

Annex B – Draft Cost benefit analysis

1. Rationale for Government intervention

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.

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).¹ Therefore the UK government is intervening in order to implement the change to the EU directive.

The amendments to the directive are as follows:

- *Permit the use of goats' milk protein in the manufacture of infant formula and follow-on formula*
- *lower the minima of protein hydrolysates used in the manufacture of follow-on milk from 0.56 g/100 kj to 0.45 g/100 kj (subject to certain conditions), in line with infant formulas*

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.

During the development of this measure, the Department of Health circulated a draft amending Directive to interested parties via an informal consultation 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.

¹ <http://www.efsa.europa.eu/en/efsajournal/pub/2603.htm>

2. Policy objectives and intended effects

Following the change to EU directive 2006/141/EC, the UK is proposing to implement a statutory instrument (SI) which will permit the use of goats' milk protein in the manufacture of infant and follow on formula milk, and lower the minima of protein hydrolysates used in the manufacture of follow-on formula. This is in line with EU recommendations which will be applied in all EU member states.

This amendment would enable manufacturers to produce and sell for the first time, infant formula based on goats' milk in the UK and allow more flexibility concerning the protein content in follow-on formula.

Although the implementation of the SI is mandatory, the implementation for UK business and consumers of these product types is not mandatory, as it is an extension to what can be produced. Therefore the decision to take advantage of the changes to compositional standards and sell goats' milk formula would be voluntary made by businesses.

DH has limited details on whether and how many UK businesses would choose to enter the goats' milk formula product market as a result of this amendment.

3. Policy options considered, including alternatives to regulation

There are only two options considered below, as the UK is obligated to make the necessary changes to national law.

Option 1: Do nothing (maintain current regulations)

Under this option, manufacturers would not be permitted to introduce goats' milk formulas to the market or modify the protein content of follow-on formula in the UK.

This would be counter to the authorisation in EU law, which would expose the UK to potentially large infraction fines from the European Commission.

Costs to government of not implementing this EU directive would be significant. Infraction fines are based on a country's GDP and therefore would be significant for

the UK. These could be from **£8m upwards**², depending on a decision by the European Commission.

Option 2: Implement EU amendments to directive 2006/141/EC

This amendment would enable 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.

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. To date, DH has limited details on whether / how many UK businesses would enter the goat's milk formula product market.

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).

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. Cost Benefit Analysis

Business Impact

Costs

- Familiarisation Cost

There would be **one off** familiarisation costs for businesses in the infant formula market in the UK in the first year of the amendment (2013/14). These manufacturers would have to familiarise themselves with the change in EU directive. These costs

²https://www.gov.uk/government/uploads/system/uploads/attachment_data/file/6029/1829681.pdf

would be applicable even if the business did not enter the goat's milk formula market.

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.

The average gross hourly wage cost for a functional manager is **£33.51**³ including on-costs. **The total one off familiarisation cost is estimated to be £85** for the five manufacturers outlined in section 3. There would be no ongoing annual costs of this nature.

To note that 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 Department 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. The consultation will address this point (Question VI) 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.⁴

- Competition effects

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.

As discussed above any other costs would be voluntary taken by the businesses if they decided to enter the market to produce goats' milk formula or modify the protein content.

Benefits

- Product innovation

³ Annual survey of Household Earnings (2012) - average hourly wage of £33.51 including on-costs of 30%

⁴ This would be based on 5 manufacturers in the medical tourism sector.

If a producer decides to include the use of goats' milk in its formulae; this could provide potential benefits to business.

- This could enable a business to potentially reach additional new customer types and could represent an additional revenue stream from the new products. This would be a benefit for an individual business as the customer could be substituting a competitor's product.
- Over short term, business could find new ways of manufacturing the product and increased efficiency with a lower cost per unit. This could be passed onto consumers in terms of lower prices for goats milk formula.

Increased diversity in the market, could encourage new ideas for products and drive competitors to innovate

Consumers

Benefits

· Choice

The impact of the amendment to this EU directive enables business to formulate infant formula from goat's milk, thereby expanding the product choice for consumers in this market. 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 predominately focussed on cow's milk based formula. The main supplier of goat's milk formula has detailed that the target consumer market will be mothers who make a conscious decision to use an alternative protein source or themselves prefer goat's based milk and want their infant to consume similar products. A 2011 survey by Mintel that approximately 5% of households uses goat's milk.⁵

As outlined above, the decision for business to enter this market is voluntary and thereby any additional costs are taken on voluntarily. This is the same for consumers, the decision to purchase goats milk based infant formula is voluntary. The amendment increases choice in the market if businesses decide to produce this type of formula these products will be available to choose for consumers. The benefit of increase choice would be particularly relevant for those consumers who are seeking alternative protein sources e.g. parents/carers who purchase goats milk for themselves. This increase in choice would be likely to increase consumer surplus and utility for this group of consumers. Yet, as this is a new product to the market, there is no data on the size of the group or estimated demand.

It is expected that the RRP of goats milk based formula would be higher than cow's milk formula. However, **this choice to purchase and thereby use goat's 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.**

⁵ Mintel 2011 Survey: Dairy Drinks, Milk and Cream - UK, May 2011(Base for this question was 1,500 adults and was surveyed online.)

- Health Impacts

The impact on health has been considered as part of an EFSA testing for safety and health impacts as the panel found that protein from goat's milk could be suitable and no adverse health effects were found.

The EFSA panel found that the protein from goat's milk could be suitable as a protein for infant and follow-on formulae, provided the final product complies with the compositional criteria laid down in Directive 2006/141/EC. This was based on Australian study that did not show statistically significant or clinically relevant differences in weight, length or head circumference development between those babies fed with cow's milk and goat's milk.⁶ The panel had no data on which to base a conclusion on the safety and suitability of the follow-on formula manufactured with unmodified goat milk, however given the similarity in composition of the goat milk infant an follow-on formulae, the fact the follow-on formula fulfils the compositional criteria laid down in the Directive 2006/141/EC, the panel considered that goat milk protein is a suitable protein source for follow-on formula in older infants who receive it in addition to complementary food.⁷

Social Impacts

As this is a voluntary decision of the parents / carers to purchase and provide goats milk formulae to an infant, there are no adverse or disproportionate effects on any groups within society.

There are no proven additional health benefits of goat's milk formula compared to other products on the market. Based on current science, formula milks based on goat's milk protein do not offer any additional benefit over cow milk formulas, in terms of nutrition or health.⁸ It should be noted that goats' milk is not suitable for infants with proven cow milk allergy, purchasing decisions would therefore be based on individual's preferences and no consumer will be excluded from health benefits as a result of higher RRP of goat's milk formula.

⁶ EFSA Panel on dietetic products, nutrition and allergies (NDA) EFSA Journal 2012;10 (3):2603

⁷ ibid

⁸ ibid