

**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

6 March 2009

Dear Dafydd

**THE PLASTIC MATERIALS AND ARTICLES IN CONTACT WITH FOOD (WALES)  
REGULATIONS 2009**

I am writing to inform you that in order to bring The Plastic Materials and Articles in Contact with Food (Wales) Regulations 2009 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 on 4 March 2009, laid in Table Office on 6 March 2009 and will come into force on 7 March 2009.

These Regulations implement in Wales Commission Directive 2008/39 EC. This amendment is the fifth amendment to the 2002 Directive, that routinely updates the European Community list of authorised monomer substances and additives permitted for use in the manufacture of food contact plastics, and lays down the necessary conditions for their safe use. A monomer is a chemical compound, mostly organic, composed of simple molecules. The new Directive also prohibits the use of additives not on the Community list of additives used for the manufacture of plastic materials and articles. Although these Regulations are not contentious, they amend earlier legislation to extend the protection of consumers from chemicals that industry accepts are in urgent need of control.

The changes to these lists of substances are made periodically when the European Food Safety Authority (EFSA) has revised an existing opinion or issued a new one on the safe use of a substance following risk assessment. 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.

The new Directive also lays down the dates by which the list of additives that may be used in the manufacture of food contact plastics will be closed, making interim arrangements for those additives that were the subject of an application for authorisation by the deadline of December 2006; it sets a date to which additives not on the positive list may continue to be used - (until 31 December 2009). This period will enable EFSA to obtain any additional information it might need for its risk assessment of the additives in question. The Directive also prohibits the use of additives not on the Community list of additives. In addition, it

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permits the trade in and use of plastic materials and articles intended to come into contact with food and complying with the Directive 2002/72/EC, as amended, from 7 March 2009 and prohibits from 7 March 2010 the manufacture and importation into the Community of food contact plastic materials and articles that do not comply with the Directive, as amended. In effect this creates a phase-out period for substances that have either been removed from the Community list, or have not been adopted on to it. Member States are required under European Law to transpose and implement the provisions of this Directive by 7 March 2009.

Unfortunately, due to restructuring within the Agency, it did not prove possible to bring forward the twelve week public consultation exercise until late September 2008. In addition, the Welsh Assembly Government's Legal Services Department did not receive the final keyed version of the draft England SI until 4 February 2009. Therefore, because of this it has not been possible to make the Regulations through the negative procedure route, as they will not meet the coming into force date of 7 March 2009.

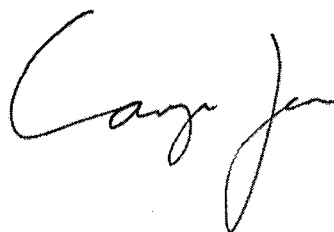
Parallel Regulations will come into force in England, Scotland and Northern Ireland on 7 March 2009. Therefore, there is a need to ensure legislative parity with the rest of the UK. Not making the legislation in Wales to come into force on the same date may lead to accusations of compromised public health 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) as consumers elsewhere in the UK, it is necessary to breach the 21 day rule in order that the Regulations come into force on 7 March 2009 in Wales.

Due to the length and complexity of the Regulations and the need to introduce them in Wales to come into force on 7 March 2009, the Deputy Minister for Social Services has deemed that it would not be reasonably practicable for them to be made bilingually within the timescale. However, a Welsh translation of the Regulations will be available in due course.

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 Janet Ryder, Chair of the Subordinate Legislation Committee and Bethan Davies, Clerk to the Subordinate Legislation Committee.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Janet Ryder', is written in a cursive style.