

## THE SCHEDULE

Regulation 14(1)

## Specified provisions of Regulation 10/2011

<i>Specified provision</i>	<i>Subject matter</i>
Article 4(e), as read with Articles 17 and 18	Prohibition on placing on the market plastic materials or articles if they do not meet specified compositional and declaration requirements
Article 5(1) and Annex I, as read with Article 6	Requirement, subject to certain derogations, to use only authorised substances in the manufacture of plastic layers in plastic materials and articles
Article 8, first sentence	General quality and purity standards that must be observed for substances used in the manufacture of plastic layers in plastic materials and articles
Article 9 as read with Annex I	Particular restrictions and specifications for substances used in the manufacture of plastic layers in plastic materials and articles
Article 10 as read with Annex II	General restrictions on plastic materials and articles
[ <sup>F1</sup> Article 11(1) and Annex 1, as read with Article 11(3) and (4)]	Specific limits on the degree to which constituents of plastic materials and articles are permitted to migrate into foods
Article 12	Overall limits on the permitted level of migration of the constituents of plastic materials and articles into food simulants
Article 13(1),(3),(4) and (5) and Annex I as read with Article 13(2)	Particular restrictions and specifications for the composition of each plastic layer in plastic multi-layer materials and articles
Article 14(1) and (5) and Annex 1, as read with Article 14(2),(3) and (4)	Particular restrictions and specifications for the composition of each plastic layer in multi-material multi-layer materials and articles
F2	F2
...	...

**F1** Words in Sch. substituted (25.12.2020) by [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments\) \(England\) Regulations 2020 \(S.I. 2020/1410\)](#), regs. 1(2), **4(16)(a)**

**F2** Words in Sch. omitted (25.12.2020) by virtue of [The Food and Feed Hygiene and Safety \(Miscellaneous Amendments\) \(England\) Regulations 2020 \(S.I. 2020/1410\)](#), regs. 1(2), **4(16)(b)**

[<sup>F3</sup>SCHEDULE 2

Regulation 10

## BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND CADMIUM

**F3** Sch. 2 inserted (31.12.2020) by [The Materials and Articles in Contact with Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), reg. 1, **Sch. 1**; 2020 c. 1, Sch. 5 para. 1(1)

**Changes to legislation:** There are currently no known outstanding effects for the The Materials and Articles in Contact with Food (England) Regulations 2012. (See end of Document for details)

**Modifications etc. (not altering text)**

**C1** Sch. 2 applied in part (with modifications) (N.I.) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(b), **Sch. 2** (with regs. 7, 8)

1. Test liquid  
4 % (v/v) acetic acid, in a freshly prepared aqueous solution.
2. Test conditions
  - (a) Carry out the test at a temperature of  $22 \pm 2$  °C for a duration of  $24 \pm 0,5$  hours.
  - (b) When the migration of lead is to be determined, cover the sample by an appropriate means of protection and expose it to the usual lighting conditions in a laboratory. When the migration of cadmium or of lead and cadmium is to be determined, cover the sample so as to ensure that the surface to be tested is kept in total darkness.
3. Filling
  - (a) Samples which 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; the distance is measured from the upper rim of the sample. Samples with a flat or slightly sloping rim should be filled so that the distance between the surface of the liquid and the overflow point is no more than 6 mm measured along the sloping rim.
  - (b) Samples which 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.
4. Determination of the surface area  
The surface area of the articles in Category 1 is equal to the surface area of the meniscus formed by the free liquid surface obtained by complying with the filling requirements set out in paragraph 3 above.]

**[<sup>F4</sup>SCHEDULE 3**

Regulation 10

**METHODS OF ANALYSIS FOR DETERMINATION  
OF THE MIGRATION OF LEAD AND CADMIUM**

**F4** Sch. 3 inserted (31.12.2020) by The Materials and Articles in Contact with Food (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/704), reg. 1, **Sch. 2**; 2020 c. 1, Sch. 5 para. 1(1)

**Modifications etc. (not altering text)**

**C2** Sch. 3 applied in part (with modifications) (N.I.) (1.10.2023) by The Windsor Framework (Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions) Regulations 2023 (S.I. 2023/959), regs. 1(2), 4(b), **Sch. 2** (with regs. 7, 8)

1. Object and field of application  
The method allows the specific migration of lead and/or cadmium to be determined.
2. Principle

The determination of the specific migration of lead and/or cadmium is carried out by an instrumental method of analysis that fulfils the performance criteria of paragraph 4.

### 3. Reagents

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

Where reference is made to water, it means distilled water or water of equivalent quality.

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

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

- (b) Stock solutions

Prepare stock solutions containing 1 000 mg/litre of lead and at least 500 mg/litre of cadmium respectively in a 4 % acetic acid solution, as referred to in paragraph (a).

### 4. Performance criteria of the instrumental method of analysis

- (a) 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 the 4 % acetic acid solution, as referred to in paragraph 3(a) which gives a signal equal to twice the background noise of the instrument.

- (b) The limit of quantification for lead and cadmium must be equal to or lower than— 0,2 mg/litre for lead; 0,02 mg/litre for cadmium.

- (c) Recovery. The recovery of lead and cadmium added to the 4 % acetic acid solution, as referred to in point 3(a), must lie within 80-120 % of the added amount.

- (d) Specificity. The instrumental method of analysis used must be free from matrix and spectral interferences.

### 5. Method

- (a) Preparation of the sample

The sample must be clean and free from grease or other matter 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. Drain and dry so as to avoid any stain. The surface to be tested is not to be handled after it has been cleaned.

- (b) Determination of lead and/or cadmium

The sample thus prepared is tested under the conditions laid down in Schedule 2.

Before taking 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.

Carry out a blank test on the reagent used for each series of determinations.

Carry out determinations for lead and/or cadmium under appropriate conditions.]

[<sup>F5</sup>SCHEDULE 4

Regulation 10A

## DECLARATION OF COMPLIANCE

**F5** Sch. 4 inserted (31.12.2020) by The Materials and Articles in Contact with [Food \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/704\)](#), reg. 1, **Sch. 3** (as amended by [S.I. 2020/1504](#), regs. 1(2), **16(8)**); 2020 c. 1, **Sch. 5 para. 1(1)**

**Modifications etc. (not altering text)**

**C3** Sch. 4 applied in part (with modifications) (N.I.) (1.10.2023) by [The Windsor Framework \(Retail Movement Scheme: Public Health, Marketing and Organic Product Standards and Miscellaneous Provisions\) Regulations 2023 \(S.I. 2023/959\)](#), regs. 1(2), 4(b), **Sch. 2** (with regs. 7, 8)

1. The written declaration referred to in regulation 10A must contain the following information—
  - (a) the identity and address of the company which manufactures the finished ceramic article and of the importer who imports it into Great Britain;
  - (b) the identity of the ceramic article;
  - (c) the date of the declaration;
  - (d) the confirmation that the ceramic article meets relevant requirements in these Regulations and Regulation 1935/2004.
2. The written declaration must permit an easy identification of the goods for which it is issued and must be renewed when substantial changes in the production bring about changes in the migration of lead or cadmium or both.]

[<sup>F6</sup>SCHEDULE 5

Regulation 12(1)

LIST OF SUBSTANCES AUTHORISED IN THE  
MANUFACTURE OF REGENERATED CELLULOSE FILM

**F6** Sch. 5 inserted (31.12.2022) by [The Food and Feed \(Miscellaneous Amendments\) Regulations 2022 \(S.I. 2022/1351\)](#), reg. 1(1), **Sch. 1**

**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 on one or both sides.

**LIST OF SUBSTANCES AUTHORISED IN THE MANUFACTURE OF REGENERATED CELLULOSE FILM**

Notes:

- The percentages in this Schedule, in the 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.

**First Part: Uncoated regenerated cellulose film**

<i>Denominations</i>	<i>Restrictions</i>
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 1200.
— 1.2-polypropylene oxide polypropyleneglycol [= 1.2	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 <sup>2</sup> of the uncoated film.
— Acetic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Ascorbic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Benzoic acid and sodium benzoate	
— Formic acid and its NH <sub>4</sub> , Ca, Mg, K and Na salts	
— Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids	

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<b>Denominations</b>	<b>Restrictions</b>
and the NH <sub>4</sub> , 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 <sub>4</sub> , 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 from 8 to 20 inclusive	
— 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 1200 and 4000.
— Sodium propionate	
Second class	The total quantity of the substances may not exceed 1 mg/dm <sup>2</sup> of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2 mg/dm <sup>2</sup> (or

<b>Denominations</b>	<b>Restrictions</b>
	a lower limit where one is specified) of the uncoated film.
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) benzene sulphonate	
— Sodium isopropyl naphthalene sulphonate	
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) sulphate	
— Sodium alkyl (C <sub>8</sub> -C <sub>18</sub> ) sulphonate	
— Sodium dioctylsulphosuccinate	
— Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05 mg/dm <sup>2</sup> of the uncoated film.
— Ammonium, magnesium and potassium lauryl sulphates	
— 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 <sup>2</sup> of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm <sup>2</sup> of the uncoated film.
— Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products:	Free formaldehyde content not greater than 0.5 mg/dm <sup>2</sup> of the uncoated film.
butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free melamine content not greater than 0.3 mg/dm <sup>2</sup> 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 <sup>2</sup> of the uncoated film.
	Free melamine content not greater than 0.3 mg/dm <sup>2</sup> 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;	

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<b>Denominations</b>	<b>Restrictions</b>
(c) polyamide-epichlorhydrin 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	
— Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm <sup>2</sup> of the uncoated film.
— Condensation product of urea-formaldehyde unmodified, or which may be modified with one or more of the following products:  aminomethylsulphonic acid, sulphanilic acid, butanol, diaminobutane, diaminodiethylamine, diaminodipropylamine, diaminopropane, diethylenetriamine, ethanol, guanidine, methanol, tetraethylenepentamine, triethylenetetramine, sodium sulphite	Free formaldehyde content not greater than 0.5 mg/dm <sup>2</sup> of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm <sup>2</sup> of the uncoated film.
— Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
— Monoethanolamine lauryl sulphate	

### Second Part: Coated regenerated cellulose film

<b>Denominations</b>	<b>Restrictions</b>
A. Regenerated cellulose	See first part.
B. Additives	See first part.
C. Coating	
1. Polymers	The total quantity of substances may not exceed 50 mg/dm <sup>2</sup> 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 <sup>2</sup> 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.



<b>Denominations</b>	<b>Restrictions</b>
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs and which is used solely for the preparation of regenerated cellulose films with cellulose nitrate based coatings.
— Casein	
— Colophony and/or its products of polymerization, hydrogenation, or disproportionation and their esters of methyl, ethyl or C <sub>2</sub> to C <sub>6</sub> polyvalent alcohols, or mixtures of these alcohols	
— Colophony and/or its products of polymerization, 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 <sub>2</sub> to C <sub>6</sub> 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 <sup>2</sup> 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 <sup>2</sup> of the coating on the side in contact with foodstuffs.

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<b>Denominations</b>	<b>Restrictions</b>
— 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 <sup>2</sup> 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 <sup>2</sup> 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 <sup>2</sup> 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 <sup>2</sup> (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 carbon atoms from 8 to 20 inclusive and of ricinoleic acid with ethyl, butyl, amyl and oleyl linear alcohols	
— Montan waxes, comprising purified montanic (C <sub>26</sub> to C <sub>32</sub> ) acids 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	

<b>Denominations</b>	<b>Restrictions</b>
— Dimethylpolysiloxane	Not more than 1 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Epoxidised soya-bean oil (oxirane content 6 to 8 %)	
— Refined paraffin and microcrystalline waxes	
— Pentaerythritol tetrastearate	
— Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Aliphatic acids (C <sub>8</sub> to C <sub>20</sub> ) esterified with mono- or di-(2-hydroxyethyl)amine	
— 2- and 3-tert.butyl-4-hydroxyanisole [= butylated hydroxyanisole — BHA]	Not more than 0.06 mg/dm <sup>2</sup> 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 <sup>2</sup> of the coating on the side in contact with foodstuffs.
— Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs.
5. Solvents	The total quantity of substances may not exceed 0.6 mg/dm <sup>2</sup> 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	

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<b><i>Denominations</i></b>	<b><i>Restrictions</i></b>
— Toluene	Not more than 0.06 mg/dm <sup>2</sup> of the coating on the side in contact with foodstuffs. ]

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