POLICY NOTE

THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) AMENDMENT REGULATIONS 2014

SSI 2014/12

1. Description

The above instrument was made in exercise of the powers conferred by sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990, and all other powers enabling them to do so.

2. Policy Objective

2.1 These Regulations are necessary to meet the following policy objectives:

To amend the Infant Formula and Follow-on Formula (Scotland) Regulations 2007, in order to implement Commission Directive 2013/46/EU of 28 August 2013 amending Directive 2006/141/EC with regard to protein requirements for infant formula and follow-on formula, which takes effect from 28 February 2014.

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.

3. Policy background

3.1 Following requests from industry and positive opinions from EFSA (European Food Safety Authority), the Commission drafted a legislative proposal to make the necessary changes to EU law. These changes were agreed unanimously by Member States on 29 April 2013 and are beneficial for product innovation and will permit a wider choice of products for parents and carers who choose to use formula milks.

4. Consultation

4.1 One hundred and twenty two interested parties were consulted between 15th November 2013 to 13th December 2013 on the draft Scottish Regulations and the Business and Regulatory Impact Assessment (BRIA). This included food manufacturers, trade organisations, consumer organisations, dieticians, public health authorities, enforcement authorities, nutritional charities and the consultation was available on the FSA website.

4.2 The FSA in Scotland received six responses from stakeholders including public health authorities, nutritional charities, midwife and parenting consultant and a professional organisation representing midwives.

4.3 Two stakeholders agreed that the draft SSI enables the provisions of Directive 2013/46/EU in terms of the two compositional criteria, however both raised concerns that some parents/carers might be misled into thinking that goats' milk-based formula is suitable for infants diagnosed with cows' milk allergy. One stakeholder raised a number of concerns regarding the proposals and suggested that these had been driven by industry to increase product innovation and consumer choice and felt that this may be driven by commercial interest rather than the best interest of the consumer. The FSA envisages that the impact of the regulations is positive but limited, since the change simply represents a widening of the choices of infant formula and follow-on formula for manufacturers, retailers and consumers. Overall, no specific objections to the draft Regulation or comments on the BRIA were received.

5. Other Administrations

5.1 These Regulations apply in relation to Scotland only and will come into force on 28 February 2014. Separate but parallel legislation is being made for England, Wales and Northern Ireland.

6. Guidance

6.1 There are no immediate plans to update current guidance on these Regulations. However, current advice provided by public health authorities and health care professionals to parents and carers will need to be amended, as this advises against the use of goats' milk formula.

7. Financial Implications

7.1 A final Business and Regulatory Impact Assessment has been prepared following public consultation and no concerns were raised or comments were received on the financial estimates set out in the BRIA. The overall impact is felt to be low, although we will keep this under review.

7.2 Costs to local authorities should be minor, relating only to familiarisation with the new legislation.

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