EXPLANATORY MEMORANDUM TO

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

2014 No. 11

1. Introduction

1.1 This Explanatory Memorandum has been prepared by the Department of Health Social Services and Pubic Safety to accompany the Statutory Rule (details above) which is laid before the Northern Ireland Assembly.

1.2 The Statutory Rule (SR) is made under the powers conferred by Articles 15(1)(e), 16(1), and 47(2) of the Food Safety (Northern Ireland) Order 1991 and section 2(2) of the European Communities Act 1972 and is subject to the negative resolution procedure.

1.3 The rule is due to come into operation on 28 February 2014.

2. Purpose

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

To amend the Infant Formula and Follow-on Formula Regulations (Northern Ireland) 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. Legislative 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. Matters of special interest to the Health Committee

4.1 None.

5. Consultation

5.2 A formal public consultation on the Infant Formula and Follow-on Formula (Amendment) Regulations (Northern Ireland) 2014 was held between 15 November 2013 and 6 December 2013.

5.3 Two responses were received in Northern Ireland. The responses raised the importance of goats' milk-based formula being labelling in accordance with the law in this area. Concerns that some parents/carers might be misled into thinking that goats' milk-based formula is suitable for infants diagnosed with cows' milk allergy were also raised. No specific objections to the draft Regulations or comments on the cost benefit analysis were received.

6. Position in Great Britain

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

7. Equality Impact

7.1 There is no impact on equality of opportunity in relation to enforcement of this Statutory Rule.

8. Guidance

8.1 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.

9. Financial Implications

9.1 A cost benefit analysis was completed by colleagues in the Department of Health in England and is believed to be equally representative of the position in Northern Ireland. Overall the impact was felt to be low, although this will be kept under review.

9.2 Costs to enforcement authorities should be minor, relating only to familiarisation with the new legislation.

11. Contact

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