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FINAL BUSINESS AND REGULATORY IMPACT ASSESSMENT

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

File No: REGULATORY POLICY BRANCH/FSAS
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Stage: Final
Source of intervention: EU
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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 amend The Infant Formula and Follow-on Formula (Scotland) Regulations 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.

Background

- 2.2 The Infant Formula and Follow-on Formula (Scotland) Regulations 2007¹ 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 2004², following a request from the European Commission, the European Food Safety Authority's (EFSA) Nutrition Panel on Dietetic Products, Nutrition and Allergies (NDA), issued a scientific opinion related to the evaluation of goat milk protein as a protein source for infant formula and follow-on formula. This was followed by a statement in 2005 which 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 2012³, 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 2005⁴, 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

¹ SSI 2007 No. 549

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>

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.

- 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 changes 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.

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 was 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).⁵ Therefore government intervention is necessary 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 to 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.

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.

⁵ <http://www.efsa.europa.eu/en/efsajournal/pub/2603.htm>

3. Consultation

Within Government

- 3.1. The FSA in Scotland kept colleagues in Scottish Government Food and Drink Industry Division and the Child and Maternal Health Division updated on the development of the draft EU proposals and subsequent consultation on the domestic statutory instrument.
- 3.2. The Scottish Government's Better Regulation and Industry Engagement team have been consulted during the preparation of this Business and Regulatory Impact Assessment.

Stakeholders

- 3.3. The Department of Health represented the UK at EU discussions on this proposal and provided an update to interested parties, trade associations, enforcement authorities in May 2013.

Public Consultation

- 3.4. A 4 week public consultation took place in Scotland between 15 November 2013 and 13 December 2013 with similar consultations carried out by Department of Health in England, Welsh Government and FSA in Northern Ireland. There were 6 responses received in Scotland including public health authorities, Royal College of Midwives, Midwife and Parenting consultant, Dietician and two Nutritional charities. Four respondents provided substantive comments to the consultation. Two stakeholders confirmed that the regulations enabled the provisions of the Directive. Two comments received were in relation to labelling and concerns regarding potential use of goats' milk formula for infants with cows' milk allergy.
- 3.5. The consultation asked the following questions:

Question 1

Do stakeholders agree with the key proposals above?

One stakeholder raised concerns that the changes have been instigated by industry to increase innovation in product design and to increase consumer choice and suggest that this is driven by commercial interest rather than in the best interests of consumers. They also raised concerns that introduction of goats' milk protein as an ingredient will create confusing messages for parents.

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?

Two stakeholders felt that the draft SSI enables the provisions of the Directive in terms of the two compositional criteria, but it does not address labelling concerns from consumers that goats' milk protein infant formula and follow-on formula to be suitable for infants with cows' milk allergy.

Two stakeholders commented that an additional requirement on businesses in terms of labelling of formula using goats' milk is appropriate.

Question 3

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

No specific comments or information was received on this question.

Question 4

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

Two stakeholders commented that any milk available over the counter to parents should not be included in foods for special medical purposes, including any goats' milk based products.

Question 5

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

Retailers have not commented directly on familiarisation costs, and have not raised concerns about the impact of the proposed regulations.

Question 6

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

Two stakeholders commented that the parental and caregiver perceptions of goats' milk formula are unknown and that it would be beneficial for qualitative research to be undertaken in Scotland and the UK to find out more about the likelihood of these formulas being misused for cows' milk allergy treatment.

3.5 **Conclusion**

In the rest of the UK responses received from stakeholders indicated they were content with the proposed regulations. Similar comments were received to those in Scotland in regards to labelling and requests for research to be undertaken to understand the parental and caregiver perceptions of goats' milk formula.

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 (LAs) are responsible for enforcement of the regulations.

Table 1 below shows the number of LAs by UK country.

Table 1: Number of Local Authorities affected by UK country

	Scotland	England	Wales	NI	UK
Number of Local Authorities	32	354	22	26	434

Public Health Authorities

- 4.5. The FSA in Scotland is aware that NHS Health Scotland printed information for parents and carers is regularly updated for factual accuracy and amendments. A decision to remove and destroy current stock would occur only if content was deemed to be 'dangerous' i.e. can someone's health be damaged by current advice. NHS Health Scotland advise that they do not envisage that they will replace current stock as a result of the new regulations and changes in wording will occur when the publication is next due for reprint. NHS Health Scotland is currently in contact with the Maternal and Infant Nutrition Team at Department of Health to ensure consistent messages are provided across the UK.

Parents and Carers of Infants

- 4.6. The inclusion of goats' milk protein as a source of protein for infant formula and follow-on formula will expand product choice and is not intended to undermine breastfeeding. The benefits of increased choice will be a positive impact for parents and carers of infants, as manufacturers will be able to formulate infant formula from goats' milk. 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 (Interdepartmental Business Register) 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. No specific comments were received from retailers, the decision to stock infant formula and follow on formula which contains goats' milk protein is entirely a matter for individual businesses.

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 significant 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 could be significant. Infraction fines are based on a country's GDP and therefore would be significant for the UK, should action be taken. These could be from **£8 million pounds upwards**⁶, 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.

⁶ https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/6029/1829681.pdf

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**⁷ 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 market size. It is not expected to be more than an additional £85 in the first year of the policy.⁸ We did not receive any comments from this sector on this point.

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 £21.13⁸ which yields a total one off cost of familiarisation of £10.57 per LA. This figure is multiplied by the number of LAs and to provide the familiarisation cost to LAs by UK location and is shown in Table 3. Local Authorities have not raised any comments on these figures.

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

	Scotland	England	Wales	NI	UK
Familiarisation Cost	£338.24	£3741.78	£232.54	£274.82	£4587.38

⁷ Annual survey of Household Earnings (2012) - average hourly wage of £33.51 including on-costs of 30%

⁸ This would be based on 5 manufacturers in the medical tourism sector.

⁸ Wage rate obtained from Annual Survey of Hours and Earnings 2012, <http://www.ons.gov.uk/ons/publications/re-reference-tables.html?edition=tcn%3A77-280149>. Median hourly wage rate of a 'health and safety officers' was used, £16.25, plus 30% overheads, totalling £21.13.

Costs to Retailers

Familiarisation (One-off-Cost)

- 4.17 Although the requirements in the new Scottish Regulations 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.

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 Health Scotland that currently available publicity materials on Formula feeding for infants advises against the use of goats' milk. These publication materials are available as hard copy and web-based and are issued to parents and families across Scotland. This advice has been highlighted for amendment when the publication is next due for reprint.

5. Scottish Firms Impact Test

- 5.1 We found there to be no infant formula or follow-on formula manufacturers based in Scotland. 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 framework⁹, 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.

⁹ http://www.offt.gov.uk/shared_offt/reports/comp_policy/oft876.pdf

6. Legal Aid Impact Test

- 6.1 The Infant Formula and Follow-on Formula (Scotland) Amendment Regulations 2014 do not introduce new criminal sanctions or civil penalties; therefore there are no legal aid implications. This BRIA has been reviewed by the Scottish Legal Aid Board who concur that there will be no impact on the legal aid fund as a result of the Regulations.

7. Enforcement, sanctions and monitoring

Enforcement

- 7.1 Enforcement of the Regulations in Scotland will remain 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 final Business and Regulatory Impact Assessment (BRIA) and I am satisfied that (a) it represents a fair and reasonable view of the expected costs, benefits and impact of the policy, and (b) that the benefits justify the costs I am satisfied that business impact will be assessed with the support of businesses in Scotland.

Signed:

Date:

Minister's Name, Title & Department:

Michael Matheson, Minister for Public Health.

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