Explanatory Memorandum to The Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014

This Explanatory Memorandum has been prepared by the Health Improvement Division and is laid before the National Assembly for Wales in conjunction with the above subordinate legislation and in accordance with

Standing Order 27.1.

Minister's Declaration

In my view, this Explanatory Memorandum gives a fair and reasonable view of the expected impact of The Infant Formula and Follow-on Formula (Wales) (Amendment) Regulations 2014.

I am satisfied that the benefits outweigh any costs.

Mark Drakeford, Minister for Health and Social Services

22 January 2014

Description

The instrument amends the Infant Formula and Follow-on Formula (Wales) Regulations 2007 in line with, and to implement, the European Commission Directive 2013/46/EU. The new regulations will

- Authorise for the first time the use of goats' milk protein in the manufacturer of formula milks; and

- Lower the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates, to bring it in-line with that for infant formula.

Matters of special interest to the Constitutional and Legislative Affairs Committee

None

Legislative background

The powers enabling this instrument to be made are conferred by sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990 ("the 1990 Act") and section 2(2) of and paragraph 1A of Schedule 2 to the European Communities Act 1972 ("the 1972 Act").

Powers under the 1990 Act, so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by the National Assembly for Wales (Transfer of Functions) Order 1999, as read with section 40(3) of the Food Standards Act 1999, and were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to the Government of Wales Act 2006 ("GOWA 2006").

The Welsh Ministers are designated for purposes of section 2(2) of the 1972 Act in relation to measures relating to food (including drink) including the primary production of food. The relevant designation order is the European Communities (Designation No.2) Order 2005, which conferred functions on the National Assembly for Wales. Those functions were transferred to the Welsh Ministers by paragraph 30 of Schedule 11 to GOWA 2006.

Purpose & intended effect of the legislation

The Infant Formula and Follow-on Formula (Wales) Regulations 2007, implement European Directive 2006/141/EC of 22 December 2006, on infant formula and follow-on formula covering the composition, labelling and advertising of these products. The regulations make detailed provision in relation to the essential nutritional composition of formula milks, including protein.

Directive 2006/141/EC currently allows the manufacture of formula milks only from cows' milk protein and soya protein isolates, alone or in a mixture. The use of goats' milk protein as an alternative source has been subject to debate for some time.

With effect from 28 February 2014, European Directive 2013/46/EU of 28 August 2013, will amend Directive 2006/141/EC with regard to protein requirements for infant formula and follow-on formula. The 2013 Directive makes two technical changes to the compositional criteria following applications to a recent positive assessment from European Food Safety Authority (EFSA).

The new provisions are to:

- Authorise for the first time the use of goats' milk protein in the manufacture of infant formula and follow-on formula milks; and

- Lower the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates, to bring it in line with that for infant formula.

These provisions are beneficial for product innovation and will permit a wider choice of products for parents and carers of infants who choose to use formula milks. It is voluntary for businesses to reformulate or introduce new products to the market in-line with the new compositional criteria; therefore no significant costs have been identified.

Products conforming to the new compositional criteria will not be permitted to be placed on the market until the implementing measure takes effect on 28 February 2014. The proposed regulations will give effect to the relevant provisions of the Directive, and must be in place by that date.

Consultation

A public consultation on these regulations ran from 15 November 2013 to 13 December 2013. Parallel consultations were conducted by England, Scotland and Northern Ireland. The consultation was available on the Welsh Government website and officials sent copies to all interested parties including, food manufacturers, public health professionals, enforcement officers, dieticians and health professionals.

Ten consultation responses were received in Wales. Eight of these were Wales-specific, two were received by all the UK nations. Six further responses, were received for England and four further responses were received for Scotland . No further responses were received for Northern Ireland.

No objections to the draft Regulations or comments on the cost benefit analysis were received. Therefore, no amendments have been made to these Regulations as a result of the consultation.

Comments from seven respondents raised the importance of goats' milk-based formula being labelled in accordance with the law. Three respondents thought that the introduction of a new product to the market will lead to further confusion. Five respondents raised concerns that some parents/carers might be misled into thinking that goats' milk-based formula is suitable for infants diagnosed with cow's milk allergy.

Other Administrations

These Regulations apply in relation to Wales and will come into force on 28 February 2014. Separate but parallel regulations are being made in England, Scotland and Northern Ireland.

Regulatory Impact Assessment (RIA)

A Regulatory Impact Assessment has not been prepared for these Regulations because there are no identifiable costs to consumers. Costs to local authorities, Local Health Boards and businesses will be minimal. Further costs to businesses are voluntary and will be incurred only if they choose to reformulate or introduce new products to the market in line with the new compositional criteria.

These regulations will not impose any new burden on Government or enforcement officers. The proposal will have no impact on race, gender or disability equality.