

## **Explanatory Memorandum to the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017**

This Explanatory Memorandum has been prepared by the Food Standards Agency and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with Standing Order 27.1.

### **Member's Declaration**

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017

**Rebecca Evans AM**

Minister for Social Services and Public Health

11 August 2017

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## **1. Description**

The making of the Materials and Articles in Contact with Food (Wales) (Amendment) Regulations 2017 (“the Regulations”).

The Regulations will provide for the execution and enforcement of amendments made recently to Regulation (EU) No 10/2011 on plastic materials and articles intended to come into contact with food by Regulation (EU) 2016/1416. The Regulations will also allow enforcement authorities to issue improvement notices for non-compliance with specified requirements instead of bringing criminal prosecutions.

## **2. Matters of Special Interest to the Constitutional Affairs Committee**

None.

## **3. Legislative Background**

The powers enabling the Regulations to be made are conferred by sections 16(2), 17(1) and (2) and 48(1) of the Food Safety Act 1990.

The powers given by these sections, which were vested in UK Government Ministers prior to devolution, were transferred to the National Assembly for Wales in 1999 by the National Assembly for Wales (Transfer of Functions) Order 1999 (SI 1999/672) and were subsequently transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006.

The Regulations will be made by statutory instrument subject to the negative resolution procedure.

## **4. Purpose and Intended Effect of the Legislation**

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”). This lays down the framework for the regulation of all such materials and articles intended to come into contact with food. Commission Regulation (EU) No. 10/2011 (“the principal Regulation”) on plastic materials and articles in contact with food is a specific measure within the meaning of Article 5(1) of the framework Regulation and establishes the specific rules for plastic materials and articles intended to come into contact with food.

Harmonised EU rules on food contact plastics are laid down in the principal Regulation. This is routinely amended, on the basis of advice from the European Food Safety Authority (“EFSA”), to improve the clarity of the rules and to keep up with technological innovation by adding new substances to the authorised Union list of substances that may be used in the manufacture of food contact plastics. The principal Regulation was most recently amended by Commission Regulations 2016/1416 and 2017/752.

Commission Regulation (EU) 2016/1416 (“Regulation 2016/1416”) amending and correcting the principal Regulation was published in the Official Journal on 25 August 2016. It came into force on 14 September 2016, and is directly applicable throughout the EU. There is a transitional period of one year for materials and articles that were compliant with the principal Regulation before Regulation 2016/1416 entered into force.

The new EU Regulation is available to download from the EURlex website at: <http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32016R1416>

Regulation 2016/1416 amends Articles 3, 6, 11, 13, 17 and 18 of the principal Regulation. It also makes amendments to the provisions concerning food simulants, to correct the definition of ‘fatty foods’ and assigns a food simulant category for peeled fresh fruit and vegetables in the list of simulants to be used for migration testing of food contact plastics not yet in contact with food in Table 2 of Annex III to the principal Regulation. The authorised Union list is amended to include new substances, and the entries for existing ones are amended following risk assessments published by the EFSA. Regulation 2016/1416 also updates Annexes I, II, III IV and V to the principal Regulation on the basis of new information that has become available.

The Regulations will amend the Materials and Articles in Contact with Food (Wales) Regulations 2012 (“the 2012 Regulations”) to provide for the execution and enforcement, in Wales, of Commission Regulation 10/2011 on plastic materials and articles intended to come into contact with food as recently amended by Commission Regulations (EU) No. 2016/1416 and 2017/752.

The Regulations will also enable authorised officers to issue improvement notices for a failure to comply with specific provisions of the 2012 Regulations and the EU legislation that those Regulations enforce, instead of issuing criminal proceedings.

## **5. Consultation**

A public consultation exercise was carried out by the Food Standards Agency (FSA) between 11 April 2017 and 4 July 2017.

The only response received was that of the Laboratory of the Government Chemist (LGC).

The response relates to one of the amendments made to the principal Regulation by Regulation 2016/1416, authorising silicone dioxide, silanated, for use in food contact materials if the particles are of a particular size. The LGC response highlights the lack of a standardised method for determining engineered nanoparticle size, their work to develop one, and that until a standardised method is available it will be difficult for laboratories to substantiate the specification for substances such as silicon dioxide.

No changes are required to the Regulations as a result of this response.

## **6. Regulatory Impact Assessment**

A Regulatory Impact Assessment has not been prepared to accompany these Regulations as there are no changes to the current controls and therefore no identified costs to consumers, businesses or enforcement authorities associated with implementation of these Regulations.