



MATERIALS AND ARTICLES IN CONTACT WITH FOOD REGULATIONS 2019

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Statutory Document No. 2019/0368

*European Communities (Isle of Man) Act 1973*

MATERIALS AND ARTICLES IN CONTACT WITH FOOD REGULATIONS 2019¹

*Laid before Tynwald: 8 October 2019**Coming into Operation: in accordance with regulation 2*

The Council of Ministers makes the following Regulations under sections 2B and 2C of the European Communities (Isle of Man) Act 1973.

Editorial Note: This instrument, made under the European Communities (Isle of Man) Act 1973, is continued by virtue of section 6 of the European Union and Trade Act 2019.

1 Title

These Regulations are the Materials and Articles in Contact with Food Regulations 2019.

2 Commencement

These Regulations come into operation on the day after they are made¹.

3 Interpretation

(1) In these Regulations —

“**Directive 84/500/EEC**” [Revoked]²

“**Directive 2007/42/EC**” [Revoked]³

“**Regulation 1935/2004**” means Regulation (EC) No 1935/2004 of the European Parliament and of the Council of 27 October 2007 on materials and articles intended to come into contact with food and repealing Directives 80/590/EEC and 89/109/EEC²;

¹ Section 2B(9) of the European Communities (Isle of Man) Act 1973 specifies that regulations made under section 2B shall be laid before Tynwald as soon as possible after they are made and if Tynwald at the sitting before which the regulations are laid or at the next following sitting resolves that the regulations shall be annulled, the regulations shall upon such resolution cease to have effect.

² OJL 338, 13.11.2004, p. 4.

“**Regulation 1895/2005**” means 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 food³;

“**Regulation 2023/2006**” means Commission Regulation (EC) No 2023/2006 of 22 December 2006 on good manufacturing practice for materials and articles intended to come into contact with food⁴;

“**Regulation 282/2008**” means Commission Regulation (EC) No. 282/2008 on recycled plastic materials and articles intended to come into contact with foods and amending Regulation (EC) No. 2023/2006⁵; ⁴

“**Regulation 450/2009**” means Commission Regulation (EC) No 450/2009 of 25 May 2009 on active and intelligent materials and articles intended to come into contact with food⁶; and

“**Regulation 10/2011**” means Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food⁷;

“**Regulation 2018/213**” means Commission Regulation (EU) No. 2018/213 on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No. 10/2011 as regards the use of that substance in plastic food contact materials⁸.⁵

(2) In these Regulations –

“**the Act**” means the Food Act 1996;

“**authorised officer**” means any person, whether or not an officer of the competent authority concerned, who is authorised in writing by a competent authority to act in matters arising under these Regulations;

“**Department**” means the Department of Environment, Food and Agriculture;

“**food examiner**” has the meaning specified in section 24(8) of the Act;

“**preparation**” includes manufacture and any form of treatment or process, and “**prepare**” is to be construed accordingly; and

“**public analyst**” means a person appointed under section 22 of the Act.

(3) Expressions used in these Regulations and in Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 450/2009 Regulation 10/2011, Regulation 2018/213 or Regulation 282/2008 bear the same meaning in these Regulations as they bear in those Regulations.⁶

³ OJL 302, 19.11.2005, p. 28.

⁴ OJL 384, 29.12.2006, p. 75.

⁵ Paragraph 58(6) of the Schedule to the European Union and Trade Act 2019 (Retained Direct EU Legislation) (DEFA and OFT) Regulations 2019 [SD 2019/0037].

⁶ OJL 135, 30.5.2009, p. 3.

⁷ OJL 12, 15.10.2011, p. 1.

⁸ Paragraph 58(7) of the Schedule to the European Union and Trade Act 2019 (Retained Direct EU Legislation) (DEFA and OFT) Regulations 2019 [SD 2019/0037].

- (4) Any reference in these Regulations to an instrument defined in regulation 3(1) is a reference to that instrument as amended from time to time.⁷

4 Scope

The provisions of these Regulations do not apply in relation to those materials and articles specified in paragraph (3) of Article 1 (purpose and subject matter) of Regulation 1935/2004.

PART 2 - GENERAL REQUIREMENTS FOR MATERIALS AND ARTICLES

5 Offences of contravening specified provisions of Regulation 1935/2004

- (1) A person must not place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food any material or article that does not comply with the requirements of Article 3(1) (general requirements) or Article 4(1),(2),(3) or (4) (special requirements for active and intelligent materials and articles).
- (2) A person must not place on the market any material or article that does not comply with the requirements of Article 3(2), 4(5) or (6) or 15(1),(3),(4),(7) or (8) as read with Article 15(2) (labelling).
- (3) Any person who contravenes paragraph (1) or (2) or Article 11(4) or (5) (authorisation) or 17(2) (traceability) is guilty of an offence.⁸
- (4) In this regulation a reference to a numbered Article is a reference to that Article in Regulation 1935/2004.

6 Offence of contravening Article 4 of Regulation 2023/2006

Any person who fails to comply with the requirements of Article 4 (conformity with good manufacturing practice) of Regulation 2023/2006 is guilty of an offence.

7 Competent authorities for the purposes of Regulation 1935/2004 and Regulation 2023/2006

- (1) The body designated as the competent authority for the purposes of the provisions of Regulation 1935/2004 specified below is the Department or any person or body appointed by the Department to act as a competent authority on its behalf for the purposes of this Regulation —
- (a) Articles 9 (application for authorisation of a new substance); and⁹
- (b) Articles 16 (declaration of compliance) and 17(2) (traceability).¹⁰

- (2) The competent authority for the purposes of Article 6(2) (quality control system) and 7(3) (documentation) of Regulation 2023/2006 is the Department or any person or body appointed by the Department to act as a competent authority on its behalf for the purposes of this Regulation.

PART 3 - REQUIREMENTS FOR ACTIVE AND INTELLIGENT MATERIALS AND ARTICLES

8 Offences of contravening specified provisions of Regulation 450/2009

- (1) Subject to the transitional provisions contained in Article 14 (entry into force and application) of Regulation 450/2009, any person who places on the market any active or intelligent material or article which does not comply with the requirements of Article 4 of that Regulation is guilty of an offence.
- (2) [Revoked]¹¹

9 Competent authority for the purposes of Regulation 450/2009

The competent authority for the purposes of Article 13 of Regulation 450/2009 is the Department or any person or body appointed by the Department to act as a competent authority on its behalf for the purposes of this Regulation.

PART 4 - REQUIREMENTS FOR CERAMIC ARTICLES

10 Interpretation of this Part

In this Part —

- (a) “ceramic article” means an article to which Regulation 1935/2004 applies by virtue of its Article 1(2) as read with 1(3) that —
- (i) is manufactured from a mixture of inorganic materials with a generally high argillaceous or silicate content to which small quantities of organic materials may have been added,
 - (ii) is first shaped, with the shape thus obtained having been permanently fixed by firing, and
 - (iii) may be glazed, enamelled and/or decorated.
- (b) [Revoked]¹²

11 Limits on the quantities of lead and cadmium transferred from ceramic articles

- (1) The quantities of lead and cadmium transferred from ceramic articles must not exceed the limits set out in paragraph (4) as read with paragraphs (3) and (5).¹³
- (2) Unless it is demonstrated that the materials used to make the ceramic article did not contain lead or cadmium, the quantities of lead and cadmium transferred from ceramic articles must be determined by means of a test, the conditions of which are specified in Schedule 2, using the method of analysis described in Schedule 3.
- (3) Where a ceramic article consists of a vessel fitted with a ceramic lid, the lead or cadmium limits (or both) which may not be exceeded (mg/dm² or mg/litre) must be that which applies to the vessel alone. The vessel alone and the inner surface of the lid must be tested separately and under the same conditions. The sum of the two lead or cadmium extraction levels thus obtained must be related as appropriate to the surface area or the volume of the vessel alone.
- (4) A ceramic article is to be recognised as satisfying the requirements of these Regulations relating to such articles if the quantities of lead and/or cadmium extracted during the test carried out under the conditions laid down in Schedule 2 and Schedule 3 do not exceed the following limits relating to the appropriate category of ceramic article for the ceramic article to be tested, —

Categories of ceramic articles	Lead (Pb) limit	Cadmium (Cd) limit
Category 1, — Articles which cannot be filled and articles which can be filled, the internal depth of which, measured from the lowest point to the horizontal plane passing through the upper rim, does not exceed 25 mm.	0.8 mg/dm ²	0.07 mg/dm ²
Category 2, — All other articles which can be filled.	4.0 mg/l	0.3 mg/l
Category 3, — Cooking ware; packaging and storage vessels having a capacity of more than three litres.	1.5 mg/l	0.1 mg/l

- (5) However, where a ceramic article does not exceed the above quantities by more than 50%, that article is nevertheless to be recognised as satisfying the requirements of these Regulations relating to such articles if at least three other articles with the same shape, dimensions, decoration and glaze are subjected to a test carried out under the conditions laid down in

Schedule 2 and Schedule 3 and the average quantities of lead and/or cadmium extracted from those articles do not exceed the limits set, with none of those articles exceeding those limits by more than 50%.¹⁴

11A Restrictions on placing on the market a ceramic article that does not comply with regulation 11¹⁵

- (1) A person must not place on the market a ceramic article that does not comply with the requirements of regulation 11(1) as read with regulation 11(2).¹⁶
- (2) At the marketing stages up to and including the retail stage, ceramic articles which are not yet in contact with foodstuffs must be accompanied by a written declaration in accordance with Article 16 of Regulation 1935/2004. That declaration is to be issued by the manufacturer or by a seller in the United Kingdom and must contain the information laid down in Schedule 4.
- (3) Appropriate documentation to demonstrate that the ceramic articles comply with the migration limits for lead and cadmium set out in regulation 11 must be made available by the manufacturer or the importer to the competent authorities on request. That documentation must contain the results of the analysis carried out, the test conditions and the name and the address of the laboratory that performed the testing.
- (4) The documentation specified in paragraph (3) is not required where documentary evidence is provided to show that the materials used to make the ceramic article did not contain lead or cadmium.
- (5) Paragraphs (2) and (3) do not apply in relation to a ceramic article which is second-hand.¹⁷

PART 5 - REQUIREMENTS FOR REGENERATED CELLULOSE FILM

12 Interpretation of this Part

- (1) In this Part —
 - (a) “regenerated cellulose film” means a thin sheet material obtained from refined cellulose derived from unrecycled wood or cotton, with or without the addition of suitable substances, either in the mass or on one or both surfaces, but does not include synthetic casings of regenerated cellulose;
 - (b) “URCF” means uncoated regenerated cellulose film;
 - (c) “CRCF” means coated regenerated cellulose film with coating derived from cellulose; and

- (d) “PRCF” means coated regenerated cellulose film with coating consisting of plastics.
- (2) This Part applies to regenerated cellulose film which —
 - (a) constitutes a finished product in itself; or
 - (b) is part of a finished product containing other materials,and is intended to come into contact with food or, by being used for that purpose, does come into contact with food.
- (3) [Revoked]¹⁸

13 Controls and limits

- (1) URCF and CRCF may be manufactured using only the substances or groups of substances listed in Schedule 5 (list of substances authorised in the manufacture of regenerated cellulose film) and subject to the restrictions set out in that Schedule but, by way of derogation, substances other than those listed in Schedule 5 may be used when these substances are employed either as —
 - (a) dyes and pigments; or
 - (b) adhesives,provided that there is no trace of migration of the substances, detectable by a validated method, into or on to foodstuffs.¹⁹
- (2) PRCF may be manufactured, prior to coating, using only substances or groups of substances listed in the first part of Schedule 5 and subject to the restrictions set out in that part.²⁰
- (3) The coating to be applied to PRCF may be manufactured using only substances or groups of substances listed in Annex I to Regulation 10/2011 and subject to the restrictions in that Annex.
- (4) Materials and articles made of PRCF must comply with Article 12 (overall migration limit) as read with Article 17 (expression of migration test results) and Article 18 (rules for assessing compliance with migration limits) of Regulation 10/2011.
- (5) Printed surfaces of regenerated cellulose film must not come into contact with foodstuffs.
- (6) Any material or article made of regenerated cellulose film that is not by its nature clearly intended to come into contact with food must, at a marketing stage other than the retail stage, be accompanied by a written declaration attesting that it complies with the legislation applicable to it.
- (7) Where special conditions of use are indicated, the material or article made of regenerated cellulose film must be labelled accordingly.

- (8) No person may place on the market any regenerated cellulose film which has been manufactured in contravention of the requirements of paragraphs (1) to (4), or which fails to comply with paragraphs (5) or (7).²¹

PART 6 - REQUIREMENTS FOR PLASTIC MATERIALS AND ARTICLES

14 Interpretation of Part 6 and the Schedule

In this Part and in the Schedule any reference to a numbered Article or Annex is a reference to that Article of, or Annex to, Regulation 10/2011.

15 Offences of contravening specified provisions of Regulation 10/2011

- (1) Any person who places on the market a plastic material or article that fails to comply with a requirement of Regulation 10/2011 specified in column 1 of the Schedule is guilty of an offence.
- (2) [Revoked]²²

16 Competent authority for the purposes of Regulation 10/2011

The competent authority for the purposes of Regulation 10/2011 is the Department or any person or body the Department appoints as a competent authority for the purposes of this Regulation.

PART 6A – REQUIREMENTS FOR RECYCLED PLASTIC MATERIALS AND ARTICLES²³

16A Interpretation of this Part

In this Part any reference to a numbered Article is a reference to that Article of Regulation 282/2008.²⁴

16B Offences of contravening Article 3(1) of Regulation 282/2008

Subject to the transitional provisions contained in Article 14, any person who places on the market a material or article that fails to comply with Article 3(1) (requirements for plastic materials and articles) is guilty of an offence.²⁵

16C Competent authority for the purposes of Regulation 282/2008

The competent authority for the purposes of Article 10 is the Department.²⁶

PART 7 - REQUIREMENTS FOR CERTAIN EPOXY DERIVATIVES

17 Restrictions on the use of certain epoxy derivatives (BADGE, BFDGE and NOGE)

- (1) In this Part —
 - (a) any reference to a numbered Article or Annex is a reference to that Article or Annex in Regulation 1895/2005; and
 - (b) paragraph (2) is subject to Article 1(3) (scope).²⁷
- (2) Subject to Article 6(1), (2) and (4) (transitional provisions), a person must not place on the market or use, in the course of a business in connection with the storage, preparation, packaging, sale or service of food —
 - (a) any material or article in contravention of Article 3 (prohibition on use or presence of BFDGE) or Article 4 (prohibition on use or presence of NOGE); or
 - (b) any material or article that fails to comply with the restrictions contained in Article 2 (BADGE) as read with Annex I (specific migration limit for BADGE and certain of its derivatives).
- (3) [Revoked]²⁸
- (4) Any person who contravenes paragraph (2) is guilty of an offence.²⁹

18 Competent authority for the purposes of Regulation 1895/2005

The competent authority for the purpose of Article 6(4) is the Department or any person or body appointed to act on behalf of the Department for the purposes of this Regulation.

PART 7A — REQUIREMENTS FOR BISPHENOL A³⁰

18A Interpretation of Part 7A

In this Part, any reference to a numbered Article is a reference to the Article so numbered in Regulation 2018/213.³¹

18B Offences of contravening Article 2 of Regulation 2018/213

Subject to the transitional provisions contained in Article 6, any person who places on the market a material or article that fails to comply with Article 2 is guilty of an offence.³²

18C Competent authority for the purposes of Regulation 2018/213

The competent authority for the purposes of Article 4(3) is the Department.³³

PART 8 - REQUIREMENTS FOR VINYL CHLORIDE**19 Limits on quantities of vinyl chloride in materials and articles, other than those materials and articles controlled by Regulation 10/2011**

- (1) Materials and articles, other than those materials and articles controlled by Regulation 10/2011, which are manufactured with vinyl chloride polymers or copolymers –
 - (a) must not contain vinyl chloride monomer in a quantity exceeding 1 milligram per kilogram of the material or article; and
 - (b) must be manufactured in such a way that they do not transfer to foods with which they are in contact any quantity of vinyl chloride exceeding 0.01 milligrams of vinyl chloride per kilogram of food.
- (2) A person must not –
 - (a) place on the market; or
 - (b) use in the course of a business in connection with the storage, preparation, packaging, selling or service of food,any material or article that does not comply with paragraph (1).
- (3) The criteria applicable to the method of determining the level of vinyl chloride in materials and articles and of determining vinyl chloride released by materials and articles are as set out in paragraphs (4), (5), and (6).³⁴
- (4) The level of vinyl chloride in materials and articles and the level of vinyl chloride released by materials and articles to foodstuffs are determined by means of gas-phase chromatography using the ‘headspace’ method.³⁵
- (5) For the purposes of determining vinyl chloride released by materials and articles to foodstuffs, the detection limit is 0.01 mg/kg.³⁶
- (6) Vinyl chloride released by materials and articles to foodstuffs is in principle determined in the foodstuffs. When the determination in certain foodstuffs is shown to be impossible for technical reasons, competent authorities may permit determination by simulants for these particular foodstuffs.³⁷

PART 9 - ENFORCEMENT

20 Offences and penalties

- (1) Any person who contravenes regulation 11A(1), 13(8) or 19(2) is guilty of an offence.
- (2) Any person who fails to comply with a compliance notice served on them under regulation 20A is guilty of an offence.
- (3) Any person who intentionally obstructs a person acting in the execution of Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 or these Regulations is guilty of an offence.
- (4) Any person who, without reasonable excuse, fails to provide any assistance or information a person may reasonably require for the performance of their functions under the Regulations mentioned in paragraph (3) is guilty of an offence.
- (5) Any person who, in purported compliance with any requirement under paragraph (4), knowingly or recklessly supplies information that is false or misleading in any material particular is guilty of an offence.
- (6) A person guilty of an offence is liable –
 - (a) in the case of an offence created by regulation 18B –
 - (i) on conviction on information to a fine or to a term of imprisonment not exceeding 2 years or both; or
 - (ii) on summary conviction to a fine not exceeding level 5 on the standard scale or to a term of imprisonment not exceeding 6 months or both;
 - (b) in the case of an offence created by paragraphs (1), (2), (3), (4) or (5) of this regulation or by regulation 5(3), 6, 8(1), 15(1), 16B or 17(4) on summary conviction to a fine not exceeding level 5 on the standard scale.
- (7) Nothing in paragraph (3) or (4) is to be construed as requiring a person to answer any question or give any information if to do so might incriminate that person.³⁸

20A Compliance notices

- (1) If an authorised officer has reasonable grounds for believing that any person has not complied with, is not complying with, or is not likely to comply with a provision specified in regulation 20B (which provisions concern declarations of compliance with legislative requirements or supporting documentation), the officer may serve a compliance notice on that person.
- (2) A compliance notice must state –

- (a) the reason for the service of the notice and the steps the person on whom the notice has been served must take;
 - (b) the date and, if appropriate, the time by which each step must be taken;
 - (c) that a failure to comply with the notice is an offence; and
 - (d) the details of the right to appeal against the notice under regulation 20C.
- (3) An authorised officer may serve a notice on a person withdrawing, varying or suspending a compliance notice.³⁹

20B Provisions of compliance notices

The provisions are —

- (a) paragraphs (2) and (3) of regulation 11A;
- (b) paragraph (6) of regulation 13;
- (c) Article 16 of Regulation 1935/2004;
- (d) Article 5 of Regulation 1895/2005;
- (e) Articles 10(3) and 12 of Regulation 282/2008;
- (f) Articles 12 and 13 of Regulation 450/2009;
- (g) the second sentence of Article 8, Article 15 as read with Annex 4 and Article 16 of Regulation 10/2011;
- (h) Article 4 of Regulation 2018/213.⁴⁰

20C Appeal against a compliance notice

- (1) Any person served with a compliance notice may appeal against that notice to a court of summary jurisdiction.
- (2) The procedure on appeal to a court of summary jurisdiction under paragraph (1) is by way of complaint, and the Summary Jurisdiction Act 1989 applies to the proceedings.
- (3) The period within which an appeal under paragraph (1) may be brought is one month from the date on which the compliance notice was served on the person wishing to appeal and the making of a complaint is deemed for the purposes of this paragraph to be the bringing of the appeal.
- (4) A compliance notice is not suspended pending an appeal unless —
 - (a) an authorised officer suspends it under regulation 20A(3); or
 - (b) the court directs that it be suspended.
- (5) The court may —
 - (a) confirm the notice or any requirement contained in it;
 - (b) vary the notice or any requirement contained in it; or

- (c) revoke the notice or any requirement contained in it.⁴¹

20D Execution and enforcement

The Department must execute and enforce Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011, Regulation 2018/213 and these Regulations.⁴²

21 Offences due to the act or default of a third party

Where the commission by a person of an offence under these Regulations is due to the act or default of some other person, that other person is guilty of the offence; and a person may be charged with and convicted of the offence whether or not proceedings are taken against the first mentioned person.

22 Time limit for prosecutions

- (1) A prosecution for an offence under these Regulations must not be begun after the expiry of 3 years from the commission of the offence or one year from its discovery by the Attorney General, whichever is the earlier.
- (2) Paragraph (1) does not apply to an offence under regulation 20(3) or (4).⁴³

23 General defences

- (1) In any proceedings for an offence under these Regulations it is, subject to paragraph (5), a defence to prove that the person accused (“the accused”) took all reasonable precautions and exercised all due diligence to avoid the commission of the offence by the accused or by a person under the control of the accused.
- (2) Without prejudice to the generality of paragraph (1), a person accused of an offence under regulation 5(3), 8(1), 15(1), 16B, 17(4), 18B or 20(1) who did not import or prepare the material or article in respect of which the offence is alleged to have been committed is taken to have established the defence provided by paragraph (1) if the requirements of paragraphs (3) or (4) are satisfied.⁴⁴
- (3) The requirements of this paragraph are satisfied if it is proved that –
 - (a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;
 - (b) either –
 - (i) the accused carried out all such checks of the material or article in question as were reasonable in all the circumstances, or

- (ii) it was reasonable in all the circumstances for the accused to rely on checks carried out by the person who supplied the accused with that material or article; and
 - (c) the accused did not know and had no reason to suspect at the time the offence was committed that the act or omission would amount to an offence under these Regulations.
- (4) The requirements of this paragraph are satisfied if the offence is one of placing on the market and it is proved that —
 - (a) the commission of the offence was due to the act or default of some other person who was not under the control of the accused, or to reliance on information supplied by such a person;
 - (b) the placing on the market of which the offence consisted was not done under the name or mark of the accused; and
 - (c) the accused did not know and could not reasonably be expected to know at the time the offence was committed that the act or omission would amount to an offence under these Regulations.
- (5) If in any case the defence provided by this regulation involves the allegation that the commission of the offence was due to the act or default of another person, or to reliance on information supplied by another person, the accused must not without leave of the court be entitled to rely on that defence unless —
 - (a) at least 7 clear days before the hearing; and
 - (b) where the accused has previously appeared before the court in connection with the alleged offence, within one month of the first such appearance,

the accused has served on the Attorney General a written notice giving such information identifying or assisting in the identification of that other person as was then in the possession of the accused.

24 Procedure where a sample is to be analysed

- (1) An authorised officer who has procured a sample under section 23 (procurement of samples) of the Act and who considers it should be analysed must divide the sample into 3 parts.
- (2) If the sample consists of sealed containers and opening them would, in the opinion of the authorised officer, impede a proper analysis, the authorised officer must divide the sample into parts by putting the containers into 3 lots, and each lot must be treated as being a part.
- (3) The authorised officer must —
 - (a) if necessary place each part in a suitable container and seal it;
 - (b) mark each part or container;

- (c) as soon as is reasonably practicable, give one part to the owner and notify the owner in writing that the sample will be analysed;
- (d) submit one part for analysis in accordance with section 24 (analysis etc of samples) of the Act; and
- (e) retain one part for future submission under regulation 25 (secondary analysis by the public analyst or a food examiner).

25 Secondary analysis by the public analyst or a food examiner

- (1) Where a sample has been retained under regulation 24(3)(e) and —
 - (a) proceedings are intended to be or have been commenced against a person for an offence under these Regulations; and
 - (b) the Attorney General intends to adduce as evidence the result of the analysis mentioned in regulation 24(1),paragraphs (2) to (7) apply.
- (2) The authorised officer —
 - (a) may of the officer's own volition; or
 - (b) must —
 - (i) if requested by the Attorney General;
 - (ii) if the court so orders, or
 - (iii) subject to paragraph (6), if requested by the accused,send the retained part of the sample to the public analyst or a food examiner for analysis.
- (3) The public analyst or food examiner, as the case may be, must analyse the part sent under paragraph (2) and send to the authorised officer a certificate specifying the results of the analysis.
- (4) Any certificate of the results of analysis transmitted by public analyst or the food examiner must be signed by or on behalf of the public analyst or the food examiner, but the analysis may be carried out by any person under the direction of the person who signs the certificate.
- (5) The authorised officer must immediately on receipt supply the Attorney General and the accused with a copy of the certificate of analysis provided by the public analyst or the food examiner.
- (6) Where a request is made under paragraph (2)(b)(iii) the authorised officer may give notice in writing to the accused requesting payment of a fee specified in the notice as the authorised officer considers is reasonable to defray some or all of the public analyst's or food examiner's charges for performing the functions under paragraph (3), and in the absence of agreement by the accused to pay the fee specified in the notice the authorised officer may refuse to comply with the request.

- (7) In this regulation “the accused” includes a person against whom the Attorney General is intending to commence proceedings.

26 Application of various provisions of the Act

- (1) The following provisions of the Act apply for the purposes of these Regulations with the modification that any reference in those provisions to the Act or Part of it is to be construed as a reference to these Regulations –
- (a) section 2 (extending meaning of “sale” etc);
 - (b) section 24(7) (analysis etc. of samples).
- (2) Section 3 of the Act (presumptions that food intended for human consumption) applies for the purposes of these Regulations with the following modifications –
- (a) any reference in that section to the Act is to be construed as including a reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213, as appropriate, and to these Regulations; and⁴⁵
 - (b) the references to “sold” and “sale” is to be deemed to include references to “placed on the market” and “placing on the market” respectively.
- (3) Section 26 of the Act (powers of entry) applies for the purposes of these Regulations with the modification that the reference to the Act in subsection (1) is to be construed as including a reference to Regulation 1935/2004, Regulation 1895/2005, Regulation 2023/2006, Regulation 282/2008, Regulation 450/2009, Regulation 10/2011 or Regulation 2018/213 as appropriate.⁴⁶

MADE 24 SEPTEMBER 2019

SCHEDULE

[Regulation 15 (1)]

SPECIFIED PROVISIONS OF REGULATION 10/2011

Specified provision	Subject matter
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
Article 11(1) and Annex 1, as read with Article 11(3) and (4) ⁴⁷	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
[Revoked] ⁴⁸	

SCHEDULE 2⁴⁹

(Regulation 11)

**BASIC RULES FOR DETERMINING THE MIGRATION OF LEAD AND
CADMIUM****1 Test liquid**

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

2 Test conditions

- (1) Carry out the test at a temperature of $22 \pm 2^{\circ}\text{C}$ for a duration of $24 \pm 0,5$ hours.
- (2) 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

- (1) Samples which can be filled, —
 - (a) Fill the article with a 4% (v/v) acetic acid solution to a level no more than 1mm from the overflow point; the distance is measured from the upper rim of the sample.
 - (b) 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 6mm measured along the sloping rim.
- (2) Samples which cannot be filled, —
 - (a) 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.
 - (b) 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.

SCHEDULE 3⁵⁰

(Regulation 11)

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

- (1) The detection limit for lead and cadmium must be equal to or lower than, —

- (a) 0,1 mg/litre for lead;
- (b) 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.

- (2) The limit of quantification for lead and cadmium must be equal to or lower than, —

- (a) 0,2 mg/litre for lead;
- (b) 0,02 mg/litre for cadmium.

- (3) 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.

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

5 Method

- (1) Preparation of the sample
- (a) The sample must be clean and free from grease or other matter likely to affect the test.
 - (b) Wash the sample in a solution containing a household liquid detergent at a temperature of approximately 40°C.
 - (c) Rinse the sample first in tap water and then in distilled water or water of equivalent quality.
 - (d) Drain and dry so as to avoid any stain.
 - (e) The surface to be tested is not to be handled after it has been cleaned.
- (2) Determination of lead and/or cadmium
- (a) The sample thus prepared is tested under the conditions laid down in Schedule 2.
 - (b) 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.
 - (c) Carry out a blank test on the reagent used for each series of determinations.
 - (d) Carry out determinations for lead and/or cadmium under appropriate conditions.

SCHEDULE 4⁵¹

(Regulation 11A)

DECLARATION OF COMPLIANCE**1 Written declaration**

The written declaration referred to in regulation 11A 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 the United Kingdom;
- (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 1935/2004.⁵²

2 Identification of goods

The written declaration must permit an easy identification of the goods for which it is issued.

3 Renewal of written declaration

The written declaration must be renewed when substantial changes in the production bring about changes in the migration of lead or cadmium or both.

SCHEDULE 5³

[Regulation 13]

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

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

Denominations	Restrictions
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 [= 1.2 polypropyleneglycol]	Average molecular weight not greater than 400 and free 1.3-propanediol content not greater than 1% (w/w) in substance.
– Sorbitol	

– Tetraethyleneglycol	
– Triethyleneglycol	
– Urea	
2. Other additives	Not more than 1% (w/w) in total.
First class	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² of the uncoated film.
– Acetic acid and its NH ₄ , Ca, Mg, K and Na salts	
– Ascorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
– Benzoic acid and sodium benzoate	
– Formic acid and its NH ₄ , Ca, Mg, K and Na salts	
– Linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also behenic and ricinoleic acids and the NH ₄ , Ca, Mg, K, Na, Al, Zn salts of these acids	
– Citric, d- and l-lactic, maleic, l-tartaric acids and their Na and K salts	
– Sorbic acid and its NH ₄ , Ca, Mg, K and Na salts	
– Amides of linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and also the amides of behenic and ricinoleic acids	
– Natural edible starches and flours	
– Edible starches and flours modified by chemical treatment	
– Amylose	
– Calcium and magnesium carbonates and chlorides	
– Esters of glycerol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive and/or with adipic, citric, 12-hydroxystearic (oxystearin), ricinoleic acids	
– Esters of polyoxyethylene (8 to 14 oxyethylene groups) with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms from 8 to 20 inclusive	
– Esters of sorbitol with linear fatty acids, saturated or unsaturated, with an even number of carbon atoms 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 ² of the uncoated film and the quantity of the substance or group of substances in each indent may not exceed 0.2 mg/dm ² (or a lower limit where one is specified) of the uncoated film.
– Sodium alkyl (C8-C18) benzene sulphonate	
– Sodium isopropyl naphthalene sulphonate	
– Sodium alkyl (C8-C18) sulphate	
– Sodium alkyl (C8-C18) sulphonate	
– Sodium dioctylsulphosuccinate	
– Distearate of dihydroxyethyl diethylene triamine monoacetate	Not more than 0.05 mg/dm ² of the uncoated film.
– Ammonium, magnesium and potassium lauryl 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 ² of the uncoated film.
Third class — Anchoring agent	The total quantity of substances may not exceed 1 mg/dm ² of the uncoated film.
– Condensation product of melamine-formaldehyde unmodified, or which may be modified with one or more of the following products: butanol, diethylenetriamine, ethanol, triethylenetetramine, tetraethylenepentamine, tri-(2-hydroxyethyl) amine, 3,3'-diaminodipropylamine, 4,4'-diaminodibutylamine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.
– Condensation product of melamine-urea-formaldehyde modified with tris-(2-hydroxyethyl)amine	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film. Free melamine content not greater than 0.3 mg/dm ² of the uncoated film.

<p>– Cross-linked cationic polyalkyleneamines: (a) polyamide-epichlorhydrin resin based on diaminopropylmethylamine and epichlorhydrin; (b) polyamide-epichlorhydrin resin based on epichlorhydrin, adipic acid, caprolactam, diethylenetriamine and/or ethylenediamine; (c) polyamide-epichlorhydrin resin based on adipic acid, diethylenetriamine and epichlorhydrin, 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</p>	
– Polyethyleneamines and polyethyleneimines	Not more than 0.75 mg/dm ² of the uncoated film.
<p>– 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</p>	Free formaldehyde content not greater than 0.5 mg/dm ² of the uncoated film.
Fourth class	The total quantity of substances may not exceed 0.01 mg/dm ² of the uncoated film.
– Products resulting from the reaction of the amines of edible oils with polyethylene oxide	
– Monoethanolamine lauryl sulphate	

Second Part: Coated regenerated cellulose film

Denominations	Restrictions
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 ² of the coating on the side in contact with foodstuffs.
– Ethyl, hydroxyethyl, hydroxypropyl and methyl ethers of cellulose	

– Cellulose nitrate	Not more than 20 mg/dm ² of the coating on the side in contact with foodstuffs; nitrogen content between 10.8% (w/w) and 12.2% (w/w) in the cellulose nitrate.
2. Resins	The total quantity of substances may not exceed 12.5 mg/dm ² of the coating on the side in contact with foodstuffs and 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 2 to C 6 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 2 to C 6 polyvalent alcohols or mixtures of these alcohols	
– Esters derived from bis(2-hydroxyethyl) ether with addition products of betapinene and/or dipentene and/or diterpene and maleic anhydride	
– Edible gelatine	
– Castor oil and its products of dehydration or hydrogenation and its condensation products with polyglycerol, adipic, citric, maleic, phthalic and sebacic acids	
– Natural gum [= damar]	
– Poly-beta-pinene [= terpenic resins]	
– Urea-formaldehyde resins (see anchoring agents)	
3. Plasticisers	The total quantity of substances may not exceed 6 mg/dm ² of the coating on the side in contact with foodstuffs.
– Acetyl tributyl citrate	
– Acetyl tri(2-ethylhexyl) citrate	
– Di-isobutyl adipate	
– Di-n-butyl adipate	
– Di-n-hexyl azelate	
– Dicyclohexyl phthalate	Not more than 4.0 mg/dm ² of the coating on the side in contact with foodstuffs.

– 2-ethylhexyl diphenyl phosphate (synonym: phosphoric acid diphenyl 2 ethylhexyl ester)	The amount of 2-ethylhexyl diphenyl phosphate shall not exceed: (a) 2.4 mg/kg of the foodstuff in contact with this type of film; or (b) 0.4 mg/dm ² in the coating on the side in contact with foodstuffs.
– Glycerol monoacetate [= monoacetin]	
– Glycerol diacetate [= diacetin]	
– Glycerol triacetate [= triacetin]	
– Di-butyl sebacate	
– Di-n-butyl tartrate	
– Di-isobutyl tartrate	
4. Other additives	The total quantity of substances may not exceed 6 mg/dm ² in the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs.
4.1. Additives listed in the first part	Same restrictions as in the first part (however the quantities in mg/dm ² refer to the uncoated regenerated cellulose film, inclusive of the coating on the side in contact with foodstuffs).
4.2. Specific coating additives	The quantity of the substance or group of substances in each indent may not exceed 2 mg/dm ² (or a lower limit where one is specified) of the coating on the side in contact with foodstuffs.
– 1-hexadecanol and 1-octadecanol	
– Esters of linear fatty acids, saturated or unsaturated, with an even number of 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 26 to C 32) 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	
– Dimethylpolysiloxane	Not more than 1 mg/dm ² of the coating on the side in contact with foodstuffs.
– Epoxidised soya-bean oil (oxirane content 6 to 8 %)	
– Refined paraffin and microcrystalline waxes	

– Pentaerythritol tetrastearate	
– Mono and bis(octadecyldiethyleneoxide)-phosphates	Not more than 0.2 mg/dm ² of the coating on the side in contact with foodstuffs.
– Aliphatic acids (C 8 to C 20) 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 ² of the coating on the side in contact with foodstuffs.
– 2,6-di-tert.butyl-4-methylphenol [= butylated hydroxytoluene – BHT]	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
– Di-n-octyltin-bis(2-ethylhexyl) maleate	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs.
5. Solvents	The total quantity of substances may not exceed 0.6 mg/dm ² of the coating on the side in contact with foodstuffs.
– Butyl acetate	
– Ethyl acetate	
– Isobutyl acetate	
– Isopropyl acetate	
– Propyl acetate	
– Acetone	
– 1-butanol	
– Ethanol	
– 2-butanol	
– 2-propanol	
– 1-propanol	
– Cyclohexane	
– Ethyleneglycol monobutyl ether	
– Ethyleneglycol monobutyl ether acetate	
– Methyl ethyl ketone	
– Methyl isobutyl ketone	
– Tetrahydrofuran	
– Toluene	Not more than 0.06 mg/dm ² of the coating on the side in contact with foodstuffs. ”.

ENDNOTES

Table of Endnote References

¹ The format of this legislation has been changed as provided for under section 75 of, and paragraph 2 of Schedule 1 to, the Legislation Act 2015. The changes have been approved by the Attorney General after consultation with the Clerk of Tynwald as required by section 76 of the Legislation Act 2015.

² Definition of “Directive 84/500/EEC” revoked by SD2023/0284.

³ Definition of “Directive 2007/42/EC” revoked by SD2023/0284.

⁴ Definition of “Regulation 282/2008” inserted by SD2023/0284.

⁵ Definition of “Regulation 2018/213” inserted by SD2023/0284.

⁶ Para (3) amended by SD2023/0284.

⁷ Para (4) substituted by SD2023/0284.

⁸ Para (3) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.

⁹ Subpara (a) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.

¹⁰ Subpara (b) amended by SD2019/0374 with effect from 31/12/2020 at 23:00.

¹¹ Para (2) revoked by SD2023/0284.

¹² Para (b) revoked by SD2023/0284.

¹³ Para (1) substituted by SD2023/0284.

¹⁴ Reg 11 substituted by SD2019/0374 with effect from 31/12/2020 at 23:00.

¹⁵ Reg 11A heading amended by SD2023/0284.

¹⁶ Para (1) substituted by SD2023/0284.

¹⁷ Reg 11A inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

¹⁸ Para (3) revoked by SD2023/0284.

¹⁹ Para (1) amended by SD2023/0284.

²⁰ Para (2) amended by SD2023/0284.

²¹ Para (8) amended by SD2023/0284.

²² Para (2) revoked by SD2023/0284.

²³ Part 6A inserted by SD2023/0284.

²⁴ Reg 16A inserted by SD2023/0284.

²⁵ Reg 16B inserted by SD2023/0284.

²⁶ Reg 16C inserted by SD2023/0284.

²⁷ Subpara (b) amended by SD2023/0284.

²⁸ Para (3) revoked by SD2023/0284.

²⁹ Para (4) amended by SD2023/0284.

³⁰ Part 7A inserted by SD2023/0284.

³¹ Reg 18A inserted by SD2023/0284.

³² Reg 18B inserted by SD2023/0284.

³³ Reg 18C inserted by SD2023/0284.

³⁴ Para (3) inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

³⁵ Para (4) inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

³⁶ Para (5) inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

³⁷ Para (6) inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

³⁸ Reg 20 substituted by SD2023/0284.

³⁹ Reg 20A inserted by SD2023/0284.

⁴⁰ Reg 20B inserted by SD2023/0284.

⁴¹ Reg 20C inserted by SD2023/0284.

⁴² Reg 20D inserted by SD2023/0284.

⁴³ Para (2) amended by SD2023/0284. [Editorial Note: Para 5(15) of Sch.9 to SD2023/0284 incorrectly refers to “regulation 8(2), 15(2) or 12(2) or (3)” instead of “regulation 8(2), 15(2) or 20(2) or (3)”.]

⁴⁴ Para (2) amended by SD2023/0284.

⁴⁵ Subpara (a) amended by SD2023/0284.

⁴⁶ Para (3) amended by SD2023/0284.

⁴⁷ Entry substituted by SD2023/0284.

⁴⁸ Entry revoked by SD2023/0284.

⁴⁹ Sch 2 inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

⁵⁰ Sch 3 inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

⁵¹ Sch 4 inserted by SD2019/0374 with effect from 31/12/2020 at 23:00.

⁵² Para 1 amended by SD2023/0284.

⁵³ Sch 5 inserted by SD2023/0284.