



BSI Standards Publication

Safety of packaging machines

Part 3: Form, fill and seal machines; fill and seal machines

National foreword

This British Standard is the UK implementation of EN 415-3:2021. It supersedes BS EN 415-3:1999+A1:2009, which is withdrawn.

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 committee manager.

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Machines d'emballage à former, remplir et sceller ;
machines d'emballage à remplir et sceller

Sicherheit von Verpackungsmaschinen - Teil 3: Form-,
Füll- und Verschleißmaschinen; Füll- und
Verschleißmaschinen

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European foreword

This document (EN 415-3:2021) 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of an identical text or by endorsement, at the latest by April 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.

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

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).

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

This document supersedes EN 415-3:1999+A1:2009.

The following significant changes have been made:

- Scope now includes fill and seal machines and multi-head weighers;
- Cartoning machines have been removed from the scope;
- Safety requirements have been rewritten so they are in line with EN 415-10:2014;
- 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: Cartoning and case-packing machines;*
- *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.*

Any feedback and questions on this document should be directed to the users' national standards body. A complete listing of these bodies can be found on the CEN website.

According to the CEN-CENELEC Internal Regulations, the national standards organisations of the following countries are bound to implement this European Standard: 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 the United Kingdom.

Introduction

Form, fill and seal machines and fill and seal machines are used extensively in Europe, in an increasingly wide range of industries. They contain many hazards and have the potential to cause serious injury.

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

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 above-mentioned 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. 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.

1 Scope

This document establishes safety requirements for the main types of form, fill and seal machines, fill and seal machines and the filling machines which are frequently fitted to these machines.

Form fill and seal machines within the scope of this document are:

- flow wrapping machine;
- vertical form, fill and seal machine;
- horizontal sachet form, fill and seal machine;
- thermoform, fill and seal machine;
- tubular bag form, fill and seal machine;
- mandrel form, fill and seal machine.

Fill and seal machines within the scope of this document are:

- pre-made bag, erect, fill and seal machine;
- cup or tub fill and seal machine;
- sack fill and seal machine.

Filling machines commonly fitted to form, fill and seal machines and fill and seal machines within the scope of this document are:

- auger filler;
- volumetric cup filler;
- nett weigher;
- multi-head weigher.

Other types of form, fill and seal machine which are described in 3.3 have similar hazards to these machines and Clause 4 indicates which clauses of this document are applicable to these machines.

This document covers the safety requirements for machine design, construction and all phases of life of the machines including installation, commissioning, operation, adjustment, maintenance and cleaning.

This document applies to machines manufactured after the date of publication of this document.

This document does not apply to:

- blow mould fill and seal machines;
- bulk container fill and seal machines;
- cartoning machines;
- food depositors, including volumetric piston depositors in the scope of EN 15180;
- thermoforming machines in the scope of EN 12409.

This document does not consider:

- hazards due to the products packed in these machines, but does consider the hazards caused by dusts, modified atmosphere gases, and flammable products;
- hazards resulting from the operation of the machines in a potentially explosive atmosphere.

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 618:2002+A1:2010, *Continuous handling equipment and systems — Safety and EMC requirements for equipment for mechanical handling of bulk materials except fixed belt conveyors*

EN 620:2002+A1:2010, *Continuous handling equipment and systems — Safety and EMC requirements for fixed belt conveyors for bulk materials*

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

EN 1127-1:2019, *Explosive atmospheres — Explosion prevention and protection — Part 1: Basic concepts and methodology*

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

EN 15180:2014, *Food processing machinery — Food depositors — Safety and hygiene requirements*

EN 60079-14:2014, *Explosive atmospheres — Part 14: Electrical installations design, selection and erection (IEC 60079-14:2013)*

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

EN 60825-4:2006, *Safety of laser products — Part 4: Laser guards*

EN 61496-1:2013, *Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests*

EN 61496-2:2013, *Safety of machinery — Electro-sensitive protective equipment — Part 2: Particular requirements for equipment using active opto-electronic protective devices (AOPDs) (IEC 61496-2:2013)*

EN IEC 61496-3:2019, *Safety of machinery — Electro-sensitive protective equipment — Part 3: Particular requirements for active opto-electronic protective devices responsive to diffuse Reflection (AOPDDR) (IEC 61496-3:2018)*

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

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

EN ISO 13850:2015, *Safety of machinery — Emergency stop function — Principles for design (ISO 13850:2015)*

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 13856-2:2013, *Safety of machinery — Pressure-sensitive protective devices — Part 2: General principles for design and testing of pressure-sensitive edges and pressure-sensitive bars (ISO 13856-2:2013)*

EN ISO 13857:2019, *Safety of machinery — Safety distances to prevent hazard zones being reached by upper and lower limbs (ISO 13857:2019)*

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 14122-4:2016, *Safety of machinery — Permanent means of access to machinery — Part 4: Fixed ladders (ISO 14122-4:2016)*

EN ISO 14123-1:2015, *Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 1: Principles and specifications for machinery manufacturers (ISO 14123-1:2015)*

EN ISO 14123-2:2015, *Safety of machinery — Reduction of risks to health resulting from hazardous substances emitted by machinery — Part 2: Methodology leading to verification procedures (ISO 14123-2:2015)*

EN ISO 14159:2008, *Safety of machinery — Hygiene requirements for the design of machinery (ISO 14159:2002)*

ISO 3864-1:2011, *Graphical symbols — Safety colours and safety signs — Part 1: Design principles for safety signs and safety markings*

ISO 3864-2:2016, *Graphical symbols — Safety colours and safety signs — Part 2: Design principles for product safety labels*

ISO 3864-3:2012, *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 415-1:2014, EN 415-10:2014 and the following apply.

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>

3.1 Definitions of terms

3.1.1

automatically adjustable guard

movable guard attached to a moveable machine element (e.g. moving side of a pre-made bag magazine) and a fixed machine element (e.g. machine frame) which moves automatically when the moveable element is adjusted

Note 1 to entry: An automatically adjustable guard does not comply with this definition unless it has been dimensioned and positioned using relevant tables of EN ISO 13857:2019.

3.1.2

bag

flat or gusseted flexible container longitudinally seamed and closed at one or both ends made from paper, plastic film, foil, laminate, etc.

Note 1 to entry: Bags produced on form, fill and seal machines will typically have a seal at both ends and a longitudinal seal running down the centre of the rear face of the bag.

3.1.3

change parts

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

3.1.4

change part guard

fixed or interlocking guard which has been made to suit one product or pack size and must be changed every time the product or pack size is changed

Note 1 to entry: A change part guard does not comply with this definition unless it has been dimensioned and positioned using relevant tables of EN ISO 13857:2019.

3.1.5

cup

tub

thin walled tapered container

3.1.6

deformable material

material which can be formed by the application of pressure alone

3.1.7

food depositor

machine that dispenses a food product in a predetermined volume or shape

3.1.8

film reel

packaging material reel

continuous sheet of paper, carton board, plastic film, metal foil or flexible laminate wound on a cylindrical core

3.1.9

film web

continuous sheet of paper, plastic film, metal foil or laminate

3.1.10

fixed guard

guard affixed in such a manner (for example, by screws, nuts, and welding) that it can only be opened or removed by the use of tools or by destruction of the means by which the guard is affixed

Note 1 to entry: A fixed guard does not comply with this definition unless it complies with subclause 4.1.2.2 of this document.

3.1.11

hot melt adhesive

adhesive that is solid at room temperature and which is melted and applied at elevated temperature

3.1.12

interlocking guard

guard associated with an interlocking device so that, together with the control system of the machine, the following functions are performed:

- the hazardous machine functions “covered” by the guard cannot operate until the guard is closed;
- if the guard is opened while hazardous machine functions are operating, a stop command is given;
- when the guard is closed, the hazardous machine functions “covered” by the guard can operate (the closure of the guard does not, by itself, start the hazardous machine functions)

Note 1 to entry: An interlocking guard does not comply with this definition unless it complies with subclause 4.1.2.2 of this document.

3.1.13

longitudinal seal

seal made on a package in line with the direction of material travel in the machine

3.1.14

magazine

mechanical assembly designed to hold stacks of cartons, carton blanks, pre-made bags, pre-made sacks, leaflets, labels, lids or stackable containers

3.1.15

mandrel

mechanical assembly around which a flexible package or carton is formed

3.1.16

manually adjustable guard

adjustable guard where the adjustment is made manually and the adjustment remains fixed during a particular operation

Note 1 to entry: A manually adjustable guard does not comply with this definition unless it complies with subclause 4.1.2.2 of this document.

3.1.17

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.

3.1.18

pack

package

assembly of product and packaging materials produced by a packaging machine

3.1.19

packaging material

material used to make a package

EXAMPLES Film laminate, carton board, paper.

3.1.20

packaging material transport mechanism

mechanical assembly which transports packaging material through the packaging machine

3.1.21

pre-made bag

pre-formed flat or gusseted flexible package longitudinally seamed and closed at one end made from paper, plastic film, foil, laminate or a woven material

3.1.22

pre-made sack

pre-formed flat or gusseted sack longitudinally seamed and closed at one or both ends made from paper, plastic film, laminate, or a woven material

3.1.23

product

substance, article pack or package that is handled in the packaging machine

3.1.24

reclosing feature applicator

mechanism which applies a zip or self-adhesive packaging component to a package on a packaging machine

3.1.25

sachet

flat package which when formed from two webs of flexible material is sealed on four sides and when formed from one web is sealed on three or four sides

3.1.26

sack placer

mechanism which places an empty pre-made sack onto a filling spout

3.1.27

sack transfer mechanism

mechanism which takes empty sacks from a sack magazine and transfers them to a sack placer

3.1.28

soil

any unwanted matter, including product residues, micro-organisms, residual detergent or disinfecting agents

3.1.29

transverse seal

seal made on a package at right angles to the direction of material travel in the machine

3.1.30

trip guard

interlocking guard which is designed to move easily when touched by someone and which stops the machine before a hazard zone can be reached

3.1.31

tubular bag

flexible package closed at both ends and made from a flat film tube

3.2 Definitions of machines covered by this document

3.2.1 Form, fill and seal machines

3.2.1.1

flow-wrapping machine

horizontally operating form, fill and seal machine with material reel mounted above the operating level, the product loaded horizontally and a longitudinal seal formed below the pack

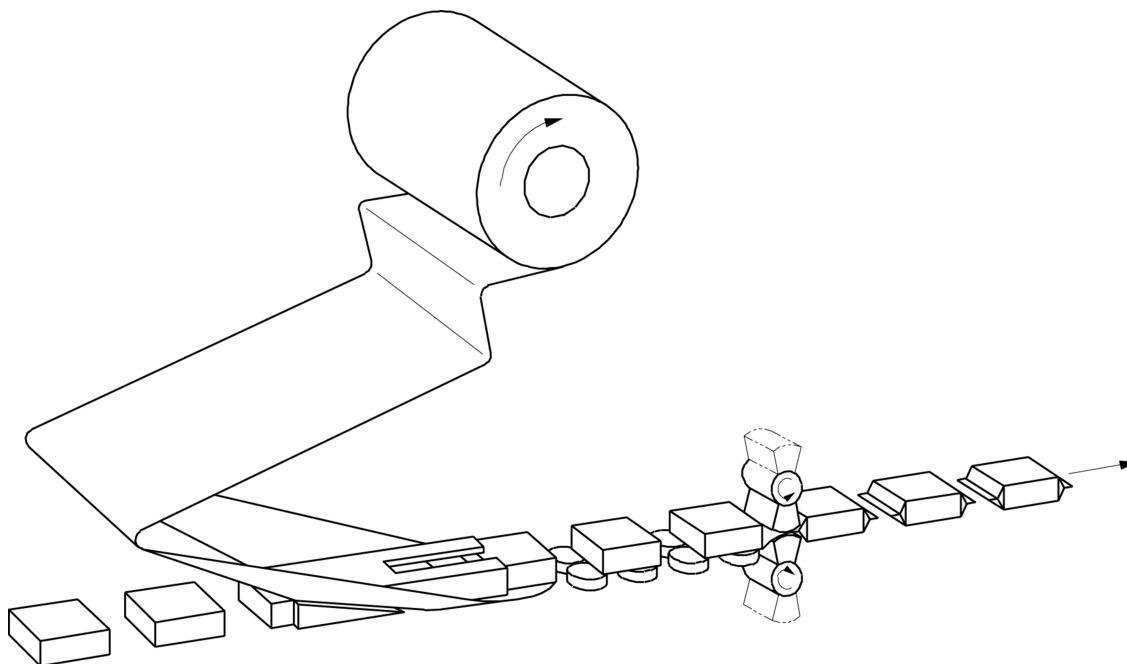


Figure 1 — Principle of operation of a typical flow-wrapping machine

3.2.1.2

vertical form, fill and seal machine

machine which uses flexible packaging material to form a tube, which is then filled vertically with product and sealed in a sequence of operations whilst the packaging material is transported vertically downwards

Note 1 to entry: There are several variants of this typical design, including one where the bag is formed vertically and then transferred to a horizontal mechanism for filling and sealing.

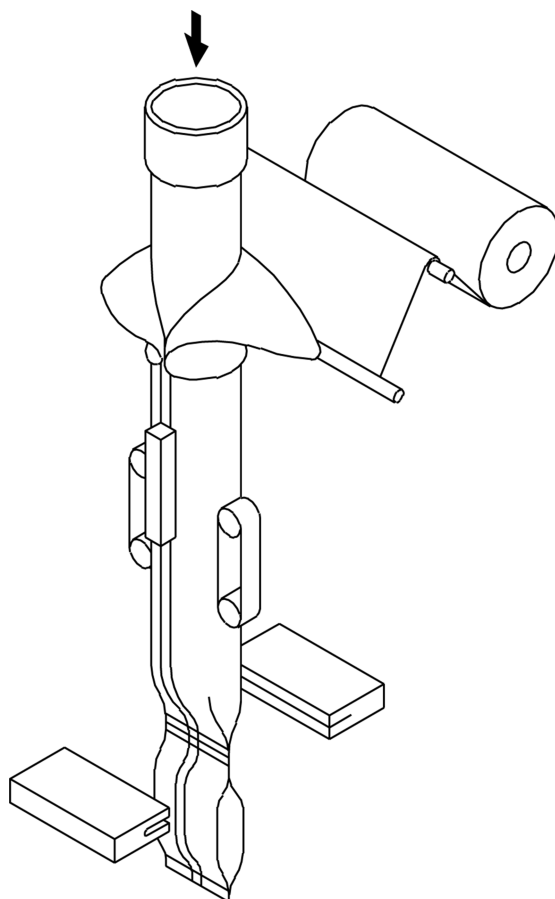


Figure 2 — Principle of operation of a typical vertical form, fill and seal machine

3.2.1.3

horizontal sachet form, fill and seal machine

horizontally operating form, fill and seal machine in which packs are formed, sealed on 2 or 3 sides, filled vertically with product and sealed on the remaining side whilst the film web is moved horizontally with the pack vertical

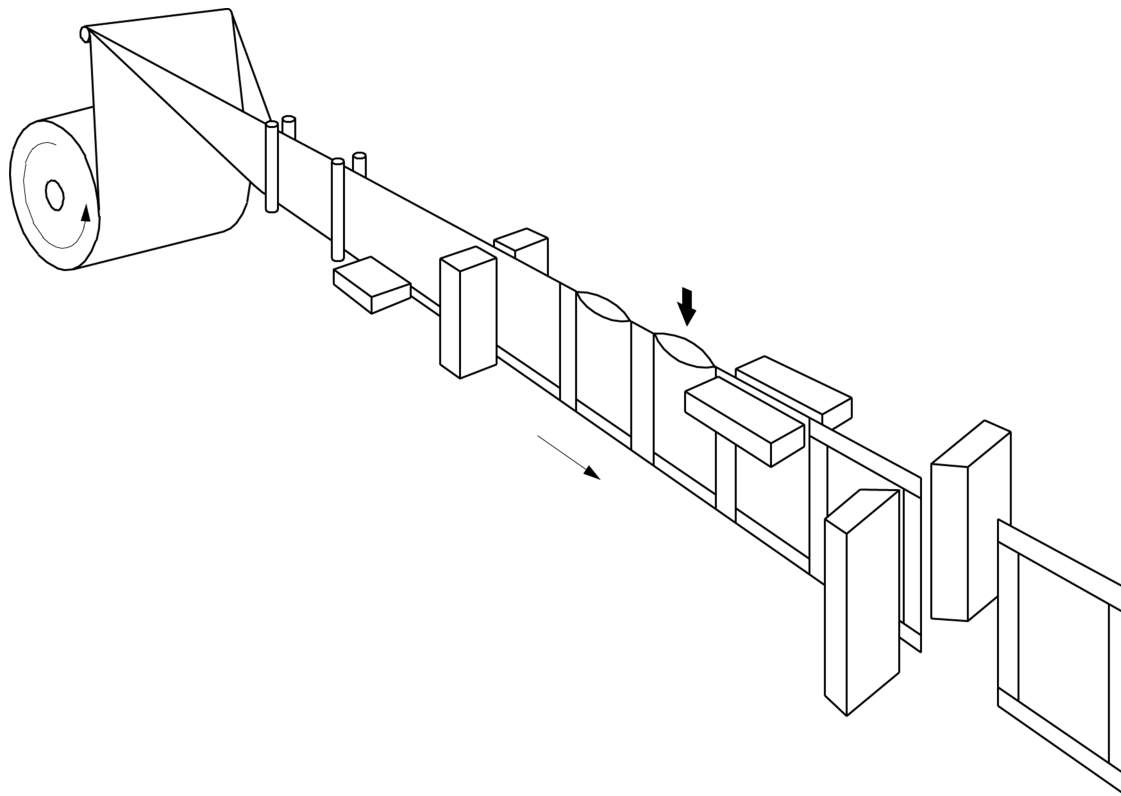


Figure 3 — Principle of operation of a typical horizontal sachet form, fill and seal machine

3.2.1.4

thermoform, fill and seal machine

machine in which a web of thermoformable material is heated and formed with pressure and/or vacuum, before being filled vertically with product, sealed with a top film or pre-formed lid and finally cut to produce individual packs

Note 1 to entry: Machines can produce one or more lanes of packs and some machines incorporate equipment to evacuate packages before they are sealed.

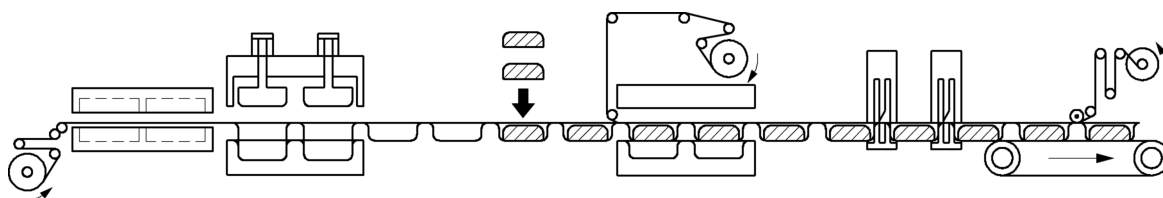


Figure 4 — Principle of operation of a typical thermoform, fill and seal machine

3.2.1.5

tubular bag form, fill and seal machine

machine which forms a bag or sack from a reel of lay flat tubular flexible packaging film, before it is filled with product and sealed

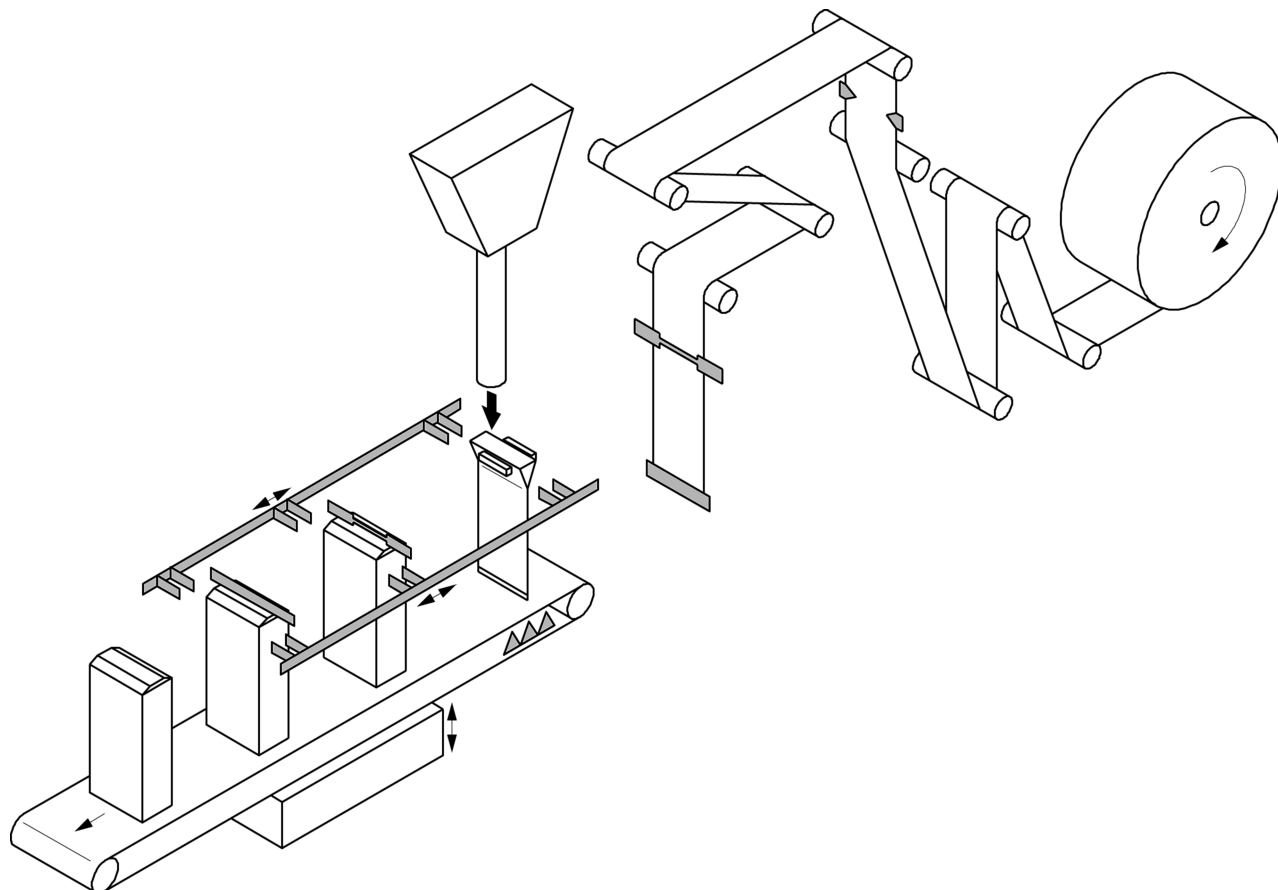


Figure 5 — Principle of operation of a typical tubular bag form, fill and seal machine

3.2.1.6

mandrel form, fill and seal machine

machine which forms packs from a reel of flexible material or carton blanks, on one or more mandrels, before filling the packs with product and sealing their tops within the machine

Note 1 to entry: On some machines the mandrels are mounted vertically and on others horizontally as shown in Figure 6.

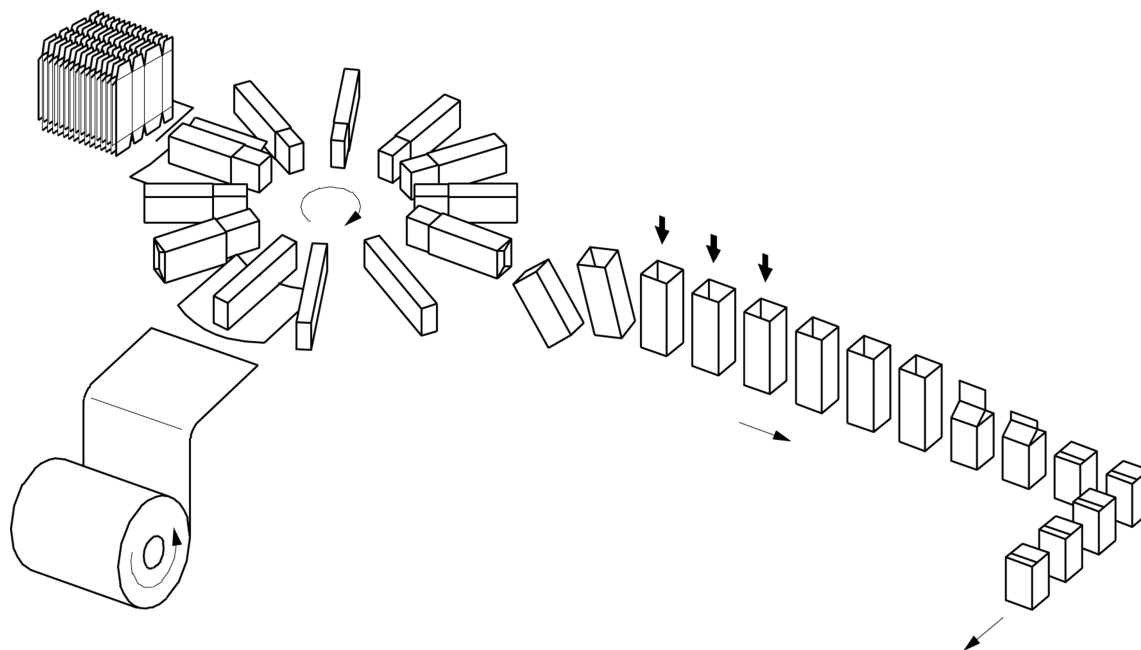


Figure 6 — Principle of operation of a typical mandrel form, fill and seal machine

3.2.2 Fill and seal machines

3.2.2.1

pre-made bag fill and seal machine

machine in which a pre-made bag is taken from a magazine, opened, filled with product and then sealed

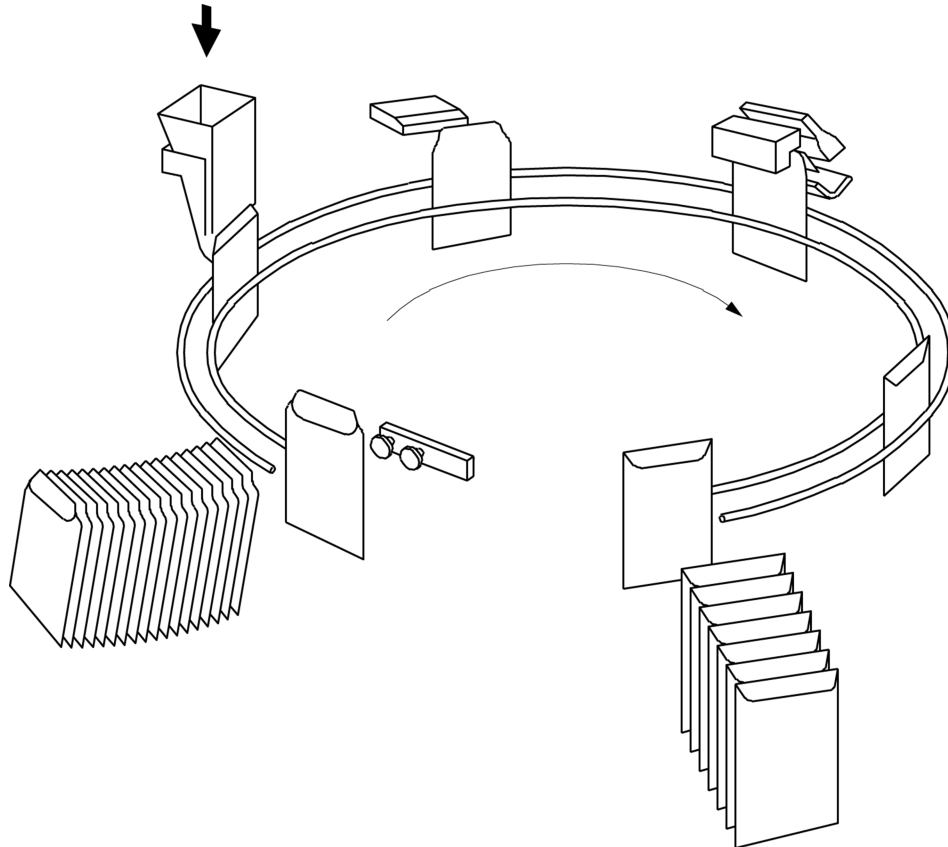


Figure 7 — Principle of operation of a typical pre-made bag fill and seal machine

3.2.2.2

sack fill and seal machine

machine in which a pre-made sack is filled with product and sealed

Note 1 to entry: The operation of the machine is rotary on some machines and linear on others.

Note 2 to entry: On some machines the pre-made sack is opened and placed in the machine manually, but on others it is taken automatically from a magazine, before being opened ready for filling.

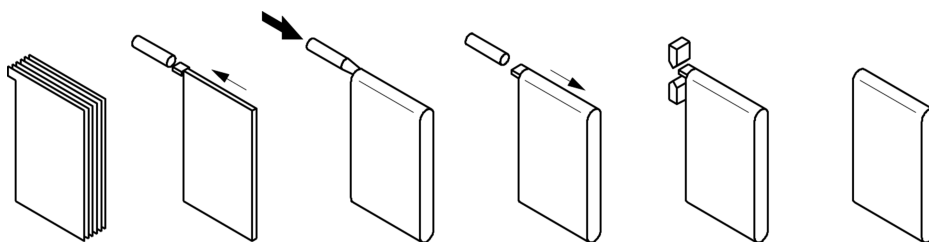


Figure 8 — Principle of operation of a typical in-line sack fill and seal machine

3.2.2.3

cup or tub fill and seal machine

machine in which a pre-made cup or tub is taken from a magazine, filled and then closed with a heat sealed foil or a pre-formed lid

Note 1 to entry: The operation of the machine shown in Figure 9 is linear, but some machines of this type are rotary.

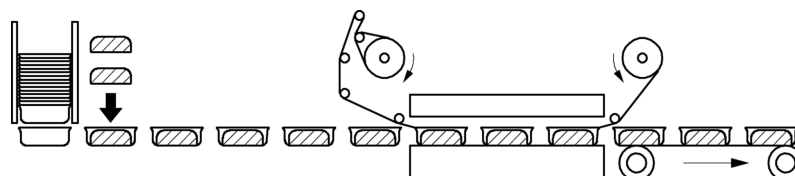


Figure 9 — Principle of operation of a typical cup/tub fill and seal machine

3.2.3 Filling machines

3.2.3.1

auger filling machine

filling machine which measures out a product, usually a powder, using an auger which rotates for a predetermined number of revolutions

3.2.3.2

volumetric cup filling machine

filling machine which measures out a product, usually free-flowing solids or powder, in a cup of predetermined volume

3.2.3.3

nett weigher

filling machine which measures out a predetermined mass of product, usually free-flowing solids, before dispensing it as a fill

3.2.3.4

multi-head weigher

selective combination weigher

nett weighing machine with multiple weighing units, which computes an appropriate combination of loads to achieve the predetermined mass and discharges them together as a fill

3.3 Definitions of machines which have similar hazards to those machines covered by this document

NOTE The following machines have similar hazards to those on the machines covered by this document.

3.3.1

lower reel flow-wrapping machine

horizontally operating form, fill and seal machine, with film reel mounted below the operating level, the product placed on to the film web and a longitudinal seal formed above the pack

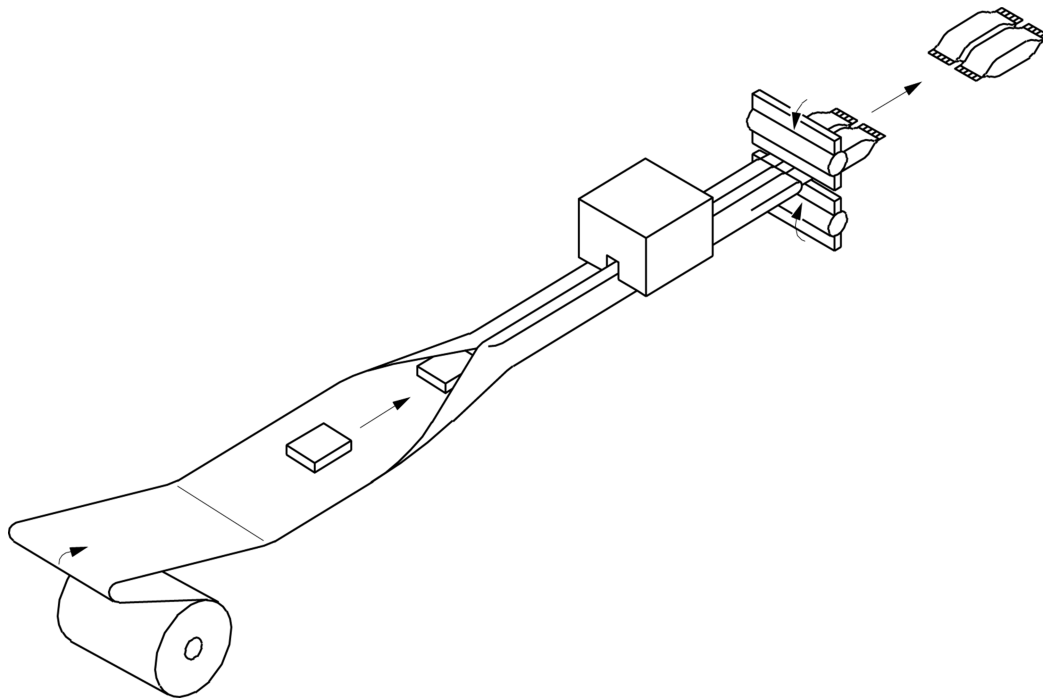


Figure 10 — Principle of operation of a typical lower reel flow-wrapping machine

3.3.2

stick packing machine

vertical form, fill and seal machine which produces small cross-section stick shaped packs

Note 1 to entry: Machines typically produce several lanes of packages at the same time.

3.3.3

edge sealing machine

horizontally operating form, fill and seal machine in which product is placed on a horizontal web of film before being sealed on 3 or 4 sides to an upper web of film

Note 1 to entry: Machines can have one or two reels of film and can produce one or more lanes of packs.

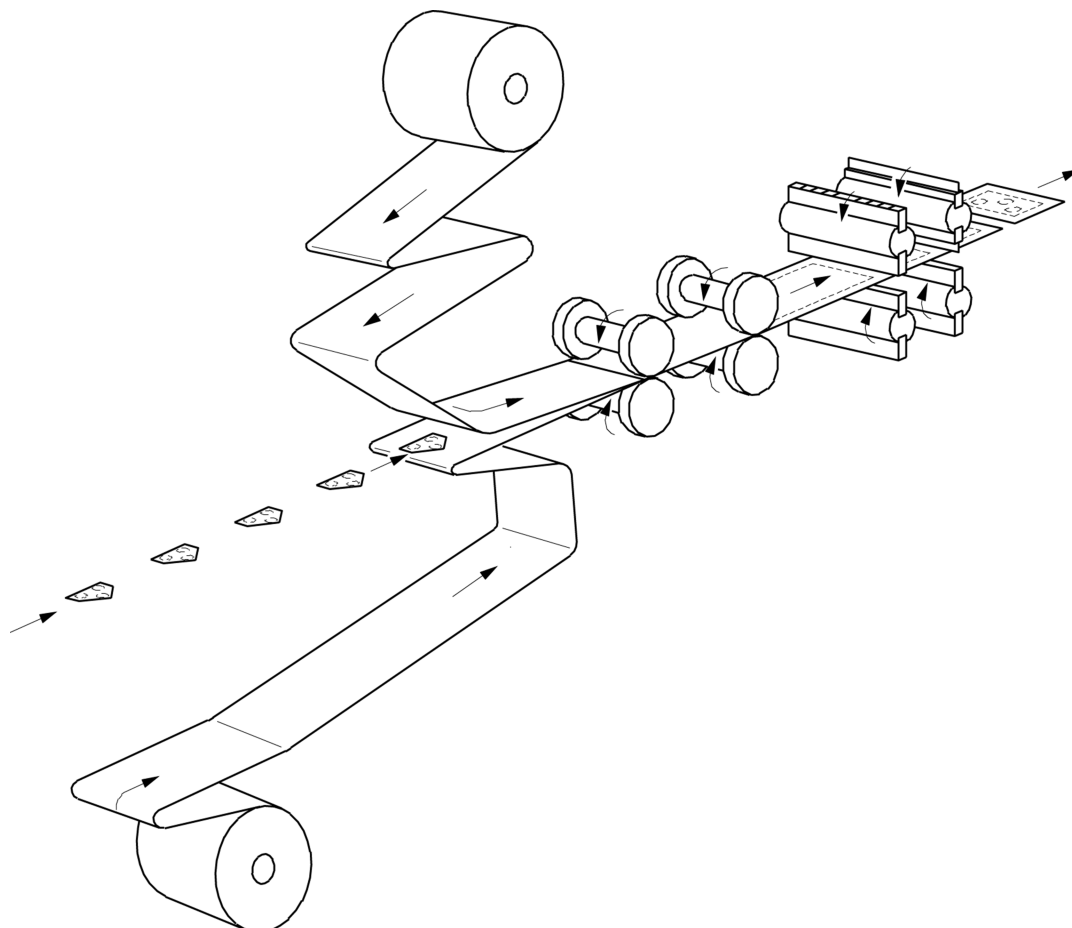


Figure 11 — Principle of operation of a typical edge sealing machine

3.3.4

vertical sachet form, fill and seal machine

vertically operating form, fill and seal machine which uses one or two webs of film which are formed vertically, filled with product and sealed to produce a 3 or 4 side sealed sachet

Note 1 to entry: Machines can have one or two reels of film and can produce one or more lanes of packs.

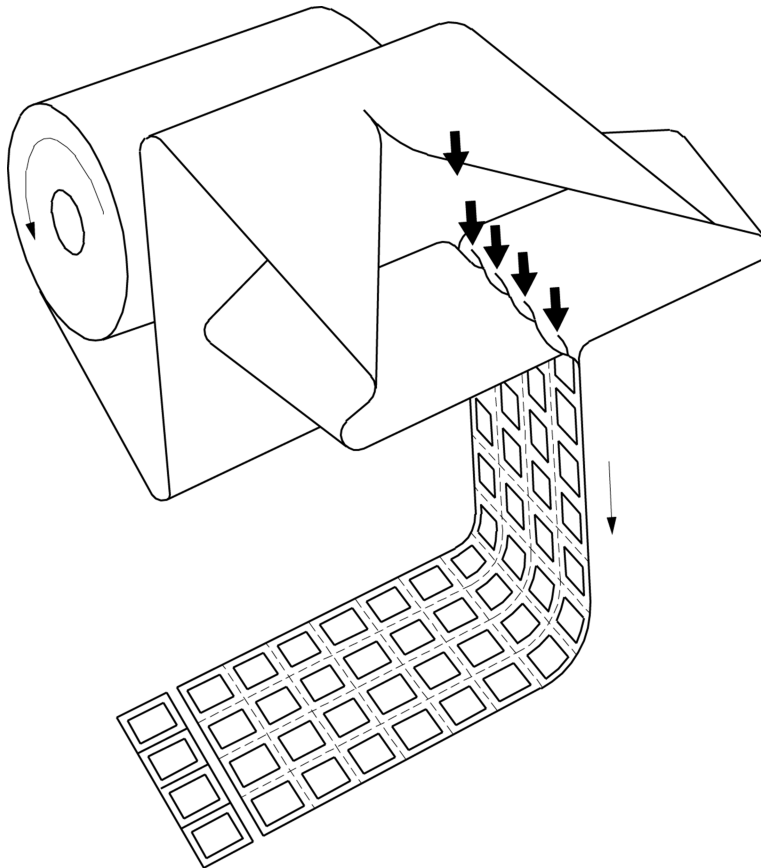


Figure 12 — Principle of operation of a typical vertical sachet form, fill and seal machine

3.3.5

strip packing machine

vertically operating sachet form, fill and seal machine which produces strips of individually sealed packs joined together in predetermined lengths

3.3.6

vertical form, fill and seal machine for carton board

vertically operating form fill and seal machine which uses a carton board laminate, which is formed, filled with product and sealed to produce a pack resembling a carton

Note 1 to entry: The pack is usually filled with a liquid.

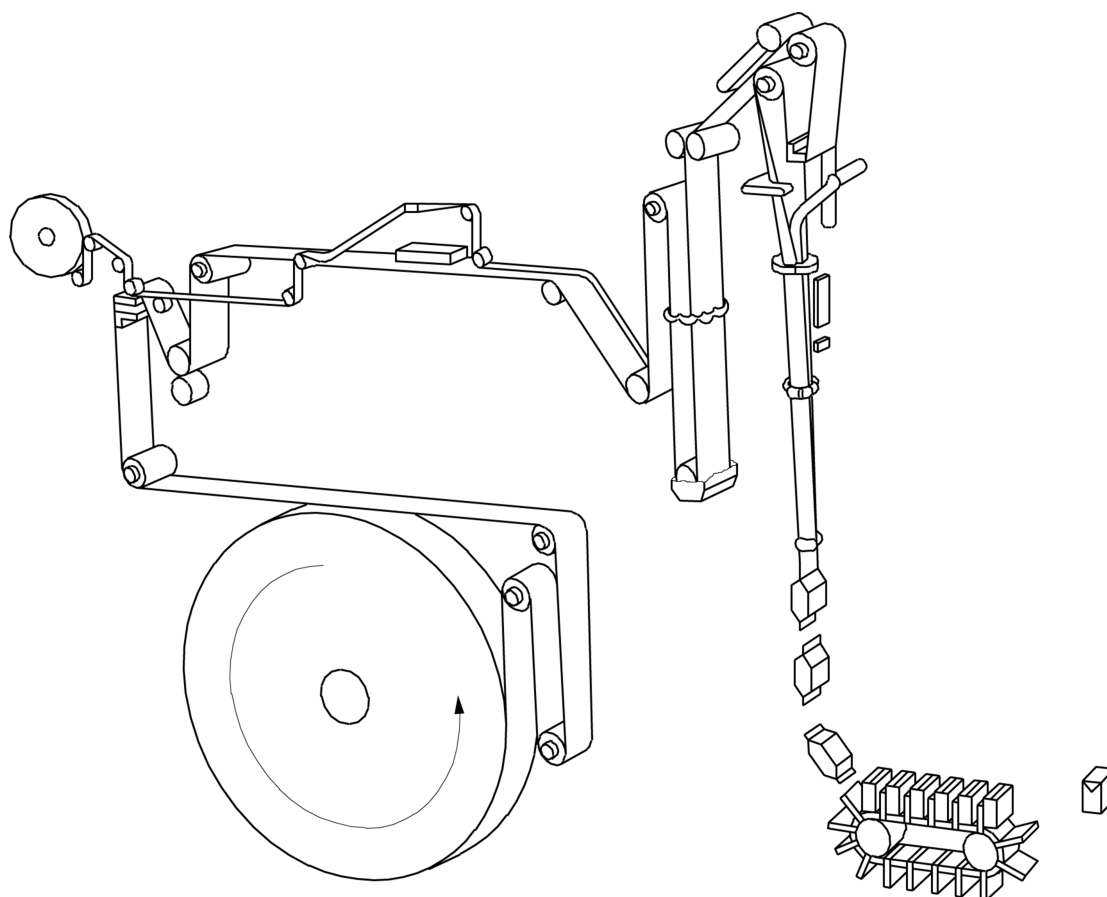


Figure 13 — Principle of operation of a typical vertical form, fill and seal machine for carton board

3.3.7

deep draw fill and seal machine

machine in which a web of deformable material is formed under pressure in a die press, before being filled vertically with product, sealed with a top film or pre-formed lid, and finally cut to produce individual packs

Note 1 to entry: Machines can produce one or more lanes of packs.

Note 2 to entry: The operation of the machine in Figure 14 is linear, but some machines of this type are rotary.

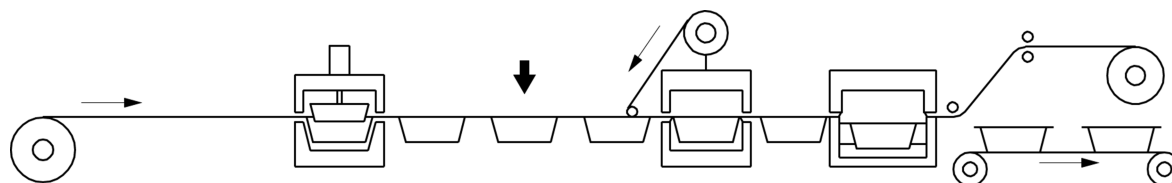


Figure 14 — Principle of operation of a typical deep draw fill and seal machine

3.3.8

count filling machine

filling machine which measures out solids according to a predetermined count

4 Safety requirements

4.1 General requirements

4.1.1 General

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 4.2 to 4.14 where the equivalent hazard exists. In addition, machines shall comply with clauses of EN 415-10:2014 where they are specifically referenced in this document.

Where a machine has hazards, which are not on a typical machine and so are not described in Annex A, the machine shall be designed according to EN 415-10:2014.

4.1.2 Requirements to minimize mechanical risks

4.1.2.1 Inherently safe design

Inherently safe design measures shall be applied as far as possible to eliminate or reduce risks and shall comply with the requirements of EN 415-10:2014, 5.2.1.1. Subclauses 4.2 to 4.14 identify some of the mechanisms where inherently safe design measures can typically be applied, for example by limiting the forces applied by the mechanisms.

With the exception of cutting mechanisms, accessible parts of the machine shall have no sharp edges, no sharp angles and no rough surfaces likely to cause injury.

4.1.2.2 Design of safeguards

Safeguards shall comply with 4.1.2.2, 4.1.2.4 and EN 415-10:2014, 5.2.1.4. Interlocking guards shall comply with EN 415-10:2014, 5.2.1.5 and 5.16.2.3 and EN ISO 14120:2015, 5.2.3.

Where the smallest dimension of a rectangular opening or diameter of a circular opening in a guard is less than or equal to 120 mm, the safety distances in Tables 3, 4 and 6 of EN ISO 13857:2019 shall apply. Where the opening is larger than 120 mm, the safety distances shown in EN 415-10:2014, 5.2.1.3 shall apply.

When an interlocking guard is opened, it shall not be possible to reach a hazard zone before the hazardous movement has stopped. Where this objective is not achieved, a guard locking device or internal baffle which prevents direct access to the hazard zone shall be fitted. Where a baffle is used it shall be dimensioned and positioned so that the person's movement will be impeded or slowed down sufficiently for the hazardous movement to stop before the hazard zone can be reached.

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

Where there is a risk that someone could be shut inside a guarded area, the interlocking guard that gives access to this area shall be fitted with an interlocking device that minimises the risk of the guard being closed accidentally and EN 415-10:2014, 5.16.2.3 shall apply.

Where a good view to zones inside the machine is necessary and the design of the guards causes shadows that prevent good visibility of the process within the machine, the machine shall be equipped with interior lighting.

The design of the guards shall ensure that it is not possible to reach hazard zones in the machine by reaching over guards when standing on a means of access described in this document. Where guards are open at the top the safety distance in Table 2 of EN ISO 13857:2019 shall apply.

Where electro-sensitive protective equipment (ESPE) is used instead of a guard it shall comply with EN 61496-1:2013 and shall be positioned in accordance with EN ISO 13855:2010.

4.1.2.3 Pneumatic and hydraulic equipment

4.1.2.3.1 General

The machine shall be equipped with an isolation device for each supply for fluid power which shall be located outside hazard zones and shall be readily accessible, clearly labelled, and have features to allow them to be locked in the off position.

The machine shall have a facility to release stored energy in a safe manner.

The control system shall be designed to prevent unexpected start-up following the requirements of EN 415-10:2014, 5.1.6.

4.1.2.3.2 Pneumatic

Pneumatic components and piping shall comply with the requirements of EN ISO 4414:2010.

An air service unit shall be provided with an isolation valve complying with EN ISO 4414:2010, 5.2.8; a pressure build-up valve, pressure regulator, pressure gauge and condensate discharge valve shall also be provided.

4.1.2.3.3 Hydraulic

Hydraulic components and piping shall comply with the requirements of EN ISO 4413:2010.

Hydraulic isolation valves shall comply with EN ISO 4413:2010, 5.4.7.2.1.

4.1.2.4 Size or product changing

4.1.2.4.1 Design of guards

The design of the machine and its guards shall ensure that danger zones on the machine are safeguarded without the need for adjustment of safeguards, for all the product and pack sizes for which the machine has been specified.

Where this is not possible adjustable guards or change part guards shall be used.

Adjustable guards shall be either:

- a) adjusted in a positive mode by adjusting the functional parts either manually or under power, or
- b) fitted with interlocking devices which ensure that the machine cannot be started or operated unless the guards are adjusted correctly.

Change part guards shall be either:

- a) connected to the functional parts so that the machine cannot function without the appropriate guarding being fitted, or
- b) fitted with interlocking devices so that the machine cannot be started or operated without the required guard in place.

4.1.2.4.2 Size or product changing under power

Where parts of the machine are adjusted under power, the risks presented by these powered movements shall be eliminated using the following hierarchy of measures:

- a) ensuring that the movements are not hazardous by following the safety by design principles described in 4.1.2.1, or
- b) if a) is not possible by ensuring that movements can only take place when the machine's interlocking movable guards are closed or;
- c) where it is not possible to fulfil the requirements of a) or b), the movement can only take place using a hold-to-run control device complying with EN 415-10:2014, 5.16.3.

4.1.2.5 Drive mechanisms

Drive mechanisms shall be enclosed with fixed or interlocking guards.

4.1.2.6 Hand-wheels

Where handles or hand-wheels are provided to operate mechanisms manually, they shall preferably be disconnected when the machine runs automatically.

If the hand-wheel is designed to rotate under power during automatic operation it shall comply with EN 415-10:2014, 5.20.5.

4.1.2.7 Measures to minimize slip, trip and fall risks

The measures described in EN 415-10:2014, 5.2.2 shall apply.

4.1.2.8 Tasks requiring guards to be open while mechanisms are moved under power

The design of the machine shall avoid the need to carry out any task where it is necessary to move machine mechanisms while a guard is open. If mechanisms need to be moved in manual mode, this shall only be possible with all the interlocking guards in the closed position.

Where for technical reasons this is not practicable, movement of the machine parts shall only be possible if all of the requirements of EN 415-10:2014, 5.16.3 have been satisfied.

4.1.3 Electrical equipment

4.1.3.1 General requirements

Electrical equipment fitted to machines in the scope of this document shall comply with EN 415-10:2014, 5.3, 5.5 and 5.6 and 5.14.

4.1.3.2 Emergency stop devices

All machines in the scope of this document shall be fitted with at least one emergency stop device that complies with EN ISO 13850:2015 and shall be positioned according to EN 415-10:2014, 5.14.

4.1.3.3 Electrostatic phenomena

On machines where hazards may arise from the generation of static electricity, sufficient earth bonding or static elimination equipment shall be provided to ensure that hazardous levels of static electricity do not occur. This equipment shall ensure that electrostatic discharge shall lead neither to any injury nor to the ignition of potentially explosive atmospheres or combustible substances.

Electrostatic discharge elimination devices shall be protected using interlocking guards and the control system shall ensure that the static elimination devices are turned off when the interlocking guard is open.

4.1.4 Thermal hazards

The external temperature of exposed parts of the machine, like guards, control panels and electric motors, shall not exceed the burn threshold temperatures stated in EN ISO 13732-1:2008, 4.2, which take into account the contact material and the foreseen contact time.

Where the machine includes parts, like heating mechanisms with a foreseeable temperature greater than the burn thresholds described in EN ISO 13732-1:2008, the machine design shall minimize the risk of accidental contact, for instance by fitting insulation or guards to prevent unintentional contact and by fitting the “warning hot surface” pictogram specified in 6.3 on the outside of the machine or adjacent to the hot parts.

If having taken these measures, there is still a residual risk of touching hot surfaces this shall be stated in the instructions together with the measures which can be taken to avoid burn injuries, like wearing gloves or other personal protection equipment.

4.1.5 Noise reduction

The most common sources of noise emissions from machines in the scope of this document are:

- Drive motors;
- Products impacting on solid surfaces;
- Vacuum pumps;
- Vibrating mechanisms;
- Release of compressed air.

Machines in the scope of this document shall be designed to minimize noise at its source using state of the art noise reduction technology.

Noise shall be reduced by the methods stated in this document. Where these measures are not applicable or insufficient, additional measures stated in EN ISO 11688-1:2009 shall be applied to reduce noise at source.

The criterion for assessing the efficiency of a noise reduction measure is the actual noise emission value of the machine and not the nature of the reduction measure itself.

4.1.6 Vibrating mechanisms

Machines fitted with vibrating mechanisms shall be designed so that harmful levels of vibration are not transmitted to other parts of the machine or the surface on which the machine is fixed. The vibrating mechanisms shall be designed so it is not necessary for operators to touch or hold the parts while they are vibrating.

4.1.7 Radiation

Where machines incorporate radiation sources other than laser devices, this equipment shall comply with the requirements of EN 415-10:2014, 5.9.

Where ultraviolet (UV) light is used to sterilize packaging materials or components, the machine shall be designed so, that no hazardous amounts of UV-light are emitted from the machine. Where the UV light causes thermal hazards, 4.1.4 shall apply.

4.1.8 Products and substances used on machines which pose a risk

4.1.8.1 Hazards from products

Where the machine has been specified to pack a hazardous product, the machine shall comply with the requirements of EN ISO 14123-1:2015 and EN ISO 14123-2:2015.

Where a flow of product presents a hazard, measures shall be provided to prevent a hazardous flow of product during operator interventions and instructions shall be provided on how to prevent a hazardous flow of product during maintenance interventions.

4.1.8.2 Dusty products

Where the machine is specified to pack a dusty product, it shall be supplied with either

- dust extraction equipment that complies with EN ISO 14123-1:2015, or
- dust collection spouts that can be connected to the customer's central dust extraction system.

4.1.8.3 Potentially explosive dusty products

Where the machine is specified to pack potentially explosive dusty products, the machine shall comply with the requirements of EN 1127-1:2019 and electrical equipment shall comply with EN 60079-14:2014.

4.1.8.4 Modified atmosphere packaging

4.1.8.4.1 General

Where machines are fitted with modified atmosphere packing equipment the following requirements shall apply:

- a) all vessels, pipes and fittings shall be designed to safely contain the modifying gas;
- b) the gas supply shall be fitted with a manual isolation valve which can be locked in the off position and shall be clearly labelled to indicate which type of gas or gases shall be used;
- c) where a non-hazardous gas like nitrogen is used to reduce oxygen levels in packages, the design of the machine or the gas control system shall ensure that oxygen levels around the machine do not fall below 19 % during normal use and during machine interventions.
- d) on machines where mixtures of gases can be selected, flow meters shall be provided which display the flow rate of the different gases which are being delivered to the machine;
- e) the machine's instructions shall detail:
 - the gases that can be used with the machine;
 - the maximum pressure of the gas supply;
 - the safe procedure for connecting the gas supply;
 - the specifications of the pressure reducer and safety relief valves needed to ensure safe operation;
 - the specification for the ventilation system needed to remove or disperse the modifying gas;
 - that the machine shall not be operated with the modifying gas if the film is damaged or not present.

4.1.8.4.2 Oxygen

Where the modifying gas is oxygen, the following additional requirements shall apply:

- a) all components which can come into contact with oxygen, such as pumps, hoses, pipes, fittings, instruments, seals or containers, shall be suitable for use with high concentrations of oxygen;
- b) the design of the oxygen flow control system shall prevent the generation of flammable atmospheres inside or around the machine;
- c) to avoid overheating or setting fire to the packaging material, the heat-sealing control system shall be designed so that the sealing temperature and the sealing contact time cannot be changed by unauthorized persons. One method of achieving this objective is to require a password to be used to change the settings.
- d) the design shall minimize the risk of oxygen coming into contact with fat or oil. Where there is a risk of oxygen coming into contact with fat or oil the machine design shall ensure that no lubricants or sealants are used which could self-ignite when in contact with oxygen;
- e) the instructions shall state:
 - the lubricants which can be used;
 - the parts that fat or oil shall be cleaned from before the equipment is used;
 - cleaning instructions to remove any debris from parts which can come into contact with oxygen;
 - the measures to be taken to avoid hazards caused by high oxygen concentrations when emptying the system and ensuring that no ignition sources such as hot surfaces, electrostatic or electrical ignition sparks are present during emptying;
 - the need for regular inspections of seals to prevent hazardous oxygen concentrations;
 - the need for oxygen measurements to be taken around the machine 500 mm from the machine during commissioning and routinely during use to ensure that the oxygen concentration around the machine does not exceed 22 %. The instructions shall provide the specification of the equipment to be used for these measurements and the required frequency for the routine measurements;
 - the ventilation requirements in the room where the machine is to be installed to ensure oxygen levels do not rise above 22 %.

4.1.8.4.3 Gases harmful to health

Where gases or gas mixtures harmful to health are used the following additional requirements shall apply:

- a) where a space inside the machine contains a hazardous atmosphere, and opening a guard exposes the operator to this hazardous atmosphere, this guard shall be interlocked with a guard locking device and controlled so that this guard cannot be opened until the atmosphere inside the machine is safe to breathe. This guard door shall be released either by a sensor that can determine that the atmosphere inside the machine is safe to breathe or after a time delay which is sufficient for the harmful gases inside the machine to be extracted by the extraction system;

- b) the design of the machine and the gas control system shall ensure that dangerous levels of the modifying gas do not build up around the machine. The concentration of the modifying gas shall be monitored at 500 mm from possible gas emission points like the gas chamber.

To prevent the emission of hazardous amounts of modifying gases, the machine shall be provided with:

- a) a solenoid valve to shut off the supply of the modifying gas automatically when the machine stops;
- b) a pressure reducer and a safety relief valve, which discharges gas to a safe location, at the interface with the gas supply. Where this equipment is not supplied with the machine, the specification for this equipment shall be stated in the operator's manual;
- c) extraction equipment to remove dangerous levels of the modifying gas to a safe area. Where this equipment is not supplied with the machine, the specification for this equipment shall be stated in the instructions;
- d) where the installation incorporates flexible hoses, control devices which can sense that a hose has been damaged or the gas flow is excessive and automatically shut off the supply of modifying gas to the machine.

4.1.8.5 Substances used to sterilize packaging materials and components

Machines using hazardous substances (for example hydrogen peroxide) to sterilize or disinfect packaging materials and components shall be designed so that all foreseen interventions inside the machine can be carried out safely and so that airborne emissions of the sterilizing substance from the machine to the work area around the machine are kept to a safe level.

The sterilizing substance shall be kept in as closed a system as possible, and the seals and gaskets fitted to guard doors and other possible leakage points shall be made of materials that resist the sterilizing substance being used.

Access to areas of the machine where hazardous concentrations of sterilizing substances may be present, shall be prevented by interlocking guards fitted with guard locking devices. The control system shall prevent these guards from opening as long as a hazardous concentration of the sterilizing substance is present. Measures to decrease the time to reach a safe concentration include:

- fitting the machine with an extraction system to extract the sterilizing substance to a safe area outside of the building or to a central extraction system;
- spraying the area with water to absorb the sterilizing substance into water

If interventions are foreseen in an area while a hazardous concentration of the sterilizing substance exists, suitable additional measures shall be provided, such as fitting the machine with glove boxes to allow access while maintaining the integrity of the enclosure.

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 the sterilizing substance shall be designed to safely contain the sterilizing substance. Pipe connections shall be used that can only be dismantled using tools. If the machine is designed to be supplied with a sterilizing substance 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.

Equipment shall be provided to prevent the build-up of hazardous levels of the sterilizing substance near the machine, such as:

- fitting extraction systems at, for example, discharge tunnels. To avoid carryover of the substances by the conveyors, the transfer from the discharge conveyor shall be positioned within the machine or the discharge tunnel;
- ducting air streams to points where they can be connected to an extraction system; and
- rinsing sterilizing substances from the outside of packages within the machine.

The operator's manual shall contain the following information, where it is relevant:

- intervals and criteria for inspection and replacement of seals and gaskets to prevent leakage of sterilizing substances;
- instructions for inspection and maintenance of any fitted extraction or spraying system;
- safe working procedures for access to areas where hazardous concentrations of sterilizing substances may occur;
- safe working procedures to conduct maintenance on the supply system of the sterilizing substance;
- the technical specifications for the room ventilation in the area where the machine will be installed; and
- the specifications of any personal protective equipment to be used.

4.1.9 Ergonomic design

4.1.9.1 Loading points for packaging materials

The requirements of EN 415-10:2014, 5.11.4 shall apply.

4.1.9.2 Product loading or unloading points

The requirements of EN 415-10:2014, 5.11.5 shall apply.

4.1.9.3 Hand-wheels

Where a hand-wheel is used to move a mechanism by hand, the force that shall be applied to the circumference of the hand-wheel to move the mechanism shall not exceed 50 N if one hand is used and 75 N if two hands are used.

4.1.9.4 Change parts

On machines where change parts are used, hazards from excessive effort or strain shall be eliminated or reduced by the following measures:

- a) designing the machine and its change parts so that their handling operations are assessed as acceptable according to EN 1005-2:2003+A1:2008, selecting 25 kg as the reference mass, M_{ref} , for the adult users as stated in Table 1 of EN 1005-2:2003+A1:2008;
- b) designing the machine and its change parts so that their handling operations can be performed by two persons and are assessed as acceptable according to EN 1005-2:2003+A1:2008, selecting 40 kg as the reference mass M_{ref} ;

- c) Where the measures described in a) and b) are not possible for technical reasons, and specially designed lifting equipment is necessary, this lifting equipment shall be provided with the machine.

NOTE Examples for generally available and therefore not special lifting equipment are: fork lift trucks, cranes, lifting tables or mobile elevating work platforms.

The maximum mass shall be calculated using the M_{ref} given in this document following the procedure described in EN 1005-2:2003+A1:2008, 4.3.

4.1.10 Hygienic design requirements

Machines intended to pack foodstuffs shall comply with the requirements of EN 1672-2:2020. Machines intended to pack cosmetics, pharmaceuticals or other products where hygiene is a concern shall comply with the requirements of EN ISO 14159:2008. In addition, the machine manufacturer shall:

- identify the level of hygienic design appropriate for the product. When the machine manufacturer is unable to find this information, he shall define the limitation of use for the machine and clearly state this in the instructions, for example "This machine has been designed to pack foodstuffs with the following characteristics";
- describe appropriate and safe cleaning procedures in the instructions including information on the cleaning or disinfection agents that shall be used;
- design the machine so that fallen packs or spilled products or substances can be easily detected and removed from the machine.

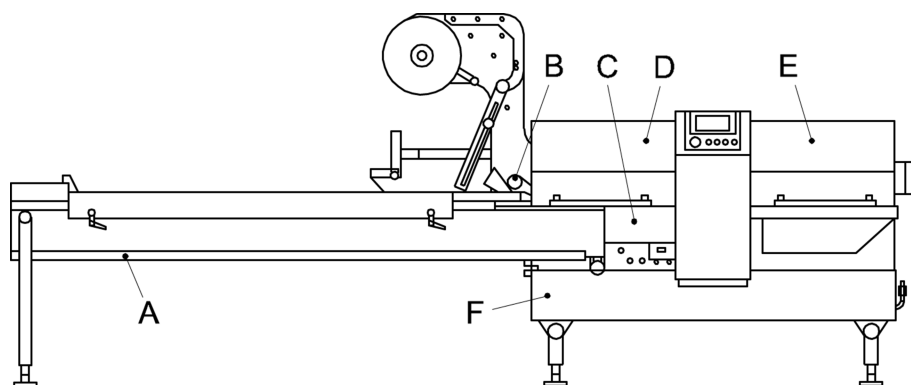
4.2 Safety requirements for a flow-wrapping machine

4.2.1 General

The hazards described in A.1.2 shall be eliminated or safeguarded by the following measures and those described in 4.1.

These safety requirements also apply to a lower reel flow-wrapping machine (3.3.1) and an edge sealing machine (3.3.3) where the equivalent hazard exists.

Figure 15 shows the guards on a typical flow-wrapping machine.



Key

- | | |
|----------------------------|---|
| A infeed chain guard | D transverse seal mechanism infeed guard |
| B infeed trip device | E transverse seal mechanism discharge guard |
| C longitudinal seal guards | F drive mechanism guard |

Figure 15 — Guards on a typical flow-wrapping machine

4.2.2 Product feed

4.2.2.1 General

On machines which are to be fed by hand, the feeding area shall be designed to eliminate shearing, crushing and entanglement hazards, but at the same time shall allow access to the product pushing devices, using the methods described in 4.2.2.2, 4.2.2.3 and 4.2.2.4.

4.2.2.2 Chains and drives

The return chain run with its pushing devices and drive and tail sprockets of the chain infeed conveyor shall be safeguarded with fixed or interlocking guards.

If these guards need to be removed once a day or more frequently, they shall be fitted with interlocking devices complying with EN ISO 14119:2013 and comply with the requirements for interlocking guards. Where cables make this area of the machine difficult to clean, mechanical trapped key interlocking devices complying with EN ISO 14119:2013 type 2 can be used, if they have a suitable performance level.

The tail sprocket guard shall be designed to avoid shearing hazards for example by creating a tunnel guard.

Where machines are equipped with product side guides which are adjustable without the need for tools, movement of these guides shall not expose any hazard.

4.2.2.3 Product pushing devices

Product pushing devices shall be designed so that they do not present cutting, shearing or crushing hazards in the hand loading area and where they enter the folding box.

The risk of impact between a pusher and the hand of an operator in the hand loading area can be considered negligible if the pusher has no sharp edges, there is no risk of entanglement or drawing-in and the speed of the conveyor is lower than 2 m/s.

Other methods of eliminating hazards from pushing devices include the following:

- a) pushing devices designed so that they come away from the chain in the event of a lateral force greater than 135 N being applied to them. The impact force shall not exceed 180 N and the static pressure on the body surface shall not exceed 60 N/cm²;

NOTE 1 These limits assume that the pushing devices will be applying the force to hands or fingers.

- b) pushing devices designed so that they can bend when a lateral force greater than 135 N is applied to them. The impact force shall not exceed 180 N and the static pressure on the body surface shall not exceed 60 N/cm².

NOTE 2 These limits assume that the pushing devices will be applying the force to hands or fingers.

- c) pushing device linkages designed so that the pushing devices are free to bend backwards as they enter the folding box;
- d) a trip guard fitted with an interlocking device complying with EN ISO 14119:2013 like the one shown in Figure 16.

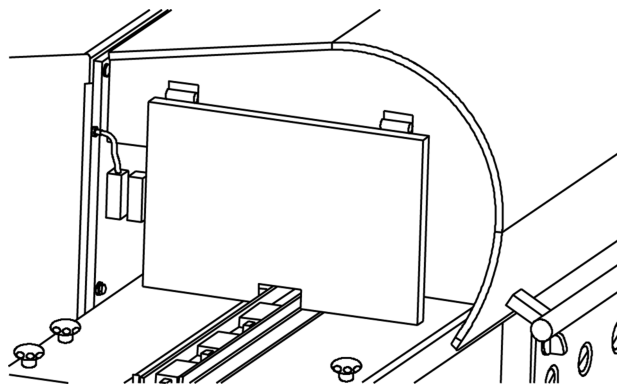


Figure 16 — Guards and trip device fitted in front of the folding box

4.2.2.4 Flat belt infeed conveyor

Where flat belt conveyors are used to feed products, they shall comply with EN 415-10:2014, 5.20.4.

4.2.2.5 Automatic product feeding mechanisms

Where automatic product feeding mechanisms are not safe by design as defined by EN 415-10:2014, 5.2.1.1, they shall be enclosed with interlocking guards complying with 4.1.2.2.

4.2.3 Film reel unwind mechanism

4.2.3.1 General

The film reel unwind mechanism shall be designed and positioned in accordance with 4.1.9.1.

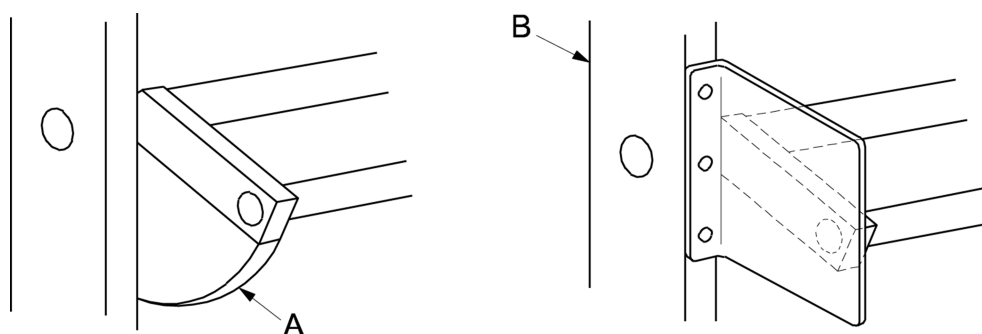
Film reel unwind mechanisms shall either be made safe by design using the measures indicated in 4.1.2.1 or they shall be enclosed with interlocking guards.

Where the moving film edge presents a cutting hazard, the film path shall be enclosed with fixed or interlocking guards.

4.2.3.2 Tension roller assembly

The shearing hazard between the tension roller assembly and the machine frame shall be eliminated either by ensuring that the moving assembly is at least 25 mm from the frame or by incorporating one of the devices shown in Figure 17.

Where the film braking or compensating mechanism cannot be made safe by design, it shall be enclosed with interlocking guards.



Key

A solid piece eliminates shearing hazard

B plate attached to the machine frame eliminates hazard

Figure 17 — Methods of safeguarding the tension roller assembly

4.2.3.3 Coders

Where a coding device is integrated with the film reel unwind mechanism, the power supplies for the coder (for example electricity and compressed air) shall be isolated when the machine's isolators are turned off.

The coder shall be installed following the coder manufacturer's instructions.

Hot foil coders shall be guarded or insulated so touchable surfaces do not exceed the burn thresholds indicated in EN ISO 13732-1:2008. Where there is a residual risk of burning a "warning hot surface" pictogram shall be fitted.

Laser coders rated as class 3 or 4 shall be mounted in a class 1 safety enclosure that complies with EN 60825-4:2006 and shall be provided with a suitable extraction system. For all classes of laser coder, a laser hazard warning pictogram (EN ISO 7010:2020/ W004) shall be fixed on the machine housing next to the coder or on the class 1 safety enclosure. Instructions for safe use, adjustment and maintenance of the laser coder shall be included in the instruction manual.

Where the coder is fitted in a hazard zone, the machine's hazardous functions shall be stopped and maintained in a stopped condition by a safety-related stop function complying with PLr "d" of EN ISO 13849-1:2015, when the coder needs to be accessed, for example because of a malfunction or to change the foil.

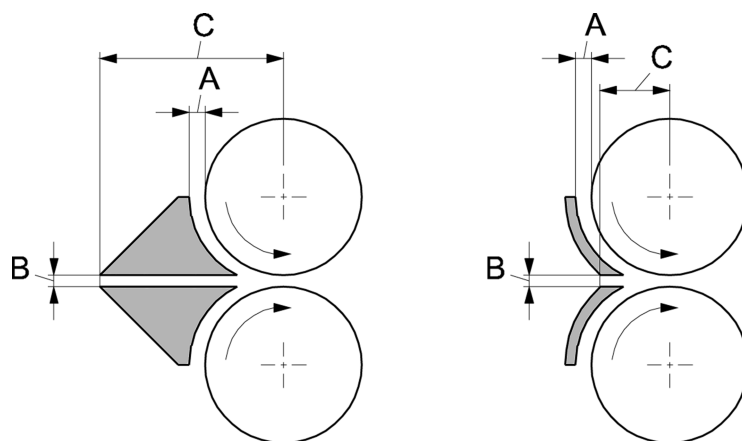
4.2.3.4 Power unwind mechanism

Drive mechanisms for power unwind devices shall be fitted with fixed guards. The in-running nips of the film driving rollers shall be safeguarded by one of the methods shown in Figure 18 or the assembly shall be enclosed with interlocking guards.

The clearance between the guard and roller A in Figure 18 and the safety distance C in Figure 18 shall be determined according to Table 1. The guard design shall ensure that it is not possible to access the rollers from the sides.

Table 1— Safety distance (C) for different film openings (B) in Figure 18

Film opening (B)	Safety distance (C)
$0 \text{ mm} < B \leq 4 \text{ mm}$	$\geq 2 \text{ mm}$
$4 \text{ mm} < B \leq 6 \text{ mm}$	$\geq 10 \text{ mm}$
$B > 6 \text{ mm}$	See Table 4 of EN ISO 13857:2019

**Key**

- A clearance between guard and roller (≤ 4 mm) C safety distance
 B film opening

Figure 18 — Methods of safeguarding power unwind mechanism

4.2.3.5 Automatic splicing mechanism

Where the automatic splicing mechanism cannot be made safe by design using the methods described in 4.1.2.1 or the mechanism incorporates a cutting device, the mechanism shall be enclosed with an interlocking guard or ESPE. This interlocking guard shall be interlocked so that the splicer cannot operate when the splicer guard is open, but allows the main machine to continue to run.

The design of the guards shall ensure that hazard zones on the main machine cannot be reached when the splicer's guard is open.

NOTE This can usually be achieved with fixed guards.

4.2.3.6 Static elimination equipment

Where elimination equipment presents a hazard, it shall comply with 4.1.3.3.

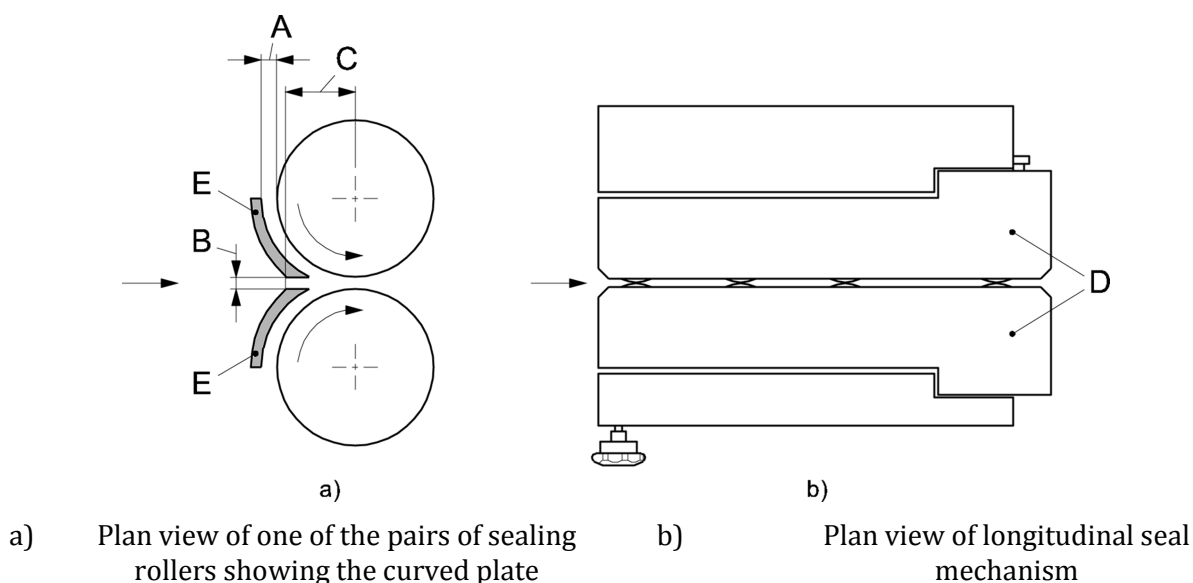
4.2.3.7 Reclose feature mechanism

Mechanisms for attaching a reclose feature to a package shall be enclosed with interlocking guards. The reclose feature reel unwind mechanism shall comply with 4.2.3.2. Where heat is used to attach the reclose feature, 4.1.4 shall apply.

4.2.4 Longitudinal sealing mechanism

The longitudinal sealing mechanism shall be safeguarded in one of the following ways:

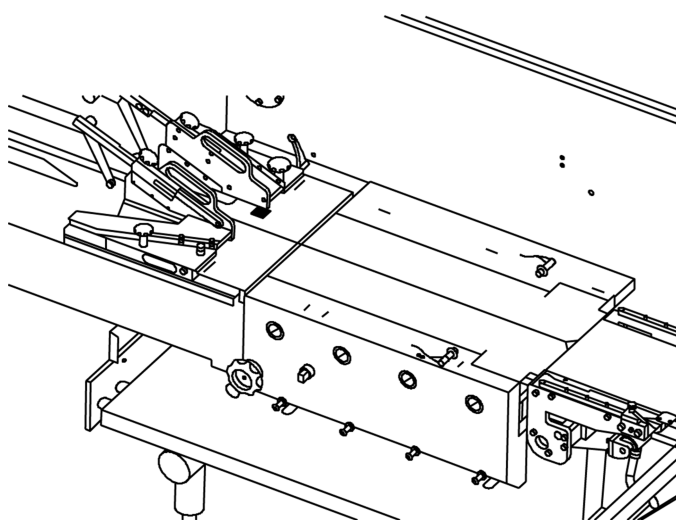
- a) enclosing the mechanism with an interlocking guard fitted with a trip guard as described in 4.2.2.3 d) and in Figure 16, or
- b) using a series of curved fixed guards in front of each set of rollers as shown in Figure 19 a). The clearance between the curved fixed guards "E" and the drive rollers "A" shall be less than or equal to 4 mm. Where the film opening "B" is less than or equal to 4 mm, the safety distance to the danger zone "C" shall be at least 2 mm. Where the film opening "B" is less than or equal to 6 mm, the safety distance to the danger zone "C" shall be at least 10 mm. Where the film opening is greater than 6 mm the safety distance shall comply with Table 4 of EN ISO 13857:2019.

**Key**

A	clearance between guard and roller (≤ 4 mm)	D	hinged plates
B	film opening	E	curved fixed guards
C	safety distance		

Figure 19 — Curved guard longitudinal sealing mechanism guarding solution

- c) using interlocked flat plates as shown in Figure 20. Where the film opening between the plates is less than or equal to 4 mm, the safety distance to the danger zone shall be at least 2 mm. Where the film opening is less than or equal to 6 mm, the safety distance to the danger zone shall be at least 10 mm. Where the film opening is greater than 6 mm the safety distance shall comply with Table 4 of EN ISO 13857:2019.

**Figure 20 — Flat guard longitudinal sealing mechanism guarding solution**

Where the longitudinal sealing mechanism is heated, the requirements of 4.1.4 shall apply.

When any of the interlocking guards described in 4.2.4 (a), (b) or (c) are open the control system shall ensure that the mechanisms cannot move unexpectedly, however it is not necessary for the heating circuit to be disconnected.

4.2.5 Transverse sealing and cutting mechanisms

The transverse sealing and cutting mechanisms shall be safeguarded with interlocking guards which prevent access to the mechanisms through both the infeed and discharge openings as illustrated by the guards marked as “D” and “E” in Figure 15.

Where the transverse sealing mechanism is pneumatically operated, it shall incorporate a brake mechanism or solenoid valve to ensure that the mechanism does not move unexpectedly when the guards are open or the compressed air supply is disconnected.

Where the transverse sealing mechanism is heated, the requirements of 4.1.4 shall apply.

When the transverse sealing mechanism interlocking guard is open the control system shall ensure that the mechanisms cannot move unexpectedly, however it is not necessary for the heating circuit to be disconnected.

4.2.6 Discharge mechanism

Where the discharge mechanism is a flat belt conveyor it shall comply with EN 415-10:2014, 5.20.4. Other discharge mechanisms which are not safe by design shall be enclosed with interlocking guards.

4.2.7 Integrity of safety related control systems

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

Safety function	PLr
Stopping the sealing and cutting mechanisms when the interlocking guard is opened	d
Preventing unexpected start-up of the sealing and cutting mechanisms when the interlocking guard is open	d
Disconnecting and dissipating energy from the static eliminator when the interlocking guard is opened	c
Stopping the chains and drives when the interlocking guard is opened	d
Stopping the infeed conveyor when the trip guard is touched	d
Stopping transmission parts when their interlocking guard is opened	c
Stopping product feeding devices when their interlocking guard is opened	c
Stopping the film reel unwind mechanism when the interlocking guard is opened	c
Stopping the discharge mechanism when the interlocking guard is opened	c
Stopping the tension roller assembly when its interlocking guard is opened	c
Stopping the automatic splicing mechanism when its interlocking guard is opened	c
Stopping all hazardous processes by the emergency stop circuit	c