conveyor – top view

Where containers or crates are conveyed over accessible areas, the manufacturer shall provide suitable means like nets to catch the crates. These devices for containment shall be easily accessible to remove caught crates.

The manufacturer shall provide cleaning information for these devices of containment in order to minimize biological risks.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

The safety related parts of the control system for the listed safety functions shall achieve the following minimum required performance levels (PL_r) according to EN ISO 13849-1:2015.

Safety function	PL_r
Stop by interlocking guards	b

4.2.2.3 Air conveyor

Methods of reducing noise on this machine include

— enclosing fans in sound attenuating material

— using filters made from sound attenuating material or design

— avoiding hitting of bulks of bottles

— enclosing the area of bottle transport, e.g. by noise attenuating material.

4.2.2.4 Neck gripper conveyor

The drive mechanisms and deflection rolls shall be safeguarded.

Where the gripping force of the pliers or of the moving container exceeds the values for fingers of ISO/TS 15066:2016 or if their shape is likely to cause entanglement or drawing-in the container transfer areas (in-feed and discharge) shall be safeguarded.

4.2.2.5 Vacuum transfer conveyor

4.2.2.5.1 Reduction of mechanical risks

The transfer area shall be enclosed with guards.

No guarding of the transfer area is required if only flexible empty containers are conveyed and the transfer height is no higher than 1,5 m.

Crossing under the belt shall be prevented.

4.2.2.5.2 Reduction of noise risks

The dropping height of the containers shall be minimized in order to avoid the generation of noise.

The manufacturer shall minimize the emission of noise from vacuum generating equipment by adopting measures listed in 4.2.6.4 and the area of bottle transport shall be enclosed, e.g. by acrylic glass.

4.2.3 Container ejection mechanism (pusher)

Inherently safe design is achieved by:

a) Providing a minimum gap which prevents from crushing and shearing according to EN ISO 13854:2019, e.g. 25 mm for fingers or, as shown in Figure 5, 50 mm for hands.

b) Providing a maximum gap of 4 mm between fixed/moving and moving parts which prevents from crushing and shearing

c) Designing the shape of the pusher smooth and without sharp edges and limitation of the speed of the pusher in order to keep within the limits according to 4.1.2

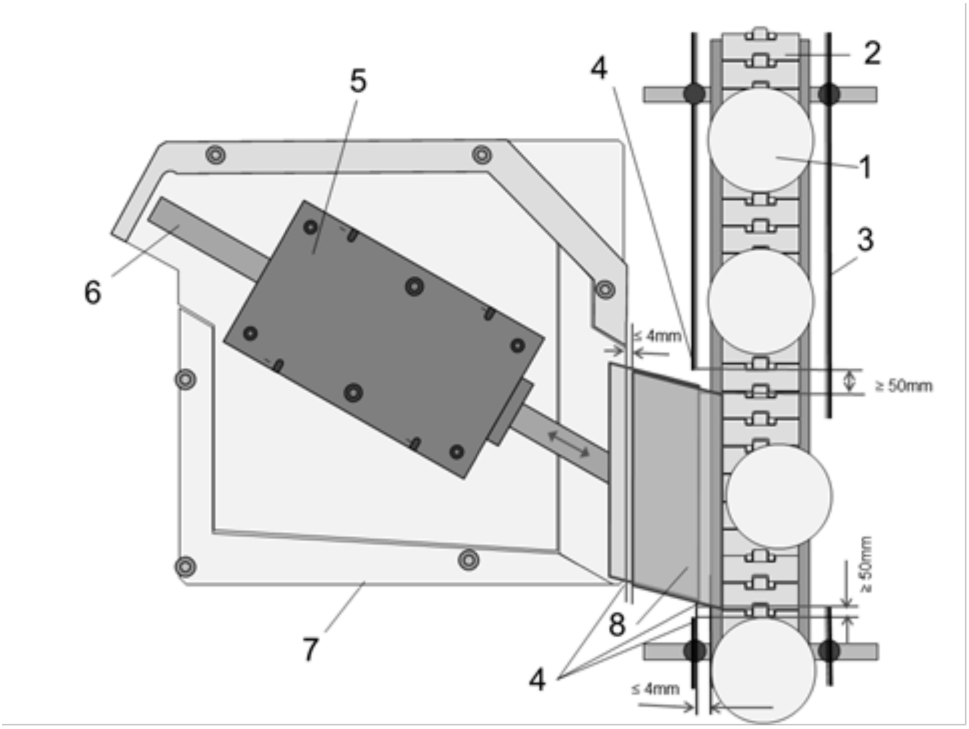
Where inherently safe design cannot be achieved for technical reasons, the pusher shall be guarded. The guards shall be designed to retain any ejected product or shards.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

For example. the moveable back end of the pusher rod shall be enclosed within the enclosure of the device.

In case of a jam that causes the stop of the pusher, the control system shall prevent unexpected start-up. In case of pneumatic energy either the energy supply shall be interrupted, and residual energy shall be dissipated, or the residual energy shall be safely enclosed.

Where foreseeably breakable containers will be ejected, the manufacturer shall prevent ejection of shards by solid guards. If specific collection containers are necessary to retain containers or materials the manufacturer shall supply these containments with the machine. Otherwise the manufacturer shall give detailed information of the characteristics of containments and about the safe way to use it with the device.



Key

1	container	2	conveyor
3	guide rail	4	possible gap
5	pneumatic cylinder	6	pusher rod
7	enclosure / machine frame	8	pusher plate

Figure 5 — Example for safe design of a pusher top view

4.2.4 Keg stopping device

Where the keg stopping device cannot be made safe by design, e.g. where positive conveyors or rubber conveyors are used which usually generate higher values than stated in 4.1.2, the device shall be guarded by a combination of fixed and interlocked guards or ESPE. Dimensioning the safeguards shall consider the crushing risk caused by subsequent kegs.

4.2.5 Keg lift and inverting machine

A device operating automatically shall be safeguarded. Dimensioning the guards shall consider the crushing risk caused by subsequent kegs.

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

If it is foreseen that the operator has to start every single movement of the device, this shall be performed by a hold-to-run control from a position with a clear view to all danger zones of the device. In this case no guards are necessary. When the distance between the control panel and the hazard zone is 2 m or less, a two-hand control type IIIA in accordance with EN ISO 13851:2019 shall be used for operation from the position of the control panel.

To prevent uncontrolled movement, e.g. during cleaning or maintenance a positive mechanical locking device shall be provided.

For prevention of falling kegs conveyors shall be fitted with side rails so that kegs cannot tilt or fall from the conveyor.

4.2.6 Extraction or ventilation system or blower

4.2.6.1 General

A safety related extraction system shall deliver a safety related run-signal to the machine.

4.2.6.2 Reduction of mechanical risks

Where the moving fan can be reached after opening an interlocked guard, this guard shall be interlocked with guard locking. Where there is a hazard of uncontrolled movement of the fan by air flow the fan shall be fitted with a brake.

4.2.6.3 Reduction of fall risks

Preferably the filters of the extraction system shall be positioned so that they can be reached from floor level. If this is not possible, risk from falling shall be prevented according to 5.2.2.3 of EN 415-10:2014.

4.2.6.4 Reduction of noise risks

Noise emission shall be minimized according to 4.1.7. Especially the following methods are known to be effective:

a) reducing the working pressure and differential pressure to the minimum which is necessary for the process;

b) avoiding obstacles in the fluid stream;

c) avoiding excitation of air columns;

d) reducing the peripheral speed of rotors to a minimum;

e) enclosing the blower in noise damping or isolating material avoiding any gaps in the enclosure;

f) designing the extraction system including the extraction mouth, the piping and the blower shall minimize the noise emission by the air flow;

g) reducing excitation of piping for air transport of components by using or fitting sound damping material such as multi-layer sheet;

h) minimising the flow velocity of the transport air;

i) avoiding bends in the piping for components If this is not possible avoiding small radiuses of bends (e.g. ≥ 800 mm) to reduce the impact energy of components hitting on the pipe wall;

j) avoiding noise transmission by fitting connections of elements with elastic material so that rigid components have no contact with other rigid components;

AVA Documents Document Sharing Hub

Full document details: 22/30426665 DC

k) stopping the extraction system when the machine is not in operation;

l) avoiding fluctuation of pressure of air columns;

m) avoiding resonance of material, e.g. by using sandwich material or perforated metal plate or by applying noise damping material.

NOTE 1 This list is not exhaustive.

For choice of methods and calculation, EN ISO 11688-2:2000 should be used.

4.2.6.5 Reduction of chemical risks

Where the extraction equipment is needed to prevent the build-up of hazardous concentrations of hazardous substances, the control system shall ensure that the machine shall only be capable of running when the extraction system is in operation. This shall be done by a flow meter which ensures that a sufficient air flow is present.

The manufacturer shall provide means to avoid the emission of hazardous substances from the extraction system to the working environment, e.g. by filters.

In addition to the measures according to 5.9.2 and 5.10 of EN 415-10:2014 the instructions shall detail the necessary intervals and the procedures of monitoring and filter changing and specify the characteristics of necessary personal protective equipment.

Where the machine is foreseen to be connected to the user's extraction system, the manufacturer shall provide sufficient information to allow the connection to this extraction system. This may include information on the necessary air flow.

4.2.6.6 Reduction of fire or explosion risks

The extraction system provided with a machine shall be designed:

a) to prevent generation of an external potentially explosive atmosphere by the machine,

b) to prevent generation of a potentially explosive atmosphere in the internal components of the system.

If the build-up of explosive atmosphere cannot be excluded, the following shall apply:

1) All components in the fluid stream shall be designed for the use in the foreseeable explosion zone.

2) All piping shall be of conductible material, connected by conductible means and earthed properly; and

3) the relevant parameters, e.g. pressure, temperature or air flow shall be monitored and controlled; and

4) the extraction system shall be fed by an uninterruptible power supply (UPS) if the loss of energy would lead to dangerous explosive atmosphere around the machine.

5) The control system shall ensure that the machine shall only be capable of running when the extraction system is in operation. This shall be done by a flow meter which ensures that a sufficient air flow is present.

The instructions shall inform of the intervals and extent of checks and controls of the protective measures.

AVA Documents Document Sharing Hub

Full document details: 22/30426665 DC

4.2.6.7 Reduction of biological risks

In addition to the measures according to 5.10 and 5.12 of EN 415-10:2014the instructions shall detail the necessary intervals and the procedures of monitoring and filter changing and specify the characteristics of necessary personal protective equipment.

4.2.7 Closure unscrambler

4.2.7.1 Reduction of slip, trip or fall risks

The machine design shall allow refilling or troubleshooting from floor level. Where this is not possible, suitable platforms and mean of access complying with 4.1.4.2 shall be provided.

4.2.7.2 Reduction of noise risks

The dropping height of closures or caps shall be minimized in order to avoid the generation of noise. Where components such as closures are fed pneumatically, the bend radius of pipes shall be at least 800 mm and bends of pipes shall be covered by noise damping material. The components shall be conveyed the hopper tangentially.

4.2.7.3 Reduction of ergonomic risks

4.1.11 shall apply.

4.2.8 Carousel type machines

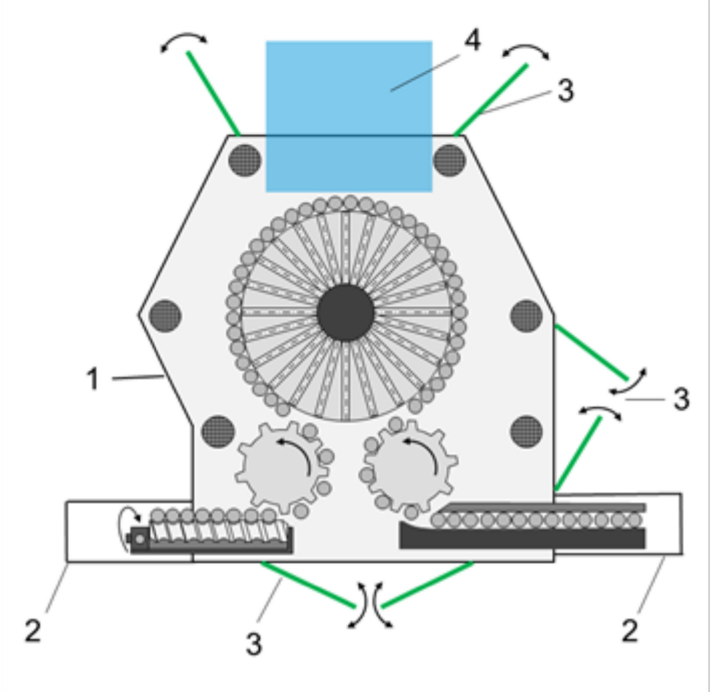
4.2.8.1 Reduction of mechanical risks

Rotary mechanisms shall be guarded.

Where a platform is located above the machine (e.g. for access to an overhead cap feeder), it shall comply with 4.1.4.2 and access to mechanisms shall be prevented by safeguards.

Guards shall be capable of retaining all solid material and liquids which can possibly be ejected from the machine.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC



Key

1	fixed guard	2	tunnel guard
3	interlocked movable guard	4	minimum workspace

Figure 6 — Schematic example of safeguarding the rotary mechanism - top view

4.2.8.2 Reduction of ergonomic risks

Where access to the carousel is necessary for regular intervention the available working area in front of the carousel shall not be less than 800 mm length and 800 mm width with guards open as shown in Figure 6.

Where place is limited by labelling aggregates the width at the carousel shall not be less than 350 mm.

4.2.9 Coding and marking equipment incorporated in a packaging machine

4.2.9.1 All coders – reduction of risks from applied energy

Where energy remains applied at coders while the machine is in a safe stop condition, all residual hazards at the coding device shall be stated in the instructions and a suitable warning sign shall be fixed next to the coding devices.

4.2.9.2 Hot foil coder

4.2.9.2.1 Reduction of mechanical risks

Where the coder is enclosed in the safeguards of the machine the hazardous functions of the coder shall stop together with the hazardous machine functions.

4.2.9.2.2 Requirements for Safety functions

Where interlocking guards are used to stop hazardous movements of rollers the performance level required shall be PL_r = c.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

4.2.9.3 Laser coder

4.2.9.3.1 Reduction of radiation risks

The requirements of Clause 4.1.8.2.1 apply.

Furthermore, while the machine or the coder is in a safety-stop condition (e.g. emergency stop, stop after opening an interlocked guard), the emission of the laser beam shall be prevented, e.g. by a shutter. The position of the shutter shall be monitored by the machine controls and the laser shall be cut off when the shutter doesn't close correctly. If the laser head is placed outside the machine and is guided to the coding are by an optical fibre, the output of the fibre shall be treated as laser source inside the machine.

4.2.9.3.2 Reduction of chemical risks

The laser coder shall have an extraction and cooling system which comply with 4.2.6. The control system shall ensure that the laser coder cannot operate without the extraction system running.

4.2.9.3.3 Requirements for Safety functions

The safety related control systems shall as a minimum comply with the following performance levels of EN ISO 13849-1:2015

Safety function	**PL_r**
safety related closing of a shutter or switching off laser initiated by guard interlock or ESPE	d
stopping laser if shutter initiated by interlocked guard does not close	d
prevention of unexpected start-up / release of radiation	d
prevention of laser start without running the extraction system	c
emergency stop including emergency switching-off of the laser	d

4.2.9.4 Ink jet coder

4.2.9.4.1 Reduction of slip, trip or all risks

Jetting ink on traffic areas or workplaces shall be prevented, e.g. by screens.

The design shall allow fixing the ink tank in a stable position to avoid tilting and spillage of ink.

4.2.9.4.2 Reduction of chemical risks

The instructions shall detail the safe handling of ink and safe cleaning methods and the characteristics of required personal protective equipment.

4.2.9.4.3 Reduction of fire or explosion risks

Where flammable ink is intended or foreseeable to be used the piping shall be isolated from any source of ignition, e.g. by enclosing these components in a separate enclosure.

The piping shall be as short as possible and fixed so that damage and spillage to traffic or work areas by fault is prevented.

Where the amount of ink could generate hazardous explosive atmosphere, the spraying zone shall be a extraction system complying with 4.2.6 in order to keep the concentration below the lower explosion limit.

The design shall allow fixing the ink tank in a stable position to avoid tilting and spillage of ink.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

The instructions shall detail the necessary measures to avoid hazardous amounts and concentrations of the flammable substance and to avoid ignition sources in the hazard zone.

4.2.9.5 Emboss coder

4.1.4 shall apply.

4.3 Plastic bottle unscrambling machine

The rotary disk shall be designed smooth without protruding parts and the gap between the disk and other parts of the machine or the sorting mechanism shall not exceed 4 mm. Otherwise the disk shall be guarded.

Automatic lifting and tilting mechanisms shall be made safe by design or, if this is not possible be guarded.

Where whole body access is possible under lifted parts of the lifting and tilting mechanism measures shall be taken against uncontrolled lowering the following shall apply. Mechanical elements which support a load shall be designed and constructed in such a way as to withstand the static overload without permanent deformation or patent defect.

A static test coefficient 1,5 shall apply.

In addition the following elements which support a load shall have the working coefficients as listed below when using only 1 element:

— rope 5

— chain 4

— belt 5

— textile fibre 7

— toothed belt 5

Other mechanical parts of lifting mechanism shall be calculated according to good engineering practices.

The manufacturer of these elements may certify the “load limit” which incorporates the safety coefficient. The “load limit” can be used as reference data for the design of the elements of the power transmission. Preferably more than one chain, rope or fibre should be used.

Where two or more elements are used the minimum working coefficient of each component shall be not less than the factors stated above divided by the number of elements but at least the factor shall be 2.

Where hydraulic equipment holds the lifted parts, they shall be equipped with an automatic device to limit unintentional lowering to less than 100 mm even in the event of rupture of the hoses in the hydraulic supply line. Rupture protection valve mounted directly on the hydraulic cylinder(s) is one mean of meeting this requirement.

The instructions shall describe the safe procedures and measures following a breakdown of the listed elements or a response of the listed devices. This shall include how to move the lifting mechanism to a safe position, prevention of any hazardous movement of lifting units, safe access, and safe removal of load as well as the necessary maintenance instruction.

AVA Documents
Document Sharing Hub

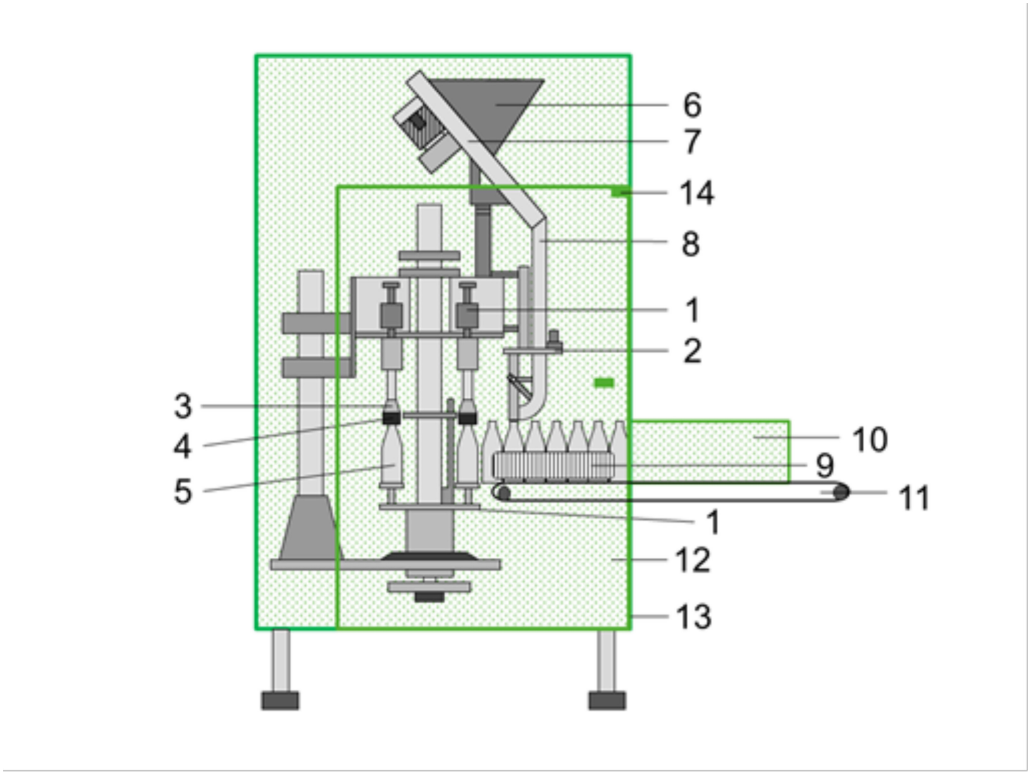
Full document details: 22/30426665 DC

4.4 Machines for applying caps or removing packaging components or materials from containers

4.4.1 Screw cap removing machine, screw capping machine, crown capping machine, roll-on capping machine and plugging/corking machine

4.4.1.1 General

Figure 7 shows an example of a carousel type capping machine with safeguards.



Key

1	carousel	2	cap feed
3	capping/uncapping/plugging head	4	thread roller, capping/uncapping/plugging mechanism
5	container	6	hopper
7	cap unscrambler	8	cap stopper
9	in-feed scroll	10	tunnel guard
11	conveyor	12	interlocked door
13	fixed and interlocking guards	14	interlocking device

Figure 7 — Schematic example of measures on a carousel type capping machine - sectional view

4.4.1.2 Reduction of biological risks

Preferably the exhaust air of the extraction system for removed caps on de-capping machines shall be conducted to an outdoor location. The manufacturer shall provide the necessary means and the instruction shall detail the requirements for the exhaust system.

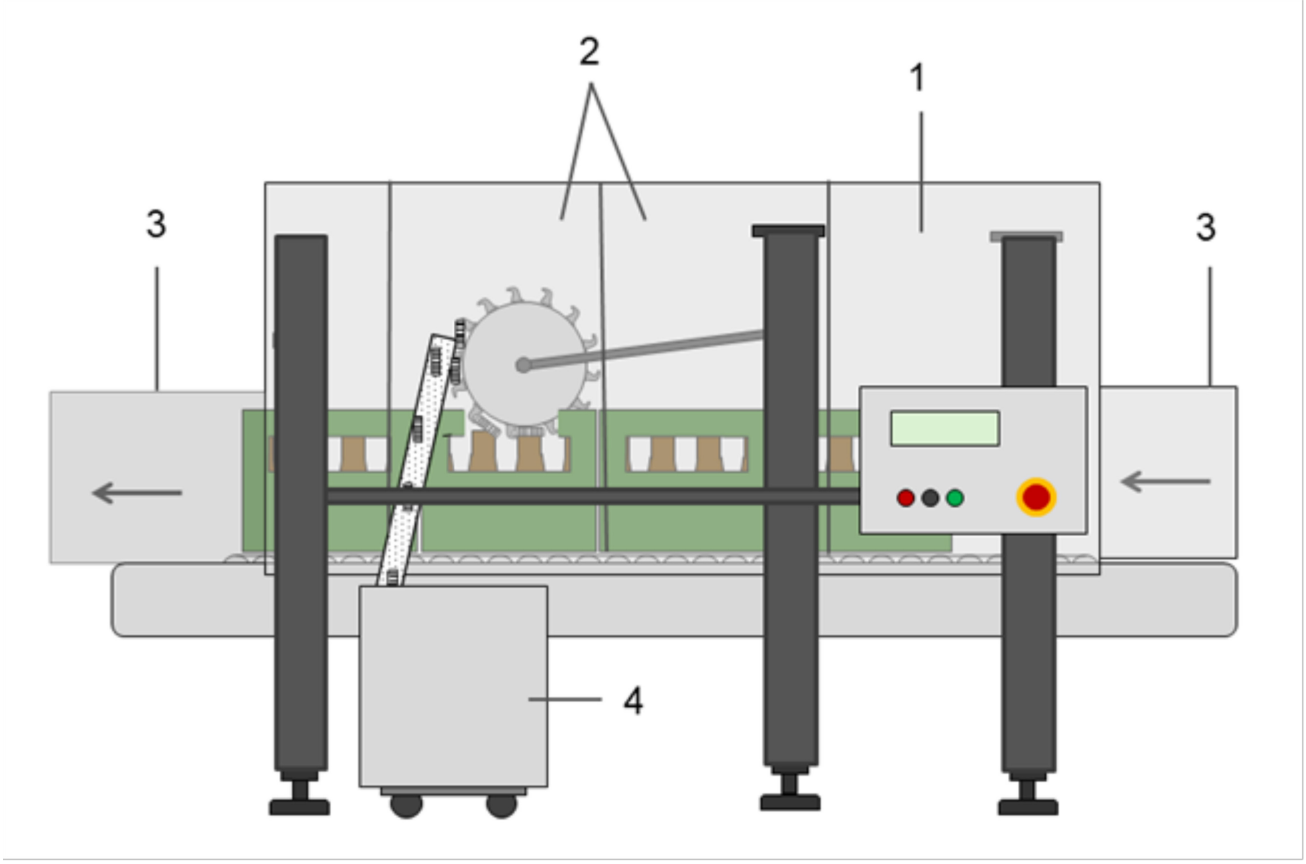
Otherwise, the extraction system shall be fitted with filters for the exhaust air to prevent contamination of the working area by biological hazards. The instructions shall detail the necessary intervals and the procedure of filter changing and specify the characteristics of necessary personal protective equipment.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC

4.4.2 Crown cork removing machine

4.4.2.1 Reduction of mechanical risks

Figure 8 shows the safety measures on a crown cork removing machine.



Key

1 fixed guard 2 interlocked guard
3 tunnel guard 4 waste crown cork bin

Figure 8 — Example of safety measures on a crown cork removing machine - sectional view

The minimum distance between the safeguard around the aperture or the in-feed tunnel and the passing crate shall be 60 mm to avoid crushing or shearing of fingers or hands.

Where crates run on each other the impact energy, force and pressure shall be reduced to the values for inherent safe design, e.g. by using a conveyor with low friction.

Where a crate stop is used that is not inherently safe, 4.1.4 shall apply. Where the waste cap container is part of the safeguard it shall be interlocked with the hazardous functions of the machine.

The manufacturer shall provide a means to fix the rotary cylinder to avoid unexpected movement e.g. for maintenance.

The instructions shall detail the use and characteristics of tools and personal protective equipment which are needed especially for trouble shooting, cleaning or maintenance of the rotary de-capping tool.

4.4.2.2 Reduction of slip, trip or fall risks

The manufacturer shall provide means to collect removed caps in a container.

AVA Documents
Document Sharing Hub

Full document details: 22/30426665 DC

The design of the machine shall allow the easy positioning of a container for the removed caps.

4.4.2.3 Reduction of noise risks

Measures to reduce noise emission include:

— controlling the acceleration of the crates in order to avoid impact;

— reducing the falling height of removed caps;

— reducing the impact energy of the tools on the crown corks by the design of the tools and of the cylinder.

Where crown corks are extracted by vacuum the respective requirements of 4.2.6 shall apply.

4.5 Cleaning machines

4.5.1 Bottle washing machines

4.5.1.1 Reduction of mechanical risks

4.5.1.1.1 Moving Parts in general

The machine shall be fitted with a reset button for each ESPE (e.g. light curtain) or interlocking guard located next to this device but not reachable from the danger zone.

Removing of any collection containers used with the machine shall not lead to exposure to hazardous functions. Otherwise the container shall be interlocked with the hazardous functions.

For hatches, 4.5.1.8.1 shall apply.

For inspection windows, 4.5.1.8.2 shall apply.

Where access to the interior is necessary for maintenance or detailed visual checks, the manufacturer shall provide a sufficient number of safe means of access.

For whole body access suitable means for safe communication shall be provided. Inching shall only be possible with an enabling device.

The instructions shall detail the requirements for safe change of carriers.

The instructions shall detail the procedures and provisions for interior inspection and maintenance and for changing the main chain.

The machine design shall allow the safe and easy removal of shards, e.g. by avoiding crevices.

The instructions shall warn of the risks at removing shards by pressurized water or air, detail the procedure of safe removal of shards and give characteristics of personal protective equipment to be used.

Covers on the machine top which can be dismantled, e.g. for maintenance like change of baskets, shall be fitted with fixings which can only be removed or opened with tools. Where, deviating from 4.1.3 the covers remain in closed position when the fixings are open for technical reasons, the design of the fixings shall indicate their open position.

Whole body access under the machine shall be prevented by design or by fixed barriers both ensuring maximum width of apertures of 180 mm in one direction. In addition, access to drawing-in or shearing hazards shall be prevented by guards.

Documents
Document Sharing Hub
Full document details: 22/30426665 DC