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14 February 2012 [shall come into force from 17 February 2012];

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If a whole or part of a paragraph has been amended, the date of the amending regulation appears in square brackets at the end of the paragraph. If a whole paragraph or sub-paragraph has been deleted, the date of the deletion appears in square brackets beside the deleted paragraph or sub-paragraph.

Republic of Latvia

Cabinet Regulation No. 808 Adopted 19 October 2011

Regulations Regarding Materials and Articles Intended to Come into Contact with Food

Issued pursuant to Section 10, Paragraph one of the Law on the Supervision of the Handling of Food

I. General Provisions

- 1. This Regulation prescribes:
- 1.1. the mandatory harmlessness requirements for the materials and articles intended to come into contact with food (hereinafter the materials and articles);
- 1.2. the procedures for registering manufacturing, processing, and distribution establishments of the materials and articles, for suspending and restoring their operation, as well as for cancelling their registration;
- 1.3. the procedures for suspending distribution and use of the materials and articles, as well as the procedures for the further use and destruction of the materials and articles in case of violation of laws and regulations.
- 1. This Regulation shall not apply to the materials and articles which natural persons import in their personal luggage or receive in an international postal consignment and which are intended for personal use.

- 2. It shall be permitted in Latvia to manufacture, import, distribute and use the materials and articles which comply with the requirements laid down in this Regulation and laws and regulations of the European Union:
- 2.1. general requirements for the materials and articles are laid down 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 repealing Directives 80/590/EEC and 89/109/EEC (hereinafter Regulation No 1935/2004 of the Parliament and of the Council);
- 2.2. the materials and articles are manufactured in conformity with the conditions of good manufacturing practice which are laid down by 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 (hereinafter – Commission Regulation No 2023/2006);

- 2.3. the special requirements for plastic materials and articles are 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 (hereinafter Commission Regulation No 10/2011);
- 2.4. the use of recycled plastic materials and articles into contact with food is laid down in Commission Regulation (EC) 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 (hereinafter Commission Regulation No 282/2008);
- 2.5. the restriction of use of epoxy derivatives in the materials and articles intended to come into contact with food is determined by 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:
- 2.6. the special requirements for the marketing of active and intelligent materials and articles are laid down in Commission Regulation (EC) No 450/2009 of 29 May 2009 on active and intelligent materials and articles intended to come into contact with food.
- 2.¹ [26 September 2017]
- 3. In order to use the substances which are not referred to in this Regulation and laws and regulations of the European Union, for the manufacturing of materials and articles, the procedure laid down in Article 9 of Regulation No 1935/20014 of the Parliament and of the Council shall be followed, when submitting an application to the State scientific institute "Institute of Food Safety, Animal Health and Environment "BIOR" (hereinafter the Institute).

[26 September 2017]

II. Materials and Articles Made of Regenerated Cellulose Film

- 4. Regenerated cellulose film shall be a thin sheet material which is manufactured from purified cellulose obtained from non-recycled wood or cotton. In order for the film to obtain certain technical characteristics, different substances may be added thereto during manufacturing process both in the mass and on the surface. Regenerated cellulose film may have a coating on one or both sides.
- 5. Regenerated cellulose film shall be used as a material which comes into contact with food or constitute a part of the material which comes into contact with food. This condition shall not apply to synthetic regenerated cellulose protective casings.
- 6. The regenerated cellulose film referred to in Paragraph 4 of this Regulation shall correspond to one of the following types:
 - 6.1. a regenerated cellulose film without a coating;
 - 6.2. a regenerated cellulose film with a coating derived from cellulose;
 - 6.3. a regenerated cellulose film with a coating consisting of plastics.
- 7. The regenerated cellulose film referred to in Sub-paragraphs 6.1 and 6.2 of this Regulation shall only be manufactured from the substances or groups of substances listed in Annex 3 to this Regulation by complying with the restrictions laid down therein. [14 February 2012]
- 8. Substances other than referred to in Annex 3 to this Regulation may only be used as colouring matters (dyes and pigments) or adhesives, if in using an approved method of

analysis it has not been established that such substances migrate to or from food. An approved method of analysis shall conform to the provisions referred to in Annex III to Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules.

[14 February 2012]

- 9. The regenerated cellulose film with a coating consisting of plastics shall be manufactured, prior to coating, by using only the substances or groups of substances referred to in Chapter I of Annex 3 to this Regulation, subject to the restrictions laid down therein. [14 February 2012]
- 10. Coating consisting of plastics and used for regenerated cellulose film shall be manufactured by using only the substances or groups of substances listed in Annex 1 to Commission Regulation No 10/2011 by complying with the restrictions laid down therein.
- 11. The materials and articles made of regenerated cellulose film with a coating consisting of plastics shall comply with the requirements referred to in Articles 12, 13, 17 and 18 of Commission Regulation No 10/2011.
- 12. Printed surfaces of the regenerated cellulose film may not come into contact with foodstuffs.
- 13. At all marketing stages, except for the retail, the materials and articles made of regenerated cellulose film which are intended to come into contact with food shall be accompanied by a written declaration in accordance with the requirements laid down in Article 16(1) of Regulation No 1935/2004 of the Parliament and of the Council.
- 14. The requirement referred to in Paragraph 13 of this Regulation shall not apply to the materials and articles made of regenerated cellulose film which by their nature are clearly intended to come into contact with food. Officials of the Food and Veterinary Service (hereinafter the Service) shall, if necessary, request a written declaration for the abovementioned materials in accordance with Article 16(1) of Regulation No 1935/2004 of the Parliament and of the Council.

[26 September 2017]

15. If the materials and articles made of regenerated cellulose film have specific provisions of use, they shall be marked appropriately.

III. Ceramic Articles

- 16. Ceramic article shall be an article which is manufactured from a mixture of inorganic materials with a high clay and silicate content slightly mixed with organic substances. Such articles are first given the shape and then the obtained shape is strengthened by firing. They may be glazed, enamelled, decorated.
- 17. Migration of lead and cadmium from specific ceramic articles which, in their finished state, are intended to come into contact with food, or which come into contact with food and are intended for such purpose shall be determined in compliance with the requirements laid down in Annex 4 to this Regulation, and shall not exceed the quantities indicated in Paragraph 20 of this Regulation.

[14 February 2012]

- 18. If a ceramic article is a container with a ceramic lid, the quantity of lead and cadmium or lead or cadmium which may not be exceeded (milligrams per square decimetre or milligrams per litre) shall be such that only applies to the container.
- 19. Inner surface of a container and lid shall be examined individually and under equal conditions. The sum of the quantity of lead and cadmium or lead or cadmium so obtained shall only be attributable to the surface or volume of the container.
- 20. The quantity of the lead and cadmium or lead or cadmium migrating from a ceramic article shall not exceed the following quantities depending on the category of the ceramic article:
- 20.1. the quantity of lead 0.8 milligrams per square decimetre, and the quantity of cadmium 0.07 milligrams per square decimetre for a category 1 ceramic article (an article which may not be filled, or an article which may be filled and the inner depth of which measured from the lowest point to the horizontal plane that goes through the upper edge does not exceed 25 millimetres);
- 20.2. the quantity of lead 4.0 milligrams per litre, and the quantity of cadmium 0.3 milligrams per litre for a category 2 ceramic article (other articles which may be filled);
- 20.3. the quantity of lead 1.5 milligrams per litre, and the quantity of cadmium 0.1 milligrams per litre for a category 3 ceramic article (cooking ware, as well as food packing and storage tanks the volume of which exceeds three litres).
- 21. In order to establish the quantity of lead and cadmium or lead, or cadmium in accordance with Annex 4 to this Regulation, four ceramic articles of similar shape and size with similar decoration and glazing shall be taken by dividing them into two samples respectively: the first sample one article, the second sample three articles.

 [26 September 2017]
- 21. Testing shall be commenced with the first sample. A ceramic article complies with the requirements of this Regulation, provided the quantity of lead and cadmium or lead, or cadmium in the first sample does not exceed the quantity referred to in Paragraph 20 of this Regulation. In this case the second sample shall not be tested additionally. [26 September 2017]
- 21.² A ceramic article also complies with the requirements of this Regulation, provided the quantity referred to in Paragraph 20 of this Regulation has been exceed in the first sample, but by not more than 50 per cent, and the second sample has been tested additionally where the average quantity of lead and cadmium or lead, or cadmium does not exceed the quantity indicated in Paragraph 20 of this Regulation, and none of the articles constituting the second sample exceeds the quantity indicated in Paragraph 20 of this Regulation by more than 50 per cent.

- 22. At all marketing stages, including the retail, ceramic articles which have not yet come into contact with food shall be accompanied by a written declaration in conformity with Article 16 of Regulation No 1935/2004 of the Parliament and of the Council.
- 23. A written declaration shall be issued by a manufacturer or a seller. The written declaration shall contain the following information:
- 23.1. the name and address of the establishment which manufactures ceramic articles ready for use, and of the importer who imports such articles into the European Union;

- 23.2. the name of the ceramic article:
- 23.3. the date of the declaration;
- 23.4. the confirmation that the ceramic article complies with the requirements laid down in 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, and Regulation (EC) No 1935/2004 of the Parliament and of the Council. [26 September 2017]
- 24. A written declaration shall permit an identification of the goods for which it is issued. The written declaration shall be renewed if changes in the manufacturing cause changes in the migration of lead and cadmium.
- 25. A manufacturer or an importer of a ceramic article shall, upon the request of the Service, present corresponding documentation which confirms that the ceramic article corresponds to the quantities of lead and cadmium or lead or cadmium indicated in this Regulation. The results of the performed analyses, testing conditions, and the name and address of the laboratory where testing was performed shall be indicated in the documentation.

IV. Rubber or Elastomer Teats and Soothers

- 26. Rubber or elastomer teats and soothers may not release N-nitrosamines or substances likely to be transformed into N-nitrosamines.
- 27. N-nitrosamines or substances likely to be transformed into N-nitrosamines that may be established by an approved method which complies with the criteria laid down in Annex 5 to this Regulation may not release in release test liquid (saliva test solution) in conformity with the conditions referred to in Annex 5 to this Regulation. The following quantity may be established by the abovementioned method:
- 27.1. the quantity of 0.01 milligram of the entire N-nitrosamines released per one kilogram of the parts of teat or soother made of rubber or elastomer;
- 27.2. the quantity of 0.1 milligram of the entire N-nitrosatable substances released per one kilogram.

[14 February 2012]

28. At all marketing stages, except for the retail, the rubber or elastomer teats and soothers shall be accompanied by a written declaration in conformity with Article 16(1) of Regulation No 1935/2004 of the Parliament and of the Council. [26 September 2017]

V. Procedures for Registering Production, Processing and Distribution Establishments of Materials and Articles

29. A production, processing and distribution establishment of materials and articles (hereinafter – the establishment) shall be registered in the register of objects under supervision of the Service. It is not necessary to register a retail establishment if it purchases materials and articles for distribution from the production or wholesale establishments registered in the Service.

[26 September 2017]

30. The establishment shall submit an application for the registration of production, processing and distribution of materials and articles (Annex 6) to the territorial unit of the

Service or send it by post or electronically, provided it has been prepared in conformity with the laws and regulations regarding drawing up of electronic documents. [14 February 2012]

- 31. After receipt of the application referred to in Paragraph 30 of this Regulation, the Service shall, within five working days, register the establishment, assign a registration number thereto, and place the information on a publicly accessible website.
- 32. If the establishment wishes, the Service shall issue a registration certificate. The following shall be indicated in the registration certificate:
- 32.1. the name of the establishment, address of the object under supervision (the given name, surname for a natural person);
- 32.2. the registration number of the establishment in the Commercial Register (the personal identity number for a natural person);
 - 32.3. the type of activity of the establishment;
- 32.4. the registration number of the establishment in the register of objects under supervision of the Service.
- 33. The establishment which intends to use a plastic recycling process in its operation that is not included in the register of recycling processes authorised in the European Union shall submit an application addressed to the European Food Safety Authority for obtaining the authorisation of recycling process and the technical documentation laid down in Commission Regulation No 282/2008 to the Institute.

[26 September 2017]

34. The Institute shall send the application and technical documentation referred to in Paragraph 33 of this Regulation to the European Food Safety Authority. After receipt of the opinion from the European Food Safety Authority, the Institute shall inform the Service by sending the necessary information.

[26 September 2017]

- 35. If the European Commission takes a decision to issue authorisation of recycling process, the Service shall register the establishment or make a relevant note in the register of objects under supervision regarding the authorised recycling process.
- 36. A representative of the establishment shall inform the Service electronically or in writing regarding changes in the operation of the establishment, as well as regarding termination of the operation before introduction of such changes.

VI. Procedures for Suspending Distribution and Use of Materials and Articles, for Further Using and Destructing Thereof, and for Suspending and Restoring Operation of Establishments, as well as for Cancelling Registration Thereof

- 37. Each year the Service shall develop a programme for the supervision and control of the registered establishments.
- 38. If information is received or reasonable suspicions arise during the control process regarding harm of materials and articles to human health, the Service shall take a decision to suspend manufacturing, processing, distribution or use of the materials and articles until complete clarification of circumstances.

- 39. If necessary, the Service shall take samples and send them to the Institute for laboratory investigations. If it is established that the materials and articles fail to comply with the requirements of this Regulation, the establishment shall cover expenses for laboratory investigations in accordance with the laws and regulations regarding the price list for activities carried out by the Institute within the framework of State administration tasks. [26 September 2017]
- 40. If the establishment has eliminated the non-conformities established by the Service, and materials and articles may not cause harm to human health, the Service shall repeal the decision referred to in Paragraph 38 of this Regulation by notifying the establishment of this in writing.

[26 September 2017]

- 41. The Service shall cancel the registration of a manufacturing, processing or distribution establishment if:
- 41.1. it establishes that incomplete or incorrect information has been indicated in the submitted documents;
 - 41.2. the establishment terminates its operation;
- 41.3. the operation of the establishment fails to comply with the requirements laid down in the laws and regulations regarding the materials and articles intended to come into contact with food:
- 41.4. the establishment has failed to rectify the established non-conformities within the time period laid down by the Service. [26 September 2017]
- 42. The establishment shall suspend the distribution of the materials and articles which fail to comply with the requirements of this Regulation, and prevent the use thereof in the handling of food. If it is not possible to ensure the conformity of the materials and articles, the establishment shall withdraw them from the market and ensure processing and use thereof in the activities not related to the handling of food, or destruction thereof in conformity with the laws and regulations regarding waste management. Any expenses related to the withdrawal from market, processing and destruction of non-compliant materials and articles shall be covered by the establishment.

[26 September 2017]

VII. Closing Provisions

- 43. The establishment which performs activities involving materials and articles during coming into force of this Regulation shall submit an application to the Service for registration of the establishment by 1 July 2012.
- 44. Until 1 July 2012 the Service may extend the period laid down in Paragraph 31 of this Regulation for registration of the establishment for not more than 10 working days.
- 44. The requirements referred to in Annex 1 to this Regulation for general and specific migration test of plastic materials and articles shall be applicable until 31 December 2015. [14 February 2012]
- 44.² It is allowed to use the food simulants referred to in Annex 2 to this Regulation and suitable for testing migration of parts of plastic materials and articles until 31 December 2012. [14 February 2012]

45. This Regulation shall come into force on 1 January 2012.

Informative Reference to European Union Directives

[14 February 2012]

This Regulation contains legal norms arising from:

- 1) 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:
- 2) Commission Directive 93/11/EEC of 15 March 1993 concerning the release of the N-nitrosamines and N-nitrosatable substances from elastomer or rubber teats and soothers;
- 3) Commission Directive 2005/31/EC of 29 April 2005 amending Council Directive 84/500/EEC as regards a declaration of compliance and performance criteria of the analytical method for ceramic articles intended to come into contact with foodstuffs;
- 4) 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;
- 5) Council Directive 82/711/EEC of 18 October 1982 laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs;
- 6) Commission Directive 93/8/EEC of 15 March 1993 amending Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs;
- 7) Commission Directive 97/48/EC of 29 July 1997 amending for the second time Council Directive 82/711/EEC laying down the basic rules necessary for testing migration of the constituents of plastic materials and articles intended to come into contact with foodstuffs;
- 8) Council Directive 85/572/EEC of 19 December 1985 laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs;
- 9) Commission Directive 2007/19/EC of 30 March 2007 amending Directive 2002/72/EC relating to plastic materials and articles intended to come into contact with food and Council Directive 85/572/EEC laying down the list of simulants to be used for testing migration of constituents of plastic materials and articles intended to come into contact with foodstuffs.

Prime Minister	V. Dombrovski	

Minister for Agriculture J. Dūklavs

Requirements for General and Specific Migration Test of Plastic Materials and Articles

List of Food Simulants to be Used for Testing Migration of Parts of Plastic Materials and Articles

Substances Authorised in Manufacturing of Regenerated Cellulose Film

I. Regenerated cellulose film without coating

No.	Name of the substance in the Latvian language	Name of the substance in the English language	Restrictions
1.	Reģenerēta celuloze	Regenerated cellulose	Not less than 72 % (w/w)
2.	Piedevas	Additives	
2.1.	Mīkstinātāji	Softeners	Not more than 27 % (w/w) in total
2.1.1. 2.1.2.	Bis(2-hidroksietil)ēteris [dietilēnglikols] Etāndiols [monoetilēnglikols]	Bis(2-hydroxyethyl) ether [diethyleneglycol] Ethanediol [monoethyleneglycol]	Only for the films intended to be coated and used for packing of dry food (food the surface of which is not moist). The total amount of bis(2-hydroxyethyl)ether and ethanediol present in the food which has been into contact with the abovementioned film, may not exceed 30 mg/kg of the food.
2.1.3.	1,3-butāndiols	1,3-Butanediol	
2.1.4.	Glicerīns	Glycerol	
2.1.5.	1,2-propāndiols [1,2-propilēnglikols]	1,2-Propanediol [1,2-propyleneglycol]	
2.1.6.	Polietilēnoksīds [polietilēnglikols]	Polyethylene oxide [polyethyleneglycol]	Average molecular weight between 250 and 1200
2.1.7.	1,2-polipropilēnoksīds [1,2-polipropilēnglikols]	1,2-Polypropylene oxide [1,2-polypropyleneglycol]	Average molecular weight not exceeding 400 and free 1,3-propanediol content not exceeding 1 % (w/w) in the substance
2.1.8.	Sorbīts	Sorbitol	
2.1.9.	Tetraetilēnglikols	Tetraethyleneglycol	
2.1.10.	Karbamīds (urīnviela)	Urea	
2.2.	Citas piedevas. Pirmā grupa	Other additives (First class)	Other additives not more than 1 % (w/w) in total. The quantity of each substance or group of

			substances in the film without coating may not exceed 2 mg/dm ²
	Etiķskābe un tās NH4, Ca, Mg, K un Na sāļi	Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	_
2.2.2.	Askorbīnskābe un tās NH ₄ , Ca, Mg, K un Na sāļi	Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
2.2.3.	Benzoskābe un nātrija benzoāts	Benzoic acid and sodium benzoate	
	Skudrskābe un tās NH4, Ca, Mg, K un Na sāļi	Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
	nepiesātinātas lineāras taukskābes ar 8 līdz 20 pārskaita oglekļa atomiem, behēnskābe un ricinolskābe un to NH ₄ , Ca,	Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and their NH ₄ , Ca, Mg, K, Na, Al and Zn salts	
2.2.6.	Citronskābe, D-pienskābe un L-pienskābe, maleīnskābe, L-vīnskābe un to Na un K sāļi	maleic, L-tartaric acids and	
	Sorbīnskābe un tās NH4, Ca, Mg, K un Na sāļi	Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
	atomiem, behēnskābes un ricinolskābes amīdi	saturated or unsaturated, with an even number of	
	Dabiskās pārtikas cietes un milti	Natural edible starches and flours	
	Ķīmiski modificētas pārtikas cietes un milti	Edible starches and flours modified by chemical treatment	
2.2.11.	Amiloze	Amylose	
	Kalcija un magnija karbonāti un hlorīdi	Calcium and magnesium carbonates and chlorides	
	atomiem un/vai adipīnskābes, citronskābes, 12-hidroksistearīnskābes,	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	
	lineāro taukskābju ar 8 līdz		

	Piesātinātu vai nepiesātinātu lineāro taukskābju ar 8 līdz 20 pārskaita oglekļa atomiem un sorbīta esteri	Esters of sorbitol with linear	
	etāndiola, bis(2- hidroksietil)ētera, trietilēnglikola monoesteri	Mono- and/or di-esters of stearic acid with etha- nediol and/or bis(2- hydroxyethyl) ether and/or triethylene glycol	
2.2.18.	Polietilēnoksīds [polietilēnglikols]	Polyethylene oxide [polyethyleneglycol]	Average molecular weight between 1200 and 4000
2.2.19.	Nātrija propionāts	Sodium propionate	
	Citas piedevas. Otrā grupa	class)	The total quantity of the second group substances in the film without coating may not exceed 1 mg/dm ² . The quantity of each substance or group of substances in the film without coating may not exceed 0.2 mg/dm ² or a lower limit as specified
2.3.1.	Alkil $(C_8$ - $C_{18})$ benzola nātrija sulfonāts	Sodium alkyl (C_8-C_{18}) benzene sulphonate	
2.3.2.		Sodium isopropyl naphtalene sulphonate	
2.3.3.	Nātrija alkil(C ₈ -C ₁₈)sulfāts	Sodium alkyl (C_8-C_{18}) sulphate	
2.3.4.	Nātrija alkil(C_8 - C_{18})sulfonāts	Sodium alkyl (C_8-C_{18}) sulphonate	
2.3.5.	Nātrija dioktilsulfosukcināts	Sodium dioctylsulphosuccinate	
2.3.6.	Dihidroksietildietilēna triamīna monoacetāta distearāts		Not more than 0.05 mg/dm ² in the film without coating
2.3.7.	NH ₄ , Mg un K laurilsulfāti	NH ₄ , Mg and K lauryl sulphates	
	N,N'-distearoildiaminoetāns, N,N'dipalmitoildiaminoetāns	•	

	un NN'	dipalmitoyl diaminoethane	
	un N,N'- dioleoildiaminoetāns	and N,N'-dioleolyl diamino-ethane	
2.3.9.	2-heptadecil-4,4-bis	2-Heptadecyl-4,4-bis	
2.3.9.	(metilēnstearāta)oksazolīns	(methylene-stearate) oxazoline	
2.3.10.	Polietilēnaminostearamīda etilsulfāts	Polyethylene- aminostearamide ethylsulphate	Not more than 0.1 mg/dm ² in the film without coating
2.4.	Polimērnesēji. Trešā grupa	Anchoring agents (Third class)	The total quantity of substances may not exceed 1 mg/dm ² in the film without coating
2.4.1.	kondensācijas produkts, nemodificēts vai modificēts ar vienu vai vairākām šādām vielām: butanolu, dietilēntriamīnu, etanolu,	unmodified, or which may be modified with one or more of the following products: butanol, iethylenetriamine, ethanol, triethylenetet-ramine, tetraethylenepentamine, tri-	more than 0.5 mg/dm ² in the film without coating. Free melamine – not more than 0.3 mg/dm ² in the film without coating.
2.4.2.	(urīnvielas)-formaldehīda kondensācijas produkts,	melamine-urea-formal-	Free formaldehyde – not more than 0.5 mg/dm ² in the film without coating. Free melamine – not more than 0.3 mg/dm ² in the film without coating.
2.4.3.	Šķērsšūtie katjonie polialkilēnamīni	Cross-linked cationic polyalkyleneamines	
	diaminopropilmetilamīna un epihlorhidrīna	polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin	
2.4.3.2.	epihlorhidrīna, adipīnskābes, kaprolaktāma,	polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine	
2.4.3.3.	adipīnskābes,		

		T	T
	dimetiladipāta un dietilēntriamīna	on epichlorhydrin, dimethyl adipate and diethylenetriamine	
	poliamīda-poliamīna- epihlorhidrīna sveķi, iegūti no epihlorhidrīna, adipamīda un diaminopropilmetilamīna	on epichlorhydrin,	
	Polietilēnamīni un polietilēnimīni	Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm ² in the film without coating
	(urīnvielas)-formaldehīda, nemodificēts vai modificēts ar šādām vielām: aminometilsulfonskābi, sulfanilskābi, butanolu, diaminobutānu, diamino dietilamīnu, diaminodipropilamīnu, diaminopropānu, dietilēntriamīnu, etanolu, guanidīnu, metanolu, tetraetilēnpentamīnu,	urea-formaldehyde unmodified, or which may be modified with one of the following products: aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodiethylamine,	more than 0.5 mg/dm ² in the film without coating
2.5.	Ceturtā grupa	Fourth class	The total quantity of substances – not more than 0.01 mg/dm ² in the film without coating
2.5.1.		Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
2.5.2.	Monoetanolamīna laurilsulfāts	Monoethanolamine lauryl sulphate	

II. Regenerated cellulose film with coating

No.	Name of the substance in the Latvian language	Name of the substance in the English language	Restrictions
1.	Reģenerēta celuloze	Regenerated cellulose	Not less than 72 % (w/w)
2.	Piedevas		Not more than 27 % (w/w) in total
3.	Pārklājums	Coating	

3.1.	Polimēri	Polymers	The total quantity of substances may not exceed 50 mg/dm ² of the coating on the side of the film which comes into contact with food
3.1.1.	Celulozes etilēteri, hidroksietilēteri, hidroksipropilēteri un metilēteri	Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	
3.1.2.	Celulozes nitrāts	Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side of the film which comes into contact with food, nitrogen content between 10.8 % and 12.2 % (w/w) in the cellulose nitrate
3.2.	Sveķi	Resins	The total quantity of substances may not exceed 12.5 mg/dm ² of the coating on the side of the film which comes into contact with food; this only applies to the treatment of regenerated cellulose film with cellulose nitrate based coatings
3.2.1.	Kazeīns	Casein	Only for manufacturing of regenerated cellulose film with cellulose nitrate or vinyl chloride and vinyl acetate copolymer coating
3.2.2.	polimerizācijas, hidrogenēšanas vai disproporcionēšanas produkti un to metilspirta, etilspirta vai C ₂ -C ₆ daudzvērtīgo spirtu esteri	Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C ₂ -C ₆ polyvalent alcohols, or mixtures of these alcohols	
3.2.3.	polimerizācijas, hidrogenēšanas vai disproporcionēšanas produkti, kondensēti ar akrilskābi, maleīnskābi,	propane formaldehyde and esterified with methyl,	

	matilanintu atilanintu vai	alachala or mivturas of	
	C ₂ -C ₆ daudzvērtīgajiem	alcohols or mixtures of	
	spirtiem vai to		
	maisījumiem		
3.2.4.		Esters derived from bis(2-	
		hydroxyethyl) ether with	
	pievienojot betapinēna		
	un/vai dipentēna un/vai		
	diterpēna produktus un	dipentene and/or diterpene	
		and maleic anhydride	
3.2.5.	Pārtikas želatīns	Edible gelatine	
3.2.6.		Castor oil and its products	
	hidrogenēšanas vai		
	dehidratācijas produkti un		
		condensation products with polyglycerol, adipic, citric,	
	adipīnskābi, citronskābi,		
	maleīnskābi, ftālskābi un		
	sebacīnskābi		
3.2.7.	Dabiskie sveķi [damars]		
3.2.8.	Polibetapinēns [terpēna	Poly-beta-pinene [terpenic	
	sveķi]	resins]	
3.2.9.	` '	Urea-formaldehyde resins	
	, ,	(see anchoring agents)	
	polimērnesēji)		
3.3.	Plastifikatori	Plasticizers	The total quantity of
			substances may not exceed
			6 mg/dm ² of the coating on the side of the film which
			comes into contact with
			food
3.3.1.	Acetiltributilcitrāts	Acetyl tributyl citrate	
3.3.2.	Acetiltri(2-etilheksil)citrāts	Acetyl tri(2-ethylhexyl)	
	,	citrate	
3.3.3.	Di-izobutiladipāts	Di-isobutyl adipate	
3.3.4.	Di-n-butiladipāts	Di-n-butyl adipate	
3.3.5.	Di-n-heksilazelāts	Di-n-hexyl azelate	
3.3.6.	Dicikloheksilftalāts	Dicyclohexyl phthalate	Not more than 4.0 mg/dm ²
			of the coating on the side of
			the film which comes into
			contact with food
3.3.7.	2-etilheksildifenilfosfāts	2-ethylhexyl diphenyl	
	(sinonīms: fosforskābes		ethylhexyl diphenyl
	difenil2-etilheksilesteris)	phosphoric acid diphenyl 2-	
		ethylhexyl ester)	1) 2.4 mg/kg of the food which comes into contact
			with this type of film; or
			2) 0.4 mg/dm^2 of the
			coating on the side of the
<u> </u>		1	

			film which comes into contact with food
3.3.8.	Glicerīna monoacetāts [monoacetīns]	Glycerol monoacetate [monoacetin]	
3.3.9.	Glicerīna diacetāts [diacetīns]	Glycerol diacetate [diacetin]	
3.3.10.	Glicerīna triacetāts [triacetīns]	Glycerol triacetate [triacetin]	
3.3.11.	Dibutilsebacināts	Di-butyl sebacate	
3.3.12.	Di-n-butiltartrāts	Di-n-butyl tartrate	
3.3.13.	Di-izobutiltartrāts	Di-isobutyl tartrate	
3.4.	Citas piedevas	Other additives	The total quantity of substances in regenerated cellulose film without coating may not exceed 6 mg/dm ² , including the coating on the side of the film which comes into contact with food
3.4.1.	1 . · ·	Additives listed in the first part	The restrictions referred to in Chapter I of this Annex (however, the quantity applies to the regenerated cellulose film without coating, including the coating on the side of the film which comes into contact with food)
3.4.2.	Īpašās pārklājumu piedevas	Specific coating additives	The quantity of the substance or group of substances referred to in each Sub-paragraph may not exceed 2 mg/dm² (or a lower limit as specified) of the coating on the side where it comes into contact with food
3.4.2.1.	1-heksadekanols un 1- oktadekanols	1-Hexadecanol and 1-octadecanol	
3.4.2.2.	atomiem un ricinolskābes un etilspirta un lineāro butilesteri, amilesteri un		
3.4.2.3.	attīrītas montānskābes (C ₂₆ -	Montan waxes, comprising purified montanic (C ₂₆ -C ₃₂) acids and/or their esters	

	un/vai 1,3-butāndiola	with ethanediol and/or 1,3-	
	esterus un/vai to Ca un K	butanediol and/or their Ca	
-	,	and K salts	
	karnaubvasks	Carnauba wax	
		Beeswax	
	esparto vasks	Esparto wax	
3.4.2.7. l	kandelila vasks	Candelilla wax	
3.4.2.8.	dimetilpolisiloksāns	Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side of the film which comes into contact with food
	2 //	Epoxidized soya-bean oil (oxirane content 6 to 8)	
3.4.2.10. r	*	Refined paraffin and microcrystalline waxes	
3.4.2.11. p	pentaeritrīta tetrastearāts	Pentaerythritol tetrastearate	
		(octadecyldiethyleneoxide)	Not more than 0.2 mg/dm ² of the coating on the side of the film which comes into contact with food
6	esterificētas ar mono- vai di-(2-hidroksietil)amīnu	Aliphatic acids (C_8-C_{20}) esterified with mono- or di- (2-hydroxyethyl)amine	
	hidroksianizols [butilēts	hydroxyanisole [butylated	Not more than 0.06 mg/dm ² of the coating on the side of the film which comes into contact with food
1	metilfenols [butilets	methylphenol [butylated hydroxytoluene - BHT]	Not more than 0.06 mg/dm ² of the coating on the side of the film which comes into contact with food
	·	Di-n-octyltin-bis(2- ethylhexyl) maleate	Not more than 0.06 mg/dm ² of the coating on the side of the film which comes into contact with food
3.5.	Šķīdinātāji	Solvents	The total quantity of substances may not exceed 6 mg/dm ² of the coating on the side of the film which comes into contact with food
3.5.1. I	Butilacetāts	Butyl acetate	
3.5.2. I	Etilacetāts	Ethyl acetate	
3.5.3. I	Izobutilacetāts	Isobutyl acetate	
	r '1 ,=,	Isopropyl acetate	
3.5.4. I	Izopropilacetāts	isopropyr acctaic	_
+		Propyl acetate	

3.5.7.	1-butanols	1-Butanol	
3.5.8.	Etanols	Ethanol	
3.5.9.	2-butanols	2-Butanol	
3.5.10.	2-propanols	2-Propanol	
3.5.11.	1-propanols	1-Propanol	
3.5.12.	Cikloheksāns	Cyclohexane	
3.5.13.	Etilēnglikola monobutilēteris	Ethyleneglycol monobutyl ether	
3.5.14.	Etilēnglikola monobutilētera acetāts	Ethyleneglycol monobutyl ether acetate	
3.5.15.	Metiletilketons	Methyl ethyl ketone	
3.5.16.	Metilizobutilketons	Methyl isobutyl ketone	
3.5.17.	Tetrahidrofurāns	Tetrahydrofuran	
3.5.18.	Toluols	Toluene	Not more than 0.06 mg/dm ² of the coating on the side of the film which comes into contact with food

Notes.

- 1. The percentages have been expressed in weight/weight ratio (w/w) and are calculated in relation to the quantity of anhydrous regenerated cellulose film without coating.
- 2. The usual technical denominations have been given in square brackets, and substances have good technical quality with regard to the purity criteria.

Minister for Agriculture

Determination of the Migration of Lead and Cadmium

I. Requirements for the determination of the migration of lead and cadmium

1. Test liquid (food simulant) shall be a freshly prepared 4 % (volume/volume) acetic acid in aqueous solution.

2. Test conditions:

- 2.1. test shall be performed at a temperature of 22 ± 2 0 C, and its duration shall be 24 ± 0.5 hours;
- 2.2. in the case of the determination of the migration of lead, a sample shall be covered by corresponding protective equipment and placed in a laboratory in normal light;
- 2.3. in the case of the determination of the migration of cadmium or lead and cadmium, a sample shall be covered so that the tested surface is kept in total darkness.

3. Filling:

- 3.1. samples which may be filled:
- 3.1.1. shall be filled with a 4 % (volume/volume) acetic acid solution to a level which does not exceed 1 mm from the overflow point when measuring from the top edge of the sample;
- 3.1.2. if a sample has a flat or slightly steep edge, it shall be filled so that the distance between the surface of the liquid and the overflow point does not exceed 6 mm when measuring along the steep edge;
- 3.2. samples which may not be filled:
- 3.2.1. the surface of a sample not intended to come into contact with food shall first be covered by a suitable protective layer which may withstand effect of a 4 % (volume/volume) acetic acid;
- 3.2.2. after covering the sample shall be immersed in a container with acetic acid so that the surface intended to come into contact with food is fully covered by the test liquid.

4. Determination of the surface area.

The surface area for the first category articles shall be equal to the meniscus area which is comprised of the free liquid surface obtained in compliance with the filling requirements.

II. Methods of analysis for the determination of the migration of lead and cadmium

1. Object and field of application.

The method allows to quantify the specific migration of lead and cadmium.

2. Principle.

The quantitative determination of the specific migration of lead and (or) cadmium shall be carried out by an instrumental method of analysis which complies with the performance criteria specified in Paragraph 4 of this Chapter.

3. Reagents:

- 3.1. all reagents shall comply with analytical quality, unless it is otherwise determined;
- 3.2. where reference is made to water, it shall mean that distilled water or water of equivalent quality is used;
- 3.3. 4 % (volume/volume) acetic acid in aqueous solution shall be prepared by adding 40 ml of glacial acetic acid to water and making up to 1000 ml;
- 3.4. stock solutions which shall be prepared in 4 % acetic acid solution (in accordance with Sub-paragraph 3.3 of this Chapter) and contain 1000 mg/litre of lead and at least 500 mg/litre of cadmium respectively.
- 4. Performance criteria of the instrumental method of analysis:
 - 4.1. the determination limits for lead and cadmium shall be as follows:
 - 4.1.1. for lead -0.1 mg/litre or less;
 - 4.1.2. for cadmium 0.01 mg/litre or less;
- 4.2. the determination limits shall be defined as the concentration of the element in 4 % acetic acid solution, which gives a signal equal to twice the background noise of the instrument. 4 % acetic acid solution shall be prepared in accordance with Sub-paragraph 3.3 of this Chapter;
 - 4.3. the quantitative determination limits for lead and cadmium shall be as follows:
 - 4.3.1. for lead -0.2 mg/litre or less;
 - 4.3.2. for cadmium 0.02 mg/litre or less;
 - 4.3.3. the quantity of lead and cadmium to be determined which is added to 4 % acetic acid solution (in accordance with Sub-paragraph 3.3 of this Chapter) should lie within the limits of 80–120 % of the added amount;
- 4.4. specificity the instrumental method of analysis used shall be free from matrix and spectral interferences.

5. Method:

- 5.1. preparation of a sample:
- 5.1.1. a sample shall be clean and free from grease or other substances which might affect the test;
- 5.1.2. a sample shall be washed in a solution containing a household liquid detergent at a temperature of approximately 40 0 C. First, the sample shall be rinsed in tap water and then in distilled water or water of equivalent quality. It shall be drained and dried so as to avoid any stain. The surface to be tested shall not be touched after cleaning;
- 5.2. quantitative determination of lead and cadmium:
- 5.2.1. the sample prepared in accordance with Sub-paragraph 5.1 of this Chapter shall be tested under the conditions laid down in this Annex;
- 5.2.2. before taking the test solution for the quantitative determination of lead and cadmium, the content of the sample shall be homogenised by using an appropriate method, which allows to avoid any loss of solution and abrasion of the tested surface;
- 5.2.3. a blank test shall be performed on the reagent which is used for each series of the quantitative determination;
- 5.2.4. the quantitative determination of lead and cadmium shall be performed under appropriate conditions.

Minister for Agriculture

Requirements for the Determination of the Release of N-nitrosamines and N-nitrosatable Substances

1. Release test liquid (saliva test solution).

The release test liquid shall be obtained by dissolving 4.2 g of sodium bicarbonate (NaHCO₃), 0.5 g of sodium chloride (NaCl), 0.2 g of potassium carbonate (K₂CO₃) and 30.0 mg of sodium nitrite (NaNO₂) in one litre of distilled water or water of equivalent quality. The solution shall have a pH value of 9.

2. Test conditions.

Samples of material obtained from an appropriate number of teats or soothers shall be immersed in the test release liquid for 24 hours at a temperature of 40 ± 2 0 C.

- 3. Criteria applicable to the method for the determination of the release of N-nitrosamines and N-nitrosatable substances:
- 3.1. Release of N-nitrosamines shall be determined in one aliquot part of each solution (which has been obtained in accordance with the requirements referred to in Paragraphs 1 and 2 of this Annex).

The N-nitrosamines shall be extracted from the aliquot part with nitrosamine-free dichloromethane (DCM) and determined by gas chromatography;

3.2. Release of N-nitrosatable substances shall be determined in another aliquot part of each solution (which has been obtained in accordance with the requirements referred to in Paragraphs 1 and 2 of this Annex). N-nitrosatable substances shall be converted into N-nitrosamines by acidification of the aliquot part with hydrochloric acid. The obtained N-nitrosamines shall be extracted from the solution with DCM and determined by gas chromatography.

Minister for Agriculture

Application for Registering Production, Processing and Distribution Establishments of Materials and Articles

1. Establishment (in capital letters)
(name of a legal person or given name, surname of a natural person)
or
(registration number in the Commercial Register) (personal identity number)
2. Address of the object under supervision
3. Contact details:
3.1. telephone number
3.2. mobile phone number
3.3. fax number
3.4. e-mail address
4. Type of activity (mark as appropriate):
manufacture of plastics and articles thereof
distribution of plastics and articles thereof
manufacture of ceramics
distribution of ceramics
manufacture of rubber, elastomer and articles thereof
distribution of rubber, elastomer and articles thereof
manufacture of regenerated cellulose film and articles thereof
distribution of regenerated cellulose film and articles thereof
manufacture of other materials and articles
(indicate what)
distribution of other materials and articles
(indicate what)
5. Head or representative of the establishment
(given name, surname)

6. To be filled in by an official of the Food and Veterinary Service

6.1. Seal of the official of the Food and Veterinary Service*	6.2. Registration date of application*	6.3. Official of the Food and Veterinary Service
1 ood and vetermary service	date of application	vetermary service
		(given name, surname, signature*)

7. Registration of establishment

Registration number of the establishment					
in the register of objects under supervision]
of the Food and Veterinary Service					-

Note. * Details of the document "date", "signature", and "place for a seal" shall not be completed if the electronic document has been drawn up in accordance with the laws and regulations regarding drawing up of electronic documents.

Minister for Agriculture