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The National Food Agency's regulations on materials and articles intended to come into contact with food;

Adopted on 20 June 2023.

By virtue of Sections 5, 6, 30 and 31 of the Food Ordinance (2006:813) and Section 30 of Ordinance (2008:245) on chemical products and biotechnological organisms, the Swedish National Food Agency lays down[1] the following.

Chapter 1 – General provisions

Scope

Section 1 These regulations contain provisions on requirements concerning materials and articles intended to come into contact with food, and their import, as well as provisions on the registration of certain operations that manufacture, process or import materials and articles intended to come into contact with food.

These provisions supplement, inter alia, the provisions 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 repealing Directives 80/590/EEC and 89/109/EEC, and provisions which have been adopted by virtue of that regulation.

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1 See Directive (EU) 2015/1535 of the European Parliament and of the Council of 9 September 2015 laying down a procedure for the provision of information in the field of technical regulations and of rules on Information Society services.

Section 2 Provisions on:
operations that shall be registered are in Chapter 2;
requirements concerning the handling of food are in Chapter 3;
materials and articles of regenerated cellulose film are in Chapter 4;
ceramic articles are in Chapter 5;
elastomer or rubber children's dummies are in Chapter 6; and
imports from third countries are in Chapter 7.

Chapter 2 – Activities that shall be registered

Notification for registration

Section 1 Operators that are engaged in an activity other than a food establishment and that manufacture, process or import from third countries materials and articles intended to come into contact with food, shall notify the activity in writing so that it can be registered.

The first paragraph does not apply to activities that during a financial year are estimated to have a turnover – from materials and articles intended to come into contact with food – of less than SEK 80 000, and that are expected to produce, process or import fewer than 1 000 units of materials and articles intended to come into contact with food.

The first paragraph also does not apply to activities within the Swedish Armed Forces, the Swedish Fortifications Agency, the Swedish Defence Materiel Administration, the Swedish National Defence Radio Establishment, or activities by or on behalf of one of these authorities.

Content of a notification

Section 2 A notification for the registration of an activity shall contain the following information.

1. The name and contact details of the operator.
2. The corporate identity, personal identity, or coordination number of the operator or, in the absence of such, corresponding identification information.
3. Information on the premises, space or location where the activity is carried out.
4. A description of the nature and scope of the activity.

5. Where appropriate, information on how long the activity will be carried out.

An operator shall also provide, upon request, additional information required by the authority to process the notification.

Authorities handling the notification

Section 3 A notification for registration shall be submitted to the authority competent to register the activity in accordance with Section 23 of the Food Ordinance (2006:813).

If the conditions for registration of an activity are met, the authority shall register the activity.

Commencement of activities

Section 4 The activity that shall be notified for registration may commence once the authority has registered the activity. However, the activity may commence two weeks after the notification has been received by the authority if the authority still has not yet registered the activity.

Chapter 3 – Special requirements for the handling of foodstuffs

Food handling

Section 1 In the handling of food, the following may not be used:

1.

vessels, lids, barrels or the like, during the use of which the food comes into contact with:

a) a galvanised surface;

b) a surface giving off more than a total of 3 milligrams of lead per litre of the vessel's capacity when boiled out for half an hour three times, each time with a new 4 % aqueous acetic acid solution;

c) a surface giving off more than 0.1 milligrams of cadmium per litre of vessel's capacity when leached with an acetic acid solution as specified in point b at room temperature for 24 hours;

2. other equipment where the food comes into contact with lead or cadmium.

Section 2 The provisions of Section 1 shall not apply to plastic lids covered by the provisions of Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food.

The provision of Section 1(1)(a) does not apply to vessels or other equipment for drinking water.

The provisions of Section 1(1)(b) and (c) do not apply to ceramic articles that are covered by these regulations.

Dispensation

Section 3 The National Food Agency may grant exemptions (dispensation) from Chapter 3, Section 1.

Chapter 4 – Special requirements for regenerated cellulose film

Regenerated cellulose film

Section 1 The provisions of this Chapter apply to materials and articles intended to come into contact with food and which are made of regenerated cellulose film (cellophane) and which form a finished product or form part of a finished product which also contains other materials.

Regenerated cellulose film shall belong to the following groups:

1. uncoated regenerated cellulose film;
2. coated regenerated cellulose film with coating derived from cellulose; or
3. coated regenerated cellulose film with coating consisting of plastics.

The provisions of this Chapter do not apply to synthetic intestines made of regenerated cellulose film.

Section 2 For the purposes of these regulations, the term ‘regenerated cellulose film’ means thin films made of refined cellulose from new wood or cotton raw material. To meet technical requirements, other substances may be added either in the mass or on the surface. Regenerated cellulose film may be coated on one or both sides.

List of substances authorised for use in manufacturing

Section 3 Regenerated cellulose film referred to in Section 1, second paragraph, (1) and (2), may only be produced from the substances or groups of substances listed in Annex 1 and with the restrictions specified therein.

In addition to that which is stated in Annex 1, dyes (soluble dyes and pigments) and binders may be used, provided that there is no detectable transfer (migration) of such substances to food, as determined by a validated method.

Section 4 In the production of regenerated cellulose film as referred to in Section 1, second paragraph, (3), prior to coating, only the substances or groups of substances listed in Section 1 of Annex 1 may be used, with the restrictions specified therein.

In the production of the coating to be used on the regenerated cellulose film referred to in Section 1, second paragraph, (3), only the substances or groups of substances specified in Article 6 and Annex I to Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food may be used, with the restrictions specified therein.

Regenerated cellulose film specified in Section 1, second paragraph, (3), shall comply with Articles 12, 17 and 18 and Annex V to Regulation (EU) No 10/2011.

Section 5 Printed text or images on regenerated cellulose film may not come into contact with food.

Declaration of compliance

Section 6 Materials and articles intended to come into contact with food and which are made of regenerated cellulose film shall be accompanied, at the marketing stage prior to retail, by a written declaration of compliance certifying that they meet the requirements of these regulations.

The first paragraph does not apply to materials and articles intended to come into contact with food which are made of regenerated cellulose film and are clearly intended to come into contact with food.

Where special conditions of use apply, the material or article shall be labelled accordingly.

Chapter 5 – Special requirements for ceramic articles

Ceramic articles

Section 1 The provisions of this Chapter apply to materials and articles intended to come into contact with food and which are made of ceramics (ceramic articles).

This Chapter contains provisions on the maximum permissible amounts (thresholds) of lead and cadmium that may be released from ceramic articles into food.

Section 2 The term 'ceramic articles' in these regulations means articles produced from a mixture of inorganic materials, generally with a large proportion of clay or silicate, possibly with the addition of small amounts of organic materials. Such objects are shaped and the shape thus obtained is permanently fixed by firing. They may be glazed, enamelled and/or decorated.

Thresholds

Section 3 The maximum permissible amounts of lead and cadmium that may be released from ceramic articles into food are as follows.

	Lead	Cadmium
Articles which cannot be filled and articles which can be filled but whose interior depth, from bottom to upper edge, does not exceed 25 mm	0.8 mg/dm^2	0.07 mg/dm^2
Cookware; packaging and storage containers of more than 3 litres	1.5 mg/l	0.1 mg/l
Other articles that can be filled	4.0 mg/l	0.3 mg/l

Section 4 If the amount of lead or cadmium released from a ceramic article does not exceed the threshold in Section 3 by more than 50 %, the article may be marketed if the following conditions are met:

– at least three other articles of the same shape, dimension, decoration and glazing shall be examined in accordance with the requirements set out in Parts 1 and 2 of Annex 2;

– the average amounts of lead and cadmium, respectively, released from these three articles may not exceed the thresholds laid down in Section 3; and

– the amount of lead and cadmium, respectively, released from any of these articles may not exceed the stipulated thresholds by more than 50 %.

Section 5 The amount of lead and cadmium released from ceramic articles shall be determined in accordance with the requirements set out in Parts 1 and 2 of Annex 2.

Declaration of compliance

Section 6 Ceramic articles not yet in contact with food shall be accompanied at all stages of marketing, up to and including retail, by a written declaration of compliance in accordance with Article 16 of Regulation (EC) No 1935/2004.

The declaration shall be issued by the manufacturer or a vendor established in the European Union.

Section 7 A declaration of compliance pursuant to Chapter 5, Section 6 shall contain the following information.

1. The names and addresses of the company that manufactured the ceramic finished product and the importer of it into the European Union.
2. The identity of the ceramic article.
3. The date of the declaration.
4. Confirmation that the ceramic article complies with the applicable requirements of this Chapter and of Regulation (EC) No 1935/2004.

The written declaration shall be formatted such that it is very clear as to which article it concerns and it shall be renewed when significant changes in production entail changes in the migration of lead and cadmium.

Provision of documentation

Section 8 Appropriate documentation showing that the ceramic articles comply with the migration thresholds for lead and cadmium as per Sections 3 and 4 of this Chapter shall, upon request, be made available to the control authority by the manufacturer or importer to the European Union. Such documentation shall include the results of the completed analysis, the testing conditions, and the name and address of the laboratory that performed the test.

Chapter 6 – Special requirements for elastomer or rubber children's dummies

Thresholds for children's dummies

Section 1 Into a test solution (artificial saliva solution), the elastomer or rubber parts of teats and dummies may not release more than:

– a total of 0.01 milligrams of N-nitrosamines per kilogram of material;

– a total of 0.1 milligrams N-nitrosatable substances per kilogram of material. N-nitrosatable substances are substances that can be converted into N-nitrosamines.

Analytical controls shall be performed in accordance with the basic rules in point 1 of Annex 3, using a validated analytical method that meets the criteria set out in point 2 of Annex 3.

Chapter 7 – Provisions on imports from third countries

Imports from third countries

Section 1 Plastic kitchenware as referred to in Article 1 of Commission Regulation (EU) No 284/2011 of 22 March 2011 laying down specific conditions and detailed procedures for the import of polyamide and melamine plastic kitchenware originating in or consigned from the People's Republic of China and Hong Kong Special Administrative Region, China, and imported from third countries may only be brought into Sweden at the following specific first points of introduction:

– Gothenburg Landvetter;
– Helsingborg;

– Stockholm Arlanda;
– Stockholm Norvik; and
– Södertälje.

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1. These regulations enter into force on 1 August 2023.
2. As a result of these regulations, the following are hereby repealed:

a) The National Food Agency's regulations (LIVSFS 2011:7) on materials and articles intended to come into contact with food;

b) The National Food Agency's regulations (LIVSFS 2011:10) on the import of materials and articles intended to come into contact with food.

3. However, the provisions in Chapter 2, on registration, take effect on 1 July 2024. The provision in Chapter 2, Section 4 does not apply to activities commenced before 1 July 2024.

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Annex 1

List of substances authorised for the manufacture of regenerated cellulose film

1. The substances which may be used for the manufacture of regenerated cellulose film must be of good technical quality in terms of purity. For some substances there are specific restrictions, for toxicological reasons.

2. The column 'Restrictions' below contains content restrictions. The percentages in the list are expressed as percentage by weight (w/w) and are calculated in relation to the amount of anhydrous uncoated regenerated cellulose film.

Section 1

Uncoated regenerated cellulose film

Name	***Restrictions***
A. Regenerated cellulose	≥ 72 % in the film
B. Additives	
B1. *Moisture stabilisers*	≤ 27 % total of these substances in the film

Name	*Restrictions*
– bis(2-hydroxyethyl)ether [= diethylene glycol] – ethanediol [monoethylene glycol]	Only for films intended to be coated and used for food that is not moist, i.e. which does not contain water which is physically free at the surface. Film of regenerated cellulose in contact with food may not transfer bis(2-hydroxyethyl)ether and ethanediol in total amounts greater than 30 mg/kg of food.
– 1,3-butanediol – glycerol – 1,2-propanediol [= 1,2-propylene glycol]	
– polyethylene oxide [= polyethyleneglycol] – 1,2-polypropylene oxide [= 1,2 polypropylene glycol] – sorbitol – tetraethylene glycol – triethylene glycol – urea	Average molecular weight 250–1 200 Average molecular weight $\leq$ 400 and free 1,3-propanediol content $\leq$ 1 % (w/w)
B2. *Other additives*	$\leq$ 1 % total of these substances in the film
Group 1	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

Name	*Restrictions*
– 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, saturated or unsaturated fatty acids with an even number of carbon atoms (C_8–C_{20}) and behenic acid and ricinoleic acid and their NH_4, Ca, Mg, K, Na, Al and Zn salts – citric acid, dl-lactic acid, maleic acid, l-tartaric acid and their Na and K salts – sorbic acid and its NH_4, Ca, Mg, K and Na 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 – chemically modified edible starch and flour – amylose – calcium and magnesium carbonates and chlorides – esters of glycerol with linear, saturated or unsaturated fatty acids with an even number of carbon atoms (C_8–C_{20}) and/or esters with adipic acid, citric acid, 12-hydroxystearic	

Name	*Restrictions*
acid (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 (C_8–C_{20}) – esters of sorbitol with linear, saturated or unsaturated fatty acids 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 of aluminium, calcium, magnesium and potassium, anhydrous and with water of crystallisation – polyethylene oxide [= polyethyleneglycol] – sodium propionate	Average molecular weight 1 200–4 000

Name	*Restrictions*
Group 2	≤ 1 mg/dm^2 total of these substances in the uncoated film and the amount of the substance or group of substances in each indent may not be greater than 0.2 mg/dm^2 (or a lower threshold, if specified) in the uncoated film
– sodium alkyl (C_8–C_{18}) benzene sulphonate – sodium isopropyl naphthalene sulphonate – sodium alkyl (C_8–C_{18}) sulphate – sodium alkyl (C_8–C_{18}) sulphonate – sodium dioctylsulphosuccinate – distearate of dihydroxyethyl diethylene triamine monoacetate – ammonium, magnesium and potassium lauryl sulphate – N,N'-distearoyl diaminoethane, N,N'-dipalmitoyl diaminoethane and N,N'-dioleoyl diaminoethane	≤ 0.05 mg/dm^2 total of this substance in the uncoated film
– 2-heptadecyl-4,4-bis(methylene stearate) oxazoline – polyethylene-aminostearamide ethylsulphate	≤ 0.1 mg/dm^2 total of this substance in the uncoated film
Group 3 – Anchoring agents	≤ 1 mg/dm^2 total of these substances in the uncoated film
– condensation products of melamine-urea-formaldehyde modified with tris(2-hydroxyethyl)amine	Content of free formaldehyde in the uncoated film ≤ 0.5 mg/dm^2 Content of free melamine in the uncoated film ≤ 0.3 mg/dm^2

Name	*Restrictions*
– condensation products of unmodified melamine-formaldehyde, or which may be modified with one or more of the following substances: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl)amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine – polyalkylene amines, cross-linked and as cations (a) polyamide-epiclorhydrin resin based on diaminopropylmethylamine 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 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	Content of free formaldehyde in the uncoated film $\leq$ 0.5 mg/dm^2 Content of free melamine in the uncoated film $\leq$ 0.3 mg/dm^2

Name	*Restrictions*
– polyethyleneamines and polyethyleneimines – condensation product of unmodified urea-formaldehyde, or which can be modified with one or more of the following substances: aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	$\leq$ 0.75 mg/dm^2 total of these substances in the uncoated film Content of free formaldehyde in the uncoated film < 0.5 mg/dm^2
Group 4	$\leq$ 0.01 mg/dm^2 total of these substances in the uncoated film
– products from reaction between amines of edible oils and polyethylene oxide – monoethanolamine lauryl sulphate	

Section 2

Coated regenerated cellulose film

A.	**Regenerated cellulose**	See Section 1
B.	**Additives**	See Section 1
C.	**Coating**	≤ 50 mg/dm^2 in the coating on the side in contact with food
C1. *Polymers*		≤ 50 mg/dm^2 total of these substances in the coating on the side in contact with food
– ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose		
– cellulose nitrate		≤ 20 mg/dm^2 of this substance in the coating on the side in contact with food; nitrogen content between 10.8 % and 12.2 % in cellulose nitrate
C2. *Resins*		≤ 12.5 mg/dm^2 total of these substances in the coating/surfacing of the coating on the side in contact with food and solely for the manufacture of regenerated cellulose film with cellulose nitrate coatings

– casein – colophony and/or its products of polymerisation, hydrogenation or disproportionation and their esters of methanol, ethanol or polyvalent alcohols (C_2–C_6) or mixtures of these alcohols – colophony and/or its products of polymerisation, hydrogenation or disproportionation condensed with acrylic acid, maleic acid, citric acid, fumaric acid and/or phthalic acid and/or 2,2 bis (4-hydroxyphenyl)propane formaldehyde and esterified with methanol, ethanol or polyvalent alcohols (C_2–C_6) or mixtures of these alcohols	
– esters derived from bis(2-hydroxyethyl) ether with addition products of β-pinene 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 acid, citric acid, maleic acid, phthalic acid and sebacic acid – natural gum [= damar] – poly-β-pinene [= terpene resins] – urea-formaldehyde resins (see anchoring agents)	
C3. Plasticisers	$\leq$ 6 mg/dm^2 total of these substances in the coating on the side in contact with food

– acetyl tributyl citrate –acetyl tri(2-ethylhexyl) citrate – di-isobutyl adipate – di-n-butyl adipate – di-n-hexyl azelate – butyl benzyl phthalate – di-n-butyl phthalate – dicyclohexyl phthalate	≤ 2 mg/dm^2 of this substance in the coating on the side in contact with food ≤ 3 mg/dm^2 of this substance in the coating on the side in contact with food ≤ 4 mg/dm^2 of this substance in the coating on the side in contact with food
– 2-ethylhexyl diphenyl phosphate – glycerol monoacetate [= monoacetin] –glycerol diacetate [= diacetin] – glycerol triacetate [= triacetin] – dibutyl sebacate – di(2-ethylhexyl) sebacate [= dioctyl sebacate] – di-n-butyl tartrate – di-isobutyl tartrate	≤ 2.4 mg/kg of food in contact with this type of coating, or < 0.4 mg/dm^2 in the coating on the side in contact with food
C4. *Other additives*	≤ 6 mg/dm^2 total of these substances in the uncoated regenerated cellulose film including the coating on the side in contact with food

C4.1. *Additives listed in Section 1*	The same restrictions as in Section 1 (however, the amount expressed as mg/dm^2 refers to both the uncoated regenerated cellulose film and the coating on the side in contact with food)
C4.2. *Specific coating additives*	The amount of the substance or group of substances in each indent may not be greater than 2 mg/dm2 (or a lower threshold, if specified) in the coating on the side in contact with food
– 1-hexadecanol and 1-octadecanol – 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, n-amyl and oleoyl alcohol – montan waxes, comprising purified montanic acids (C_{26}–C_{32}) and/or their esters with ethanediol and/or 1,3 butanediol and/or their calcium and potassium salts	
–carnauba wax –beeswax –esparto wax –candelilla wax – dimethylpolysiloxane – epoxidised soya-bean oil (ethylene oxide content 6 % to 8 %) – refined paraffin and refined microwaxes – pentaerythritol tetrastearate – mono- and bis(octadecyldietylenoxide) phosphates – aliphatic acids (C_8–C_{20}) esterified with	< 1 mg/dm^2 of this substance in the coating on the side in contact with food < 0.2 mg/dm^2 of these substances in the

mono- or di-(2-hydroxyethyl)amine – 2- and 3-tert-butyl 4-hydroxyanisole [= butylated hydroxyanisole - BHA] –2,6-di-tert-butyl-4-methylphenol [= butylated hydroxytoluene - BHT] –di-n-octyltin-bis(2-ethylhexyl) maleate	coating on the side in contact with food < 0.06 mg/dm^2 of this substance in the coating on the side in contact with food < 0.06 mg/dm^2 of this substance in the coating on the side in contact with food < 0.06 mg/dm^2 of this substance in the coating on the side in contact with food
C5. *Solvents*	The total amount of all substances included may not be greater than 0.6 mg/dm^2 in the coating on the side in contact with food
– 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	
–ethyleneglycol monoethyl ether –ethyleneglycol monoethyl ether acetate –ethyleneglycol monomethylether –ethyleneglycol monomethylether acetate –methyl ethyl ketone –methyl isobutyl ketone –tetrahydrofuran	≤ 0.06 mg/dm^2 of this substance in the

–toluene	coating on the side in contact with food

Part 1 – Basic rules for determining migration of lead and cadmium

1. Test solution (simulator)

A freshly prepared 4 % (by volume) solution of acetic acid in water.

2. Test conditions

2.1 Perform the testing at a temperature of 22 ±2°C for 24 ± 0.5 hours.

2.2 When determining the migration of lead, cover the sample appropriately and expose it to ordinary laboratory lighting.

When determining the migration of cadmium or lead and cadmium, cover the sample so that the extracted surface is with certainty in total darkness.

3. Filling

3.1 Articles that can be filled

Fill the sample with the acetic acid solution to a level not exceeding 1 mm from the point of overfill, as measured from the top edge of the sample.

Samples with a flat or slightly sloping edge should be filled so that the distance between the surface of the liquid and the point of overfill is no more than 6 mm, as measured along the sloping edge.

3.2 Articles that cannot be filled

The part of the article surface that is not intended to come into contact with food is first covered with an appropriate protective layer that can withstand the action of the acetic acid solution. The sample is then immersed in a container with a known volume of acetic acid solution in such a way that the surface intended to come into contact with food is fully covered by the test solution.

4. Determination of surface area

The surface area of category 1 articles is equal to the surface area of the meniscus formed by the free liquid surface resulting from observing the filling requirements of point 3 above.

Part 2 – Analysis methods for determining migration of lead and cadmium

1. Purpose and scope

This method makes it possible to determine the specific migration of lead or cadmium.

2. Principle

The determination of the specific migration of lead or cadmium is carried out using an instrumental method of analysis that meets the quality requirements set out in point 4.

3. Reagents

– All reagents shall be of analytical quality, unless otherwise specified.
– Any reference to water shall refer to distilled water or water of equivalent quality.

3.1 4 % (by volume) solution of acetic acid in water

Add 40 ml of glacial acetic acid to water and make a mixture of 1 000 ml.

3.2 Stock solutions

Prepare stock solutions containing 1 000 mg lead per litre and at least 500 mg of cadmium per litre in the 4 % acetic acid solution referred to in point 3.1.

4. Quality requirements for the instrumental analysis method

4.1 Limit of detection

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

– 0.1 mg/litre for lead;
– 0.01 mg/litre for cadmium.

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

4.2 Limit of quantification

The limit of quantification for lead and cadmium must be equal to or lower than:

– 0.2 mg/litre for lead;
– 00.02 mg/litre for cadmium.

4.3 Recovery

The recovery of lead and cadmium added to the 4 % acetic acid referred to in point 3.1 must be within 80 % to 120 % of the added amount.

4.4 Specificity

The instrumental analysis method must be free from matrix-related and spectral interference.

5. Method

5.1 Preparation of the sample

The sample must be clean and free from grease and other substances likely to affect the test.

Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40 °C. Rinse the sample first in tap water and then in distilled water or water of equivalent quality. Let the water drain and then dry to avoid stains. The surface to be examined shall not be touched after cleaning.

5.2 Determination of lead or cadmium

The prepared sample shall be tested as set out in Part 1.

– Before removing the test solution for determining lead and/or cadmium, homogenise the content of the sample by an appropriate method, which avoids any loss of solution or abrasion of the surface being tested.
– Perform a blank test on the test solution used for each series of determinations.
– Perform determinations for lead and cadmium under appropriate conditions.

Annex 3

1. Basic rules for determining release of N-nitrosamines and N-nitrosatable substances

1.1 Test solution (artificial saliva solution)

The test solution (artificial saliva solution) is produced as follows: dissolve 4.2 g of sodium bicarbonate ($NaHCO_3$), 0.5 g sodium chloride (NaCl), 0.2 g potassium carbonate (K_2CO_3) and 30.0 mg sodium nitrite ($NaNO_2$) in one litre of distilled water or water of equivalent quality. The pH of the solution shall be 9.

1.2 Testing conditions

Samples of material from an appropriate number of teats or dummies shall be fully immersed in the artificial saliva solution for 24 hours at a temperature of 40 $\pm$ 2°C.

2. Criteria for the method of determining release of N-nitrosamines and N-nitrosatable substances

2.1 The release of N-nitrosamines is determined in a volume of each sample solution as prepared in accordance with point 1. The N-

nitrosamines are extracted from the sample solution with nitrosamine-free dichloromethane (CH_2Cl_2) and determined by gas chromatography.

2.2 The release of N-nitrosatable substances is determined in a different volume of each sample solution as prepared in accordance with point 1. The nitrosatable substances are transferred (converted) to nitrosamines by acidifying the test solution with hydrochloric acid. The nitrosamines are then extracted from the dichloromethane solution and determined by gas chromatography.