

Informative translation of Danish Order on food contact materials and on provisions for penalties for breaches of related EU legislation¹

(Bekendtgørelse nr. 681 af 25. maj 2020)

This is a translation of the Danish Order on food contact materials and on provisions for penalties for breaches of related EU legislation. In any case of misinterpretation between the translated version and the Danish version, the Danish version has legal force.

Pursuant to § 25, § 25 a, § 49(1) and § 60(1) of the Food Act (see Consolidation Act No 999 of 2 July 2018), the following is hereby laid down by authorisation under § 7, No 3 of Order No 596 of 5 May 2020 on the duties and powers of the Danish Veterinary and Food Administration:

Chapter 1

Scope and definitions

§ 1. The provision applies to food contact materials covered by Regulation (EC) No 1935/2004 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. For the purposes of this Order:

1) Regenerated cellulose film: Thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface.

Regenerated cellulose film may be coated on one or both sides. Regenerated cellulose film includes:

- a. uncoated regenerated cellulose film,
- b. coated regenerated cellulose film with coating derived from cellulose, or
- c. coated regenerated cellulose film with coating consisting of plastics.

2) Ceramic articles: Articles manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added. These articles are first shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

3) Paper and board: Materials and articles made of cellulose-based natural fibres, both bleached and unbleached, from primary and recycled sources. In addition, paper and board may contain artificial fibres, functional additives and other treatment substances and polymeric binding substances for organic and non-organic pigments. Paper and board may also contain inks, varnish, surface treatments and glue used in the conversion process.

§ 3. In this Order, food contact materials are defined as materials and substances as described in Regulation (EC) No 1935/2004 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC, Article 1(2).

§ 4. In this Order, plastic is defined as in Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Article 3(1)(a and b), as well as plastic defined in Article 3(2) in the same Regulation.

Paragraph 2 For the application of this Order, the other relevant definitions in Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, Article 3 apply.

§ 5. In addition to the definitions in § 2-4, the definitions in Regulation (EC) No 1935/2004 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 apply.

Chapter 2

Placement on the market, use and withdrawal

§ 6. Food contact substances may not be placed on the market if they do not comply with the general requirements in Regulation (EC) No 1935/2004 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 and regulations issued pursuant to this.

Paragraph 2 Businesses that import, produce or pack foods may not use food contact materials if they do not comply with the general requirements in Regulation (EC) No 1935/2004 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 and regulations issued pursuant to this. The businesses must also ensure that they only use food contact materials for the purposes for which they are intended.

§ 7. If a business, producer or importer of food contact materials believes or has reason to believe that food contact materials which the business has produced, imported or distributed do not comply with the requirements for food safety and the products are no longer controlled by the manager, producer or importer of the business, it shall take measures with a view to withdrawing the relevant food contact materials from the market.

Paragraph 2 In the cases specified in paragraph 1, the manager, producer or importer shall inform the Danish Veterinary and Food Administration at once.

Paragraph 3 If food contact materials have reached the consumers, the manager, producer or importer shall effectively and precisely inform the consumers about the reason why the product is being withdrawn. If necessary, the business shall recall the product from the consumers.

Chapter 3

Special production, use and testing conditions, etc. for certain food contact materials

Paper and board

§ 8. Food contact materials made of paper and board in which perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been used may not be placed on the market.

Paragraph 2 Notwithstanding paragraph 1, food contact materials made of paper and board in which perfluoroalkyl and polyfluoroalkyl substances (PFAS) have been used may be placed on the market if a function barrier is used in the product to prevent the substances migrating into the food.

Plastic and recycled plastic

§ 9. In the use of additives which are solely used as surface biocides and which are intended to remain in the finished material or the finished article, only those biocides listed in Annex 1 may be used and only with the restrictions and/or specifications stated in the Annex.

Vinyl chloride

§ 10. Food contact materials may not release vinyl chloride which can be shown using the method meeting the criteria laid down in Chapter 2 for food which is or has been in contact with these food contact materials.

Regenerated cellulose film

§ 11. Regenerated cellulose film as referred to in § 2(1)(a and b) may only be produced from the substances or groups of substances listed in Chapter 3 and only in accordance with the conditions stated there.

Paragraph 2 Regenerated cellulose film, as referred to in § 2(1)(c) may only be produced before coating from the substances or groups of substances listed in Chapter 3 and only in accordance with the conditions stated there. The substance used for coating of the film specified in § 2(1)(c) may only be made from the substances or groups of substances listed in the Annexes to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food and only in accordance with the conditions laid down, taking into account Article 6 in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

Paragraph 3 Notwithstanding paragraphs 1 and 2, other substances or groups of substances can be used as inks or binders if these substances are not transferred into food.

Paragraph 4 Food contact materials made of regenerated cellulose film, as referred to in § 2(1)(c), shall comply with the regulations on plastic, cf. Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

§ 12. Regenerated cellulose film surfaces may not come into contact with foodstuffs.

§ 13. The provisions in paragraph 11 do not apply to synthetic regenerated cellulose casings.

Ceramic and enamelled articles and glassware

§ 14. Ceramic and enamelled articles and glassware may not release for lead or cadmium than stated in Chapter 4, though cf. paragraph 2.

Paragraph 2 If ceramic or enamelled articles or glassware release lead or cadmium in amounts exceeding the limits stated in Chapter 4 but not more by more than 50 %, the item can be legally sold if analyses of at least three other articles of the same form and dimensions and with the same decoration and glazing show that the amount of lead or cadmium released from these articles does not on average exceed the limits stated in Chapter 4 and none of these articles exceeds these limits by more than 50 %.

Paragraph 3 Ceramic and enamelled articles and glassware shall observe the basic regulations for general and specific monitoring of migration laid down in § 16 in this Order.

Chapter 4

Special documentation and declaration requirements

§ 15. Food contact materials shall be accompanied by statements of compliance in accordance with the requirements laid down in Chapter 5. In addition, the manager of the business shall on request produce relevant background documentation, cf. Chapter 5.

Paragraph 2 The requirement in paragraph 1, point 1, is considered to have been met if the declarations of compliance appear on the home page of the producer or importer and the next stage in the chain has been informed accordingly.

Paragraph 3 The food contact material businesses shall document in accordance with Article 7 of 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 that the food contact materials have been produced in accordance with the rules in the same Regulation, cf. also § 25 in Order No 1404 of 29 November 2018 on authorisation and registration of food businesses etc.

Chapter 5

Migration test

Ceramic and enamelled articles and glassware

§ 16. Migration of lead and cadmium from ceramic or enamelled articles or glassware is determined in accordance with Chapter 6.

Paragraph 2 If a ceramic item consists of a container with a coating of ceramic, then the limit of lead or cadmium that may not be exceeded (measured in mg/dm² or mg/l) is the same as that which applies to the container alone.

Paragraph 3 The container alone and the inner surface of the lid are tested separately and on the same conditions. The sum of the two amounts of lead and/or cadmium released is related respectively to the surface or the volume of the container alone.

Chapter 6

Penalty provisions and entry into force

§ 17. Unless higher penalties are stipulated under other legislation, penalties by fine will be imposed on those who breach §§ 6-8, §§ 9-12 or §§ 14-15.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 18. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions of Regulation (EU) 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:

- 1) Article 3.
- 2) Article 4(1) or (3-6).
- 3) Article 11(5).
- 4) Article 15.
- 5) Article 17.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or

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

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 19. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions of 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:

- 1) Article 4.
- 2) Article 5.
- 3) Article 6.
- 4) Article 7.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 20. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions 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:

- 1) Article 2.
- 2) Article 3.
- 3) Article 4.
- 4) Article 5.
- 5) Article 6(4).

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 21. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions of Commission Regulation (EU) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006:

- 1) Article 3(1).
- 2) Article 7(1-2).
- 3) Article 11.
- 4) Article 12.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 22. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions 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:

- 1) Article 4.
- 2) Article 5.
- 3) Article 9.
- 4) Article 10.
- 5) Article 11.
- 6) Article 12.
- 7) Article 13.
- 8) Article 14.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 23. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food:

- 1) Article 4.
- 2) Article 5.
- 3) Article 6(3).
- 4) Article 8.
- 5) Article 9.
- 6) Article 10.
- 7) Article 11.
- 8) Article 12.
- 9) Article 13.
- 10) Article 14(1, 3 or 5).
- 11) Article 15.
- 12) Article 16.
- 13) Article 17.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 24. Unless higher penalties are stipulated by other legislation, a fine shall be imposed on those who violate the following provisions of Commission Regulation (EU) No 2018/213 of 12 February 2018 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic materials that come into contact with foodstuffs:

- 1) Article 2.
- 2) Article 3.
- 3) Article 4.

Paragraph 2 The penalty may be increased to up to 2 years' imprisonment if an infringement by act or omission is committed deliberately or with gross negligence, and the infringement:

- 1) has caused damage to health or if a risk of this has arisen, or
- 2) achieved or was intended to achieve a financial benefit for the parties concerned or others.

Paragraph 3 Entities etc. (legal persons) may be rendered criminally liable in accordance with the provisions in Chapter 5 of the Penal Code [Straffeloven].

§ 25. This notification will come into force on 1 July 2020.

Paragraph 2 Order No 1248 of 30 October 2018 on food contact materials is revoked.

Paragraph 3 Food contact materials made of paper and board that do not meet the requirements in § 7 but which comply with § 6(1) and were placed on the market before 1 July 2020 can still be placed on the market until the existing stocks have been used up.

Annex 1

List of additives which exclusively act as surface biocides and are intended to remain in the finished object, cf. § 9

PM/REF No	CAS No	Chemical description	Restrictions and/or specifications
86432/40	-	Silver-containing glass (silver-magnesium-aluminium-sodium-phosphate-silicate-borate), silver content less than 0.5 %	SML = 0.05 mg Ag/kg
86432/60	-	Silver-containing glass (silver-magnesium-sodium-phosphate), silver content less than 3 %	SML = 0.05 mg Ag/kg
86434	-	Silver sodium hydrogen zirconium phosphate	SML = 0.05 mg Ag/kg
86437	-	Silver Zeolite A (silver zinc sodium ammonium alumino silicate), silver content 2-5 %	SML = 0.05 mg Ag/kg
86437/50	-	Silver-zinc-aluminium-boron-phosphate glass, mixed with 5-20 % barium sulfate, silver content 0.35-0.6 %	SML = 0.05 mg Ag/kg
86438	-	Silver zinc zeolite A (silver zinc sodium alumino silicate calcium metaphosphate), silver content 1-1.6 %	SML = 0.05 mg Ag/kg
86438/50	-	Silver zinc zeolite A (silver-zinc sodium magnesium alumino silicate calcium phosphate), silver content 0.34-0.54 %	SML = 0.05 mg Ag/kg
86430	-	20 % (w/w) silver chloride coated onto 80 % (w/w) titanium dioxide	SML = 0.05 mg Ag/kg
86432	-	Silver-containing glass (silver-magnesium-calcium-phosphate-borate)	SML = 0.05 mg Ag/kg

Annex 2

Criteria to be used on the method to determine the content of vinyl chloride in food contact materials and to determine the vinyl chloride released by food contact materials, cf. § 10

- 1) The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the 'headspace' method.
- 2) For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit shall be 0.01 mg/kg.
- 3) Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, Member States may permit determination by simulants for these particular foodstuffs.

Annex 3

List of substances that may be used in the production of regenerated cellulose film, cf. § 11

Description of regenerated cellulose film

Regenerated cellulose film is a thin sheet material obtained from a refined cellulose derived from unrecycled wood or cotton. To meet technical requirements, suitable substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated (given a surface treatment) on one or both sides.

List of substances authorised in the manufacture of regenerated cellulose film

- The percentages in this Annex, first and second parts, are expressed in weight/weight (w/w) and are calculated in relation to the quantity of anhydrous uncoated regenerated cellulose film
- The usual technical denominations are given in square brackets
- The substances used shall be of good technical quality as regards the purity criteria

Part A

Uncoated regenerated cellulose film Denominations	Restrictions
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A. Regenerated cellulose	Not less than 72 % (w/w)
B. Additives	
1. Softeners	Not more than 27 % (w/w) in total
- Bis (2-hydroxyethyl) ether [= diethyleneglycol]	Only for films intended to be coated and then used for foodstuffs which are not moist, namely which do not contain water which is physically free at the surface. The total amount of bis(2-hydroxyethyl)ether and ethanediol present in foodstuffs that have been in contact with film of this type may not exceed 30 mg/kg of the foodstuff.
- Ethanediol [= monoethyleneglycol]	
- 1,3-butanediol	
- Glycerol	
- 1,2-propanediol [= 1,2 propyleneglycol]	
- Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 250 and 1 200.
- 1,2-polypropylene oxide [= 1,2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1,3-propanediol content not greater than 1 % (w/w) in substance.
- Sorbitol	
- Tetraethyleneglycol	
- Triethyleneglycol	
- Urea	
2. Other additives	Not more than 1 % (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film.
- Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	
- Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
- Benzoic acid and sodium benzoate	
- Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
- Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms f(C ₈ -C ₂₀) and also behenic and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, Al, Zn salts of these acids	
- Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
- Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
- Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
- Natural edible starches and flours	
- Edible starches and flours modified by chemical treatment	
- Amylose	
- Calcium and magnesium carbonates and chlorides	
- Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
- Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
- Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms (C ₈ -C ₂₀)	
- Mono-and/or di-esters of stearic acid 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	
- Polyethylene oxide [= polyethyleneglycol]	Average molecular weight between 1 200 and 4 000.
Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm ² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2 mg/dm ² (or a lower limit where one is specified) of the uncoated film.
- Sodium alkyl (C ₈ -C ₁₈) benzene sulphonate	
- Sodium isopropyl naphthalene sulphonate	
- Sodium alkyl (C ₈ -C ₁₈) sulfate	
- Sodium alkyl (C ₈ -C ₁₈) sulphonate	
- Sodium dioctylsulphosuccinate	
- Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05 mg/dm ² of the uncoated film.
- Ammonium, magnesium and potassium lauryl sulfates	
- N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	
- 2-heptadecyl-4,4-bis(methylene-stearate) oxazoline	
- Polyethylene-aminostearamide ethylsulphate	Not more than 0.1 mg/dm ² of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm ² of the uncoated film.
- Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.
- Condensation product of melamine-urea-formaldehyde modified with tris(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.
- Cross-linked cationic polyalkyleneamines a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin a mixture of 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 diaminopropylmethylamine	
- Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm ² of the uncoated film.
- Condensation product of urea-formaldehyde unmodified, or which may be modified with one or 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 not greater than 0.5 mg/dm ² of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm ² of the uncoated film.
- Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
- Monoethanolamine lauryl sulphate	

Part B

Coated regenerated cellulose film	Restrictions
Denominations	
A. Regenerated cellulose	See Part A
B. Additives	See Part A
C. Varnish	
1. Polymers	The total quantity of substances may not exceed 50 mg/dm ² of the coating on the side in contact with foodstuffs.
- Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
- Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side in contact with foodstuffs; nitrogen content 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 on the side in contact with foodstuffs and solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
- Casein	
- Colophony and/or its products of polymerisation, hydrogenation, or disproportionation and their esters of methyl, ethyl or (C ₂ -C ₆) polyvalent alcohols, or mixtures of these alcohols	
- Colophony and/or its products of polymerisation, hydrogenation, or disproportionation condensed with acrylic, maleic, citric, fumaric and/or phthalic acids and/or 2,2-bis(4-hydroxyphenyl)propane formaldehyde and esterified with methyl ethyl or (C ₂ -C ₆) polyvalent alcohols or mixtures of these alcohols	
- Esters derived from bis(2-hydroxyethyl)ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
- (Edible) gelatine	
- Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
- Natural gum [damar]	
- Poly-beta-pinene [terpenic resins]	
- Urea-formaldehyde resins (see anchoring agents)	
3. Plasticisers	The total quantity of substances may not exceed 6 mg/dm ² of the coating on the side in contact with foodstuffs.
- Acetyl tributyl citrate	
- Acetyl tri(2-ethylhexyl) citrate	
- Di-isobutyl adipate	
- Di-n-butyl adipate	
- Di-n-hexyl azelate	
- Dicyclohexyl phthalate	Not more than 4.0 mg/dm ² of the coating on the side in contact with foodstuffs.
- 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: a)

	2.4 mg/kg of the foodstuff in contact with this type of film, or b) 0.4 mg/dm ² in the coating on the side in contact with foodstuffs.
- Glycerol monoacetate [monoacetin] - Glycerol diacetate [diacetin] - Glycerol triacetate [triacetin] - Di-butyl sebacate - Di-n-butyl tartrate - Di-isobutyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6 mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1. Additives listed in the first part	Same restrictions as in the first part (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs)
4.2. Specific coating additives:	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
- 1-hexadecanol and 1-octadecanol	
- Esters of linear fatty acids, saturated or unsaturated, with an even number of C ₈ -C ₂₀ carbon atoms and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
- Montan waxes, comprising purified montanic (C ₂₆ -C ₃₂) acids and/or their esters with ethanediol and/or their calcium and potassium salt	
- Carnauba wax	
- Beeswax	
- Esparto wax	
- Candelilla wax	
- Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side in contact with foodstuffs.
- Epoxidised soya-bean oil (oxirane content 6-8 %)	
- Refined paraffin and microcrystalline waxes	
- Pentaerythritol tetrastearate	
- Mono- and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2 mg/dm ² of the coating on the side in contact with foodstuffs.
- Aliphatic acids (C ₈ -C ₂₀) esterified with mono- or bis(2-hydroxyethyl)amine	
- 2- and 3-tert-butyl-4-hydroxyanisole [butylated hydroxyanisole — BHA]	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
- 2,6-di-tert-butyl-4-methylphenol [butylated hydroxytoluene — BHT]	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
- Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.

5. Solvents	The total quantity of substances may not exceed 0.6 mg/dm ² of the coating 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	
- Ethyleneglycol monobutyl ether	
- Ethyleneglycol monobutyl ether acetate	
- Methyl ethyl ketone	
- Methyl isobutyl ketone	
- Tetrahydrofuran	
- Toluene	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.

Annex 4

Limit values for lead and cadmium from ceramic and enamelled articles as well as glassware, cf. § 14

Article ¹⁾	Lead	Cadmium
Category I:	0.8 mg/dm ²	0.07 mg/dm ²
1 Articles that cannot be filled.	0.8 mg/dm ²	0.07 mg/dm ²
2 Articles to be filled whose inner depth measured between the lowest point and the horizontal plane of the upper edge is no more than 25 mm (flat goods).	0.8 mg/dm ²	0.07 mg/dm ²
3 Articles intended to be drunk from (mouth edge). ²⁾	0.8 mg/dm ²	0.07 mg/dm ²
Category II:	4.0 mg/l	0.3 mg/l
Articles that can be filled with the exception of flat goods (category I, point 2). ²⁾	4.0 mg/l	0.3 mg/l
Category III:	1.5 mg/l	0.1 mg/l
1 Saucepans and frying pans.	1.5 mg/l	0.1 mg/l
2 Packaging and storage containers with a capacity exceeding 3 litres.	1.5 mg/l	0.1 mg/l

1) When an item has a lid, the container and the inner surface of the lid should be analysed separately. The sum of the amounts of lead or cadmium found (mg) is set in proportion to the volume (1) of the articles (but dm² of the surface of the article for category I).

2) Mugs and similar articles to be drunk from shall comply with both the requirements of category I for transfer from the mouth edge and the requirements of category II.

Requirements for documentation for businesses putting food contact materials on the market, cf. § 15

The requirement for documentation applies to all food contact materials placed onto the market at earlier stages than the retail stage. However, see point 4 relating to ceramics.

1) Plastic

When plastic food contact materials, including partly-manufactured goods, are placed onto the market at earlier stages than the retail stage, they must be accompanied by a declaration of compliance, cf. Article 15 in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food.

The manager of the business shall also on request provide relevant background documentation showing that the materials, articles and substances used to make such food contact materials meet the requirements in Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food, cf. Article 16 in the Regulation. This background information is made available to the authorities.

2) Recycled plastic

Additional requirements for the declaration of compliance appear in Article 12 of Commission Regulation (EU) No 282/2008 of 27 March 2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No 2023/2006.

3) Active and intelligent food contact materials

The requirement for a declaration of compliance and background documentation are stated respectively in Articles 12 and 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.

4) Ceramics

When ceramics that have not yet been brought into contact with foodstuffs are placed on the market, they shall up to and including the retail stage be accompanied by a written declaration in compliance with Article 16 of Regulation (EC) No 1935/2004 of the European Parliament and of the Council. The written declaration is intended to make it easier to identify the goods for which it is issued and it must be renewed when significant changes in production lead to changes in the migration of lead and cadmium. The declaration shall be issued by the manufacturer or by a merchant who is established in the European Union. The written declaration shall contain the following information:

- a) Name and address of the business making the finished ceramic article and of the importer who is importing it to the European Union.
- b) The identity of the article
- c) The date of the declaration
- d) Confirmation that the ceramic article fulfils the relevant requirements in this Order and in Regulation 1935/2004.

Manufacturers and importers of chemical articles shall also provide on request relevant background documentation showing that the ceramic articles comply with the limits for migration of lead and cadmium and make it available to the authorities. This documentation shall contain the results of the analyses carried out, conditions of the tests and the name and address of the laboratory which carried out the test.

5) Other food contact materials, including semi-manufactures

When other food contact materials than those referred to in 1)-4) are brought on the market at earlier stages than the retail stage, they shall also be accompanied by a declaration of compliance. The written statement of compliance shall make it easy to identify the food contact materials or substances for which it is issued and shall document that the current regulations are being complied with. The declaration of compliance is renewed when significant changes in production lead to changes in the migration or when new scientific data become available.

With respect to these food contact materials, the manager of the business shall also on request provide relevant background documentation showing that the food contact materials and substances/semi-manufactures used to make them meet the

requirements in this Order and make it available to the authorities. This documentation may contain test conditions and the test results, calculations, other information and proof of safety or information showing that the requirements have been fulfilled.

Annex 6

Ceramic, enamelled articles and glassware, cf. § 16

A. Basic rules for determining the migration of lead and cadmium

1. Testing conditions etc.

Test liquid: 4 % (v/v) acetic acid, in a freshly prepared aqueous solution. Carry out the extraction at a temperature of 22 ± 2 °C for a duration of 24 ± 0.5 hours.

Cover the sample so as to ensure that its surface is kept in total darkness. This is, however, not necessary if only the lead migration is to be determined.

2. Test preparations

2.1. Articles that cannot be filled

The surface of the sample which is not intended to come into contact with foodstuffs is first covered with a suitable protective layer able to resist the action of the 4 % (v/v) acetic acid solution. The sample is then immersed in a recipient containing a known volume of acetic acid solution in such a way that the surface intended to come into contact with foodstuffs is completely covered by the test liquid.

2.2. Articles that can be filled

Fill the article with a 4 % (v/v) acetic acid solution to a level (no more than 1 mm from the overflow point). If the article has a flat or slightly slanted edge, however, the article is filled in such a way that the distance between the surface of the liquid and the overflow point does not exceed 6 mm, measured along the slanting rim.

2.3 Articles to be investigated for migration from the 'mouth edge'

The article is lowered into a container with 4 % (V/v) acetic acid solution in such a way that a 2 cm wide strip along the upper edge of the article is covered by the sample liquid. Parts of the article which are not to be extracted but which due to the form of the article are covered by the sample liquid are covered as described under 2.1.

The determination of the surface for category I articles, cf. Chapter 4 on ceramic and enamelled articles and glassware.

The surface of articles that cannot be filled (category I, point 1 in Chapter 4) is calculated as the total submerged surface which can come into contact with food and is not covered, cf. point 2.1. No account is taken of any holes in the article.

The surface of articles in category I, point 2 is calculated as the area of the surface of the liquid when the article has been filled, as described under point 2.1.

The surface of articles in category I, point 3 is calculated as the area of a 2 cm wide strip along the upper edge of the article on both inner and outer sides, the so-called 'mouth edge'.

B. Methods of analysis for determining the migration of lead and cadmium

1. Principle

The determination of the specific migration of lead and cadmium is carried out by standing in 4 % acetic acid for 24 hours at 22 °C. The determination of migration of lead and/or cadmium is made by an instrumental analysis method.

The amount of migration of lead and cadmium is compared with the surface or volume of the article.

2. Reagents

All reagents must be of analytical quality, unless otherwise specified in this Annex.

Where reference is made below to water, this always means distilled water or water of equivalent quality.

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

A 1 000 ml flask halfway filled with water has 40 ml of glacial acetic acid added, and water is added to make up to 1 000 ml. This solution shall be prepared on the day that the extraction is started.

2.2. Stock solutions

Stock solutions are prepared containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution (2.1).

3. Requirements for instrumental analysis method

3.1. The detection limit for lead and cadmium must be equal to or lower than:

0.1 mg/litre for lead

0.01 mg/litre for cadmium

The detection limit is defined as the concentration of the element in 4 % acetic acid, cf. point 3.1, which gives a signal equal to twice the background noise of the instrument.

3.2. The detection limit for lead and cadmium must be equal to or lower than:

0.2 mg/litre for lead

0.02 mg/litre for cadmium

3.3. Recovery

The recovery of lead and cadmium to which 4 % acetic acid has been added, cf. point 3.1, shall be within 80-120 % of the amount added.

3.4. Specificity

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

4. Procedure

4.1. Preparation of the article for the extraction

The article must be clean and free from grease or other matter that may affect the analysis. The article is washed in a solution containing a household liquid detergent at a temperature of approximately 40 °C. It is then first rinsed in tap water and then in distilled water (or water of equivalent quality). The article is then drained and dried to avoid any form of contamination. The surface to be tested should not be handled after it has been cleaned.

4.2. Determination of lead and/or cadmium

The article thus prepared is tested under the conditions laid down in Chapter A in this Annex. Before taking the test solution for determining lead and/or cadmium, the content of the sample is to be homogenised by an appropriate method which avoids any loss of solution or abrasion of the surface being tested. A blank test is carried out on the reagent used for each series of determinations.

Lead and/or cadmium is determined under appropriate test conditions.

Official notes

¹ The Order contains provisions that transpose 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, No L 277, pages 12-16, as amended by Commission Directive 2005/31/EC of 29 April 2005, OJ 2005, No 110, pages 36-39, Commission Directive 2007/42/EC of 29 June 2007 relating to materials and articles made of regenerated cellulose film intended to come into contact with foodstuffs, OJ 2007, No L 172, pages 71-82 and Council Directive 78/142/EEA 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 1978, No L 44, pp. 15-17. The Order includes certain provisions of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food, OJ 2011, No L 12, pages 1-89. According to Article 288 of the Treaty on the Functioning of the European Union, a regulation shall be directly applicable in all Member States. The reproduction of regulations in the Order is therefore exclusively for practical reasons and does not affect the direct application of the regulations in Denmark. The draft Order has been notified in accordance with Directive 2015/1535/EU 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).