Order on food contact materials and on penal provisions violation of related EU legislation[1)]

The following is laid down by virtue of Sections 25, 25a, 49(1) and 60(3) of the Food Act (cf. Consolidation Act No 32 of 14 January 2025) and by authorisation under Section 7, No 3 of Order No 1721 of 30 November 2020 on the duties and powers of the Danish Veterinary and Food Administration:

Scope of application

Section 1. The Order applies to food contact materials, which are subject to 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.

(2) The Order lays down national special measures in accordance with Articles 5 and 18 and national provisions in accordance with Article 16 of 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, for the following:

1) Ceramics, enamelled articles and glassware.

2) Paper and cardboard.

3) Declaration of conformity.

Definitions

Section 2. The following definitions apply for the purposes of this Order:

1) Enamelled objects: Object coated with enamel. Enamel is a vitreous material resulting from the melting or heating of a mixture of inorganic constituents.

2) Regenerated cellulose film: A thin film produced from refined cellulose from non-recycled wood or cotton. For technical reasons, suitable substances may have been added to the mass or surface. Regenerated cellulose film can have a coating on one or both sides. Regenerated cellulose film includes:

a) Uncoated regenerated cellulose film of regenerated cellulose;

b) coated regenerated cellulose film with a coating agent made of cellulose; or

c) coated regenerated cellulose film with a coating agent made of plastic; or

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3) Glassware: Objects made from molten inorganic material such as silicon sand, sodium carbonate, limestone or dolomitic lime.

4) Ceramic objects: Objects made from a mixture of inorganic substances in general with a high content of clay or siliceous minerals to which small quantities of organic substances may have been added. These objects are first shaped and the shape obtained is then permanently maintained by firing. They may be glazed, enamelled and/or decorated.

5) Paper and cardboard: Materials and objects made of cellulose-based natural fibres, both bleached and unbleached, from primary and recirculated sources. In addition, paper and cardboard may contain artificial fibres, functional additives and other treatment agents and polymeric binders for organic and inorganic pigments. Paper and cardboard may also contain printing inks, varnishes, surface treatments and glues used in the conversion process.

Section 3. The definitions in 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 shall apply for the purposes of this Order.

(2) In addition, food contact materials are defined as materials and articles within the meaning of Article 1(2) of 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.

General requirements

Marketing

Section 4. Food contact materials may only be placed on the market in Denmark if they comply with the requirements laid down in this Order, in 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 in rules issued pursuant thereto.

Declaration of conformity.

Section 5. Food contact materials marketed in Denmark at earlier stages than the retail stage shall be accompanied by a declaration of conformity. The declaration of conformity shall comply with the requirements set out in Annex 1, unless otherwise required by special measures issued in accordance with Article 5 of 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.

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(2) At the request of the Danish Veterinary and Food Administration, the operator shall provide relevant background evidence that the food contact material complies with the relevant requirements of this Order, of 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 of rules issued pursuant thereto.

(3) Regardless of (1), ceramics which have not yet been brought into contact with food shall, when placed on the market up to and including the retail stage, be accompanied by declarations of conformity which comply with the requirements set out in Annex 2.

(4) A declaration of conformity must be issued by the operator and the declaration must be renewed

1) when there are relevant changes in the legislation;

2) when significant changes in the composition or manufacturing process cause changes in the migration from the materials or articles; or

3) when new scientific data are available.

(5) The requirement set out in (1) and (3) shall be deemed to be fulfilled if the declaration of conformity is available on the website of the manufacturer or importer and the next links in the chain are informed thereof.

Special measures for certain food contact materials

Vinyl chloride

§ 6. Food contact materials shall not release vinyl chloride which can be detected by the method meeting the criteria set out in Annex 3 to foodstuffs which are or have been in contact with those food contact materials.

Regenerated cellulose film

Section 7. Regenerated cellulose film within the meaning of Section 2 No 2 (a) and (b) may be manufactured exclusively from the substances or groups of substances listed in Annex 4 and only under the conditions laid down therein.

(2) Regenerated cellulose films within the meaning of Section 2 No 2 (c) may, before coating, be manufactured exclusively from the substances or groups of substances listed in Annex 4 and only under the conditions laid down therein. The coating agent for the films referred to in Section 2 No 2 (c) may be manufactured exclusively from the substances or groups of substances listed in the Annexes to Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food and under the conditions specified therein, taking

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into account Article 6 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

(3) Regardless of (1) and (2), other substances or groups of substances may be used as colourants or binders, provided that these substances do not give rise to migration into foodstuffs.

(4) Food contact materials produced from regenerated cellulose films referred to in Section 2 No 2 (c) shall comply with the rules on plastics laid down in Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

Section 8. The printed side of regenerated cellulose films shall not be put in contact with foodstuffs.

Section 9. The provisions of Section 7 shall not apply to synthetic casings of regenerated cellulose.

Ceramic and enamelled objects and glassware

Section 10. Ceramic and enamelled articles and glassware may only be placed on the market in Denmark if they comply with the migration limits for lead and cadmium set out in Annex 5.

Section 11. The migration of lead and cadmium from ceramic or enamelled articles or articles of glass shall be determined in accordance with Annex 6.

(2) Where a ceramic article consists of a container fitted with a ceramic lid, the limit for lead and cadmium which must not be exceeded (measured in mg/dm² or mg/l) is the same as that applicable to the container alone.

(3) The container alone and the inner surface of the lid shall be tested separately and under the same conditions. The sum of the two quantities of released lead and/or cadmium shall be attributed, as appropriate, to the surface or volume of the container alone.

Paper and cardboard

Section 12. Food contact materials made of paper and cardboard in which perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been used may not be placed on the market in Denmark.

(2) Regardless of (1), paper and cardboard food contact materials using perfluoroalkyl and polyfluoroalkyl substances (PFAS) may be placed on the market provided that a functional barrier is used in the product, thereby avoiding the migration of the substances into the food.

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Recall

Section 13. Where a business operator assumes or has reason to believe that food contact materials produced, imported or distributed by the business operator do not comply with food safety requirements and the products are no longer controlled by the business operator, the business operator shall immediately take action to withdraw those food contact materials from the market.

(2) In the cases referred to in (1), the operator shall immediately inform the Danish Veterinary and Food Administration.

(3) Where food contact materials have reached consumers, the business operator shall effectively and accurately inform consumers of the reasons for the recall.

Penal provisions

Section 14. A fine shall be imposed on anyone who violates Sections 4-10, 12 or 13.

(2) The penalty may be increased to up to 2 years' imprisonment if a violation by act or omission is committed deliberately or with gross negligence, and the violation:

1) caused injury or brought about the risk of injury, or

2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

(3) Companies etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code.

Section 15. Unless higher penalties are stipulated under other legislation, fines will be imposed on a person who violates:

1) Article 3, Article 4, Article 11(4) or (5), Article 15 or Article 17 of 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,

2) Articles 4-7 of Commission Regulation (EC) No. 2023/2006 of 22 December 2006 on good manufacturing practices for materials and articles intended to come into contact with food;

3) Articles 2-5 of Commission Regulation (EC) No 1895/2005 of 18 November 2005 on the restriction of use of certain epoxy derivatives in materials and articles intended to come into contact with food;

4) Article 4(1) or (3), Article 5(1) to (4) or (6), Article 6(1) or (3), Article 7 or 8 or Article 9(1) or (3) to (9) of Commission Regulation (EU) 2022/1616 of 15 September 2022 on recycled plastic materials and articles intended to come into contact with foods, and repealing Regulation (EC) No 282/2008;

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5) Article 4, Article 5(1), Article 9(1) or Article 10-13 of Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food;

6) Article 4, Article 5(1), Article 8-13, Article 14(1), (3) or (5) or Article 15-17 of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food; or

7) Articles 3-5, Article 7(1), or Article 8 of Commission Regulation (EU) 2024/3190 of 19 December 2024 on the use of bisphenol A (BPA) and other bisphenols and bisphenol derivatives with harmonised classification for specific hazardous properties in certain materials and articles intended to come into contact with food, amending Regulation (EU) No 10/2011 and repealing Regulation (EU) 2018/213.

(2) The penalty may be increased to up to 2 years' imprisonment if a violation by act or omission is committed deliberately or with gross negligence, and the violation

1) caused injury or brought about the risk of injury, or

2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

(3) Companies etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code.

Entry into force

Section 16. The Regulation shall enter into force on 1 January 2026.

(2) Order No 681 of 25 May 2020 on food contact materials and on penalties for infringement of related EU acts is repealed.

(3) However, the rules laid down in Section 10 shall not enter into force until 1 July 2026. In the period from 1 January 2026 to 1 July 2026, the rules currently in force in Section 14 of Order No 681 of 25 May 2020 on food contact materials and on penalties for infringements of related Union acts shall apply.

(4) Food contact materials of ceramic and enamelled articles and glassware lawfully placed on the market before 1 July 2026 may continue to be placed on the market until the existing stocks are exhausted.

Danish Veterinary and Food Administration, [date]

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Annex 1

Declaration of conformity, cf. Section 5(1)

The written declaration of conformity referred to in Section 5(1) shall make it easy to identify the food contact materials or substances for which it is issued and shall demonstrate compliance with the applicable rules. The declaration shall contain the following information:

a) The identity and address of the food contact materials operation issuing the declaration of conformity;

b) Identity of the material or object;

c) Date of declaration;

d) Confirmation that the material or article complies with the relevant requirements of this Order and of 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.

e) Specifications for the use of the material or article, where relevant, such as:

    1) type or types of food with which it is intended to be put in contact;

    2) the time and temperature of processing and storage in contact with the foodstuff.

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Annex 2

Declaration of conformity for ceramics, cf. Section 5(3)

The written declaration for ceramics referred to in Section 5(3) shall contain the following information:

a) Name and address of the operation producing the finished ceramic article and of the importer importing it into the EU (European Union).

b) Identity of the object

c) Date of declaration

d) Confirmation that the ceramic object complies with the relevant requirements of this Order and of 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.

The operator shall also, upon request, provide relevant background evidence that the ceramic articles comply with the migration limits for lead and cadmium and make it available to the control authorities. This documentation shall include the results of the analyses carried out, the test conditions and the name and address of the laboratory carrying out the test.

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Annex 3

Determination of vinyl chloride content and determination of vinyl chloride released from food contact materials, cf. Section 6

Criteria to be applied to the method for the determination of the vinyl chloride content in food contact materials and for the determination of vinyl chloride emitted by food contact materials:

1) Determination of the vinyl chloride content of food contact materials and determination of the amount of vinyl chloride released into food from food contact materials shall be performed by "gas chromatography" using the head space method.

2) The limit of detection for the determination of the amount of vinyl chloride released into food from food contact materials is 0.01 mg/kg.

3) The determination of the amount of vinyl chloride released into food from food contact materials is in principle carried out on foods. Where determination on certain foods proves technically impossible, Member States may authorise determination by means of simulations for those particular foods.

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Annex 4

List of substances that may be used in the manufacture of regenerated cellulose films, cf. Section 7

Description of regenerated cellulose film

Regenerated cellulose film is a thin film produced from refined cellulose from non-recycled wood or cotton. For technical reasons, suitable substances may have been added to the mass or surface. Regenerated cellulose films may be surfaced (coated) on one or both sides.

List of substances authorised in the manufacture of regenerated cellulose films

- The percentages in the first and second parts of this Annex shall be expressed in weight/weight (w/w) and shall be calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film;
- the general technical terms are indicated in square brackets;
- The substances used must be of good technical quality in terms of purity criteria.

Part A

Uncoated regenerated cellulose film of regenerated cellulose

Name	Requirements
A. Regenerated cellulose	Exceeding or equal to 72% (w/w)
D. Additives	
1. Moisture stabilizers	Total quantity less than or equal to 27% (w/w)
- Bis (2-hydroxyethyl) ether [= diethylene glycol]	Only for foils which are later to be coated and then used for non-humid food, i.e. which do not contain physical free water on the surface. The total amount of bis (2-hydroxyethyl) ether and ethanediol present in foodstuffs which have been in contact with such film shall not exceed 30 mg per kg of the food.
- Ethanediol [= mono ethylene glycol]	
- 1,3 Butanediol	
- Glycerol	
- 1,2-propanediol [= 1,2 propylene glycol]	
- Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1200.

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- 1,2 polypropylene oxide [= 1,2 polypropylene glycol]	Average molecular weight less than or equal to 400 and containing 1,3-propandiol less than or equal to 1% (w/w).
- Sorbitol	
- Tetraethyleneglycol	
- Triethyleneglycol	
- Urea	
2. Other additives (Additives)	Total quantity less or equal to 1% (w/w).
1. class	The amount of the substance or group of substances in each indent may not be greater than 2 mg/dm^2 in the uncoated film
- Acetic acid and its ammonium, calcium, magnesium, potassium and sodium salts	
- Ascorbic acid and its ammonium, calcium, magnesium, potassium and sodium salts	
- Benzoic acid and sodium benzoate	
- Formic acid and its ammonium, calcium, magnesium, potassium and sodium salts	
- Saturated or unsaturated linear fatty acids with an even number of carbon atoms (C_8-C_{20}), behenic and ricinoleic acids and ammonium, calcium, magnesium, potassium, sodium, aluminium and zinc salts of these acids	
- Citric acid, D- and L-lactic acid, maleic acid, L-tartaric acid and their sodium and potassium salts	
- Sorbic acid and its ammonium, calcium, magnesium, potassium and sodium salts	
- Amides of linear, saturated or unsaturated fatty acids with an even number of carbon atoms (C_8–C_{20}) and amides of behenic acid and ricinoleic acid	
- Naturally occurring edible starch and flour varieties	
- Chemically modified edible starch and flour varieties	
- Amylose	
- Calcium and magnesium carbonate, calcium and magnesium chloride	
- Glycerol esters with saturated or unsaturated linear fatty acids with an even number of C_8 to C_{20}carbon and/or adipic, citric, 12-hydroxystearic (oxystearin) and ricinoleic acids	
- Esters of polyoxyethylene (8-14 oxyethylene groups) with linear, saturated or unsaturated fatty acids with an even number of carbon atoms (C8–C20)	
- Esters of sorbitol with linear, saturated or unsaturated fatty acids with an even number of carbon atoms (C_8-C_{20})	
- Mono- and/or stearic acid diesters with ethanediol and/or bis (2-hydroxyethyl) ether and/or triethylene glycol	
- Oxides and hydroxides of aluminium, calcium, magnesium and silicon and silicates and hydrated silicates of aluminium, calcium, magnesium and potassium	

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- Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1200 and 4000.
Sodium propionate	
2. class	The total amount of the substances shall not exceed 1 mg/dm^2 of the uncoated film and the total amount of each substance or group of substances within each indent shall not exceed 0.2 mg/dm^2 (or a lower value where indicated) of the uncoated film.
- Sodium alkyl benzenesulphonate (C_8-C_{18})	
- Sodium isopropyl naphthalene sulphonate	
- Sodium alkyl sulphate (C_8-C_{18})	
- Sodium alkyl sulphonate (C_8-C_{18})	
- Sodium dioctylsulfosuccinate	
- Distearate of dihydroxyethyl di-ethylenetriamine monoacetate	Less than or equal to 0.05 mg/dm^2 of the uncoated film.
- Ammonium, magnesium and potassium lauryl sulphate	
- N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
- 2-heptadecyl-4,4-bis-(methylene stearate) oxazoline	
- Polyethylene-aminostearamide ethylsulphate	Less than or equal to 0.1 mg/dm^2 of the uncoated film.
3. class- anchoring agent	The total quantity of the substances (thermosetting agents) shall not exceed 1 mg/dm^2 of the non-coated film.
- Condensation product of melamine formaldehyde, either unmodified or modified with one or more of the following products: butanol, diethylenetetramine, ethanol, triethylenetetramine, tetraethylenepentamine, tri- (2-hydroxyethyl) amine, 3,3 '-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content less than or equal to 0.5 mg/dm^2 of the uncoated film Free melamine content less than or equal to 0.3 mg/dm^2 of the uncoated film.
- Condensation product of melamine-urea-formaldehyde modified with tri-(2-hydroxyethyl) amine	Free formaldehyde content less than or equal to 0.5 mg/dm^2 of the uncoated film. The content of free melamine less than or equal to 0.3 mg/dm^2 of the non-coated film.
- Polyalkyleneamines, anchored and on cation form a) Polyamide-epiclorhydrin resin based on diaminopropyl-methylamine and epichlorhydrin b) Polyamide epiclorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylene diamine c) Polyamide-epiclorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, or a mixture of	

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epichlorhydrin and ammonia d) Polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, dimethyl adipate and diethylenetriamine e) Polyamide-polyamine-epichlorhydrin resin based on epichlorhydrin, adipamide and diaminopropyl methylamine	
- Polyethyleneamines and polyethyleneimines	Less than or equal to 0.75 mg/dm^2 of the uncoated film.
- Condensation products of unmodified melamine-formaldehyde, or which may be modified with one or more of the following products: aminomethylsulphonic acid, sulphanilic acid, butanol, diethylenetriamine, diaminodiethylamine, methanol, triethylenetetramine, tetraethylenepentamine, guanidine, sodium sulphite, ethanol, 3,3'-diaminodipropylamine, diaminopropane, diaminobutane	Free formaldehyde content less than or equal to 0.5 mg/dm^2 of the uncoated film.
4. class	The total quantity of the substances shall not exceed 0.01 mg/dm^2 of the non-coated film.
- Reaction products between amines of edible oils and polyethylene oxide	
- Monoethanolamine laurylsulfate	

Part B

Coated film of regenerated cellulose

Name	Requirements
A. Cellulose regenerate	See Part A
B. Additives	See Part A
C. Varnish	
1. Polymers	The total amount of substances may not exceed 50 mg/dm^2 of the coating agent on the side in contact with foodstuffs.
- Ethyl cellulose, hydroxyethyl cellulose, methyl cellulose and hydroxypropyl cellulose	
- Cellulose nitrate	Less than or equal to 20 mg/dm^2 of the coating agent on the side in contact with foodstuffs; the nitrogen content must be between 10.8% (w/w) and 12.2% (w/w) in the cellulose nitrate.
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm^2 of the coating

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	agent on the side in contact with foodstuffs and only in the manufacturing of regenerated cellulose films coated with coating based on cellulose nitrate.
- Casein	
- Colophonium [pine resin] and/or polymerised and/or hydrogenated and/or disproportional rosin and its esters with ethanol, methanol and polyhydric alcohols ($C_2$to C_6) or mixtures of these alcohols	
- Colophonium and/or reaction products thereof by polymerisation and/or hydrogenation and/or disproportional colophonium condensed with acrylic acid, maleic acid, citric acid, fumaric acid and/or 2,2-bis (4-hydroxyphenyl) propane formaldehyde and/or phthalic acid, and esterified with ethanol, methanol or polyvalent alcohols (C_2-C_6) or mixtures of these alcohols	
- Esters of bis(2-hydroxy-ethyl) ether with addition products of beta-pinene and/or diterpene (DL-limonene) and maleic acid anhydride	
- Gelatin, (food grade)	
- Castor oil and its dehydrated or hydrogenated products, and its condensation products with adipic acid, citric acid, phthalic acid, sebacic acid, maleic acid and polyglycerol	
- Natural resin [Dammar]	
- Poly-ß-pinene [terpenic resin]	
- Modified (see cross-binding substances)	
3. Plasticisers	The total amount of substances may not exceed 6 mg/dm² of the coating agent on the side in contact with foodstuffs.
- Acetyl tributyl citrate	
- Acetyl tri(2-ethylhexyl) citrate	
- Di-isobutyl adipate	
- Di-n-butyl adipate	
- Azelate of di-n-hexyl	
- Dicylohexyl phthalate	Less than or equal to 4.0 mg/dm² of coating agent on the side in contact with foodstuffs.
- 2-ethylhexyl diphenyl phosphate	The amount of 2-ethyl-hexyldiphenyl phosphate shall

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	not exceed: a) 2.4 mg/kg of the food in contact with this type of film, or b) 0.4 mg/dm^2 of the coating agent on the side in contact with foodstuffs.
- Glycerol monoacetate [= monoacetin] - Glycerol diacetate [= diacetin] - Glycerol triacetate [= tracetin] - di-butyl sebacate - Di-n-butyl tartrate - Di-iso-butyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6 mg/dm^2 in uncoated regenerated cellulose film, including coating on the side in contact with foodstuffs.
4.1. Additives listed in part one	Same special provisions as in part one (however, the quantities in mg/dm2 relate to the side in contact with food)
4.2. Specific surface treatment additives:	The amount of individual substances or of a group of substances shall not exceed 2 mg/dm^2 (or a lower value where indicated) on the side in contact with food.
- 1-hexadecanol and 1-octadecanol (stearyl alcohol)	
- Esters of linear, saturated or unsaturated fatty acids with an even number of carbon atoms (C_8-C_{20}) and ricinoleic acid with ethanol,1-butanol, 1-pentanol [amyl alcohol] and oleoyl alcohol	
- Montan wax, including purified montanic acid (C_{26}-C_{32}) and/or its esters with ethanediol and/or its calcium and potassium salts	
- Carnauba wax	
- Beeswax	
- Esparto wax	
- Candelilla wax	
- Dimethylpolysiloxane	Less than or equal to 1 mg/dm^2 of coating agent on the side in contact with foodstuffs.
- Epoxylated soya bean oil (with an ethylene oxide content of 6-8%)	
- Purified paraffin wax and purified microcrystalline wax (microwax)	

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- Pentaerythritol tetrastearate	
- Mono- and bis(octadecyldietylenoxide) phosphates	Less than or equal to 0.2 mg/dm² of coating agent on the side in contact with foodstuffs.
- Esters of aliphatic acids (C_8-C_{20}) with mono- and/or bis-(2-hydroxyethyl amine) diethanolamine	
- 2- and 3-tert-butyl-4-hydroxyanisole [butylhydroxyanisole — BHA]	Less than or equal to 0.06 mg/dm² of coating agent on the side in contact with foodstuffs.
- 2,6-di-tert-butyl-4-methylphenol [butyl hydroxytoluene (BHT)]	Less than or equal to 0.06 mg/dm² of coating agent on the side in contact with foodstuffs.
- Di-n-octyltin bis(2-ethylhexylmaleate)	Less than or equal to 0.06 mg/dm² of coating agent on the side in contact with foodstuffs.
5. Solvents	The total amount of substances may not exceed 0.6 mg/dm² of the coating agent on the side in contact with foodstuffs.
- Butyl acetate	
- Ethyl acetate	
- Isobutyl acetate	
- Isopropyl acetate	
- Propyl acetate	
- Acetone	
- 1-butanol	
- Ethanol	
- 2-butanol	
- 2-propanol	
- 1-propanol	
- Cyclohexane	
- Ethylene glycol monobutyl ether	
- Ethylene glycol monobutyl ether acetate	
- Methyl-ethyl ketone	
- Methyl isobutyl ketone	
- Tetrahydrofuran	
- Toluene	Less than or equal to 0.06 mg/dm² of coating agent on the side in contact with foodstuffs.

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Annex 5

Limit values for lead and cadmium from ceramic and enamelled articles and glassware, cf. Section 10

Object[1)]	Lead	Cadmium
Category A:		
Objects that cannot be filled	0.3 µg/ dm^2	0.4 µg/ dm^2
Filling articles, the inner depth of which, measured between the lowest point and the horizontal plane of the upper edge, does not exceed 25 mm (flatware).		
The mouth rim of articles intended to be drunk from[2)3)]		
Category B:		
Baby bottles	1.5 µg/l	0.35 µg/l
Articles intended to be drunk by [(3)]		0.70 µg/l
Other articles that can be filled		2 µg/l

1) When an object is fitted with a lid, the container alone and the inner surface of the lid shall be analysed separately. The sum of the quantities of lead or cadmium (µg) released is related to the volume (l) of the object (however, the surface area of the object dm2 for category A).

2) Migration from a band of 20 mm measured from the top edge of objects intended to drink off.

3) The migration must meet both the requirements for category A for discharge from the mouth and the requirements for category B.

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Annex 6

Ceramics, enamelled articles and glassware, cf. Section 11

A. Basic rules for the determination of lead and cadmium emissions

1. Test fluid

4% vol/vol (v/v) acetic acid in freshly prepared aqueous solution.

2. Test conditions

The extraction shall be carried out at a temperature of 22 ± 2°C and shall extend over 24 ± 0.5 hours.

3. Filling

3.1. Articles that cannot be filled

First, the part of the surface of the article which is not intended to come into contact with food shall be covered with a suitable protective layer resistant to a 4% (v/v) acetic acid solution. Then the object is immersed in a container with a known amount of acetic acid solution so that the surface intended to come into contact with food is fully covered by the test liquid.

3.2. Articles that can be filled

Fill the object with 4% (v/v) acetic acid solution up to a maximum of 1 mm from the overrun point, this distance being measured with the upper edge of the object.

However, in the case of objects with a flat or slightly sloping rim, the object shall be filled in such a way that the distance between the surface of the liquid and the point of overflow is not more than 6 mm measured along the sloping rim.

3.3 Objects to be examined for leaching from ‘the mouth lip’

The object is immersed in a 4 per cent container. (v/v) acetic acid solution such that a 2 cm wide strip along the upper edge of the object is covered by the test liquid. Parts of the object which are not to be removed but which, due to the shape of the object, become covered by the test fluid shall be uncovered as described in 3.1.

4. Determination of the surface of objects of category A according to Annex 5

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The surface of articles which cannot be filled (category A, point 1 of Annex 5) shall be calculated as the total immersed surface which may come into contact with food and is not covered in accordance with point 3.1, without taking into account any holes in the article.

The surface of objects of category A, point 2, shall be calculated as the area of the surface of the liquid when filled as described in point 3.1.

The surface of objects of category A, point 3, is calculated as the surface of a 2 cm wide strip along the upper edge of the object on both the inner and outer surfaces, the so-called ‘mouth lip’.

B. Analytical methods for the determination of lead and cadmium migration

1. Principle

The specific release of lead and cadmium from articles is determined by deferring 4% acetic acid for 24 hours at 22 °C. Determination of the release of lead and/or cadmium is carried out by an instrumental analytical method.

The quantities of lead and cadmium emitted are related to the surface or volume of the article.

2. Reagents

All reagents shall be of analytical quality, unless other specifications are laid down in this Annex.

Where water is mentioned below, this always refers to ultrapure (type 1) water with a resistivity of at least 18.0 MΩ· cm.

2.1. 4% (v/v) acetic acid in aqueous solution

Add 40 ml glacial acetic acid to a 1,000 ml flask filled half-way with water and make up to 1,000 ml with water. This solution must have been prepared on the day the extraction begins.

2.2. Quality controls

Prepare solutions in 4% acetic acid (3.1) containing Cd and Pb at appropriate concentration levels, i.e. within the measurement range.

3. Requirements for instrumental analytical method

3.1. The limit of determination for lead and cadmium shall not exceed:

0.3 micrograms per litre for lead;

0.07 micrograms per litre for cadmium;

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3.2. Recovery

The recovery of lead and cadmium added to the 4% acetic acid referred to in point 2.1 shall be within 80 to 120% of the added amount.

3.3. Specificity

The instrumental analytical method used shall be free of matrix or spectral interference.

4. Procedure

4.1. Preparation of the object for extraction

The article must be clean and free of fat or other substances that may influence the analysis. The article is washed with a solution containing a liquid detergent for domestic use at a temperature of approximately 40 °C. It is then rinsed first with plain water and then with ultra-pure water. The object is then dripped off and dried to avoid any contamination. The surface to be tested should not be handled after it has been cleaned.

4.2. Determination of lead and cadmium

The thus prepared object is extracted as described in section A of this Annex. Before a sample is taken from the extract for the determination of lead or cadmium, it must be ensured that it is homogeneous without losing any of the extract and without scraping off from the surface of the object. For each series of determinations, a blank test shall be carried out on the reagent used.

Lead and/or cadmium shall be determined under appropriate test conditions.

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Official notes

1) The Order contains provisions transposing Council Directive 84/500/EEC 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, OJ 1984 L 277, pp. 12-16, as amended by Commission Directive 2005/31/EC of 29 April 2005, OJ 2005 L 110, pp. 36-39, Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles of regenerated cellulose film intended to come into contact with foodstuffs, OJ 2007 L 172, pp. 71-82 and Council Directive 78/142/EEC of 30 January 1978 on the approximation of the laws of the Member States relating to materials and articles which contain vinyl chloride monomer and are intended to come into contact with foodstuffs, OJ L 44, 15/02/1978, p. 15–17. A draft of this Order has been notified in accordance with Directive (EU) 2015/1535 of the European Parliament and of the Council laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services (codification).

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