Department of Health

Consultation Summary of Responses

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

December 2013

Draft Statutory Instrument – The Infant Formula and Follow-on Formula (England) (Amendment) Regulations 2014
Prepared by the Health and Wellbeing Division, Department of Health
Publication of summary of responses to the consultation
Publication date: December 2013
Target audience: Industry trade bodies; enforcement authorities; consumer organisations; health bodies; other Government Departments and Devolved Administrations in Scotland, Wales and Northern Ireland.
Contact details: Infant Formula Consultation Nutrition Legislation Team 6th Floor South Wing Department of Health Wellington House 133-155 Waterloo Road London, SE1 8UG parnutnotification@dh.gsi.gov.uk

Published to gov.uk, in PDF format only.

www.gov.uk/dh

Consultation Summary of Responses

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

Prepared by the Health and Wellbeing Division, Department of Health

The Consultation

A public consultation was held between 15 November 2013 and 6 December 2013 on the Draft Infant Formula and Follow-on Formula (England) Amendment Regulations 2014, amending the Infant Formula and Follow-on Formula (England) Regulations 2007, 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.

Consultation responses

The Department received 8 responses, but no objections to the draft Regulation or comments on the cost benefit analysis; 5 responses from individuals and health organisations 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.

List of respondents

In total the Department received eight responses to the consultation from:

Baby Milk Action

British Dietetic Association

British Specialist Nutrition Association

First Steps Nutrition Trust

Healthcare Professional (1)

Individual (1)

Royal College of Midwives

Vitacare Ltd

Responses to the specific in the consultation document

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

None of the respondents disagreed that the draft SI accurately enables the provisions of Directive 2013/46/EU.

Q 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?

None of the respondents disagreed that there would be any additional burdens on businesses beyond that required to implement the Directive.

Q 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.

Only one respondent commented on this question, stating that more consideration should be given to the risk of misuse of the product, undermining breastfeeding and costs to health.

Government response

No products would be permitted on the UK market unless compliant with the provisions in Directive 2006/141/EC on the composition, labelling and advertising of infant formula and follow-on formula. These are designed to ensure the safety of these products and ensure that breastfeeding is not undermined. As with cow's milk and soya-based formula milks, the Department considers that appropriate labelling of the product and advice from healthcare professionals, should minimise any risk of misuse of the product.

Q 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.

No data was submitted by industry in response to this question.

<u>Other key points raised</u>

1. **Five responses from individuals and health organisations raised the importance of goats' milk-based formula being labelling in accordance with existing legislation on infant formula and follow-on formula.**

   Government response

   As with all infant formula and follow-on formula, it is important that any new goats' milk-based formula milks are labelled and marketed in accordance with the Directive 2006/141/EC on Infant Formula and Follow-on Formula. Failure to comply with the Directive is an offence. Local Authority Trading Standards and Environmental Health Departments work with manufacturers to ensure compliance and that consumers are not misled to the true nature of these products.

2. **Five respondents expressed concern that parents and carers may see goats' milk formula as a healthy alternative to cows' milk, and may also use it as an alternative to cows' milk formula when cows' milk protein allergy is suspected or has been diagnosed.**

Government response

It is currently not permitted for manufacturers to market goats' milk-based formula milks as suitable for infants with cows' milk allergy. Any such claim would need to be assessed and approved under European legislation on infant formula and follow-on formula.

All infant and follow-on formula are required to be labelled with a warning that they should only be used on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care. The Department is working with manufacturers and local authority enforcement officers to ensure appropriate marketing of these products.

As this Regulation will authorise the use of goats' milk-based formula for the first time, there is a need to update current advice and educational material to take account of these products. The Department, in conjunction with Public Health England and the Food Standards Agency, is currently reviewing its advice to parents/carers and healthcare professionals on the suitability of such milks, which will include clear advice on allergy. This will be informed by the responses in this consultation, including that from industry. The provision of educational materials and advice from healthcare professionals should minimise the risk of inappropriate use of goats' milk-based formula.

3. **One producer of goats' milk-based formula milks responded with information that may indicate suitability of goats' milk-based formula for some individuals only on the advice of healthcare professionals.**

Government response

This will be taken into account, alongside the other views expressed in this consultation, when the Government reviews its advice to parents/carers and healthcare professionals on the suitability of such milks, which will include clear advice on allergy.