**FOOD STANDARDS AGENCY CONSULTATION**

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

**CONSULTATION SUMMARY PAGE**

<table>
<thead>
<tr>
<th>Date consultation launched:</th>
<th>Closing date for responses:</th>
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<tr>
<td>15 November 2013</td>
<td>13 December 2013</td>
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Who will this consultation be of most interest to?
Food manufacturers producing infant formula and follow-on formula, retailers, enforcement authorities, public health authorities, other government departments, food trade associations, consumer organisations.

What is the subject of this consultation?
The proposed Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 will amend The Infant Formula and Follow-on Formula (Scotland) Regulations 2007, in order to implement Commission Directive 2013/46/EU in Scotland.
The two new provisions are:
- To enable the use of goats' milk proteins in the manufacture of formula milks;
- To lower the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates, to bring them in line with those for infant formula.

What is the purpose of this consultation?
To provide interested parties and stakeholders with the opportunity to comment on the proposed Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 and the partial Business and Regulatory Impact Assessment (BRIA).

Responses to this consultation should be sent to:
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Standards, Hygiene and Associated Regulatory Policy Branch
FOOD STANDARDS AGENCY in SCOTLAND
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Postal address:
6th Floor, St Magnus House,
25 Guild Street
Aberdeen AB11 6NJ
Email: hazel.stead@foodstandards.gsi.gov.uk

Is a Business & Regulatory Impact Assessment (BRIA) included with this consultation? Yes ☒ No ☐ See Annex A for reason.

If you would prefer to receive future FSA consultations by e-mail, or if you no longer wish to receive information on this subject please notify the named person in this consultation.
THE INFANT FORMULA AND FOLLOW-ON FORMULA (SCOTLAND) AMENDMENT
REGULATIONS 2014

DETAIL OF CONSULTATION

Introduction

1. We would welcome your comments on:
   - The proposed Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 (“the proposed Regulations”), attached as Annex C.
   - The proposed regulations are required 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.
   - Details of changes to the national legislation are discussed in paragraphs 14-17.
   - The Partial Business and Regulatory Impact Assessment (BRIA), attached as Annex B.

2. The Department of Health in England, the Welsh Government and the Food Standards Agency in Northern Ireland will be carrying out consultations on parallel but separate Regulations relating to those parts of the UK.

Background

3. The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 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.

4. 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.

5. Any changes to this Directive require to be implemented in Scotland by means of an SSI, the most appropriate vehicle is considered to be by amendment to the Infant Formula and Follow-on Formula (Scotland) Regulations 2007.

Assessment of the safety and suitability of changes to protein criteria

Goats’ milk protein

6. In 2004, 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

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1 SSI 2007 No. 549
2005, and concluded that there was insufficient evidence to establish the suitability of goat milk as a protein source in infant formulae.

7. 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 formulae, provided the final product complies with the compositional criteria laid down in Directive 2006/141/EC.

**Protein hydrolysates**

8. On request from the Commission, EFSA 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 European Union legislation at that time. That opinion concluded that infant formula, based on 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.

9. 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**

10. 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 cows’ 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 cows’ milk-based formula. It would therefore be prohibited to market goats’ milk-based formula milks as suitable for these infants.

11. Government advice remains that goats’ milk-based formula is not suitable for infants diagnosed as being allergic to cows’ milk. General Practitioners will prescribe an appropriate infant formula with fully hydrolysed proteins.

**Directive 2013/46/EU**

12. Following requests from 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 (SCoFCAH), on 29 April 2013 and Directive 2013/46/EU was published in the Official Journal of the European Union (OJ) on 29 August 2013.

13. Commission Directive 2013/46/EU 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 EFSA.

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14. The new provisions are to:

- Authorise for the first time the use of goats’ milk protein in the manufacture 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.

15. 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 businesses have been identified.

16. The Directive requires member states to implement the necessary changes into 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. Separate but parallel legislation will be implemented in England, Wales and Northern Ireland.

Proposed SSI - The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014

17. The proposed Regulations will make two key amendments to the existing 2007 regulations. We do not envisage any cost impacts for this new SSI, but would welcome comments on this aspect.

Key proposal(s):

- To enable the use of goats’ milk proteins in the manufacture of formula milks;
- To lower the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates, to bring it in line with that for infant formula

Impact on Businesses and Enforcement Authorities

18. As there are no businesses in Scotland that currently manufacture infant formula or follow-on formula, the FSA considers that the impact on both businesses and enforcement authorities (EA) of the proposed Regulations will be negligible.

Consultation Process

19. Interested parties have previously been notified of this proposed action in the FSA in Scotland’s Foods for Specific Groups Update letter of 14 October 2013.

20. A 4-week consultation is being launched to provide interested parties with the opportunity to comment on these proposals. A shortened consultation period is necessary to achieve European timescale for implementation.
Questions asked in this consultation:

Q1: Do stakeholders agree with the key proposals detailed above?

Q2: Do stakeholders have any comments on the draft SSI? Do you think that the Regulations, if enacted as drafted, would achieve the aims of the Commission Directive?

Q3: Manufacturers of formula milks for special medical purposes also need to comply with some of the compositional for formula intended for healthy infants and will need to be familiar with the revised compositional criteria. To help inform our business and regulatory impact assessment, the FSA in Scotland would like to request data on the number of businesses operating in this sector.

Q4: We invite stakeholders to comment on whether the assumptions regarding familiarisation costs are reasonable?

Q5: We invite retailers to comment on and provide evidence on familiarisation costs in relation to the key proposals.

Q6: We invite stakeholders to comment and provide evidence on any additional costs and benefits (if any) associated with the key proposals?

Business and Regulatory Impact Assessment

21. The purpose of a Business and Regulatory Impact Assessment (BRIA) is to assess and record the likely costs and benefits of the forthcoming provisions for businesses, retailers, public health authorities, consumers and enforcement bodies (see Annex B).

22. Any comments that interested parties are able to provide in relation to the proposed amendment Regulations would be gratefully received. We are particularly keen to hear from Small and Medium Enterprises (SMEs) on any likely impact and would encourage them to comment on all aspects of this proposal.

23. Please send your response by email or post using the contact details given on page 1.

24. Following the consultation, we will review the responses received and consider whether any changes are required to the proposed legislation. A summary of all comments received and the FSA’s response to each will be published on the FSA’s website within 3 months following the end of the consultation period.

Other relevant documents


26. The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 are available on the ‘legislation.gov.uk’ website at:


Responses

27. This is a **shortened 4 week consultation** and therefore responses are required by close 13 December 2013. Please state, in your response, whether you are responding as a private individual or on behalf of an organisation/company (including details of any stakeholders your organisation represents).

28. Thank you on behalf of the Food Standards Agency in Scotland for participating in this public consultation.

Yours sincerely,

Hazel Stead
Standards, Hygiene and Associated Regulatory Policy Branch
Food Standards Agency in Scotland

Enclosed

Annex A: Standard Consultation Information

Annex B: Partial Business & Regulatory Impact Assessment

Annex C: Draft SSI – The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014

Annex D: List of interested parties
Queries

1. If you have any queries relating to this consultation please contact the person named on page 1, who will be able to respond to your questions.

Publication of personal data and confidentiality of responses

2. In accordance with the FSA principle of openness, our office in St Magnus House in Aberdeen will hold a copy of the completed consultation. The FSA will also publish a summary of responses, which may include full name. Disclosure of any other personal data would be made only upon request for the full consultation response. If you do not want this information to be released, please complete and return the Publication of Personal Data form, which is on the website at http://www.food.gov.uk/multimedia/worddocs/dataprotection.doc Return of this form does not mean that we will treat your response to the consultation as confidential, just your personal data.

3. In accordance with the provisions of Freedom of Information Act 2000/Environmental Information Regulations 2004, all information contained in your response may be subject to publication or disclosure. If you consider that some of the information provided in your response should not be disclosed, you should indicate the information concerned, request that it is not disclosed and explain what harm you consider would result from disclosure. The final decision on whether the information should be withheld rests with the FSA. However, we will take into account your views when making this decision.

4. Any automatic confidentiality disclaimer generated by your IT system will not be considered as such a request unless you specifically include a request, with an explanation, in the main text of your response.

Further information

5. A list of interested parties to whom this letter is being sent appears in Annex D. Please feel free to pass this document to any other interested parties, or send us their full contact details and we will arrange for a copy to be sent to them direct.

6. Please contact us for alternative versions of the consultation documents in Braille, other languages or audiocassette.

7. Please let us know if you need paper copies of the consultation documents or of anything specified under ‘Other relevant documents’.

8. This consultation has been prepared in accordance with HM Government Code of Practice on Consultation, available at: http://www.berr.gov.uk/files/file47158.pdf The Consultation Criteria from that Code should be included in each consultation and they are listed below:

The Seven Consultation Criteria

Criterion 1 — When to consult
Formal consultation should take place at a stage when there is scope to influence the policy outcome.
Criterion 2 — Duration of consultation exercises
Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible.

Criterion 3 — Clarity of scope and impact
Consultation documents should be clear about the consultation process, what is being proposed, the scope to influence and the expected costs and benefits of the proposals.

Criterion 4 — Accessibility of consultation exercises
Consultation exercises should be designed to be accessible to, and clearly targeted at, those people the exercise is intended to reach.

Criterion 5 — The burden of consultation
Keeping the burden of consultation to a minimum is essential if consultations are to be effective and if consultees’ buy-in to the process is to be obtained.

Criterion 6 — Responsiveness of consultation exercises
Consultation responses should be analysed carefully and clear feedback should be provided to participants following the consultation.

Criterion 7 — Capacity to consult
Officials running consultations should seek guidance in how to run an effective consultation exercise and share what they have learned from the experience.

9. Criterion 2 states that Consultations should normally last for at least 12 weeks with consideration given to longer timescales where feasible and sensible. This consultation is not being held for a full 12 weeks, as the Directive requires member states to implement the necessary changes into national law by 28 February 2014.

10. The Code of Practice states that an Impact Assessment should normally be published alongside a formal consultation. Please see the Business & Regulatory Impact Assessment attached as Annex B.

11. For details about the consultation process (not about the content of this consultation) please contact: Food Standards Agency Consultation Co-ordinator, 2nd floor, Aviation House, 125 Kingsway, London, WC2B 6NH. Tel: 020 7276 8140.

Comments on the consultation process itself

12. We are interested in what you thought of this consultation and would therefore welcome your general feedback on both the consultation package and overall consultation process. If you would like to help us improve the quality of future consultations, please feel free to share your thoughts with us by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc

13. If you would like to be included on future Food Standards Agency consultations on other topics, please advise us of those subject areas that you might be specifically interested in by using the Consultation Feedback Questionnaire at http://www.food.gov.uk/multimedia/worddocs/consultfeedback.doc. The questionnaire can also be used to update us about your existing contact details.
PARTIAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

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

File No: SHARP/FSAS
Date: November 2013
Stage: Consultation
Source of intervention: EU
Type of measure: Other
Contact for enquiries: Hazel Stead
          01224 285151
          hazel.stead@foodstandards.gsi.gov.uk
1. **Title of Proposal**

1.1. The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014.

2. **Purpose and intended effect**

   **Objectives**

2.1. The purpose of these proposals is to meet the following policy objectives:


   **Background**

2.2. The Infant Formula and Follow-on Formula (Scotland) Regulations 2007 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.

2.3. 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.

   **Assessment of the safety and suitability of changes to protein criteria**

   **Goats’ milk protein**

2.4. In 2004, 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.

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

   **Protein hydrolysates**

2.6. On request from the Commission, EFSA delivered, on 5 October 2005, 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 European Union legislation at that time. That opinion concluded that

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1. SSI 2007 No. 549
ANNEX B

infant formula, based on 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.

2.7 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

2.8 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 cows’ 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 cows’ milk-based formula. It would therefore be prohibited to market goats’ milk-based formula milks as suitable for these infants.

2.9 Government advice remains that goats’ milk-based formula is not suitable for infants diagnosed as being allergic to cows’ milk. General Practitioners will prescribe an appropriate infant formula with fully hydrolysed proteins.

Directive 2013/46/EU

2.10 Following requests from 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 (SCoFCAH), on 29 April 2013 and Directive 2013/46/EU was published in the Official Journal of the European Union (OJ) on 29 August 2013.

2.11 The Commission Directive 2013/46/EU 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 EFSA.

2.12 The key proposals are to:

- Authorise for the first time the use of goats’ milk protein in the manufacture 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.

2.13 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 businesses have been identified.

Consultation Question 1

Do stakeholders agree with the key proposals above?

2.14 The Directive requires member states to implement the necessary changes into 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. Separate but parallel legislation will be implemented in England, Wales and Northern Ireland.

Rationale for Government intervention

2.15 EU directive 2006/141/EC sets out the composition, labelling and advertising of infant formula and follow on formula (formula milks) required by law, including the essential nutrients that should be used in the manufacture of these products.

2.16 Following applications from industry to the European Commission requesting a revision of the composition of infant formula and follow-on formula, a directive making number of technical amendments to EU directive 2006/141/EC were published on 29 August 2013. This will for the first time authorise the use of goats’ milk protein in the manufacture of formula milks, and lower the minimum levels of protein permitted in follow-on formula manufactured from protein hydrolysates. This follows a positive assessment by the European Food Safety Authority (EFSA). Therefore the UK government is intervening in order to implement the change to the EU directive.

2.17 Previously goats’ milk protein was not authorised for sale in the EU, as there was insufficient evidence to establish the suitability of goats’ milk as a protein source for formula milks. New evidence was provided as part of the application to the EU which the EFSA considered, resulting in the recommendation to amend the provisions in the Directive on the essential composition of formula milks.

2.18 During the development of this measure, the FSA circulated a draft amending Directive to interested parties via an interested party letter and received no objections. The measure encourages market innovation and wider consumer choice, the measure was unanimously adopted by all member states. To note, products conforming to the new compositional provisions will not be permitted on the market until changes to national rules have been made, authorising the sale of these products from 28 February 2014.

2.19 Intervention to update EU legislation is required to authorise the use of goats’ milk protein in the manufacture of formula milks and lower the minimum levels of protein permitted in follow-on formula manufactured from protein hydrolysates. This will allow any Scottish businesses who wish to enter this market compete on an equal basis with the rest of Europe in line with the Scottish Government’s productivity and participation targets and work towards realisation of Scotland’s full economic potential.

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Devolution

2.20 The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 will apply in Scotland only. Parallel legislation will be made in England, Wales and Northern Ireland.

Consultation Question 2

Do stakeholders have any comments on the draft SSI? Do you think that the Regulations, if enacted as drafted, would achieve the aims of the Commission Directive?

3. Consultation

Within Government

3.1. The FSA in Scotland has kept colleagues in Scottish Government Food and Drink Industry Division, Child and Maternal Health Division updated on the development of the draft EU proposals through regular discussions.

3.2. The Scottish Government’s Better Regulation and Industry Engagement team have been consulted during the preparation of the consultation.

Public Consultation

3.3. The FSA in Scotland is now consulting on the draft SSI on the Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 to provide for the enforcement of EU Directive 2013/46/EU which amends Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae.

Stakeholders

3.4 There has been consultation between the FSA, trade associations, Local Authorities across the UK through issue of interested party letters during development of the EU Regulations.

4. Options

4.1. The options considered are:

OPTION 1: Do nothing – do not provide for the execution and enforcement of the EU Directive on infant formula and follow-on formula.

OPTION 2: Provide for the execution and enforcement of the EU Directive and provide the legislative framework for the requirements to be enforced under EU law.

Sectors and groups affected

Businesses

4.2. Food businesses involved in the manufacturing of infant formula and follow-on formula will need to ensure that they are aware of the changes to the regulations. Currently there are four main UK brands of infant formula which account for the majority of market share: SMA (Nestle), Aptamil and Cow & Gate (Danone) and Hipp Organic (Hipp). 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. Additionally, there is an international manufacturer of goats’ milk (Nanny Care) which is likely to enter the market under this new amendment. Vitacare is the UK brand of this company.
4.3. Informal discussions with the main trade association British Specialist Nutrition Association (BSNA) who represent all the UK infant formula and follow-on formula manufacturers' has indicated that none of these businesses are located in Scotland and there are no infant formula or follow-on formula manufacturers in Scotland.

4.4. As this amendment represents a voluntary decision for business, the impact would only be applicable only if a business chose to enter the market for goats’ milk formula or modify the composition of products.

Local Authorities

4.5. Local Authorities (LA’s) are responsible for enforcement of the regulations. Table 1 below show the number of LA’s by UK country.

Table 1: Number of Local Authorities affected by UK country

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<tr>
<th></th>
<th>Scotland</th>
<th>England</th>
<th>Wales</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Number of Local Authorities</td>
<td>32</td>
<td>354</td>
<td>22</td>
<td>26</td>
<td>434</td>
</tr>
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</table>

Public Health Authorities

4.5. We have been made aware by NHS Health Scotland that there may be a cost to in amending publicity materials issued to expectant mothers which currently advise against the use of goats’ milk for infants. This material is web-based and in hard copy may need to be revised and reissued as a result of the changes to the EU Directive.

Parents and Carers of Infants

4.6. There will be a positive impact for parents and carers of infants, as manufacturers’ will be able to formulate infant formula from goats’ milk, which expands the product choice in this market. The benefit of increased choice would be particularly relevant for those consumers who are seeking alternative protein sources. It is expected that the market size of these products is likely to be low relative to other baby milk formulas with the market likely to remain predominantly focussed on cows’ milk formula. The main supplier of goats’ milk formula has detailed that the target consumer market will be mothers who make a conscious decision to use an alternative protein source or they may prefer to consume goats’ milk and want their infant to consume similar products.

Retailers

4.7. IDBR data (2010) estimates that there are 53,070 UK food and drink retailers, of which 99 per cent are micro and small sized businesses. Of the total number of retailers, over 4,800 of the businesses operate in Scotland. Retailers may wish to take advantage of these new types of formula and choose to stock these, but this may depend on demand from parents and carers who use formula milks.

Benefits

OPTION 1: Do nothing – do not implement the new Regulations on infant formula and follow-on formula

4.8. There are no benefits associated with this option. However if the UK does not implement the Regulations, it would fail to meet requirements of EU law and the commission could open infraction procedures against the UK which could result in a cost.
OPTION 2: Provide for the execution and enforcement of the EU Directive and provide the legislative framework for the requirements to be enforced under EU law.

4.9 The benefits from this option are:

- Enables manufacturers to enter the formula milk market in the UK to sell goats’ milk infant formula and allow flexibility concerning the protein content of follow-on formula
- Widens product choice to those consumers seeking alternatives to cows’ milk formulas
- Increased diversity in the market could encourage new ideas for products and drive competitors to innovate

4.10 Option 2 is the preferred option as the UK would meet EU obligations, and provides benefits to both manufacturers’, businesses and consumers.

Costs

OPTION 1: Do nothing – do not implement the new Regulations on infant formula and follow-on formula

4.11 Doing nothing would mean failing to respect the provisions of the EU directive and costs to government would be significant. Infraction fines are based on a country’s GDP and therefore would be significant for the UK. These could be from £8 million pounds upwards\(^5\), depending on a decision by the European Commission.

OPTION 2: Provide for the execution and enforcement of the EU Directive and provide the legislative framework for the requirements to be enforced under EU law.

Familiarisation Cost

UK Businesses

4.12 There would be one off familiarisation costs for UK businesses in the infant formula market in the first year of the amendment (2013/14). These manufacturers would have to familiarise themselves with the change in EU directive. These costs would be applicable even if the business did not enter the goats’ milk formula market.

4.13 It is estimated that this would take a functional manager / director 30 minutes to read and familiarise themselves with the changes. It is assumed that the new information would be distributed to the rest of the staff as part of the normal company information processes.

4.14 The average gross hourly wage cost for a functional manager is £33.51\(^6\) including on-costs. The total one off familiarisation cost is estimated to be £85 for the five manufacturers outlined in paragraph 4.2. There would be no ongoing annual costs of this nature.

4.15 In addition, manufacturers of medical infant formulas will also need to be aware of this change as they have to comply with some of the compositional standards under the directive. These familiarisation costs would be equivalent to those outlined above; 30 minutes familiarisation time at a wage rate of £33.51 per hour. To date, the FSA does not have data on the number of businesses who fall into this category; however we expect these manufacturers to represent an extremely small proportion in terms of

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\(^5\) Annual survey of Household Earnings (2012) - average hourly wage of £33.51 including on-costs of 30%
market size. The consultation will address this point and the cost benefit analysis will be updated to reflect the small impact to these businesses. It is not expected to be more than an additional £85 in the first year of the policy.\(^7\)

**Consultation Question 3**

Manufacturers of formula milks for special medical purposes also need to comply with some of the compositional for formula intended for healthy infants and will need to be familiar with the revised compositional criteria. To help inform our business and regulatory impact assessment, the FSA in Scotland would like to request data on the number of businesses operating in this sector.

**Costs to Local Authorities**

4.16 Familiarisation (One-Off Cost)

There will be a one-off cost to local authorities (LA) from reading and familiarising themselves with the new Regulations. Familiarisation costs can be quantified by multiplying the time it takes for familiarisation with the wage rate of the official carrying it out. It is our assumption that it will be the Environmental Health Officer (EHO) that is responsible for familiarisation and that it will take one EHO per LA half an hour to familiarise themselves and disseminate the information to other key staff. The median hourly wage rate of an EHO is £21.13\(^8\), which yields a total one-off cost of familiarisation of £10.57 per LA. This figure is multiplied by the number of LA’s and to provide the familiarisation cost to LA’s by UK location and is shown in Table 3.

**Table 3: Costs of Familiarisation to Local Authorities by UK country**

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<tr>
<th></th>
<th>Scotland</th>
<th>England</th>
<th>Wales</th>
<th>NI</th>
<th>UK</th>
</tr>
</thead>
<tbody>
<tr>
<td>Familiarisation Cost</td>
<td>£338.24</td>
<td>£3741.78</td>
<td>£232.54</td>
<td>£274.82</td>
<td>£4587.38</td>
</tr>
</tbody>
</table>

**Consultation Question 4**

We invite stakeholders to comment on whether the assumptions regarding familiarisation costs are reasonable.

**Costs to Retailers**

Familiarisation (One-off-Cost)

4.17 Although the requirements in the new regulation apply specifically to the composition of infant formula and follow-on formula, retailers may want to be aware of the changes in EU requirements for Infant Formula and Follow-on Formula if they choose to retail these new products. Therefore, we anticipate there may be a one-off familiarisation cost to retailers.

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\(^7\) This would be based on 5 manufacturers in the medical tourism sector.

Costs to Parents/Carers of Infants

4.18 It is expected that the Recommended Retail Price (RRP) of goats’ milk based formula would be higher than cows’ milk formula. However, the choice to purchase and thereby use goats’ milk formula will be an individual’s decision and thereby any costs and benefits will be taken voluntarily and are not quantified in this analysis.

Costs to Public Health Authorities

4.19 We have been advised by the NHS in Scotland that currently available publicity materials on Formula feeding for infants advises against the use of goats’ milk. It is envisaged there will be a cost to Public Health Authorities (NHS) in amending hard copy and web-based materials which currently advise against the use of goats’ milk for infants.

Consultation Question 5

We invite retailers to comment on and provide evidence on familiarisation costs in relation to the key proposals.

Consultation Question 6

We invite stakeholders to comment and provide evidence on any additional costs and benefits (if any) associated with the key proposals.

5. Scottish Firms Impact Test

5.1 While we do not anticipate any manufacturing companies in Scotland being affected, retailers may want to be aware of the changes in EU requirements for Infant Formula and Follow-on formula, if they choose to retail these new products. There are no Scottish Infant Formula or Follow-on Formula manufacturers to complete face-to-face discussions with and we feel it would not be proportionate to carry out face-to-face interviews with retailers who may possibly be affected due to the very minor impact on them.

Competition Assessment

5.2 There could be potential competition effects on UK manufacturers if international competitors enter the UK market. However, UK manufacturers could enter the market and compete by producing their own goats’ milk formula. Both competition effects could lead to increased product innovation and choice for consumers.

5.3 Using the Office of Fair Trading competition assessment framework, it has been established that the preferred policy option (Option 2), we assert that this policy will not limit the number or range of suppliers directly or indirectly nor will it limit the ability or reduce incentives of suppliers to compete vigorously.

Test run of business forms

5.4 Any manufacturers’ of Infant Formula and Follow-on Formula who would intend to manufacture these new products, would need to notify FSA, Welsh Government or Department of Health as appropriate under existing foods for particular nutritional uses, medical foods and infant formula procedures. No new or additional forms will be introduced by this proposal therefore no test run need to be completed.

6. **Legal Aid Impact Test**

6.1 This partial BRIA is being reviewed to ascertain whether this policy would impact upon the legal aid fund.

7. **Enforcement, sanctions and monitoring**

**Enforcement**

7.1 Enforcement of the Regulations in Scotland will be the responsibility of Local Authority Environmental Health Departments – this will be drawn from powers within the Infant Formula and Follow-on Formula (Scotland) Regulations 2007.

**Sanctions**

7.2 No changes are being proposed to the criminal sanctions or civil penalties contained in existing legislation.

**Monitoring**

7.3 The effectiveness and impact of the Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 will be monitored via feedback from stakeholders, including Enforcement Agencies, as part of the ongoing policy process.

8. **Declaration and publication**

8.1 I have read the partial Business and Regulatory Impact Assessment (BRIA) and I am satisfied that given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the options. I am satisfied that business impact will be assessed with the support of businesses in Scotland.

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Signed:
Date:

Minister’s Name, Title & Department:

Michael Matheson, Minister for Public Health.
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**Contact point**

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2014 No.

FOOD

The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014

Made - - - - ***

Laid before Parliament ***

Coming into force - - 28 February 2014

The Scottish Ministers make the following Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972(a) and sections 16(1)(e), 17(1) and 48(1) of the Food Safety Act 1990(b) and all other powers enabling them to do so.

In accordance with section 48(4A) of the Food Safety Act 1990, they have had regard to any relevant advice given by the Food Standards Agency(c).

There has been consultation as required by Article 9 of Regulation (EC) No. 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(d).

Title and commencement

1. These Regulations may be cited as the Infant Formula and Follow-on Formula (Scotland) (Amendment) Regulations 2014 and come into force on 28th February 2014.

(a) 1972 c.68. Section 2(2) was amended by paragraph 15(3) of Schedule 8 to the Scotland Act 1998 (c. 46) (“the 1998 Act”), section 27(1) of the Legislative and Regulatory Reform Act 2006 (c.51) and Part 1 of Schedule 1 to the European Union (Amendment) Act 2008 (c.7). The functions conferred on the Minister of the Crown under section 2(2), in so far as exercisable within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not transferred, and in so far as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(b) 1990 c.16. Section 1(1) and (2) (definition of “food”) was substituted by S.I. 2004/2990. Sections 16(1), 17(1) and 48(1) were amended by Schedule 5 to the Food Standards Act 1999 (c.28), (“the 1999 Act”). By virtue of section 40(2) of the 1999 Act, amendments made by Schedule 5 to that Act are to be taken as pre-commencement enactments for the purposes of the 1998 Act. The functions of the Secretary of State, in so far as within devolved competence, were transferred to the Scottish Ministers by virtue of section 53 of the 1998 Act. In so far as not transferred, and in so far as relating to food (including drink) including the primary production of food, relevant functions were transferred to the Scottish Ministers by the Scotland Act 1998 (Transfer of Functions to the Scottish Ministers etc.) Order 2005 (S.I. 2005/849).

(c) Section 48(4A) was inserted by paragraph 21 of Schedule 5 to the 1999 Act.

Amendment of the Infant Formula and Follow-on Formula (Scotland) Regulations 2007

2.—(1) The Infant Formula and Follow-on Formula (Scotland) Regulations 2007(a) are amended as follows.

(2) In regulation 2(1) (interpretation) for the definition of “the Directive” substitute the following definition—


(3) In regulation 8(2) after the words “cows’ milk proteins” insert “or goats’ milk proteins”;

(4) For regulation 9 (compositional criteria for follow-on formula) substitute the following regulation—

“Compositional criteria for follow-on formula

9.—(1) Subject to paragraph (2), follow-on formula shall comply with the compositional criteria set out in Annex II taking into account the specifications set out in [Annex VI].

(2) In the case of follow-on formula manufactured from those protein hydrolysates specified in point 2.2 of Annex II with a protein content between the minimum and 0.56g/100kJ (2.25g/100kcal)—

(a) the suitability of the follow-on formula for satisfying the nutritional requirements of normal healthy infants in conjunction with complementary feeding shall be demonstrated through appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies; and

(b) the follow-on formula shall be in accordance with the appropriate specifications set out in Annex VI.”

(5) In regulation 15 (naming of infant formula) in both paragraphs where it occurs, after “cows’ milk proteins” insert “or goats’ milk proteins”

(6) In regulation 16 (naming of follow-on formula) in both paragraphs where it occurs, after “cows’ milk proteins” insert “or goats’ milk proteins”.

Authorised to sign by the Scottish Ministers

St Andrew’s House
Edinburgh
2013

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Infant Formula and Follow-on Formula (Scotland) Regulations 2007 in order to implement Commission Directive 2013/46/EU in Scotland.

Regulation 2(3), (5) and (6) enables the use of goats’ milk proteins in the manufacture of infant formula and follow-on formula.

Regulation 2(4) lowers the minimum protein levels permitted in follow-on formula manufactured from protein hydrolysates to bring it in line with infant formula.

A Business and Regulatory Impact Assessment has been prepared and placed in the Scottish Parliament Information Centre. Copies may be obtained from the Food Standards Agency (Scotland), 6th Floor, St Magnus House, 25 Guild Street, Aberdeen, AB11 6NJ and online at www.legislation.gov.uk.
List of Interested Parties

- Halal Food Authority
- Aberdeen City Council
- Aberdeenshire Council
- Adam Smith College
- AG BARR (Finlays NMW)
- Angus Council
- Argyll & Bute Council
- Association of Public Analysts
- Ayrshire Maternity Unit
- Bickiepegs
- BMA Scotland
- British Hospitality Association
- British Specialist Nutrition Association (BSNA)
- Charles Tennant & Co Ltd
- Children In Scotland
- City of Edinburgh Council
- Comhairle Nan Eilean Siar
- Co-operative Group (CWS) Ltd
- COSLA
- Dairy UK - Scotland
- Dumfries & Galloway Council
- Dundee City Council
- East Ayrshire Council
- East Dunbartonshire Council
- East Lothian Council
- East Renfrewshire Council
- Edinburgh Community Food Initiative
- European Parliament
- Falkirk Council
- Falkirk Royal Infirmary
- Federation of Small Businesses
- Fife Council
- Food Additives & Ingredients Association
- Food Innovation Institute (F2i)
- Food Training & Consultants Company
- Glasgow Caledonian University
- Glasgow City Council
- Glasgow Metropolitan College
- Glasgow Scientific Services
- GMB Scotland
- Health & Sport Committee
- Inverclyde Council
- JWC Services Ltd.
- Mackies Of Scotland
- Midlothian Council
- Mynfield Research Services Ltd.
- Neogen Europe Ltd.
- NFU Scotland
- NHS Borders
- NHS Fife
- NHS Fife - Nutrition & Dietetic Dept.
- NHS Forth Valley
- NHS Grampian
- NHS Health Scotland
- NHS Highland
- NHS Lanarkshire
- NHS Tayside
- NHS Tayside - Directorate of Public Health
- North Ayrshire Council
- North Lanarkshire Council
- Orkney Islands Council
- Perth & Kinross Council
- Queen Margaret University College
- Regulatory Solutions
- Renfrewshire Council
- Rowett Research Services
- Royal Environmental Health Institute for Scotland (REHIS)
- Scottish Bakers
- Scottish Borders Council
- Scottish Food & Drink Federation
- Scottish Food Enforcement Liaison Committee FSSC
- Scottish Government
- Scottish Government Criminal Justice Directorate
- Scottish Grocers Federation
- Scottish Midland Co-op Society
- Shetland Islands Council
- Soil Association Scotland
- South Ayrshire Council
- Tayside Scientific Services
- TESCO
- The British Dietetic Association
- The Infant & Dietetic Foods Association Ltd
- The Moray Council
- Unite the Union
- University of Aberdeen
- University of Dundee
- Vegetarian Economy & Green Agriculture (VEGA)
- Walkers Shortbread Ltd
- West Dunbartonshire Council
- West Lothian Council