

**SLOVENSKI STANDARD
SIST EN 12463:2021****01-april-2021****Nadomešča:
SIST EN 12463:2015**

**Stroji za predelavo hrane - Polnilniki in zamenjljiva oprema - Varnostne in
higienske zahteve**Food processing machinery - Filling machines and interchangeable equipment - Safety
and hygiene requirementsNahrungsmittelmaschinen - Füllmaschinen und auswechselbare Ausrüstung -
Sicherheits- und HygieneanforderungenMachines pour les produits alimentaires - Machines à pousser et équipements
interchangeables - Prescriptions relatives à la sécurité et l'hygiène**Ta slovenski standard je istoveten z: EN 12463:2021****ICS:**67.260 Tovarne in oprema za živilsko Plants and equipment for the
industrijo food industry**SIST EN 12463:2021****en,fr,de**

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EUROPEAN STANDARD

EN 12463

NORME EUROPÉENNE

EUROPÄISCHE NORM

January 2021

ICS 67.260

Supersedes EN 12463:2014

English Version

Food processing machinery - Filling machines and interchangeable equipment - Safety and hygiene requirements

Machines pour les produits alimentaires - Machines à pousser et équipements interchangeables - Prescriptions relatives à la sécurité et l'hygiène

Nahrungsmittelmaschinen - Füllmaschinen und auswechselbare Ausrüstung - Sicherheits- und Hygieneanforderungen

This European Standard was approved by CEN on 28 September 2020.

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

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

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European foreword

This document (EN 12463:2021) has been prepared by Technical Committee CEN/TC 153 “Machinery intended for use with foodstuffs and feed”, the secretariat of which is held by DIN.

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of an identical text or by endorsement, at the latest by July 2021, and conflicting national standards shall be withdrawn at the latest by July 2021.

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 supersedes EN 12463:2014.

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 2006/42/EC.

For relationship with EU Directive 2006/42/EC, see informative Annex ZA, which is an integral part of this document.

The significant changes with respect to the previous edition EN 12463:2014 are listed below:

- Clause 1: clarified for filling machines and interchangeable equipment;
- Clause 2: normative references updated;
- Clause 3: terms revised and supplemented; consistent use throughout the standard;
- Clause 4: table updated;
- Clause 5: structure improved and clearer;
- Subclause 5.3.5: structure and content improved and clearer;
- Clause 6: verification list updated;
- Clause 7: supplemented;
- Figures partly renewed, keys supplemented and clarified;
- Annex C: Table of Performance level required implemented;
- Annex ZA: updated.

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.

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Introduction

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);
- consumers (in case of machinery intended for use by consumers).

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 and hazardous events are covered are indicated in the scope of this document.

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 over the provisions of the other standards, for machines that have been designed and built according to the provisions of this type-C-standard.

1 Scope

1.1 General

This document applies to:

- filling machines with cylinder and piston;
- filling machines with feed intake hopper;
- filling machines with vacuum hopper;

hereafter referred to as filling machines which process, e.g. meat, cheese and other pasty substances, excluding dry or frozen materials. They pump foodstuff into casings or bring it to a subsequent process.

This document applies also to the interchangeable equipment for filling machines with which a wide range of additional functions can be implemented. For example: portioning, depositing, mincing, co-extruding, dividing and forming.

This document deals with all significant hazards, hazardous situations and events relevant to filling machines and interchangeable equipment, when they are used as intended and under the conditions foreseen by the manufacturer and also the reasonably foreseeable misuse (see Clause 4).

These significant hazards, hazardous situations and events can arise during all the life phases including transportation, assembly, dismantling, disabling and scrapping of filling machines and interchangeable equipment.

This document is not applicable to filling machines and interchangeable equipment which were manufactured before the date of publication of this document by CEN.

The following filling machines and interchangeable equipment are not covered by this document:

- Filling and sealing machines as described in EN 415-3:1999+A1:2009;
- Clipping machines as described in EN 13885:2005+A1:2010.

1.2 Types of filling machines and interchangeable equipment covered by this standard

1.2.1 Filling machines with cylinder and piston

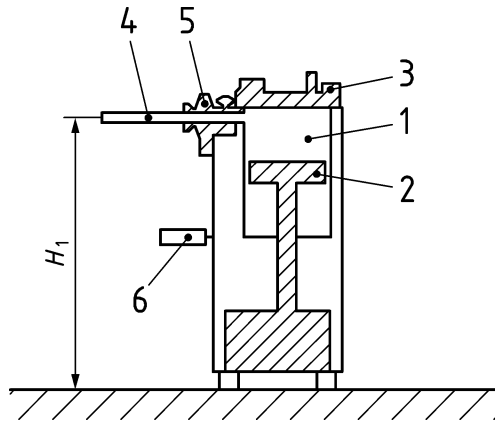
Filling machines with cylinder and piston (see Figure 1) consist of the following main parts:

- cylinder;
- piston;
- closing cover;
- filling horn;
- dividing device.

The material being processed will be fed by hand into the cylinder.

Filling machines with cylinder and piston can be fitted with a dividing device.

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**Key**

- | | | | |
|---|---------------|---|-----------------|
| 1 | cylinder | 4 | filling horn |
| 2 | piston | 5 | dividing device |
| 3 | closing cover | 6 | knee lever |

Figure 1 — Example of a filling machine with cylinder and piston

1.2.2 Filling machines with feed intake hopper

Filling machines with feed intake hopper (see Figure 2) consist of the following main parts:

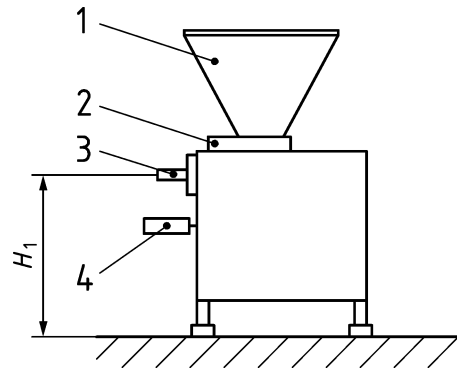
- feed intake hopper;
- feeder;
- filling horn.

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The material being processed will be fed by hand (or optionally a loading device) into the feeding hopper of the filling machine.

Filling machines with feed intake hopper can be equipped with:

- dividing device (see Figure 7a));
- closing cover or photoelectric guard at the mouth of the feed intake hopper (see Figure 10);
- pressure-sensitive protective device at the hopper edge (see Figure 10);
- divided hopper (see Figure 11);
- infeed auger (see Figure 12);
- counter auger (see Figure 12);
- step or ladder (see Figure 8 and Figure 9);
- two-hand control device at the mouth of the feed intake hopper (see Figure 9).

**Key**

- | | | | |
|---|--------------------|---|--------------|
| 1 | feed intake hopper | 3 | filling horn |
| 2 | feeder | 4 | knee lever |

Figure 2 — Example of a filling machine with feed intake hopper

1.2.3 Filling machines with vacuum hopper

Filling machines with vacuum hopper (see Figure 3) consist of the following main parts:

- vacuum hopper;
- feeder;
- outlet;
- closing cover;
- inlet valve;
- suction pipe;
- storage container;
- pipe connection inlet.

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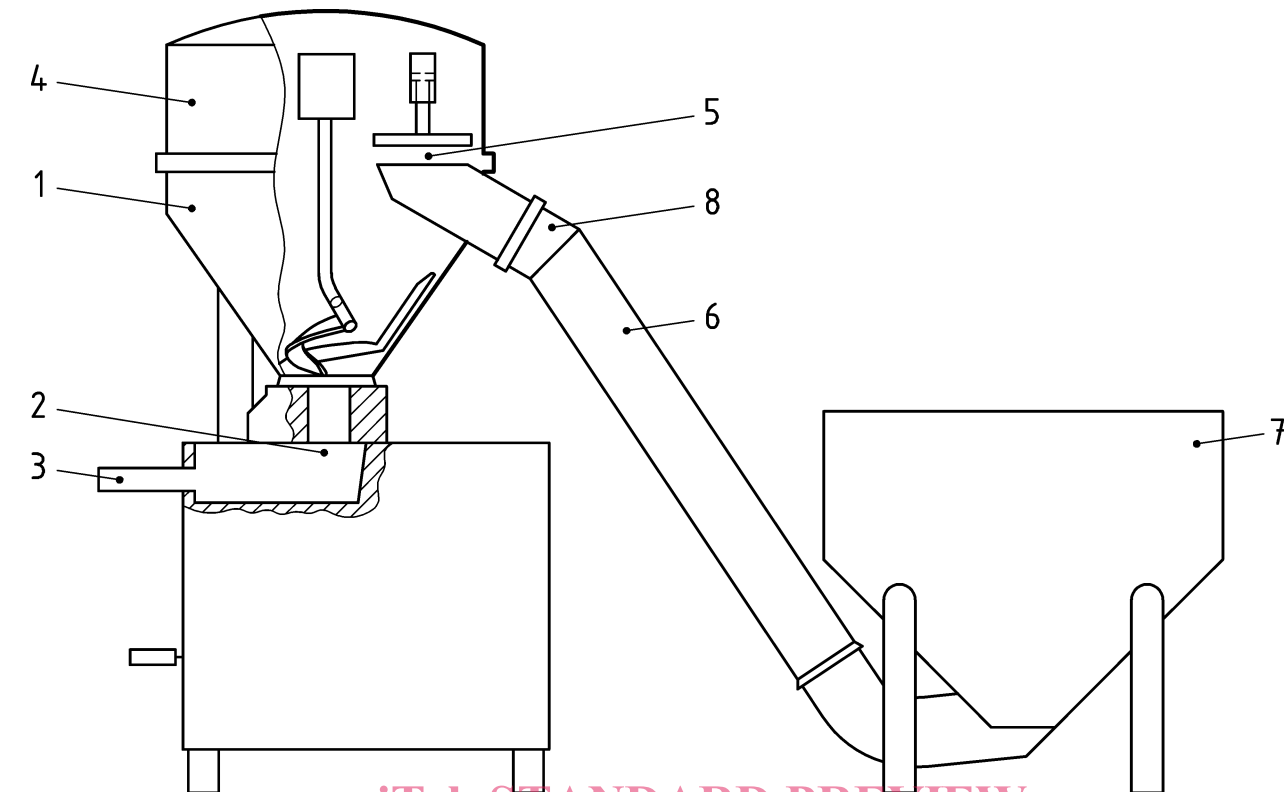
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The material being processed will be fed by hand (or optionally a loading device) into the storage container.

Filling machines with vacuum hoppers can be equipped with:

- dividing device;
- infeed auger (see Figure 12);
- counter auger (see Figure 12);
- step or ladder (see Figure 8 and Figure 9).

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Key

1 vacuum hopper	5 inlet valve
2 feeder	6 suction pipe
3 outlet	7 storage container
4 closing cover	8 pipe connection inlet

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Figure 3 — Example of a filling machine with vacuum hopper

1.2.4 Interchangeable equipment for filling machines

Interchangeable equipment are devices which can be assembled to filling machinery by the operator in order to attribute one or more new functions such as: portioning, twisting, voiding, forming, mincing. Interchangeable equipment does not operate independently. The interchangeable equipment will be actuated directly or by filling machines.

Interchangeable equipment dealt with in this document (see 5.3.5) are:

- cutting device (see Figure 14);
- forming device (see Figure 15);
- twisting device (see Figure 16);
- linking gear box (see Figure 17);
- portioning device (see Figure 18);
- holding device (see Figure 19);
- mincing device (see Figure 20);

- sausage production device (see Figure 21);
- filling stream divider device (see Figure 22);
- casing spooling device (see Figure 23);
- co-extrusion device (see Figure 24).

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 614-1:2006+A1:2009, *Safety of machinery — Ergonomic design principles — Part 1: Terminology and general principles*

EN 619:2002+A1:2010, *Continuous handling equipment and systems — Safety and EMC requirements for equipment for mechanical handling of unit loads*

EN 1005-1:2001+A1:2008, *Safety of machinery — Human physical performance — Part 1: Terms and definitions*

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

EN 1005-3:2002+A1:2008, *Safety of machinery — Human physical performance — Part 3: Recommended force limits for machinery operation*

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

EN 60204-1:2018, *Safety of machinery — Electrical equipment of machines — Part 1: General requirements (IEC 60204-1:2016, modified)*

EN 60529:1991,¹⁾ *Degrees of protection provided by enclosures (IP Code) (IEC 60529:1989)*

EN 61496-1:2013, *Safety of machinery — Electro-sensitive protective equipment — Part 1: General requirements and tests (IEC 61496-1:2012)*

EN ISO 3744:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Engineering methods for an essentially free field over a reflecting plane (ISO 3744:2010)*

EN ISO 3746:2010, *Acoustics — Determination of sound power levels and sound energy levels of noise sources using sound pressure — Survey method using an enveloping measurement surface over a reflecting plane (ISO 3746:2010)*

EN ISO 4871:2009, *Acoustics — Declaration and verification of noise emission values of machinery and equipment (ISO 4871:1996)*

1) As impacted by EN 60529:1991/A1:2000 and EN 60529:1991/A2:2013.

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EN ISO 11201:2010, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions in an essentially free field over a reflecting plane with negligible environmental corrections (ISO 11201:2010)*

EN ISO 11202:2010, *Acoustics — Noise emitted by machinery and equipment — Determination of emission sound pressure levels at a work station and at other specified positions applying approximate environmental corrections (ISO 11202:2010)*

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

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

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

3 Terms and definitions

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

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

- IEC Electropedia: available at <http://www.electropedia.org/>
- ISO Online browsing platform: available at <https://www.iso.org/obp>

3.1 twisting device

device to separate one portion from the next by twisting

3.2 dividing device

device to divide the product into portions

Note 1 to entry: Mainly used types in fillers with cylinder and piston are rotary slide or valve plate.

3.3**hanging device**

device to suspend the product from a hook or to transport it

3.4**linking gear box**

device to rotate the filling nozzle

3.5**ejector**

extractor

device for detaching the set of cutting tools

3.6**extraction claw**

tool for detaching the set of cutting tools

3.7**loading device**

device for lifting and tilting of transport cars

3.8**holding device**

device for retaining and braking the product casing on the filling horn or filling nozzle

3.9**casing clamp**

device for centring and clamping the stirred product casing

3.10**feed intake hopper**

container for receiving products to be processed

3.11**fixing device**

device for locking the transport car in the loading device

3.12**feeder**

unit for product transport

3.13**plough**

device to reduce the turning of the product with the infeed auger

3.14**divided hopper**

feed intake hopper with a disconnecting point in the upper hopper part

3.15**piston**

moving part for pressing out the product

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EN 12463:2021 (E)**3.16****blade**

cutting tool with one or several blades

3.17**rotating head**

hinged installation with one or more filling nozzles

3.18**grinder housing**

casing for holding the set of cutting tools

3.19**set of cutting tools**

arrangement of blades and hole plates for size reduction of product

3.20**counter auger**

fixed counterpart to the infeed auger

3.21**transport car**

movable container for holding the processed or unprocessed product

3.22**cutting device**

device for the cutting of portions

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3.23**closing cover**

device to close the opening of the cylinder, feed intake hopper or vacuum hopper

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3.24**infeed auger**

rotating conveying element in the feed intake hopper

3.25**vacuum suction**

suction of the product through the suction pipe into the vacuum hopper by means of negative pressure

3.26**interchangeable equipment**

device which, after the putting into service of machinery, is assembled with that machinery by the operator himself in order to change its function or attribute a new function, in so far as this equipment is not a tool

[SOURCE: 2006/42/EC, Article 2 (b), modified – The assembly with a tractor is not intended and is omitted.]

3.27**sausage production device**

device which produces products in a cylinder-like shape

Note 1 to entry: Usually, a sausage is filled in a product casing of intestine and sometimes in a product casing of synthetic material. The filling is not limited to meat.

3.28**design dimension**

sum of dimensions measured as tight string length from highest standing area (floor, steps, intermediate steps or platforms) to the hopper edge (inclusively additional physical barriers) and from the hopper edge (inclusively additional physical barriers) to the first danger point in the hopper

3.29**filling horn**

tube for filling the product, attached to the filling machine

3.30**filling nozzle**

tube for filling the product, attached to the interchangeable equipment

3.31**forming device**

device to form the product into different shape

3.32**portioning device**

device to expel the product in portions

3.33**mincing device**

device to grind the product

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3.34**filling stream divider device**

device to create more than one stream of product

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3.35**casing spooling device**

device to shirr the case on the filling horn or filling nozzle

3.36**co-extrusion device**

device to combine different product streams into one stream of product

3.37**end hole plate**

last hole plate towards the outlet

3.38**easily cleanable**

designed and constructed to be cleanable by a simple cleaning method, when necessary after removing easily dismantled parts

4 List of significant hazards

This clause contains all the significant hazards, hazardous situations and events, identified by risk assessment as significant for this type of machinery and which require measures to eliminate or reduce the risk associated with the identified hazards (see Table 1 and Table 3, and Figure 4, Figure 5 and Figure 6).