

**Carwyn Jones AM/AC**

**Y Cwnsler Cyffredinol ac Arweinydd y Tŷ  
Counsel General and Leader of the House**



Llywodraeth Cynulliad Cymru  
Welsh Assembly Government

Lord Dafydd Elis – Thomas AM  
Presiding Officer  
National Assembly Wales

30 April 2008

Dear Dafydd,

**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (WALES)  
REGULATIONS 2008**

I am writing to inform you that in order to bring The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2008 into force in Wales in line with the rest of the UK, it has become necessary to breach the 21 day rule. These Regulations were made and laid in Table Office on 30 April 2008 and will come into force on 1 May 2008.

These Regulations implement European Commission Directive 2007/19/EC and make amendments to the European Community list of authorised monomers and other starting substances contained in Annex II of the Directive 2002/72/EC; as well as the incomplete list of additives in Annex III. A monomer is a chemical compound, mostly organic, composed of simple molecules. New substances are included in the amendment as well as amending the entries for existing ones following risk assessment by the European Food Safety Authority (EFSA).

The changes to these lists of substances are made periodically when the European Food Safety Authority has revised an existing opinion or issued a new one on the safe use of a substance. This opinion establishes the amount of a substance that may be ingested daily by a person over a lifetime without harmful health effects. Those opinions are used by the European Commission as the basis for proposals to be agreed with EU Member States.

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In particular, the Directive provides for new limitations on the use of and migration limits for certain plasticisers, including epoxidised soybean oil (ESBO) and some phthalates. Phthalates are chemical compounds of the chemical phthalitic acid, and are used as substances added to plastics to increase flexibility. The Directive also amends Council Directive 85/572/EEC, which lays down the list of simulants to be used for testing migration of constituents of plastic materials in contact with food, by introducing a fat reducing factor (FRF), which provides a better estimation of consumer exposure to substances migrating into fatty food.

The Directive also provides a clear clarification of the term 'plastic multi-layer' and distinguishes it from 'plastic functional barriers', with the provisions for the use of plastic functional barriers to help in reducing the migration of substances below a specific migration limit. Metal gaskets in lids is now clarified and made clear that it falls within the scope of Directive 2002/72/EC; and provides manufacturers time to apply for evaluation of specific additives used. The amending Directive revokes the current suspension on the use of azodicarbonamide as a blowing agent in food contact plastics and replaces it with an outright ban. Azodicarbonamide is an organic chemical known as E927. It is used as a food additive or bleaching agent to flour, but is also used in the production of foamed plastics. It is currently subject to a temporary ban. These Regulations will implement an outright ban on its use within the UK.

The Directive also requires that detailed information on compliance declarations and those certificates of compliance should attest to the restrictions and/or specifications applicable to them. The Directive also provides the date by which goods complying with the provisions of the amending Directive may be placed on the market and dates from which non-compliant goods may not be manufactured or imported into the European Community.

Two formal consultations on the proposals were carried out with interested parties in Wales from October 2007 to 29 January 2008 and February 2008 to 28 March 2008, respectively. The second consultation was conducted to ensure that Welsh stakeholders had the opportunity to comment on the insertion of the remaining transitional provisions of the amending Directive, which provide for the dates by which goods complying with the provisions of the Directive may be placed on the market, 1 July 2008 and dates from which non-compliant goods will be prohibited from manufacture or import into the European Community, 1 May 2008.

European Commission Directive 2007/19/EC was published in the Official Journal on 12 April 2008 and Member States are required under European Law to transpose and implement the provisions of this Directive by 1 May 2008. Parallel Regulations will come into force in England, Scotland and Northern Ireland on 1 May 2008. Not making the legislation in Wales to come into force on the same date may lead to accusations of compromised public health safeguards for consumers in Wales. It would also be confusing for manufacturers as different rules relating to plastics in contact with foodstuffs would apply in Wales to the rest of the UK. Therefore, to ensure consistency of enforcement across the UK and to ensure that consumers in Wales are afforded the same level of public protection from the consumption of food containing chemicals used in the manufacture of food contact materials and articles (such as substances that might be toxic, mutagenic which means that they can change the physical and chemical genetic information of an organism and cause cancer and thus to reproduction) as consumers elsewhere in the UK, it is necessary to breach the 21 day rule in order that the Regulations come into force on 1 May 2008 in Wales.

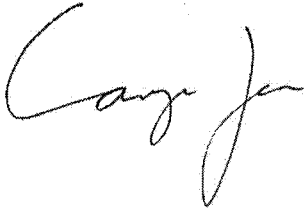
Due to the timing of the second consultation, the length and technical nature of the Regulations (the Schedule is approximately 17,000 words long and would take between 4 to

6 weeks to translate) and the need to introduce the Regulations in Wales by 1 May 2008, the Deputy Minister for Social Services has deemed that it would not be reasonably practicable for them to be made bilingually.

These Regulations have been subject to a Regulatory Impact Assessment. An Explanatory Memorandum has also been prepared, which includes the Regulatory Impact Assessment and this has been laid, together with the Regulations, in Table Office.

A copy of this letter goes Dr Dai Lloyd, Chair of the Subordinate Legislation Committee and Anna Daniel, Clerk to the Subordinate Legislation Committee.

Yours sincerely

A handwritten signature in cursive script, appearing to read 'Cange J', is written in black ink on the page.