EXPLANATORY MEMORANDUM TO

THE INFANT FORMULA AND FOLLOW-ON FORMULA (ENGLAND) (AMENDMENT) REGULATIONS 2013

2013 No. 3243

1. This explanatory memorandum has been prepared by the Department of Health and is laid before Parliament by Command of Her Majesty.

2. Purpose of the instrument

2.1 This instrument amends the Infant Formula and Follow-on Formula (England) Regulations 2007 (as amended), in order to implement Commission Directive 2013/46/EU. This Directive amends Directive 2006/141/EC with regard to protein requirements for infant formula and follow-on formula and makes two technical changes to the compositional criteria applicable to these foods to:

- 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.

3. Matters of special interest to the Joint Committee on Statutory Instruments

3.1 None

4. Legislative Context

4.1 The overarching requirements for food for Particular Nutritional Uses (Parnuts) are laid down in Directive 2009/39/EC[1] ("the Framework Directive) that was adopted on 6 May 2009. It sets out the regulatory framework for foodstuffs the composition and preparation of which are designed to meet the particular nutritional requirements of certain vulnerable groups, including infants and young children.

4.2 Commission Directive 2006/141/EC[2] was introduced under the Framework Directive to lay down detailed rules on the essential composition, labelling and advertising of infant formula (suitable from birth) and follow-on formula (suitable from 6 months of age). This specifies which protein sources may be used in the manufacture of formula milks. Currently, the only protein sources permitted for use in these foods is that from cows' milk and soya. Following applications

[1] OJ L 124, 20.5.2009, p. 21.
[2] OJ No. L401, 30.12.2006, p. 1

from industry, and positive assessment of the safety and suitability of goats' milk protein by the European Food Safety Authority, Commission Directive 2013/46/EU[3] was adopted on 28 August 2013.

4.4 The instrument implements, in England, Directive 2013/46/EU by amending the Infant Formula and Follow-on Formula (England) Regulations 2007. The Department has used 'copy out', meaning that only the necessary changes to enable the provision of Directive 2013/46/EU have been included.

4.5 A transposition note setting out how the Government has transposed the main elements of this Directive into UK law is annexed to these explanatory notes.

5. Territorial Extent and Application

5.1 This instrument applies to England. Separate, but parallel legislation is being made in Scotland, Wales and Northern Ireland.

6. European Convention on Human Rights

6.1 As the instrument is subject to negative resolution procedure and does not amend primary legislation, no statement is required.

7. Policy background

- **What is being done and why**

7.1 The instrument amends the Infant Formula and Follow-on Formula (England) Regulations 2007 to give domestic legal effect to the amendments to Directive 2006/141/EC. Failure to do so would prevent the placing on the market of new products complying with the new compositional rules.

7.2 The technical changes to Directive 2006/141/EC, will allow greater flexibility for food business operators when developing new products. It is expected that new formula milks based on goats' milk protein will be introduced to the UK market, providing greater choice for parents and carers who wish to use an alternative to formulas based on cows' milk or soya.

- **Consolidation**

7.3 The instrument amends the Infant Formula and Follow-on Formula Regulations for the second time. The EU legislation in this area is currently under review, which will result in the adoption of new rules by 20 July 2015. This should result in consolidation by 20 July 2016.

[3] OJ No. L230, 29.08.2013, p. 16

8. Consultation outcome

Informal Public Consultation

8.1 Throughout the EU negotiations on this measure, the Department has consulted consistently with all interested parties, including industry trade bodies; enforcement authorities, consumer organisations; health bodies; other Government Departments and Devolved Adminstrations.

8.2 Responses indicated that at least one company is intending to launch a goats' milk-based formula on the UK market, and confirmed that this measure would be beneficial for product innovation and consumer choice in this sector.

8.3 A concern was raised that some parents/carers could wrongly believe that goats' milk-based formula is suitable for infants diagnosed with cows' milk allergy. Existing Government advice and educational material maintains that goats' milk is not suitable for such infants, and that parents should seek advice from their healthcare professional. In order to minimise any potential risk, the Department is also working with manufacturers and the enforcement community to ensure products are appropriately marketed.

Formal Public Consultation

8.4 The Department conducted a formal public consultation from 15th November to 6th December 2013, seeking comments on the draft statutory instrument; and the cost benefit analysis prepared by the Department.

8.5 In total 8 responses were received. No significant comments were received on the draft statutory instrument or cost benefit analysis. Five comments from individuals and health organisations did however; raise the importance of goats' milk-based formula being labelled in accordance with the existing labelling requirements of the Directive. Concerns about parents being misled about the suitability of goats' milk-based formula for infants with cows' milk allergy were also raised. Legislation prevents manufacturers from making claims about the suitability of the product for those with cows' milk allergy and it requires a statement on the label advising that the product should only be used on the advice of a healthcare professional. The Department is revising educational publications to recognise the new protein source for infant milks, which will also address advice regarding allergies.

8.6 A full summary of the comments received in response to the consultation will be published on the Department's website.

9. Guidance

9.1 As this instrument implements a minor technical change, the Department of Health will not be issuing any additional guidance on the regulations. The Department will however, be writing to all interested parties to inform them of the coming into force of the legislative changes and amending advice to consumers and healthcare professionals on the suitability of formula milks based on goats' milk protein.

10. Impact

10.1 This instrument has been confirmed as a low cost fast track measure by the Regulatory Policy Committee (RPC). A partial impact assessment has been carried out, which did not identify any cost impact in the private or voluntary sector, beyond familiarisation. The introduction of products formulated in-line with the new compositional rules would be a voluntary business decision.

11. Regulating small business

11.1 The legislation applies to small business. However, the Department has not identified any small businesses operating in this specialist sector.

11.2 Any small businesses entering the market are not exempted because the instrument does not introduce any new burden other than one-off costs involved in being aware of, and becoming familiar with, the amendments it effects to national regulations.

12. Monitoring & review

12.1 The European Commission published on 29 June 2013, Regulation (EU) 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. From 20 July 2016, this will replace the existing framework under which Directive 2006/141/EC on infant formula and follow-on formula is made. This will require the adoption of detailed rules on the composition labelling and advertising of infant formula and follow-on formula by 20 July 2015. Negotiations have commenced at EU level and will review existing provisions in this area. The Department therefore do not consider a separate statutory review necessary in this instrument.

13. Contact

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