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Safety of packaging machines - Part 3: Form, fill and
seal machines; fill and seal machines

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 415-3:2021 sisaldab Euroopa standardi EN 415-3:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 415-3:2021 consists of the English text of the European standard EN 415-3:2021.
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English Version

Safety of packaging machines - Part 3: Form, fill and seal machines; fill and seal machines

Sécurité des machines d'emballage - Partie 3 :
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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COMITÉ EUROPÉEN DE NORMALISATION
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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of an identical text or by endorsement, at the latest by April 2022, and conflicting national standards shall be withdrawn at the latest by April 2022.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