Department of Health

Consultation

Draft Statutory Instrument – The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2014

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Draft Statutory Instrument – The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2014

A consultation

Prepared by the Health and Wellbeing Division, Department of Health

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Executive summary

This consultation document sets out our proposals to amend the Infant Formula and Follow-on Formula (England) Regulations 2007 (as amended), 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. This Directive makes two technical changes to the compositional criteria following applications to the European Commission to amend Directive 2006/141/EC. These follow positive assessment by the European Food Safety Authority. The new provisions:

- 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.

These provisions are beneficial for product innovation and will permit a wider choice of products for parents and carers 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 to business have been identified. The Directive requires member states to implement the necessary changes to national law by 28 February 2014. Due to the timescales available, there is not any scope to introduce the implementing measure any sooner. Products conforming to the new compositional criteria, will not be permitted to be placed on the market until the implementing measure enters into force.

We invite comments on these proposals and, in particular, responses to the questions set out in this document.

1. Introduction & Background

Legislative Background

1.1 Within England the Infant Formula and Follow-on Formula (England) Regulations 2007[1] (IFFoF), implement Directive 2006/141/EC of 22 December 2006, on infant formula and follow-on formula, which lays down rules on the composition, labelling and advertising of these products. This includes detailed rules on the essential nutritional composition of formula milks, including protein.

1.2 Directive 2006/141/EC currently only allows the manufacture of formula milks from protein from cows' milk 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.

1.3 Any changes to this Directive must be enacted in the UK by means of a Statutory Instrument to amend the IFFoF.

Assessment of the safety and suitability of changes to protein criteria

Goats' milk protein

1.4 In 2004[2], the European Food Safety Authority's (EFSA) Nutrition Panel on Dietetic Products, Nutrition and Allergies (NDA) issued, on request of the European Commission, a scientific opinion related to the evaluation of goat milk protein as a protein source for infant formula and follow-on formula, followed by a statement in 2005, and concluded that there was insufficient evidence to establish the suitability of goat milk as a protein source in infant formulae.

1.5 Industry submitted additional evidence to address earlier concerns, requesting a further assessment by EFSA. The NDA published its opinion on 15 March 2012[3], concluding that protein from goats' milk can be suitable as a protein source for infant and follow-on formula, provided the final product complies with the compositional criteria laid down in Directive 2006/141/EC.

Protein hydrolysates

1.6 On request from the Commission, the European Food Safety Authority delivered, on 5 October 2005[4], a scientific opinion on the safety and suitability for particular nutritional use by infants of formula based on whey protein partial hydrolysates with a protein content of at least 1.9 g/100 kcal, which was below the minimum level provided for in the Union legislation at that time. That opinion concluded that infant formula, based on

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[1] S.I. 2007/3521, as amended by S.I. 2008/2445, The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2008.

[2] http://www.efsa.europa.eu/en/efsajournal/pub/30.htm

[3] http://www.efsa.europa.eu/en/efsajournal/pub/2603.htm

[4] http://www.efsa.europa.eu/en/efsajournal/pub/280.htm

hydrolysates of whey protein derived from cows' milk with a protein content of 1.9 g/100 kcal (0.47 g/100 kJ) is safe and suitable for use as the sole source of nutrition of infants. On the basis of that opinion, Directive 2006/141/EC, authorises the marketing of infant formulae in-line with this criteria.

1.7 That opinion also concluded that, while no data on follow-on formulae based on hydrolysed whey protein with a protein content of 1.9 g/100 kcal (0.47 g/100 kJ) had been submitted, a follow-on formula with that protein formulation would also be suitable for older infants in conjunction with complementary foods.

Allergy

1.8 Cows' milk allergy is the most frequent allergy in the first years of life and there is a high risk of cross-reactivity with goats' milk protein in clinical studies. Consultation during the development of the Directive, raised concerns that goats' milk may be seen by parents and carers as a suitable alternative for infants diagnosed as allergic to cow's milk. The EFSA opinion states that there is no convincing evidence to support that the incidence of allergic reactions to goats' milk protein is lower when compared to feeding cow's milk-based formula. It would therefore be prohibited to market goats' milk-based formula milks as suitable for these infants.

1.9 Government advice remains that goats' milk-based formula is not suitable for infants diagnosed as being allergic to cow's milk. GPs will prescribe an appropriate infant formula with fully hydrolysed proteins.

Directive 2013/46/EU

1.10 Following requests from the industry and the positive EFSA opinions outlined above, the Commission drafted a legislative proposal to make the necessary changes to EU law. This received a unanimous vote in the Standing Committee on the Food Chain and Animal Health (SCFCAH), on 29 April 2013 and Directive 2013/46/EU was published in the Official Journal of the European Union (OJ) on 29 August 2013.

1.11 The amending Directive makes two technical changes to the compositional criteria. These are:

- 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.

1.12 The amending Directive requires member states to implement the necessary changes in national law by 28 February 2014. Separate, but parallel legislation will be implemented in Scotland, Wales and Northern Ireland.

2. The Draft Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2014

2.1 The draft statutory instrument (SI), which will apply to England only, makes the necessary changes to implement the provisions of Directive 2013/46/EU. The Department has used 'copy out', meaning that only the necessary changes to enable the provisions of Directive 2013/46/EU have been included. This is in-line with Government better regulation principles. A summary of how the draft SI transposes Directive 2013/46/EU is provided in Figure 1.

Figure 1. Transposition table

Directive 2013/46/EU	Draft Statutory Instrument
Article 1(1)(a) Inserts references to goats' milk	**Regulation 2(3)**
Article 1(1)(b) Inserts references to goats' milk	**Regulation 2(4)**
Article 1(2) Inserts references to goats' milk	**Regulation 2(5)&(6)**
Article 1(3) & Annex Amends annexes I, II, III and VI in accordance with the Directive	In the IFFoF the annexes to Directive 2006/141/EC are referenced (as amended from time to time), rather than reproduced, therefore these references will be automatically updated when the new provisions enter into force.

2.2 The statutory instrument will come into force on 28 February 2014. From this date businesses will be permitted to place on the market products in compliance with the new compositional standards.

Consultation Questions

I. Does the draft SI accurately enable the provisions of Directive 2013/46/EU? If not, please explain how the SI should be amended.

II. The SI is drafted using 'copy out', meaning it does not introduce any extra burden on businesses beyond that required to implement the Directive Do you agree?

3. The costs and benefits of the proposed regulations

3.1. Published alongside this consultation document is a cost benefit analysis (Annex B), which attempts to assess the extra costs and benefits of the proposed changes to the existing regulations. We welcome comments on the analysis as part of this consultation, and particularly your response to the question below.

3.2. Overall, we believe that the proposed change to the regulation would create minimal additional burdens on groups in society. The Department's cost benefit analysis has not identified any significant impacts on businesses. This sector is dominated by four major brands, the estimated cost to business is based on familiarisation of the updated measure, which is estimated to be a one off cost of less than £100 in the first year for the sector as a whole.

3.3. The changes to the compositional criteria, are at the request of the industry and it will be voluntary for businesses to amend existing product specifications or introduce new products taking advantage of the new compositional criteria. Consultation during the development of the EU Directive indicated that at least one business will be introducing goats' milk formula milks to the UK market. This new entry will be beneficial to parents and carers who wish to use an alternative to cows' milk based formula.

Consultation Questions

III. Do the assessments and assumptions on the cost and benefits of this measure appear reasonable?

Please give reasons if you do not consider this to be the case, with evidence if possible.

IV. Manufacturers of formula milks for special medical purposes also need to comply with some of the compositional requirements for formula intended for healthy infants, therefore will also need to be familiar with the revised compositional criteria. To inform the cost benefit analysis, the Department requests data on the number of businesses operating in this sector of the UK market.

4. How to respond

4.1. **Consultation on the specific questions as set out above closes on Friday 6 December 2013. Please can you contribute to the consultation by providing written comments to:**

By email: parnutnotification@dh.gsi.gov.uk

By post: Infant Formula Consultation
Nutrition Legislation Team
6th Floor South Wing
Department of Health
Wellington House
133-155 Waterloo Road
London, SE1 8UG

Any other comments

4.2. While it would be helpful for responses to focus on the questions set out in the document, we would also like to hear any other comments respondents think are relevant to the issues raised by the consultation. In particular, we would be grateful if you could provide us with any evidence, quantitative or qualitative, which you deem relevant and which we have missed in this Consultation Document and the accompanying cost benefit analysis.

5. Summary of responses

5.1. A report summarising the consultation response and the action taken by the Department will be published and available on the Departments website in due course at: www.gov.uk/dh

6. Confidentiality of information

6.1. We manage the information you provide in response to this consultation in accordance with the Department of Health's **Information Charter.**

6.2. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004).

6.3. If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public

authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the Department.

6.4. The Department will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties.

7. Comments on the consultation process

7.1. If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact: (**Please do not send consultation responses to this address**)

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Leeds LS2 7UE
Email: consultations.co-ordinator@dh.gsi.gov.uk