

POLICY NOTE

THE MATERIALS AND ARTICLES IN CONTACT WITH FOOD (SCOTLAND) REGULATIONS 2012

SSI 2012/318

1. Description

The above instrument was made in exercise of the powers conferred by sections 16(2), 17(1) and (2), 26(1)(a), (2)(a) and (3), 31 and 48(1) of the Food Safety Act 1990, paragraph 1A of Schedule 2 to the European Communities Act 1972 and all other powers enabling them to do so.

2. Policy Objective

- 2.1. This instrument provides for the execution and enforcement, in Scotland, of the provisions of Commission Regulation (EU) No. 10/2011 (“Regulation 10/2011”) of 14 January 2011 on plastic materials and articles intended to come into contact with food.
- 2.2. This instrument also revokes five sets of Regulations and consolidates into one instrument nearly all existing national legislation on materials and articles intended to come into contact with food, the exception being the Plastic Kitchenware (Conditions on Imports from China) (Scotland) Regulations 2011 (SSI 2011/282) (these Regulations put in place additional import controls for plastic kitchenware originating from China and will be periodically reviewed by the European Commission, taking into account information received from Member States).

3. Policy background

What is being done and why

- 3.1. Unregulated chemical migration from food contact plastics may potentially result in negative costs through detrimentally affecting consumer health (e.g. costs to the National Health Service). Consumers are unable to assess the risks involved when consuming a product because they cannot observe the level of chemical migration and do not have full information on the production methods. Therefore, they cannot make informed choices about such risk. Legislative intervention, through European legislation that is regularly updated and implemented in the domestic law of the UK

and other Member States, is necessary to reduce the risks to health and provide for consistent enforcement across the single market.

- 3.2. The general principles governing the safety of all materials and articles intended to come into contact with foods are established in Regulation (EC) No. 1935/2004 of the European Parliament and of the Council (“the Framework Regulation”). Regulation 10/2011 is a specific measure within the meaning of Article 5(1) of the Framework Regulation and establishes specific rules for plastic materials and articles intended to come into contact with foods.
- 3.3. Regulation 10/2011 repeals Commission Directive 2002/72/EC and all its amendments on plastic materials and articles intended to come into contact with foods. The Directive laid down the rules for the manufacture of plastic materials and articles; it has been the subject of substantial amendments spanning ten years. The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009 (SSI 2009/30) implemented the provisions of Directive 2002/72/EC.
- 3.4. Regulation 10/2011 applied in part from 1st May 2011. It was effectively implemented in Scotland by the Plastic Materials and Articles in Food (Scotland) Regulations 2009 (SSI 2009/30), by way of the ambulatory reference made to Directive 2002/72 in regulation 2(5) as read with Article 12 of Regulation 10/2011 (which provides that references to Directive 2002/72 should be read as references to Regulation 10/2011 from 1st May 2011).
- 3.5. Directive 2002/72/EC was most recently amended in late November 2010 by Commission Directive 2011/8/EU, which introduced restrictions on bisphenol A (BPA). Once Regulation 10/2011 came into force it was amended by Commission Implementing Regulation (EU) No. 321/2011 as regards the restriction on the use of BPA in plastic infant feeding bottles, which carried forward the restrictions originally contained in Directive 2011/8/EU. This ensured continuity of the prohibition of BPA in infant feeding bottles by an amendment to Annex I Table I of Regulation 10/2011.
- 3.6. Regulation 10/2011 updates and replaces all the existing rules on plastic materials and articles intended to come into contact with food into a single EU Regulation. This aims to protect the nature and quality of the food concerned, to provide clear and consistent conditions for trade in affected goods and to provide enforcement authorities and industry with one set of harmonised rules that apply throughout the EU.
- 3.7. It is aim of the FSA to simplify the way that rules governing materials and articles in contact with food are presented in Scotland to make them as clear as possible for the end user. Currently there are three separate principal SSIs (and two amending SSIs), which contain the rules on contact materials, which can be difficult for those that need to cross-refer between various provisions; it is also possible that the implementation of Regulation 10/2011 by ambulatory reference in SSI 2009/30 could be clearer. By using consistent definitions and terminology, by cutting down on cross-referencing and removing redundant provisions, together with having the rules on materials and articles in contact with food in one place (except SSI 2011/282), this will reduce complexity and make the legislation more accessible to the reader. This is clearly of benefit to stakeholders, including enforcement authorities and industry; the effect of

which will assist in further protecting consumers against exposure from chemicals that could migrate into food, which could carry serious long term and unacceptable risks to consumer health, particularly amongst vulnerable people.

- 3.8. To that end, this instrument provides for the continued execution and enforcement of Regulation 10/2011 by updating the provisions of SSI 2009/30 and in addition, consolidating this with other SSIs which concern materials and articles in contact with food (except SSI 2011/282). Certain Articles of Regulation 10/2011 apply from 31st December 2012 and from 31st December 2015 (in terms of Article 23 of Regulation 10/2011) and there are related transitional provisions contained in Article 22 of Regulation 10/2011; this instrument gives effect in domestic law to these Articles, from the relevant dates.
- 3.9. The SSIs being revoked and consolidated are:
- a) The Ceramic Articles in Contact with Food (Scotland) Regulations 2006, which implemented the provisions of Council Directive 84/500/EEC, as amended by Commission Directive 2005/31/EC;
 - b) The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009, which implemented Directive 2002/72/EC (as amended) and thereafter revoked and replaced by Regulation 10/2011;
 - c) The Materials and Articles in Contact with Food (Scotland) Regulations 2010 (the 'FCM' Regulations), which implemented Commission Directive 2007/42/EC and provided for the enforcement of Regulation (EC) No. 1935/2004, Commission Regulation (EC) No. 2023/2006 and Commission Regulation (EC) No. 450/2009; and
 - d) The Plastic Materials and Articles in Contact with Food (Scotland) (Amendment) Regulations 2011, which implemented the transitional arrangements contained in Commission Directive 2011/8/EU amending the now repealed Directive 2002/72/EC as regards the restriction of use of Bisphenol A in plastic infant feeding bottles.
- 3.10 The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2008 are also being revoked. These Regulations do nothing but amend instruments which are already revoked and therefore are redundant.

The Plastic Materials and Articles in Contact with Food (Scotland) Regulations 2009

- 3.11 The 2009 Regulations implemented the provisions of Commission Directive 2002/72/EC and all its amendments (that have since been repealed by Regulation 10/2011), together with the two Directives relating to the testing for compliance of plastic materials and articles intended to come into contact with foods (namely Council Directive 82/711/EEC, laying down the basic rules for testing for migration of constituents and Council Directive 85/572/EEC, which contained the lists of food simulants for migration testing).
- 3.12 The 2009 Regulations also implemented the enforcement provisions of Commission Regulation (EC) No. 1895/2005 on the restrictions on the use of certain epoxy derivatives in materials and articles intended to come into contact with food.

Regulation 1895/2005 permitted the use of BADGE in all food contact plastics, as well as adhesives and surface coatings, providing that any migration is within the Specific Migration Limit (SML) of 9 milligrams per kilogram of food or food simulant, including the hydrolysed derivatives of BADGE. It permitted trade in the use of materials and articles containing BADGE throughout the EU from 1st January 2006 and re-affirmed the ban on the use of BFDGE and NOGE.

- 3.13 The provisions for BADGE, BFDGE and NOGE are currently contained in regulation 12 of the 2009 Regulations. The enforcement of Regulation 1895/2005 will be carried over into regulation 16 of this instrument with some minor textual changes. As the provisions of Regulation 1895/2005 have not changed, there is unlikely to be a new or additional burden on business or local authorities.

The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011

- 3.14 The 2009 Regulations were recently amended to take into account the provisions of Commission Directive 2011/8/EC (amending Directive 2002/72/EC) as regards the use of Bisphenol A (BPA) in plastic infant feeding bottles. The Plastic Materials and Articles in Contact with Food (Scotland) Amendment Regulations 2011 implemented the transitional provisions of the Directive in Scotland. These Regulations will be revoked, together with the 2009 Regulations, and the provisions in relation to BPA will now be enforced in this instrument as part of the enforcement of Regulation 10/2011.

The Materials and Articles in Contact with Food (Scotland) Regulations 2010 ('the 2010 Regulations')

- 3.15 The 2010 Regulations provide for the enforcement of three European (EC) Regulations and implement the provisions of four Commission and Council Directives, and these are:
- a) Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with foodstuffs;
 - b) Regulation (EC) No. 2023/2006 on good manufacturing practice ("the GMP Regulation");
 - c) Regulation (EC) No. 450/2009 on active and intelligent materials and articles intended to come into contact with foods ("the AIM Regulation");
 - d) Commission Directive 2002/42/EC on food contact materials made from regenerated film (RCF);
 - e) Council Directive 78/142/EEC relating to vinyl chloride monomer (VCM) in food contact plastics;
 - f) Commission Directives 80/766/EEC on the methods for testing for VCM in food contact plastics; and
 - g) Commission Directive 81/432/EEC on the method for testing migration of VCM from food contact plastics.

Enforcement Provisions of the Framework Regulation, the GMP Regulation and the AIM Regulation

- 3.16 The enforcement provisions contained in the 2010 Regulations for the Framework Regulation, the GMP Regulation and the AIM Regulation remain intact and unchanged and there are no new or additional burdens on businesses or local authorities from the simplification. However, there will be minor textual changes to take into account the consolidation of the four instruments, the repealed Commission Directives 80/590/EEC and 89/109/EEC, and cross-references to other SSIs which will be removed, along with the definitions or terms such as ‘plastics’, which stem from the plastics Directive.

Provisions for Regenerated Cellulose Film (RCF)

- 3.17 In relation to the implementation of Commission Directive 2007/42/EC, the requirements for regenerated cellulose film (RCF) are redrafted in Part 5 of this instrument with minor amendments, which are closer to that Directive. The main difference is that Regulation 10/2011 has direct effect in relation to the migration limits that apply to RCF. Again, the provisions of Commission Directive 2007/42/EC remain intact and unchanged and there is unlikely to be any new or additional burden on businesses from the redrafted provisions. Instead of carrying out testing for compliance of RCF in accordance with Commission Directive 2007/42/EC, testing will now be carried out in accordance with Regulation 10/2011. References to the repealed Directive have been removed and replaced with references to Regulation 10/2011 in this instrument.
- 3.18 This instrument will not re-enact a number of provisions on RCF present in the 2010 Regulations, as these are considered to be no longer necessary. The migration limits set out in regulation 11 of the 2010 Regulations are now directly applied by Regulation 10/2011, and the saving and transitional provisions in regulation 12 are now obsolete. The transitional arrangements contained in the Materials and Articles in Contact with Food (Scotland) Regulations 2005 were time limited and this time limit has now expired.

Implementation provisions of Vinyl Chloride Monomer (VCM)

- 3.19 In relation to the provisions of the Directives (listed at 3.15 (e) to (g) above) on vinyl chloride monomer (VCM), the 2010 Regulations implemented the provisions of Directive 78/142/EEC on VCM (which predates Commission Directive 2002/72/EC on the controls of the use of VCM in food contact plastics). Although Regulation 10/2011 does not repeal this Directive, the migration limits are now contained in Annex II of that Regulation. Part 8 of this instrument re-enacts the provisions on VCM (with minor amendments to tie them into the requirements of Regulation 10/2011) which were contained in regulation 8 of the 2010 Regulations. Furthermore, the two Directives which concerned carrying out testing for VCM, namely Commission Directives 80/766/EEC and 81/432/EEC, have been repealed by Regulation 10/2011. Testing for VCM will now be carried out in accordance with Article 11 of Regulation (EC) No. 882/2004. Again, there is unlikely to be any new or additional burden on businesses.

The Ceramic Articles in Contact with Food (Scotland) Regulations 2006

- 3.20 The Ceramic Articles in Contact with Food (Scotland) Regulations 2006 will be revoked and remade by this instrument. The provisions of Council Directive 84/400/EEC, which deal with the migration into food of lead and cadmium from ceramic articles intended to be brought into contact with food, were originally implemented in the UK under powers in the Consumer Protection Act 1987 by the Ceramic Ware (Safety) Regulations 1988.
- 3.21 Regulations 9 and 10 of this instrument reproduce the operative provisions of the Ceramic Articles in Contact with Food (Scotland) Regulations 2006, implementing Council Directive 84/500/EEC. As ceramics in contact with food will no longer be regulated by a standalone SSI, the general approach taken in this instrument has been to make reference to the Directive as opposed to copying out the provisions of that Directive. The definition of “ceramic articles” has been brought into line with the Directive; this does not include “antiques” because the Framework Regulation applies to all materials and articles in contact with food, excluding antiques.

4 Consultation

Informal Consultation

- 4.1 During the course of negotiations with the Commission, FSA officials frequently conveyed information to interested organisations, including industry, research institutes, consumer groups, enforcement bodies, public analysts and others with an interest in policy issues related to food contact materials. Consultations on the harmonised rules on food contact plastics have been conducted in seven recent years: 2002, 2004, 2005, 2006, 2007, 2008, 2009, and also in 2011, when the rules on food contact plastics were last amended.
- 4.2. Two informal consultations on the proposed Regulation 10/2011 were carried out; the first in 2004 and the second in 2009. Industry welcomed the proposed consolidation of the plastics legislation into a single European Regulation, simultaneously applicable across all Member States, noting that the process of compliance demonstration would become much simpler.
- 4.3 There were no comments received from stakeholders in Scotland, although there were comments from interested organisations across the UK and these were incorporated into the UK negotiating line.

Formal Public Consultation

- 4.4 The FSA conducted a formal public consultation from 17th January to 10th April 2012, seeking comments on a draft of this instrument. Those stakeholders consulted included food industry organisations, sector specific organisations, consumer groups, non-government organisations, enforcement authorities, public and independent laboratories and others with an interest in food contact materials legislation.

- 4.5 Two comments were received in Scotland – one fully supporting the consolidation of the various pieces of legislation into a single statutory instrument and the other from the Scottish Law and Reform Division, advising they were content with the proposed penalties.
- 4.6 Comments received elsewhere in the UK in response to the consultation have been reflected, where necessary, in the Business and Regulatory Impact Assessment which accompanies this instrument.
- 4.7 A full summary of the comments received in response to the consultation in Scotland has been published on the FSA's website.

5 Other Administrations

- 5.1 This instrument applies in relation to Scotland only. Separate but parallel legislation has been made for England, Wales and Northern Ireland.

6 Impact

- 6.1 As set out in the Business and Regulatory Impact Assessment, this instrument will affect UK manufacturers of plastic materials and articles intended to come into contact with food (including food packaging, cookware, cutlery, tableware, work surfaces and food contact parts of processing equipment). They will also affect importers, retailers, including retailers of food beverage products, supermarkets, food stalls, food markets, as well as retail of food and beverages in specialised stores. For this sector, there will be a one-off cost for reading and familiarising with this instrument and the requirements of Regulation 10/2011.
- 6.2 Local Authorities (LAs) and public official control laboratories (OCLs) will also be affected by this policy as they will be required to read and familiarise themselves with this instrument, since they are responsible for enforcing food safety legislation in their respective areas. There will be a one-off cost for this.
- 6.3 In addition, there will be a one-off cost to OCLs also for reading and familiarising with the changes to testing requirements, as outlined in Regulation 10/2011.

7 Regulating small business

- 7.1 The instrument will apply to all businesses, small and large.

8 Monitoring & review

- 8.1 The FSA will work with enforcement authorities where problems or suspected infringements of this instrument arise. The effectiveness of this instrument will be monitored via general feedback from industry and enforcement authorities.

9 Contact

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November 2012