

BS EN 415-10:2014



BSI Standards Publication

Safety of packaging machines

Part 10: General Requirements

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National foreword

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The UK participation in its preparation was entrusted to Technical Committee MCE/3/3, Packaging machines.

A list of organizations represented on this committee can be obtained on request to its secretary.

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Prescriptions générales

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Allgemeine Anforderungen

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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. Up-to-date lists and bibliographical references concerning such national standards may be obtained on application to the CEN-CENELEC Management Centre or to any CEN member.

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Foreword

This document (EN 415-10:2014) has been prepared by Technical Committee CEN/TC 146 “Packaging machines - Safety”, the secretariat of which is held by UNI.

This European Standard shall be given the status of a national standard, either by publication of an identical text or by endorsement, at the latest by July 2014, and conflicting national standards shall be withdrawn at the latest by July 2014.

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

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

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

This standard is part of a series of standards comprising the following parts:

- EN 415-1, *Packaging machines safety — Part 1: Terminology and classification of packaging machines and associated equipment*;
- EN 415-2, *Packaging machines safety — Part 2: Pre-formed rigid container packaging machines*;
- EN 415-3, *Safety of packaging machines — Part 3: Form, fill and seal machines*;
- EN 415-4, *Safety of packaging machines — Part 4: Palletizers and depalletizers*;
- EN 415-5, *Safety of packaging machines — Part 5: Wrapping machines*;
- EN 415-6, *Safety of packaging machines — Part 6: Pallet wrapping machines*;
- EN 415-7, *Safety of packaging machines — Part 7: Group and secondary packaging machines*;
- EN 415-8, *Safety of packaging machines — Part 8: Strapping machines*;
- EN 415-9, *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, *Safety of packaging machines — Part 10: General requirements* (the present document).

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

Introduction

Packaging machines are used extensively in Europe in an increasingly wide range of industries. They contain several significant hazards that have the potential to cause serious injury.

This document is a Type C standard as defined in the Introduction of EN ISO 12100:2010.

The requirements of the machine specific parts of EN 415 take precedence over the requirements of EN 415-10. The requirements of the machine specific parts of EN 415 may supplement or modify the corresponding clauses of EN 415-10.

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

When provisions of this Type C standard are different from those, which are stated in Type A or B standards, the provisions of this Type C standard take precedence.

1 Scope

This European Standard gives general requirements for packaging machines which are defined in the scope of EN 415-1 or are in the scope of another relevant machine specific part of EN 415. When used together with a relevant machine specific part of EN 415, it gives the requirements for that specific type of machine.

This document deals with safety requirements and their verification for design, construction, installation, commissioning, operation, adjustment, maintenance and cleaning of packaging machines when used as intended and under the conditions of misuse foreseeable by a manufacturer.

The extent to which hazards, hazardous situations and events are covered is indicated in Clause 4.

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 dealt with in this standard, the manufacturer should assess these hazards by using the principles detailed in EN ISO 12100:2010. Such deviations or additions are outside the scope of this standard.

Exclusions

This European Standard is not applicable to the following:

- machines that were manufactured before the date of publication of this document by CEN.

This standard does not consider the following:

- the risk resulting from the use of machines in public accessed areas.

NOTE For machines used in public accessed areas different or additional requirements can apply. It is the responsibility of the manufacturer to identify such additional risks, which are outside the scope of this standard or such deviating risks which arise from this specific use, and provide suitable protective measures in accordance with EN ISO 12100.

- the use of packaging machines in potentially explosive atmospheres;
- specific health, safety or hygiene hazards associated with the products that may be handled by the machines, but does include general advice on this subject;
- hazards that may be associated with decommissioning packaging machines.

2 Normative references

The following documents, in whole or in part, are normatively referenced in this document and are indispensable for its application. For dated references, only the edition cited applies. For undated references, the latest edition of the referenced document (including any amendments) applies.

EN 349, *Safety of machinery - Minimum gaps to avoid crushing of parts of the human body*

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

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

EN 614-1, *Safety of machinery - Ergonomic design principles - Part 1: Terminology and general principles*

EN 614-2, *Safety of machinery - Ergonomic design principles - Part 2: Interactions between the design of machinery and work tasks*

EN 618, *Continuous handling equipment and systems - Safety and EMC requirements for equipment for mechanical handling of bulk materials except fixed belt conveyors*

EN 619, *Continuous handling equipment and systems - Safety and EMC requirements for equipment for mechanical handling of unit loads*

EN 626-1:1994+A1:2008, *Safety of machinery - Reduction of risks to health from hazardous substances emitted by machinery - Part 1: Principles and specifications for machinery manufacturers*

EN 626-2, *Safety of machinery - Reduction of risk to health from hazardous substances emitted by machinery - Part 2: Methodology leading to verification procedures*

EN 953, *Safety of machinery - Guards - General requirements for the design and construction of fixed and movable guards*

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

EN 1005-3, *Safety of machinery - Human physical performance - Part 3: Recommended force limits for machinery operation*

EN 1005-4, *Safety of machinery - Human physical performance - Part 4: Evaluation of working postures and movements in relation to machinery*

EN 1037, *Safety of machinery - Prevention of unexpected start-up*

EN 1672-2:2005+A1:2009, *Food processing machinery - Basic concepts - Part 2: Hygiene requirements*

EN 1837, *Safety of machinery - Integral lighting of machines*

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

EN 12198-2, *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery - Part 2: Radiation emission measurement procedure*

EN 12198-3, *Safety of machinery - Assessment and reduction of risks arising from radiation emitted by machinery - Part 3: Reduction of radiation by attenuation or screening*

EN 13478, *Safety of machinery - Fire prevention and protection*

EN 60204-1:2006,¹⁾ *Safety of machinery - Electrical equipment of machines - Part 1: General requirements (IEC 60204-1:2005, mod.)*

EN 60529:1991,²⁾ *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

EN 60825-1:2007, *Safety of laser products - Part 1: Equipment classification and requirements (IEC 60825-1:2007)*

1) This standard is impacted by the stand-alone amendment EN 60204-1:2006/A1:2009, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements (EN 60204-1:2005/A1:2008)*

2) This standard is impacted by the stand-alone amendment EN 60529:1991/A1:2000, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989/A1:1999)* and EN 60529:1991/A2:2013, *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989/A2:2013)*.

EN 60947-5-5, *Low voltage switchgear and controlgear - Part 5-5: Control circuit devices and switching elements - Electrical emergency stop device with mechanical latching function (IEC 60947-5-5)*

EN 61310-3, *Safety of machinery - Indication, marking and actuation - Part 3: Requirements for the location and operation of actuators (IEC 61310-3:2007)*

EN 61496-1:2004+A1:2008, *Safety of machinery - Electro-sensitive protective equipment - Part 1: General requirements and tests (IEC 61496-1:2004, mod.)*

EN 61800-5-2:2007, *Adjustable speed electrical power drive systems - Part 5-2: Safety requirements - Functional (IEC 61800-5-2:2007)*

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, *Graphical symbols - Safety colours and safety signs - Registered safety signs (ISO 7010)*

EN ISO 11553-1:2008, *Safety of machinery - Laser processing machines - Part 1: General safety requirements (ISO 11553-1:2005)*

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

EN ISO 13732-1:2008, *Ergonomics 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, *Ergonomics 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 13849-1:2008, *Safety of machinery - Safety-related parts of control systems - Part 1: General principles for design (ISO 13849-1:2006)*

EN ISO 13850, *Safety of machinery - Emergency stop - Principles for design (ISO 13850)*

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 13856-1, *Safety of machinery – Pressure-sensitive protective devices – Part 1: General principles for design and testing of pressure-sensitive mats and pressure-sensitive floors (ISO 13856-1)*

EN ISO 13856-2, *Safety of machinery – Pressure-sensitive protective devices – Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars (ISO 13856-2)*

EN ISO 13857:2008, *Safety of machinery - Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2008)*

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

EN ISO 14122-1:2001,³⁾ *Safety of machinery - Permanent means of access to machinery - Part 1: Choice of fixed means of access between two levels (ISO 14122-1:2001)*

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

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

CLC/TS 61496-2, *Safety of machinery - Electro-sensitive protective equipment - Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs) (IEC/TS 61496-2)*

CLC/TS 61496-3, *Safety of machinery - Electro-sensitive protective equipment - Part 3: Particular requirements for Active Opto-electronic Protective Devices responsive to Diffuse Reflection (AOPDDR) (IEC/TS 61496-3)*

ISO 3864-1, *Graphical symbols - Safety colours and safety signs - Part 1: Design principles for safety signs and safety markings*

ISO 3864-2, *Graphical symbols - Safety colours and safety signs - Part 2: Design principles for product safety labels*

ISO 3864-3, *Graphical symbols - Safety colours and safety signs - Part 3: Design principles for graphical symbols for use in safety signs*

3 Terms and definitions

For the purposes of this document, the terms and definitions given in EN ISO 12100:2010, EN 60204-1:2006, EN 415-1 and the following apply.

3.1 change parts

machine parts designed to handle a specific product, packaging material or pack size that are changed when the machine is set up to handle a different product, packaging material or pack size

3.2 film compensator

device which maintains a constant film tension

3.3 film reel mandrel

device which may be fixed to the machine or which is loose and which supports a reel of film

3.4 hot melt adhesive

adhesive that is solid at room temperature and which can be applied at elevated temperature

3.5 minimum distance

calculated distance between the safeguard and the hazard zone necessary to prevent a person or part of a person reaching the hazard zone before the termination of the hazardous machine function

3) This standard is impacted by the stand-alone amendment EN ISO 14122-1:2001/A1:2010, *Safety of machinery — Permanent means of access to machinery — Part 1: Choice of fixed means of access between two levels — Amendment 1 (ISO 14122-1:2001/Amd 1:2010)*.

Note 1 to entry: Different minimum distances may be calculated for different conditions or approaches, but the greatest of these minimum distances is used for selecting the position of the safeguard.

3.6

modified atmosphere

atmosphere where the normal atmosphere within a package is completely or partially replaced by one or more selected gases

Note 1 to entry: Usually the objective is to extend shelf or storage life of the packaged products.

3.7

packaging material

material used to make a package

EXAMPLE Corrugated board, carton board, stretch film, paper, polypropylene.

3.8

product

substance, article, pack or group of packages with or without pallet that are handled in the packaging machine

3.9

safety distance

Safe separation distance

S_r

minimum distance that a protective structure is required to be placed from a hazard zone

3.10

safety related parts of control systems

SRP/CS

part of a control system that responds to safety-related input signals and generates safety-related output signals

Note 1 to entry: The combined safety-related parts of a control system start at the point where the safety-related input signals are initiated (including, for example, the actuating cam and the roller of the position switch) and end at the output of the power control elements (including, for example, the main contacts of a contactor).

Note 2 to entry: If monitoring systems are used for diagnostics, they are also considered as SRP/CS.

[SOURCE: EN ISO 13849-1:2008, 3.1.1]

3.11

strap

band of material, usually made from mild steel, polypropylene or polyester, which is passed around a group of products, tensioned and then sealed to hold the products together

3.12

teleservice

machine control mode where faults can be diagnosed, parameters changed and machine functions can be initiated from a remote location

Note 1 to entry: Collecting data or monitoring machine parameters is not considered as teleservice.

4 List of significant hazards

4.1 General

This clause lists all the significant hazards, hazardous situations and events that can be found on most packaging machines.

Before using this document, the manufacturer shall establish that the hazards on his machine correspond to the hazards described in this document.

4.2 Mechanical hazards

4.2.1 Moving parts

Packaging machines may incorporate moving parts which present a variety of mechanical hazards including crushing, shearing, cutting, entanglement, friction, impact, drawing-in and trapping. Some of these hazards may persist after the power supply has been cut off due to stored energy or gravity.

4.2.2 Slip, trip and fall hazards

Slip accidents can occur if liquids or solids from the machine, e.g. lubricants, packaging materials or the product, spill onto traffic routes, work stations or means of access around the machine.

Trip accidents may occur if parts of the machine protrude beyond the machine frame at low level, or if cables and pipes associated with the machine are installed without proper consideration of tripping hazards.

Falls may occur if people climb or stand on parts of the machine above floor level, e.g. for magazine loading, size changing, maintenance or cleaning.

4.2.3 Loss of stability

If packaging machines become unstable and move unexpectedly or fall over, they can cause crushing and impact injuries. Loss of stability can occur in the following circumstances:

- a) while the machine is in operation, for example:
 - 1) if components are unbalanced;
 - 2) if the machine footings are unstable;
 - 3) if the centre of gravity of the machine is high or close to the boundary of the base area;
 - 4) if someone stands on the machine;
 - 5) when the machine is positioned on a slope;
- b) while the machine is being moved, for example:
 - 1) if suitable lifting instructions are not provided;
 - 2) when the volume and shape of the machine could suggest a position of the centre of gravity different from the actual centre of gravity;
 - 3) on machines fitted with wheels when the machine is being moved on a slope or uneven surface.

4.2.4 Hazards from guards

Guards may present crushing, shearing and impact hazards when they open or close or are handled if they have a high mass or move under gravity or power.

4.3 Pneumatic and hydraulic equipment

Pneumatic and hydraulic equipment present crushing, shearing, ejection of parts and injection of fluids hazards. Stored energy in pneumatic or hydraulic systems may cause mechanisms to move unexpectedly

even when power supplies are disconnected. In addition, hydraulic oil and pneumatic lubricating oil may present a potential fire hazard and can contaminate products. Failure of a hose assembly can constitute a whiplash hazard.

4.4 Hazards from electrical equipment

Electrical equipment on the machine can generate a potential electric shock and burn hazard and in the presence of combustible materials, a potential fire hazard. Electrical systems can act as an ignition source in the presence of flammable substances or products which are capable of creating an explosive atmosphere.

If liquids, e.g. product spillage or cleaning agents like water, come into contact with the electrical conductors, there is a risk of electric shock.

4.5 Hazards from electrostatic phenomena

Electric shock hazards can arise if parts of the machine or materials are electrostatically charged, e.g. a plastic guide rail that is rubbed by passing products or plastic film unwinding from a reel. Electrostatic discharge can be a source of ignition in the presence of flammable substances or explosive atmospheres.

Electrostatic discharge can cause hazards for persons with inactive or active implantable medical devices.

4.6 Thermal hazards

4.6.1 Hot Surfaces

Parts of the machine, e.g. sealing mechanisms and drive motors, which have a high surface temperature, may cause burning hazards.

The burning hazard will usually continue to exist for a period of time after power has been disconnected.

4.6.2 Cold surfaces

Parts of the machine or products, e.g. on packaging machines for frozen product, which have a very low surface temperature, may cause burning hazards.

The frostbite hazard will usually continue to exist for a period of time after power has been disconnected.

4.7 Noise

Noise generated by packaging machines can result in:

- permanent hearing loss;
- tinnitus;
- fatigue, stress, etc.;
- other effects such as loss of balance, loss of awareness;
- interference with speech communication;
- inability to hear acoustic warning signals.

4.8 Radiation

Some packaging machines incorporate sources of radiation that may give rise to hazards. For example:

- a) low frequency radio and micro-waves, e.g. induction sealing;
- b) infrared, visible light and ultraviolet light, e.g. for inspection of containers;
- c) lasers, e.g. for measuring or marking of packages or labels. Laser radiation can cause burn injuries, especially of the eyes with the potential consequence of blindness. The laser can be an ignition source and cause fire and explosion in the presence of flammable or explosive materials. The decomposition products which result from the contact of the laser on packaging materials can present hazards to health. See EN ISO 11553-1 for other hazards from lasers;
- d) X and Gamma rays, e.g. for inspection or irradiation of products or packages. Corrosion or mechanical damage of sealed radioactive sources can result in release of hazardous radiation;
- e) Alpha and Beta rays, electron ion or neutron beams, e.g. for inspection of packs.

Ionizing and non-ionizing radiation can cause hazards for persons with inactive or active implantable medical devices or cause harm to human cells like damage to skin.

4.9 Hazards from products and materials

4.9.1 Hazards generated by products

Packaging machines are used to pack a wide range of products, some of which may be potentially hazardous to persons operating or in the vicinity of the packaging machine during normal operation or if a package containing a hazardous substance is damaged in the packaging machine.

Hazards generated by the product can include:

- a) Ingestion or inhalation of harmful substances, e.g. insecticides, aggressive or harmful chemicals, pharmaceuticals;
- b) fire or explosion, e.g. by flammable liquids, explosives, dusty products;
- c) biological hazards, e.g. vaccines;
- d) impact by ejected products;
- e) electric shock from electrostatic discharges, e.g. by products rubbing against plastic guide rails (see 4.5).

4.9.2 Hazards generated by packaging materials

Packaging machines are intended to use a range of packaging materials, which can present the following hazards:

- a) inhalation of harmful smoke, gas or vapours from overheated or burning of materials;
- b) inhalation of harmful or unpleasant dusts, e.g. from paper;
- c) cuts from handling packaging materials, e.g. film, strap or paper edges;
- d) fire due to overheating of combustible packaging materials, e.g. plastic films and paper;
- e) electric shock from electrostatic discharges, e.g. at plastic film reel unwind mechanisms or plastic sheet feeding mechanisms.

4.10 Hazards due to neglecting ergonomic principles

Hazards to safety and health, e.g. fatigue, mental stress, strain injuries or occupational diseases can occur when people are carrying out the following activities on packaging machines:

- a) operating, e.g. assuming a bad posture or performing unnatural hand or arm movements or using excessive effort caused by inadequate design or location of actuators or displays;
- b) operating, cleaning and maintaining of machines under poor lighting conditions;
- c) loading packaging materials, e.g. assuming a bad posture, using excessive effort, fatigue;
- d) loading or unloading products, e.g. assuming a bad posture or performing unnatural hand or arm movements or using excessive effort;
- e) performing size or product changing, e.g. assuming a bad posture or performing unnatural hand or arm movements or using excessive effort;
- f) cleaning the machine, e.g. assuming a bad posture or performing unnatural hand or arm movements or using excessive effort;
- g) maintenance, e.g. assuming a bad posture or using excessive effort;
- h) moving the machine or the guards or other parts, e.g. using excessive effort.

4.11 Hazards due to neglecting hygienic design principles

On machines that are intended to pack foodstuffs, cosmetics, pharmaceuticals or other products where hygiene is a consideration, product contamination hazards can result if inappropriate contact materials or construction methods are used or if lubricants or other contaminating substances or improper conditions are allowed to come into contact with the product.

4.12 Hazards caused by failures

4.12.1 General

The following hazards can be generated on packaging machines by:

- a) mechanical hazards due to uncontrolled lowering or falling of machine assemblies or product;
- b) mechanical hazards due to unexpected locking of brakes or other components;
- c) mechanical hazards because of an inability to stop movements, e.g. failure of a braking function;
- d) mechanical hazards due to unexpected movement of assemblies when power is reconnected or due to stored energy;
- e) mechanical and chemical hazards due to unexpected release of substances;
- f) fire or explosion hazards, e.g. because of the inability to stop a heating function.

4.12.2 Failure of power supplies

The hazards mentioned in 4.12.1 can arise by failures of the power supplies as loss or restoration of energy or fluctuation of the power supplies. See also 4.9.1.

4.12.3 Failure of safety related parts of control systems

Hazards can arise if components in safety related parts of control systems fail. Failures may occur due to mechanical damage, contact failure, electronic component failure.

Systematic faults may occur, especially in programmable systems. Failures can lead to loss of safety functions resulting in unexpected start-up of moving parts, incorrect sequencing of machine operations or the prevention of moving parts from stopping as expected. Malfunctions or responses to an external disturbance such as electromagnetic interference can lead to a hazardous situation.

4.12.4 Failure of electronic drive systems

When the power supply of an electronic drive system is not disconnected after a safety related stop has been initiated (e.g. the guards are open), there is a risk of unexpected start-up with consequential mechanical hazards if the control system malfunctions or responds to an external disturbance such as electromagnetic interference.

Adjustable speed electrical power drive systems have an increased risk because of their working principle and high acceleration.

4.13 Hazards caused by the presence of stored energy

Stored energy may lead to hazards like unexpected movement and be caused for example by:

- a) requirement of the machine function;
- b) failure to provide a means for the automatic release of energy;
- c) failure of an energy dissipating device, e.g. because of internal or external influences, misalignment, assembly errors, ageing, lack of maintenance;
- d) operator errors, e.g. due to lack of information or not following the required procedure;
- e) operator errors because the means of energy dissipation is not easily accessible or identifiable;
- f) design of the mechanism, e.g. because parts can move under gravity or the mechanism incorporates tension or compression springs;
- g) product jam, e.g. because mechanisms move when a jammed product is removed.

4.14 Hazards due to remote diagnostics or control

Hazardous situations can arise if it is possible to control a machine from a remote location or alter the software of a machine from a remote location.

In particular, hazards by unexpected start up can occur if:

- a) guards are removed;
- b) it is possible to defeat the interlocking systems from the remote location;
- c) unauthorized people can gain access to the machine's controls in the remote location.

4.15 Reasonably foreseeable misuse

Reasonably foreseeable misuse is the use of a machine in a way that is not intended by the manufacturer and which can easily be anticipated because of known human behaviour.

If the machine can operate independently in different hazard zones, the complete stop of the whole machine can reduce the machine efficiency. This could encourage users to defeat guards.

NOTE 1 Foreseeable misuse can for example be:

- defeating of guards or protective equipment because of improper design of the machine;
- behaviour that results from the quest for convenience or efficiency (use the way of least resistance);
- access through apertures not intended for access.

NOTE 2 Reasons for defeating guards can for example be:

- time delay between the stop and the restart of the production;
- distance from the operator's position to the next safe means of access;
- available items which can be used as a step with the consequence of the possibility of climbing over the guard.

4.16 Hazards from specific elements or processes of packaging machines

4.16.1 Cutting devices

Mechanical cutting devices present a cutting or shearing hazard:

- a) when the machine is in normal operation;
- b) when the machine's power supplies are isolated and the mechanism moves unexpectedly, e.g. due to stored energy;
- c) when threading film the operator touches the exposed cutting surface;
- d) when the device is handled during setting-up, cleaning or maintenance.

4.16.2 Sealing devices

Mechanical sealing devices present a crushing hazard:

- a) when the machine is in normal operation;
- b) when the machine's power supplies are isolated the mechanism moves unexpectedly due to stored energy.

Heated sealing devices present a burning hazard during normal operation. They also present a burning hazard for a period of time after power has been disconnected from the device.

There is a risk of electrical insulation in heating elements breaking down giving rise to an electric shock hazard.

There is a risk of fire if packaging materials remain in contact with a heated sealing device for too long or if the temperature of the sealing device is too high, e.g. if the temperature of the heater controls is set too high or if the temperature control fails and the temperature rises unexpectedly.

Certain materials, such as polyester film, can give off hazardous fumes if they are overheated by the sealing device.

4.16.3 Film reel unwind mechanisms

Film reel unwind mechanisms present the following hazards:

- a) reels rotating at high speed can generate crushing or impact hazards if stopped suddenly;
- b) reels with a high mass can generate a drawing-in hazard if they are supported on rollers;
- c) the edges of the film can be a cutting hazard;
- d) there can be a drawing-in hazard when the film is passed over rollers;
- e) there can be a shearing hazard between the film compensator and fixed parts of the film reel mandrel;
- f) there can be an impact hazard if the film breaks and the film compensator move unexpectedly.

4.16.4 Conveyors

4.16.4.1 General

Some conveyors can be installed where operators can stand or walk on them. Therefore there are hazards of slipping, tripping and falling, e.g. during cleaning, maintenance and trouble shooting. Falling can also result from an automatic start of a conveyor while a person is standing or walking on it.

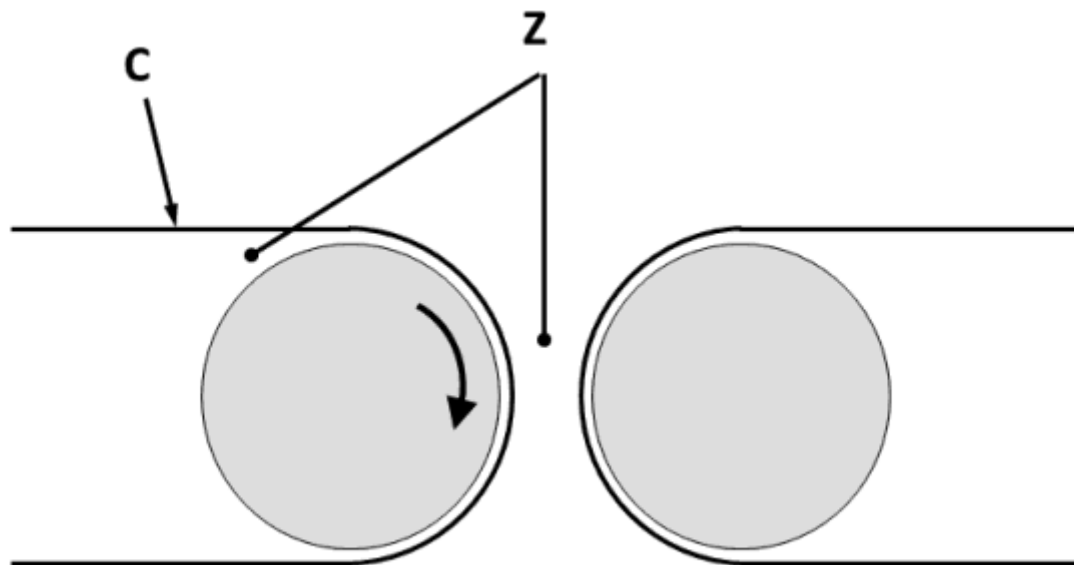
Drawing-in and entanglement hazards, especially of hair, can occur when persons are exposed below a conveyor (e.g. during cleaning, trouble-shooting or maintenance).

Drawing-in or trapping hazards can be generated by in-running nips and where traction elements pass over rollers, wheels or fixed parts of the conveyor frame.

Additional hazards can occur when fixed parts of the construction or guards are insufficiently stable against foreseeable mechanical strain, e.g. of conveyed product or packs so that they can be deformed or where abrasion or other influences expand gaps between moving and fixed parts.

4.16.4.2 Belt and slat-band conveyors

Drawing-in or trapping hazards can be generated by in-running nips where belts pass over rollers (as shown in Figure 1) or fixed parts of the conveyor frame or at conveyor junctions, e.g. when the following conveyer does not rotate, rotates slower or has less friction than the previous conveyor, as shown in Figure 1.



Key

- C conveyor
- Z hazard zone

Figure 1 — Junction of belt conveyors

4.16.4.3 Roller conveyors

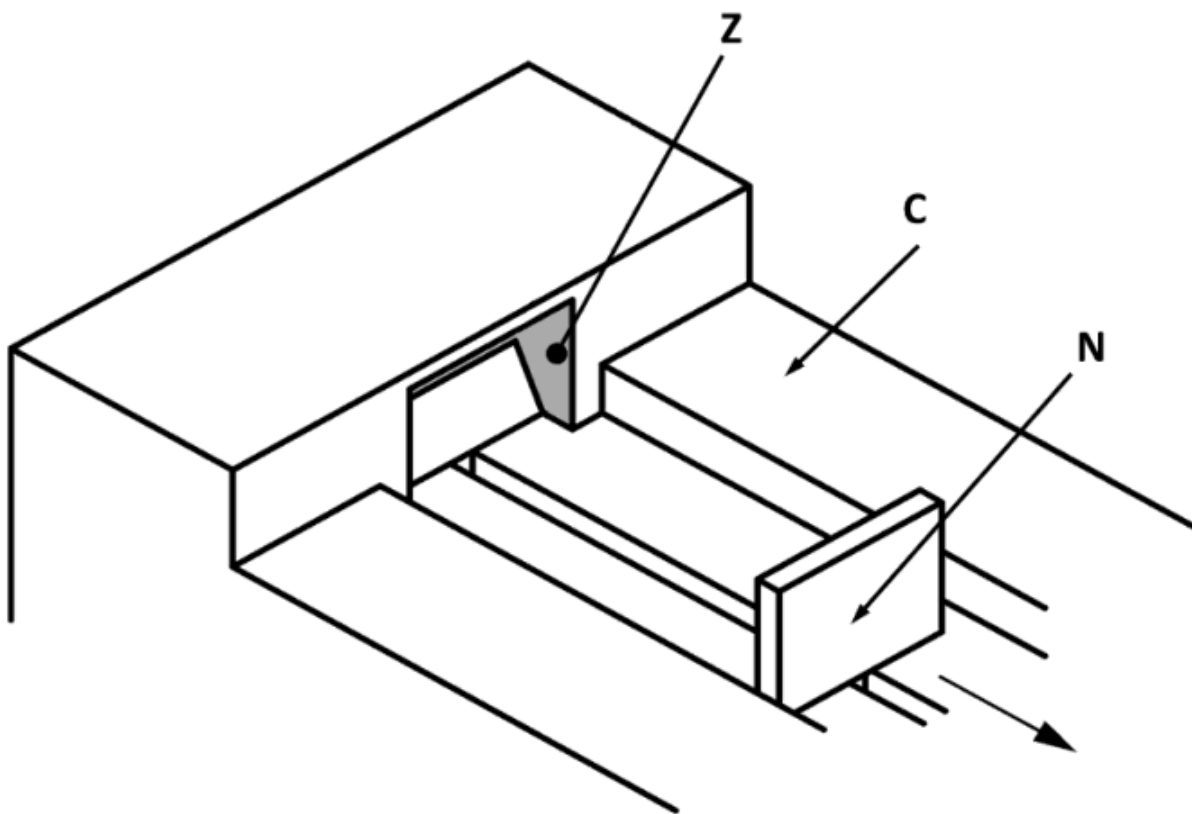
Drawing-in or trapping hazards can be generated by in-running nips between rotating rollers of roller conveyors and their substructure or machine parts.

4.16.4.4 Screw conveyors

Screw conveyors present drawing in, entanglement, shearing and crushing hazards.

4.16.4.5 Conveyors with carriers

In addition to the general hazards presented by conveyors, for conveyors with carriers there are additional entanglement, drawing-in, shearing and crushing hazards especially where carriers emerge from or run into the machine frame or pass by fixed parts, as shown in Figure 2.



Key

- C conveyor
- N carrier
- Z hazard zone

Figure 2 — Conveyor with carrier

4.16.5 Handles and hand-wheels

Handles or hand-wheels to operate machines manually, e.g. for adjustment or cleaning, can cause impact, friction or entanglement hazards if the handle or hand-wheel:

- a) moves under power;
- b) moves unexpectedly due to stored energy, e.g. because of eccentric masses or springs.

Errors in operation of manual or electronic hand wheels can cause hazardous movement of the machine.

4.16.6 Size or product changing

Typically, packaging machines are constructed to handle a range of product and pack sizes. Changes of size or product can give rise to the following hazards:

- a) hazard zones on the machine may be exposed when components are moved;
- b) handling change parts may give rise to ergonomic hazards;
- c) where size or product changing is carried out under power, mechanical hazards can arise.

4.16.7 Hot melt adhesive equipment

On machines that use hot melt adhesive, there are burning hazards from contact with hot surfaces and a scalding hazard from contact with the adhesive. When loading cold adhesive into molten adhesive, there is a risk of scalding from splashes of molten adhesive.

On machines where the adhesive is pressurised and jetted or sprayed onto the packaging material, there is a risk of scalding from adhesive jetted out of the machine, e.g. if the glue gun is misaligned or during maintenance operations.

The hot melt adhesive may generate unpleasant fumes, particularly if it is overheated. If the adhesive is overheated there is a risk of it catching fire.

4.16.8 Modified atmosphere packaging

Packaging machines may use special atmospheres during the packing process to produce packages with an enhanced shelf life. The gases used are typically oxygen, nitrogen and carbon dioxide. These gases present the following hazards:

- a) Oxygen: risk of fire and explosion. Especially on machines which use an oil lubricated rotary vane vacuum pump where is a risk of fire and explosion if the oxygen level in the pump exceeds 21 %.
- b) Nitrogen: asphyxiation or fatigue due to reduction in oxygen levels.
- c) Carbon dioxide: respiratory paralysis because of intoxication.

5 Safety requirements and/or protective measures

5.1 General

Packaging machinery shall comply with the safety requirements and/or protective measures of this clause. In addition, the machine shall be designed according to the principles of EN ISO 12100:2010 for relevant but not significant hazards, which are not dealt with by this document.

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.

When selecting protective measures, the following hierarchy applies in all phases of the life cycle:

- a) eliminate or reduce the risk by inherently safe machinery design and construction;
- b) install the necessary protective measures in relation to risks that cannot be eliminated;
- c) inform users of the residual risks due to any limitations of the protective measures adopted, indicating whether any particular training is required and specifying any need to provide personal protective equipment.

The following requirements apply to all packaging machines where the equivalent hazard exists.

5.2 Requirements to minimize mechanical risks

5.2.1 Protective measures against risks from moving parts

5.2.1.1 Inherently safe design – physical aspects

One method of inherently safe design is to reduce forces, pressure and energy to values which do not cause injuries. Examples of values that are discussed presently as applicable are given in informative Annex B.

If the values given in Annex B are not applicable, the values for energy shall not exceed 4 J in general and 10 J if the motion is reversed. The movement shall automatically be reversed within 1 s when a resistance is detected.

Crushing hazards can be considered as eliminated when the distance between moving and fixed parts and between one moving part and another is dimensioned in compliance with EN 349.

NOTE 1 The safety distances for crushing may be ineffective in case of drawing-in.

The risk of entanglement and friction presented by rotating shaft ends can be considered as minimized if they are smooth, have no protruding parts and do not protrude from the machine more than 1/4 of their diameter or 20 mm, whichever is the smaller.

NOTE 2 The measures indicated above may not be applicable or effective in all circumstances. For example, the methods for elimination of entanglement and friction hazards as described above may not be effective where clothes or personal protective equipment with high friction are used, e.g. rubber gloves. Subsequent clauses of this document indicate situations where these measures are known to be effective.

5.2.1.2 Fixed or interlocking movable guards

- a) Moving parts shall be safeguarded by fixed or interlocking movable guards complying with this clause and 5.2.1.3, 5.2.1.4, 5.10.2, 5.16.3 and EN 953. Where no specific choice for a type of guard is specified in this document, the guards shall be chosen using EN 953.
- b) Unless otherwise specified in this document the guards shall be dimensioned and positioned so that the safety distances comply with those specified in Clause 4 and Annexes A and B of EN ISO 13857:2008.
- c) Unless otherwise specified in other parts of EN 415 open topped distance guards shall be at least 2 000 mm high from the floor or other access platform.

NOTE This measure is against climbing over a guard by using easily available means.

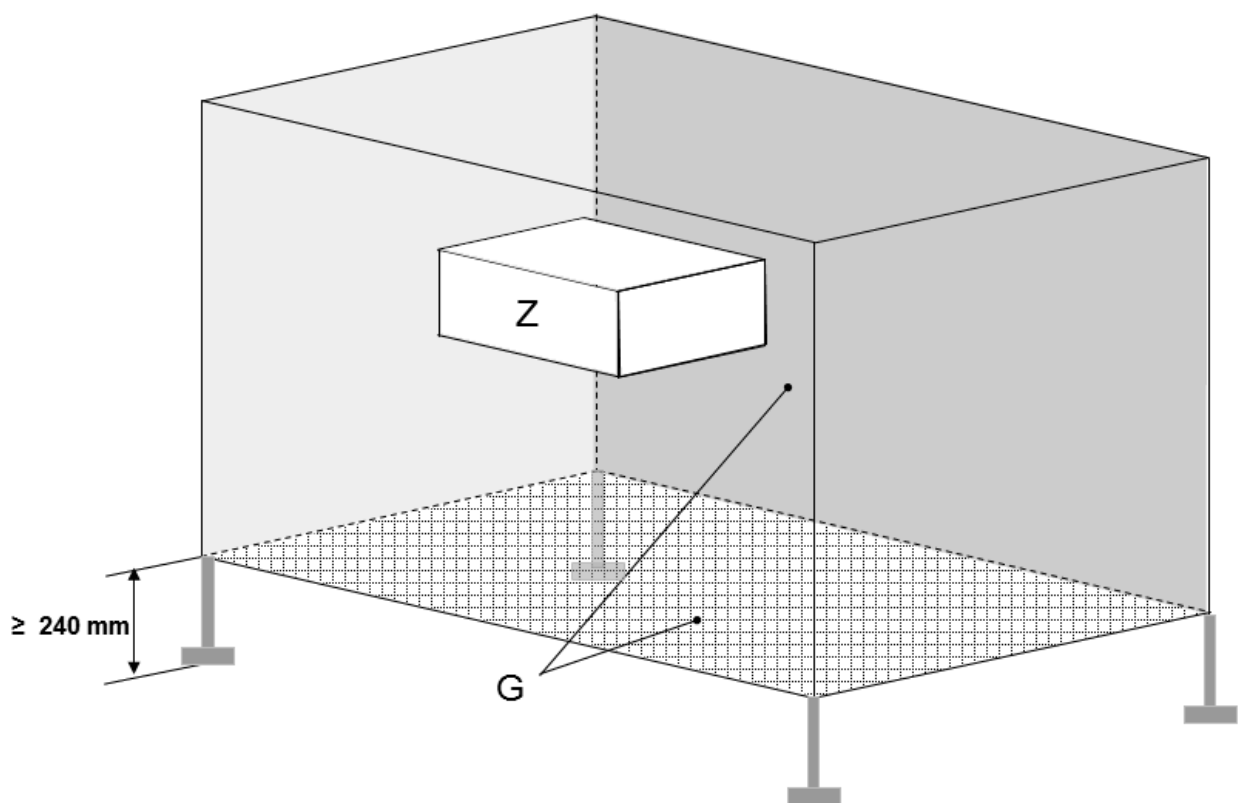
The distance from their upper edge to the nearest hazard zone shall comply with EN ISO 13857:2008, Table 2.

- d) Where there is a gap between the guard and the floor e.g. for cleaning or removing products or packs, the following requirements apply:
 - 1) if the gap is less than or equal to 20 mm the safety distances to the nearest hazard zones shall comply with EN ISO 13857:2008, Table 4;
 - 2) where the gap is greater than 20 mm but less than or equal to 40 mm, the safety distances to the nearest dangers zones shall be at least 550 mm. where access is not foreseeable, the safety distance can be reduced to 130 mm;
 - 3) where the gap is greater than 40 mm but less than or equal to 240 mm the safety distance to the nearest hazard zones shall be at least:
 - i) 850 mm, if the height of the lowest hazard zone is lower than or equal to 300 mm above the lower edge of the guard;

- ii) 550 mm, if the height of the lowest hazard zone is higher than 300 mm above the lower edge of the guard.

NOTE List entry 3) applies only when access to the hazard zone by lower limbs is not reasonably foreseeable. In all other cases EN ISO 13857:2008, Table 7 applies.

- 4) where the gap is greater than 240 mm, a guard complying to a) of this subclause shall be fixed underneath the machine (see Figure 3) or one of the protective measures indicated in 5.2.1.3 shall be used, or all hazard zones which could be reached shall be safeguarded individually according to a) and b) of this subclause;
- e) Where there is a risk of parts or products being ejected from the machine the guards and their position shall be designed to contain these parts or products;



Key

- Z hazard zone
- G fixed guard

Figure 3 — Horizontal fixed guard at the bottom

- f) where whole body access is possible to a machine, persons shall be able to leave the hazard zone, e.g. by an interlocking movable guard that can be opened from inside the machine or an aperture with ESPE. For protective measures see 5.16.2;
- g) On machines where opening an interlocking movable guard could expose a person to a hazard, the interlocking movable guard shall be fitted with a guard locking device complying with EN ISO 14119:2013, 5.7 that prevents the guard from opening as long as the hazard is present;

- h) moveable guards shall be interlocked with devices that comply with EN ISO 14119:2013, 5.7 and shall be installed as indicated in Clause 5 of that standard. Safety related parts of interlocking systems shall comply with 5.15.

If it is necessary to remove fixed guards regularly (e.g. for maintenance, cleaning) the fixing systems shall remain attached to the guard or the machinery when the guard is removed.

5.2.1.3 Apertures in guards

5.2.1.3.1 General

Apertures in guards for loading or discharging of product or packaging components shall be designed, positioned and dimensioned to prevent persons reaching into hazard zones and to prevent or, if this is not practicable, discourage whole body access.

The safety requirements to prevent access through an aperture to a hazard zone vary depending on the dimensions of the aperture, the height of the aperture from the nearest access platform, the shape of the guarding around the aperture and presence or not of a conveyor in the aperture.

Three main types of aperture are defined as shown in Figure 4:

- a) small apertures, designated as "S";
- b) medium apertures designated as "M_a", "M_b" and "M_c";
- c) large apertures designated as "L".

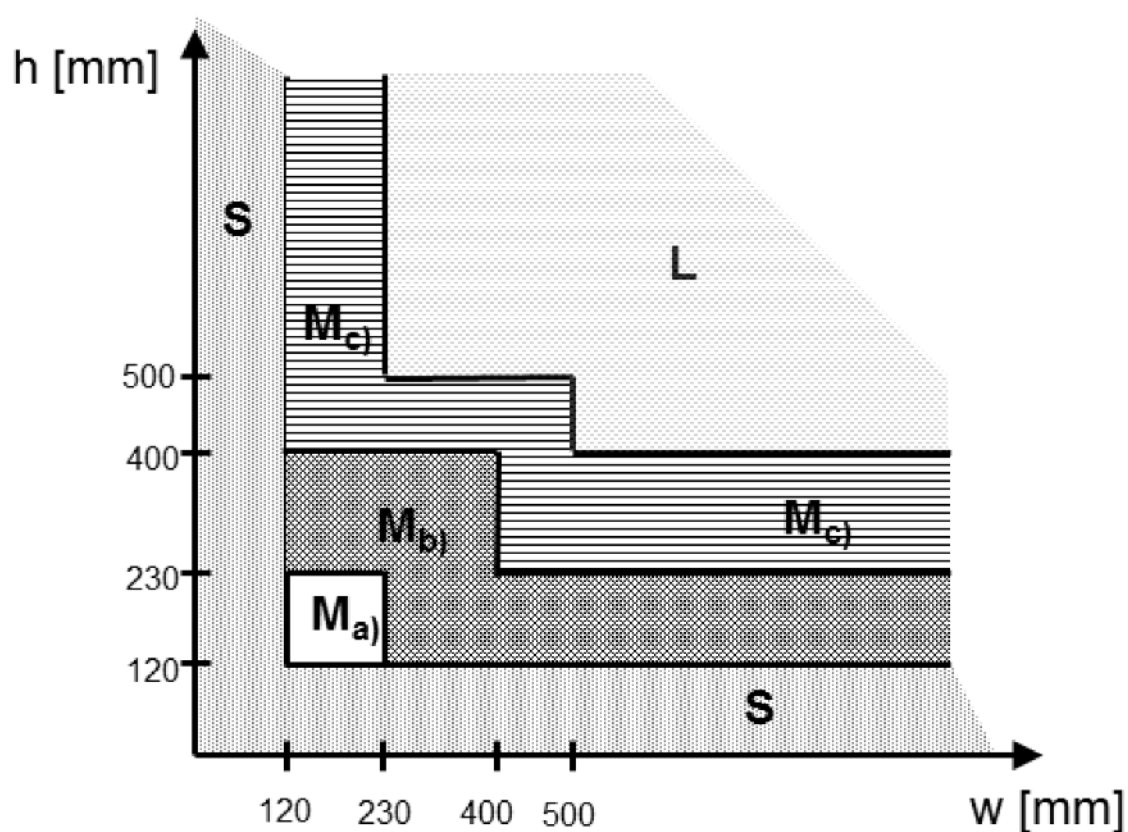
Preferably the guards around apertures for entry or exit of conveyors shall be tunnel shaped when they are greater than small apertures (S) as described in 5.2.1.3.2. Where positions behind tunnel guards have to be reached regularly, these tunnel guards or parts of them shall be designed to be movable and interlocked complying with 5.2.1.2.

One or more interlocking movable guards or apertures with ESPE complying with 5.15 shall be provided for access. These are apertures giving access to all the parts of the machine where regular access is required or foreseeable so that it is unnecessary to reach into the safeguarded zone through other apertures than the intended one. The instructions shall state the intended means of access.

The requirements for safeguarding apertures with guards shall be chosen depending on their dimensions as indicated in Figure 4.

Table 1 indicates the safety distances for medium-sized apertures according to the dimensions of the apertures under the presumption that the cross section of a possible tunnel is the same as that of the aperture.

Where the distance between the access platform and the lower edge of an aperture to the access platform or between the access platform and the conveying level is 1 600 mm or more and when there is no foreseeable reason to gain access to the entry or exit point (e.g. for troubleshooting, maintenance, cleaning) no further safeguarding is required, but EN ISO 13857:2008, Table 2 applies. Conveyors and any other installation (e.g. guards) shall be designed to prevent people climbing up to the aperture.



Key

- L dimensions of large apertures
- M dimensions of medium-sized apertures
- S dimensions of small apertures
- w clear width of the aperture
- h clear height of the aperture

Figure 4 — Entry or exit points - dimensions of apertures

Table 1 — Safety distances for medium-sized apertures

	Safety distance (mm)				
	1	2	3	4	5
Size of aperture (from Figure 4)	Apertures without a conveyor or tunnel guard (see Figure 5)	Apertures with bent tunnel guards with or without a conveyor (see Figure 6 and Figure 7)	Apertures with a conveyor but without a tunnel guard (see Figure 8)	Apertures with a conveyor and a tunnel guard (see Figure 9 and Figure 10)	Minimum tunnel and conveyor length l (see Figure 6 to Figure 10)
M_a	$s \geq 1\,000$	for $135^\circ \geq \alpha \geq 90^\circ$, for $s_2 \geq 300$ ($s+s_2$) ≥ 850	$s \geq 900$	$s \geq 850$	$l \geq 500$
M_b	$s \geq 1\,200$	$s + s_2 \geq 900$ for $135^\circ \geq \alpha \geq 90^\circ$, else: column 1 applies for $s_2 \geq 300$	$s \geq 1\,000$	$s \geq 900$	$l \geq 500$
M_c	5.2.1.3.12 applies	$s \geq 1\,100$ for $135^\circ \geq \alpha \geq 90^\circ$, else: column 1 applies	$s \geq 1\,400$	$s \geq 1\,100$	$l \geq 1\,000$

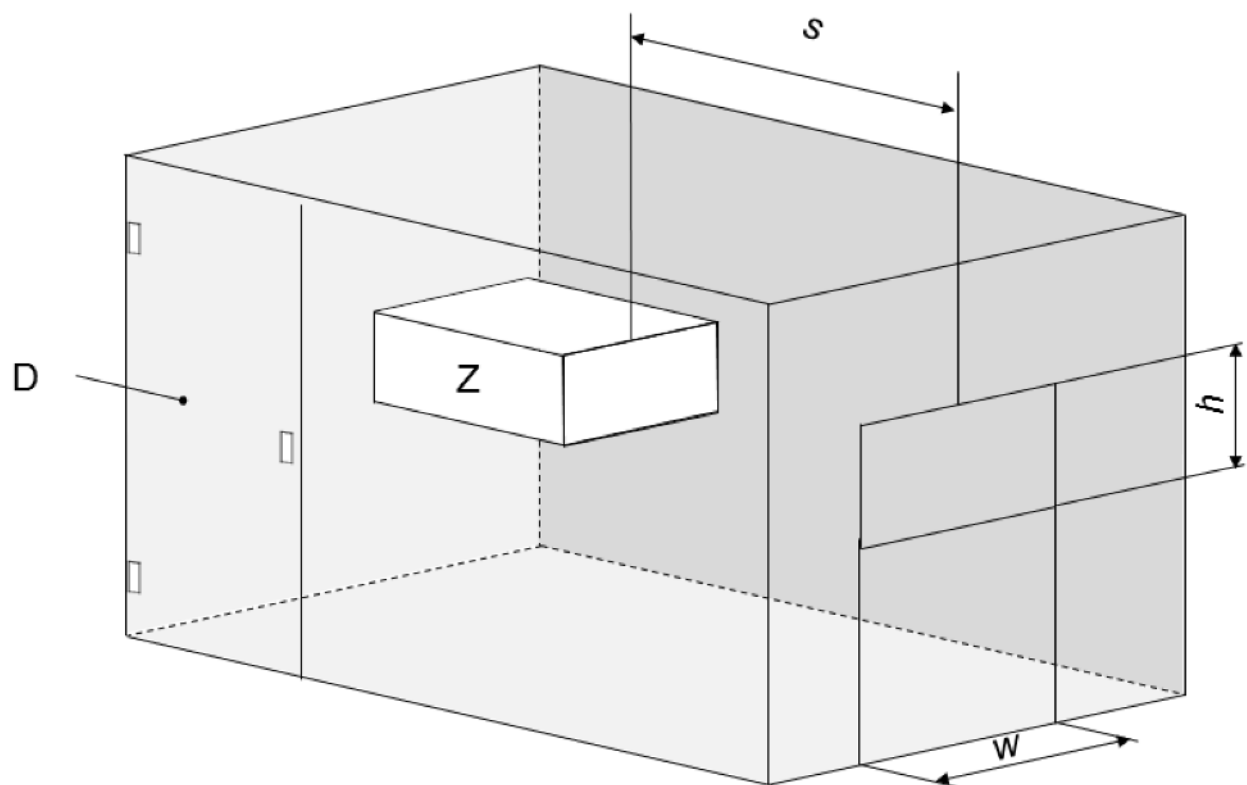
5.2.1.3.2 Small apertures

For apertures where the width or height is less than or equal to 120 mm (area S in Figure 4), the safety distance to the nearest hazard zone through the aperture shall comply with EN ISO 13857:2008, Tables 3, 4 or 6, or, on machines which can foreseeably be used in public areas, with EN ISO 13857:2008, Table 5 whichever is applicable in the respective situation.

Where for technical reasons the reach distances indicated above are not applicable, one of the safeguarding methods indicated in 5.2.1.3.3 to 5.2.1.3.18 or a method to the same effect shall be used.

5.2.1.3.3 Medium-sized apertures without conveyor

For medium-sized apertures M_a , M_b and M_c as shown in Figure 4 without entry or exit of a conveyor as shown in Figure 5 the safety distances as stated in column 1 of Table 1 shall be applied.



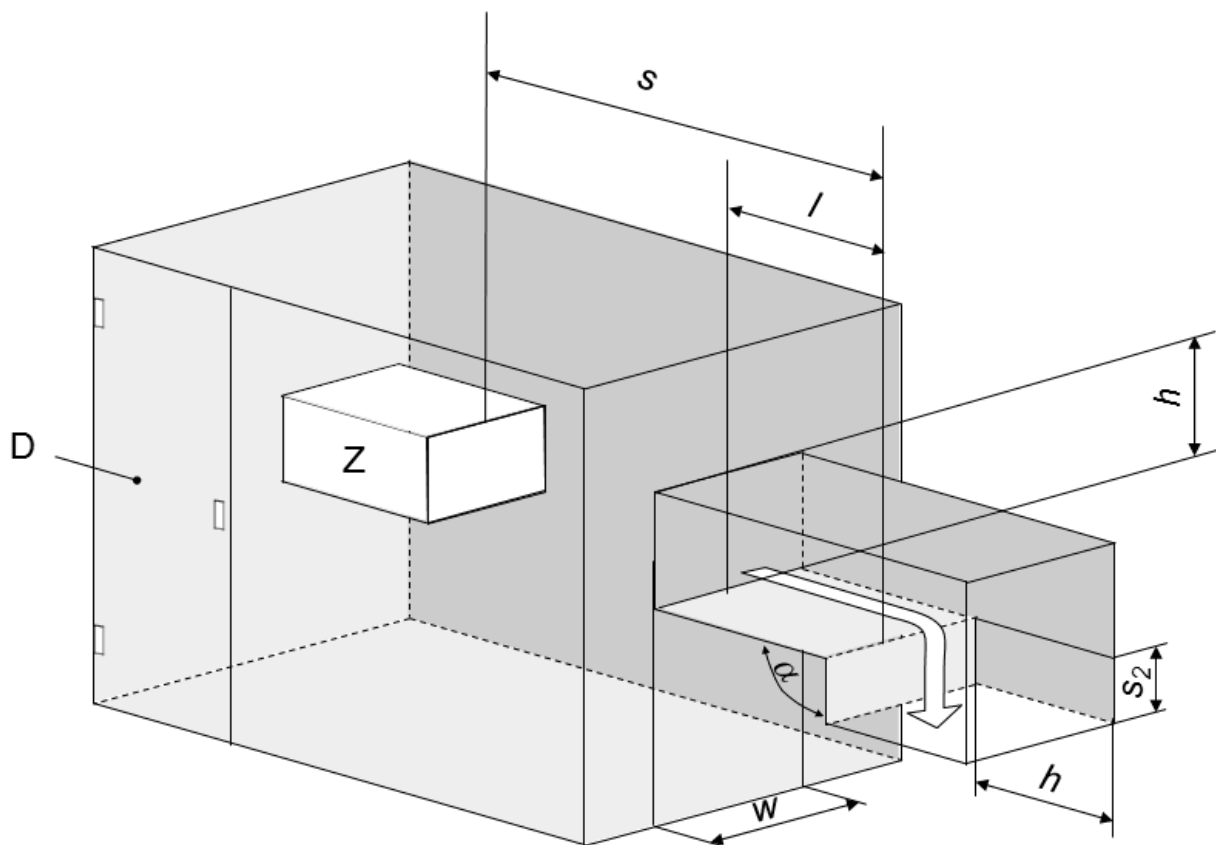
Key

- D interlocking movable guard
- Z hazard zone
- s safety distance
- h height of aperture
- w width of aperture

Figure 5 — Medium-sized aperture without conveyor and without tunnel guard

5.2.1.3.4 Medium-sized apertures with bent tunnel guard

For medium-sized apertures M_a), M_b) and M_c) as shown in Figure 4 where a bent tunnel guard is applied as shown in Figure 6 and Figure 7 the safety distances as stated in column 2 of Table 1 shall be applied.



Key

- Z hazard zone
- D interlocking movable guard
- s safety distance
- s_2 length of the vertical part of the tunnel
- h height of aperture
- w width of aperture
- l length of tunnel
- α angle of bent tunnel

Figure 6 — Medium-sized aperture with vertically bent tunnel guard