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HÜGIEENINÕUDED

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

EESTI STANDARDI EESSÕNA

NATIONAL FOREWORD

See Eesti standard EVS-EN 12463:2021 sisaldab Euroopa standardi EN 12463:2021 ingliskeelset teksti.	This Estonian standard EVS-EN 12463:2021 consists of the English text of the European standard EN 12463:2021.
Standard on jõustunud sellekohase teate avaldamisega EVS Teatajas	This standard has been endorsed with a notification published in the official bulletin of the Estonian Centre for Standardisation and Accreditation.
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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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This European Standard exists in three official versions (English, French, German). A version in any other language made by translation under the responsibility of a CEN member into its own language and notified to the CEN-CENELEC Management Centre has the same status as the official versions.

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

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Contents

Page

European foreword.....	3
Introduction.....	4
1 Scope.....	5
1.1 General.....	5
1.2 Types of filling machines and interchangeable equipment covered by this standard	5
2 Normative references.....	9
3 Terms and definitions	10
4 List of significant hazards	13
5 Safety and hygiene requirements and/or protective measures.....	16
5.1 General.....	16
5.2 Mechanical hazards – independent of type.....	17
5.3 Mechanical hazards – distinguished by type.....	22
5.4 Electrical hazards.....	42
5.5 Hazard from loss of stability	44
5.6 Noise reduction.....	45
5.7 Ergonomic requirements	45
5.8 Hygiene and cleaning.....	45
6 Verification of safety and hygiene requirements and/or protective measures.....	50
7 Information for use	53
7.1 General.....	53
7.2 Instruction handbook.....	53
Annex A (normative) Noise test code for filling machines and interchangeable equipment (grade 2)	57
Annex B (normative) Design principles to ensure the cleanability of filling machines and interchangeable equipment.....	61
Annex C (informative) Performance level required.....	66
Annex ZA (informative) Relationship between this European Standard and the essential requirements of Directive 2006/42/EC aimed to be covered	67
Bibliography.....	69

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.

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

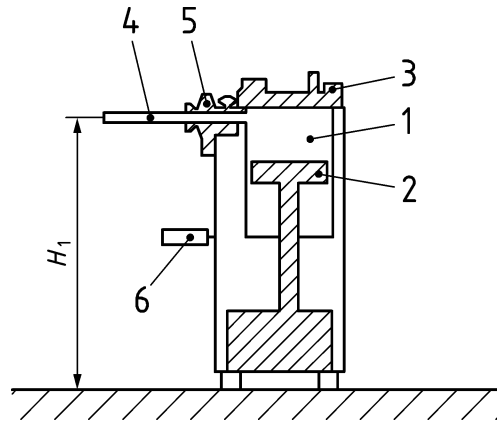
1.2.1 Filling machines with cylinder and piston

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.

**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

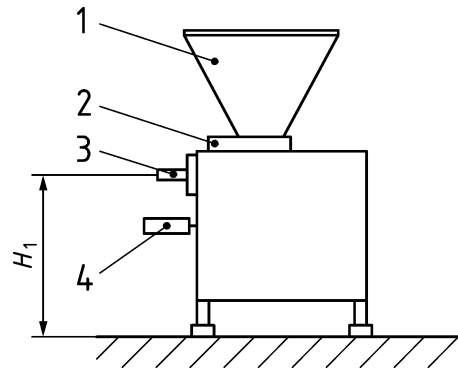
Filling machines with feed intake hopper (see Figure 2) consist of the following main parts:

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

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

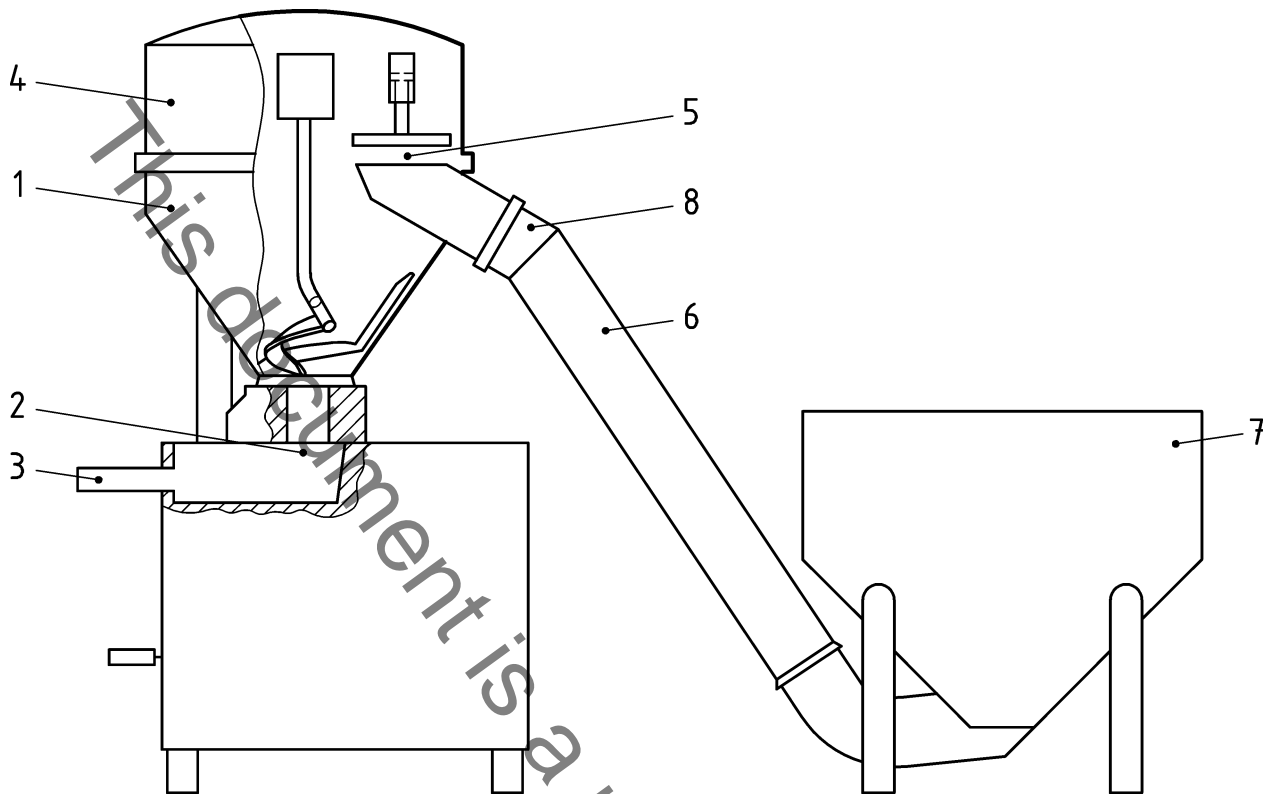
Filling machines with vacuum hopper (see Figure 3) consist of the following main parts:

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

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).

**Key**

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

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.

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.