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Food hygiene — Production and dispense of hot beverages from hot beverage appliances — Hygiene requirements, migration test

bsi.

National foreword

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Hygiène alimentaire - Production et distribution de boissons chaudes par des appareils de préparation de boissons chaudes - Exigences sanitaires, essai de migration

Lebensmittelhygiene - Herstellung und Abgabe von Heißgetränken aus Heißgetränkebereitern - Hygieneanforderungen, Migrationsprüfung

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European foreword

This document (EN 16889:2016) has been prepared by Technical Committee CEN/TC C01 “Food Products”, the secretariat of which is held by CCMC.

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of an identical text or by endorsement, at the latest by November 2016 and conflicting national standards shall be withdrawn at the latest by November 2016.

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This document is the result of the merging of DIN 10531:2011 and UNI 11460:2012.

DIN 10531 has been prepared by Working Committee NA 057-02-01 AA “Lebensmittelhygiene” (“Food hygiene”), Working Group “Getränkebereiter” (“Beverage appliances”) of the Food and Agricultural Products Standards Committee (NAL).

UNI 11460 has been prepared by the Technical Committee Assofootec/Ucimac and it has been discussed and amended by UNI Commission “Alimenti e bevande” in which there are members of “Istituto Superiore di Sanità” and “Ministero della Salute”.

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1 Scope

This European Standard specifies hygiene requirements which establish prerequisites for production of hot beverages, such as coffee and coffee specialities, tea, cocoa and dairy beverages from hot beverage appliances for commercial and household use in conformity with the food hygiene regulations and for placing on the market. Appliances for self-service are within the scope of this standard.

For this purpose, this standard specifies general hygienic requirements for the construction, material and operation of the appliances concerned. It contains, in particular, requirements for hygienic and professional operation, for cleaning, disinfection and descaling as well as requirements for a migration test.

This European Standard applies to appliances before their entering on the market (new machines) and it also gives an informative Annex for appliances already in use (see Annex A).

This European Standard does not deal with any requirements relevant to work safety. This European Standard deals neither with electrical safety nor with performance requirements. EN 60335-2-15 and EN 60335-2-75 have to be used for commercially used appliances. Methods for measuring the performance of electric household coffee makers are provided in EN 60661.

2 Normative references

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

EN 1672-2, *Food processing machinery - Basic concepts - Part 2: Hygiene requirements*

EN 60335-2-15, *Household and similar electrical appliances - Safety - Part 2-15: Particular requirements for appliances for heating liquids*

EN 60335-2-75:2004, *Household and similar electrical appliances - Safety - Part 2-75: Particular requirements for commercial dispensing appliances and vending machines (IEC 60335-2-75:2002, modified)*[1)]

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

3 Terms and definitions

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

3.1
hot beverage appliance
device for the preparation of hot beverages

3.2
hot beverage
ready to drink, prepared foodstuff to be consumed as soon as possible, if necessary after heat retention

Note 1 to entry: The point of dispense is the beverage outlet of the device.

1) This document is impacted by the amendments EN 60335-2-75:2004/A1:2005, EN 60335-2-75:2004/A2:2008, EN 60335-2-75:2004/A11:2006, and EN 60335-2-75:2004/A12:2010.

3.3
cleaning
removal of product residues and soils

3.4
disinfection
chemical and physical methods for killing microorganisms down to a level which is neither harmful to health nor impairs the quality of the foodstuffs

3.5
descaling
method for removal of lime deposits inside of the hot beverage appliance

3.6
adverse influence
effect which gives a significant reduction of the fitness for consumption of a food

3.7
food area
machinery surfaces which are exposed to the food and from which the food or other materials can drain, drip, diffuse or be drawn into (self-returned) the food or food container

3.8
splash area
area composed of surfaces on which part of the food may splash or flow along under intended conditions of use and does not return into the food

3.9
migration
process by which components of the materials touched by the product pass into the test water under specified conditions

3.10
migration test
test for determination of migration

3.11
Product type
product such as coffee, cocoa, tea and milk foam, which is characterised by the fact that the parts which come into contact with foodstuffs differ

3.12
hydraulic system
all parts of the system, except for non-heated storage containers, which come into contact with liquid food stuffs, e.g. steam, milk, water

3.13
water storage container
non-heated container for the water storage

3.14
specific release limit
SRL
describes the maximum permitted amount of a given ion or metalloid ion (in mg) when released from a material or article of a defined surface area into food (in kg) or food simulants

Note 1 to entry: According to the Directorate for the Quality of Medicines and HealthCare of the Council of Europe (EDQM): Metals and alloys used in food contact materials and articles, Council of Europe, 2013 [1]. ISBN: 978–92–871–7703–2.

4 Requirements

4.1 General

For the production and dispensation of hot beverages from hot beverage appliances to the user, the requirements for each relevant legal provision shall be conformed to.

NOTE In particular, the Regulation (EC) No 1935/2004 [2], Regulation (EC) No 2023/2006 [3] and the applicable hygiene provisions (see bibliography) apply.

To ensure this for the production and dispensation of hot beverages from hot beverage appliances, the following requirements shall be conformed to.

4.2 Proper handling of products

a) Hot beverages shall be placed on the market by way of hot beverage appliances, so that they, under observation of the necessary care, are not exposed to adverse influences during processing, storage and distribution. Depending on product, each product-specific temperature shall be taken into account.

b) Water for hot beverages from hot beverage appliances shall reach a minimum temperature of 65 °C over the course of the product preparation.

4.3 Equipment

4.3.1 Materials and surfaces

Materials in the food area shall fulfil the following requirements:

a) they shall correspond to the legal requirements;

b) they shall not dispense any parts of materials into the beverage which are questionable in regards to health, odour or taste or are technically avoidable;

c) they shall be corrosion-resistant.

NOTE 1 Corrosion-resistant materials resist the usual chemical or electrochemical stresses. This includes production processes, cleaning and disinfection in accordance with the operating instructions.

NOTE 2 For materials in the food area, Article 3 of Regulation (EC) No 1935/2004 [2] applies.

Materials in the food and splash area shall fulfil the following requirements:

d) they shall demonstrate a surface quality which corresponds with the specific operational and hygienic requirements;

e) they shall be abrasion-proof in correspondence with the intended application;

f) they shall be resistant against the foodstuffs as well as against the cleaning, disinfection and descaling agents normally used for the food and splash area;

g) they shall be temperature-resistant in correspondence with the intended application.

4.3.2 Construction

The hot beverage appliances shall be constructed so that they fulfil the basic requirements for hygienic construction in accordance with EN 1672-2 as well as the following requirements:

a) joints in the food areas shall be sealed against liquids;

b) liquids in the food areas, such as cleaning and disinfection solutions and rinsing water shall be removed to a technically unavoidable amount so that an adverse influence on the food is avoided. Liquids from the food area shall be completely drained as quickly as possible;

c) for self-service devices, a return of an already dispensed hot beverage shall not be possible under foreseeable application conditions.

4.4 Requirements for operation

4.4.1 Cleaning, descaling and disinfection of the device

The appliances shall be regularly cleaned and, if necessary, disinfected, descaled and rinsed, according to the manufacturer's instructions.

To ensure the functionality and hygiene of the hot beverage appliance, cleaning and descaling agents recommended by the manufacturer shall be used.

The test on a proper descaling presupposes the use of the decalcification agent recommended by the manufacturer.

4.4.2 Performance of a migration test on hot beverage appliances

4.4.2.1 General

The manufacturer has to ensure, in the framework of due diligence, e.g. in the framework of the type test, by means of a migration test, that no inadmissible material transfer, such as of lead and nickel, can appear in the hot beverage from the appliance. The test is performed on a sample. If the guideline values are exceeded in accordance with 4.4.2.4, the test is repeated on three structurally identical samples. The arithmetic mean of the four measured values shall not exceed the guideline value. None of the single values shall exceed the guideline values by more than 50 %. The following specified migration test should be performed according to the same principle for the assessment of further substances.

4.4.2.2 Preparation of the test water

The following chemicals (at minimum in per analysis quality) shall be dissolved in 1 l of demineralized water (stock solution):

a) 14,3 mmol/l $NaHCO_3$ (1,2 g/l);

b) 2,8 mmol/l $MgSO_4 \cdot 7\ H_2O$ (0,7 g/l);

c) 8,0 mmol/l $CaCl_2 \cdot 2\ H_2O$ (1,2 g/l).

500 ml of this stock solution are given, while stirring, into a container containing approximately 7 l of demineralized water. The container is filled up to 10 l with demineralized water, the pH balance with 0,1 mol/l HNO_3 or 0,1 mol/l NaOH is set to the pH value 7,5 and is subsequently stirred for 10 min.

The completed test water has a total hardness of 0,53 mmol/l and a carbon hardness of 0,36 mmol/l. The individual ionic concentrations are:

Ca: 16,4 mg/l, Mg: 3,3 mg/l, HCO_3: 44 mg/l, Cl: 28,4 mg/l; SO_4: 13 mg/l, Na: 16 mg/l.

The permissible tolerances in the test water are each ± 20 %.

The set test water shall be stored in sealed, closed containers so that the characteristics and components are not affected. It is permitted to be stored for a maximum of seven days.

4.4.2.3 Migration test

4.4.2.3.1 During the migration test, no products (e.g. coffee beans, chocolate powder, etc.) shall be filled into the hot beverage appliance. If necessary for testing purposes, a bridging of the product feed shall be set up by the manufacturer.

4.4.2.3.2 The test water (see 4.4.2.2.) is promptly filled into the water storage container of the device. A control sample of 125 ml is subsequently taken. For each new batch of test water, a further control sample shall be taken.

4.4.2.3.3 For point of use devices, the hot beverage appliance is connected to the test water container under the use of the appropriate valves and fittings. A control sample of 125 ml is subsequently taken.

4.4.2.3.4 The device shall be, according to the operating instructions, put into operation for the first time. Any accrued rinsing water shall be discarded. Before and during the complete test, the hot beverage appliance shall be operated with the test water in order to avoid contamination (by extraneous waters).

4.4.2.3.5 Following the operating instruction given by the manufacturer for each product type and from each product outlet, an amount of 120 ml shall be taken in a clean polyethylene or PTFE container with an airtight lid. If the total volume of the hydraulic system of the device is more than 1 000 ml, the amount of the water sample shall be 1 000 ml. If the device is operated with a steam function, steam is to be either introduced into 100 ml of test water for 45 s or steam is to be introduced for so long until the test water, taken from an initial temperature of (20 ± 5) °C, has reached a temperature of 80 °C. If the volume of the hydraulic system is more than 1 000 ml, the water volume to be heated is raised to 500 ml. If the migration water should be investigated for the presence of lead or other metals, it shall be immediately acidified with HNO_3 so that the sample reaches a concentration of 1 % (mass fraction).

4.4.2.3.6 The device is subsequently held statically in operationally-ready condition for (24 ± 1) h or for the maximum adjustable operational readiness time, this means without removing migration water, however still in heated, ready-to-use condition. For devices with automatic switch-off before the end of 24 h, the sample is taken directly before the end of the maximum adjustable operational readiness. The appliance subsequently rests for the remainder of the 24 h course. After this, a further sample is taken. For devices with automatic rinsing, a further sample shall be taken before the end of the rinsing interval.

4.4.2.3.7 Any accrued rinsing water shall be discarded.

4.4.2.3.8 After the performance of the steps according to 4.4.2.3.1 to 4.4.2.3.7, the device is decalcified, provided it is intended according to the operating instructions, and samples are subsequently taken according to 4.4.2.3.5.

4.4.2.3.9 The samples and the control sample are subsequently analysed for the concentration of the corresponding contaminants and the result of the control sample is subtracted from the results of the samples, in order to determine the contribution by the device.

4.4.2.3.10 Test sample scheme:

— 0 Water control sample

— 1 Sample after the initial putting into service

— (2) Optional before automatic switch-off

— (3) Optional before a rinse phase

— 4 After the end of 24 h

— (5) Optional after descaling

4.4.2.4 Guideline values for the migration of lead and nickel

The migration of lead in the test water shall not exceed the guideline value of 0,01 mg/kg. The guideline value for lead is associated with the SRL-value (specific release limit) of the European Directorate for the Quality of Medicines and HealthCare. By 2016 a guideline value of 0,04 mg/kg is valid. From 2017 on a guideline value of 0,01 mg/kg will be valid.

The migration of nickel in the test water shall not exceed the guideline value of 0,14 mg/kg.

5 Operating instructions and individual checks

The set-up and operating instructions as well as information for individual checks shall be enclosed with the device at the point of placing on the market. They shall take the following standards into account:

— EN ISO 12100;

— EN 60335-2-15.

The operating instructions shall contain specified information in accordance with EN 60335-2-75:2004, 7.12.101.1, 7.12.101.2, 7.12.101.3, 7.12.101.6 and 7.12.101.7 and, additionally, the following specific information for hygienic handling:

a) information on:

   — the initial putting into service, particularly information for rinsing for initial use, for extended non-use (more than 2 days) and after cleaning/descaling;

   — the daily cleaning, at minimum, after use of the parts supplying milk;

   — the daily cleaning of collection containers, e.g. the ground container;

   — the ongoing operation;

   — cleaning, disinfection and descaling of the device;

   — behaviour during dysfunctions;

   — measures during longer period operational interruptions;

   — restarting after dysfunctions.

b) information for set-up;

c) information regarding the removal of residual water, which could remain in the appliances over a longer period of time;

d) through careful rinsing with water with drinking water quality, it is ensured that only insignificant in regard to health, odour and taste and technically unavoidable remnants of cleaning and decalcification agents remain;

e) descaling shall be performed according to the manufacturer's instructions;

f) if the device is fitted with a water treatment installation, the information from the manufacturer shall be observed.

Annex A
(informative)

Testing hot beverage machines already in use

Hot beverage machines are covered by the food legislation (EC 178/2002, EC 1935/2004) [4]. The drinking water legislation does not apply.

This annex is not valid for home use appliances. Local authorities in some European countries demand a migration test at the place of operation for commercial use appliances.

To check the quality of hot beverage machines already in use, it is important that the test is practical and not too time consuming.

The principle should follow the migration test according to 4.4.2.3 of the standard.

Instead of the standardized test water, the local tap water shall be used.

It is recommended to start the test with the first usage of the machine during the test day, which means the machine was switched off before.

Initialize the machine according to the instruction manual of the manufacturer for a first usage during a day. If flushing cycles are requested for the startup by the machine manufacturer, the flushing water shall be discarded.

Prepare the machine according to 4.4.2.3.1:

During the migration test, no products (e.g. coffee beans, chocolate powder, etc.) shall be filled into the hot beverage appliance. If necessary for testing purposes, a bridging of the product feed shall be set up by the manufacturer.

Take a control sample of the feed water directly at the inlet of the machine (125 ml) immediately before the test. The sample shall be acidified with HNO_3 so that the sample reaches a concentration of 1 % (mass fraction).

Then the sampling shall be done according to paragraph 4.4.2.3.5:

For each product type and from each product outlet, an amount of 120 ml shall be taken in a clean polyethylene or PTFE container with an airtight lid. If the total volume of the hydraulic system of the device is more than 1 000 ml, the amount of the water sample shall be 1 000 ml. If the device is operated with a steam function, steam is to be either introduced into 100 ml of test water for 45 s or steam is to be introduced for so long until the test water, taken from an initial temperature of (20 ± 5) °C, has reached a temperature of 80 °C. If the volume of the hydraulic system is more than 1 000 ml, the water volume to be heated is raised to 500 ml. If the migration water should be investigated for the presence of lead or other metals, it shall be immediately acidified with HNO_3 so that the sample reaches a concentration of 1 % (mass fraction).

The samples shall be analysed according to paragraph 4.4.2.3.9:

The samples and the control sample are subsequently analysed for the concentration of the corresponding contaminants and the result of the control sample is subtracted from the results of the samples, in order to determine the contribution by the device.

If the values of the machine samples for nickel and lead are exceeding the guideline values given in the standard a detailed investigation of the complete installation, is required. The different parts of the installation shall be checked according to the applicable regulations. For the machine, the procedures described in this annex shall be repeated.

Bibliography

[1] *Metals and alloys used in food contact materials and articles, European Directorate for the Quality of Medicines & HealthCare of the Council of Europe (EDQM)*. Council of Europe, 2013, ISBN: 978-92-871-7703-2

[2] Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC. *OJEU* No L 338, 2004, pp. 4–17 [as amended]

[3] Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food. *OJEU* No L 384 from 29 December 2006, p. 75 [as amended]

[4] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety from 28 January 2002. *OJEU* No L 31, 2002, p. 1 [as amended]

[5] Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs. *OJEU* No L 226, 2004, p. 3 [in as amended]

[6] Council Regulation (EEC) No 315/93 of the Council of 8 February 1993 laying down Community procedures for contaminants in food. *OJEU* No L 37, 1993, p. 1-3 [as amended]

[7] European Hygienic Engineering & Design Group (EHEDG) Document 32, Materials of construction for equipment in contact with food

[8] Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food. *OJEU* No L 12, 2011, pp. 1-89 [as amended]

[9] Council Directive of 15 October 1984 on the approximation of the laws of the Member States relating to ceramic articles intended to come into contact with foodstuffs; *OJEU* L 277 from 20 October 1984; Corrigendum: *OJEU* L 114 from 27 April 1989 and *OJEU* L 181 from 28 June 1989, [as amended]

[10] EN 60661, *Methods for measuring the performance of electric household coffee makers (IEC 60661)*

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