

The Innovation and Regulation of Formula Milks



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It is of major concern to all public health stakeholders that breastfeeding rates in the UK remain amongst the lowest in Europe. The formula milk industry recognises that breastfeeding is best for babies, and supports the aspiration of healthcare professionals and the Department of Health to improve breastfeeding rates, including through strict adherence to relevant regulations.

Over the past year, there has been an increasing focus on the regulatory environment. In May 2016, a resolution was proposed at the World Health Assembly (WHA),¹ which called for the banning of advertising of all formulas for the first three years of life. Over the same summer, the Royal College of Paediatrics and Child Health (RCPCH) consulted its members on whether the College should receive any funding from formula milk companies. In late 2016, Alison Thewliss MP introduced a Bill to the House of Commons, *Feeding Products for Babies and Children (Advertising and Promotion)*.²

Formula milks* are amongst the most strictly regulated of all foodstuffs (Regulation EU No 2016/127;³ EU Directive 2006/141/EC⁴) and rightly so. Legislation incorporates the principles and aims of the World Health Organization (WHO) Code on Breastmilk Substitutes,⁵ and is strictly enforced. Neither BSNA nor its member companies wish the regulations to be relaxed. However, it is our view that any attempt to regulate the industry must, as a minimum, at least demonstrate a real understanding of how the industry works. It is for these reasons that BSNA and its members are developing a Code of Practice, which sets out how formula milk companies currently operate and makes a series of commitments regarding future activity and behaviour.

WHA resolution – welcomed but not endorsed

Although the recent WHA Resolution¹ was “welcomed with appreciation” by member states, it was not ‘endorsed’. Following extensive debate, member states concluded that it went too far in its proposals to prohibit contact between healthcare professionals and industry, to further restrict funding, and to consider foods given to a child up to 36 months as breastmilk substitutes.

The decision of the WHA not to endorse the Resolution has not stopped some anti-industry groups from continuing to claim or imply otherwise. Indeed, BSNA has had to write to the *Lancet* and the *British Medical Journal* (BMJ) to correct articles that falsely stated that WHA69.6 was effectively ‘endorsed’. We also wrote to Alison Thewliss MP after she repeated this claim to the House of Commons in her motion to bring her Bill.²

Both the *Lancet* and *BMJ* articles were written in response to the decision of the RCPCH membership that the College should continue to accept funding from formula milk companies, within strict pre-specified **conditions**.⁶ This decision reflected the belief of RCPCH members that, although any promotion of formula over breastfeeding would be unacceptable, there is a need for an open exchange of information between manufacturers and healthcare professionals relating to clinical research and product innovation, including formulas designed for special medical purposes. The members also recognised that a significant amount of research goes into the development of such products and that the RCPCH has a role in facilitating transparent and accountable collaborations between clinicians, researchers, and manufacturers.

Safety

The Bill put forward by Alison Thewliss MP was based on a number of serious factual errors and assumptions.

In particular, in the mistaken belief that the formula milk industry is either self-regulated or not regulated at all, it aims to establish an agency (the ‘Infant and Young Child Nutrition Agency’) to set, monitor and evaluate compositional, safety and quality standards, labelling, and nutritional claims in formula milks for babies and young children.

In fact, such an agency would duplicate those functions already available to existing official organisations under the existing law. As already mentioned, formula milks are amongst the most strictly regulated of all foods; the European Union also strictly regulates levels of any pesticides, contaminants and micro-organisms, along with packaging materials.

It is completely erroneous to suggest that formula milk is unsafe. All manufacturers are required to ensure that their food products are safe in accordance with General Food Law and standards are in many respects even tighter for formula milk, compared with foods for the general population. The nutritional content of infant formula and follow-on formula is laid down in the Regulation; this is based on the expert opinion of European Food Safety Authority (EFSA) scientists and the EU Commission. All ingredients used in formula milk must be proven safe, and undergo rigorous clinical testing.

The allegation that there is no independent verification of formula composition is also untrue. The detailed nutritional content and ingredients of formula are clearly stated on the label and additional information is made available on request to government agencies, such as the Food Standards Agency (FSA), Trading Standards and the Department of Health. New or reformulated infant formulas must be notified to the Department of Health which reviews the labelling and substantiation for any new ingredients before the products are placed on the market. The FSA works closely with local authority enforcement officers to make sure food law is applied throughout the food chain.

Regulations and innovation

As stated above, it is important to understand the nature of the regulatory framework within which formula milk companies work. Some critics of the industry, such as First Steps Nutrition Trust (FSNT) and other lobbying groups, argue that the regulations exist to dictate every ingredient that *should* be in formula.⁷ This is not the case. Instead, they cover every ingredient that *must* be included in formula. Therefore, when the authorities (such as EFSA) refer to some ingredients as being 'unnecessary', it means that a company *could* manufacture and sell a formula milk that *did not* include this ingredient. Any company wishing to place a product on the market which contains a non-mandatory ingredient must notify it to the competent authority in that country, e.g. in the UK, the Department of Health. At that stage, the authority may request substantiation for use of the ingredient.

However, throughout its various publications, FSNT instead argues that "unnecessary" is equivalent to "of no benefit".⁷ This fails to take into account the fact that the regulations are not fixed, but change to reflect our growing knowledge of infant nutrition. However,

these changes lag some time behind our scientific understanding and innovation (as might be expected).

One example is the decision to include DHA (omega-3) in the list of mandatory ingredients from February 2020.⁸ Clinical research conducted during the past 20 years or so has clearly demonstrated the benefits of DHA for non-breastfed infants. In fact, this is a clear example of where industry funding and collaboration with the healthcare profession has resulted in advancement of science and product innovation for the benefit of babies who are not ideally fed with their mother's milk.

Why companies communicate with healthcare professionals

Companies communicate with healthcare professionals primarily to share and discuss scientific developments relevant to paediatric nutrition and, when appropriate, to explain the reasons for the changes to their products; changes which are the result of a significant amount of research and considerable product innovation.

For this reason, it is incorrect to assert, as Alison Thewliss did, that any communication with healthcare professionals highlights a loophole in the regulations. On the contrary, this is a reflection of article 7.2 of the WHO Code, which specifically allows formula milk companies to communicate with healthcare professionals.

When launching a new product it is important to explain to key audiences the reasons for its development. This is particularly true in regard to formula milk, since any change to an infant's diet can cause the child to become 'unsettled'. This is likely to lead to the infant's parent raising their concern with their healthcare professional, who should be sufficiently well informed to be able to advise the parent appropriately.

Scientific and factual

UK law permits formula milk companies to advertise information "of a scientific and factual nature" to healthcare professionals.⁹

All advertising of infant formula takes place in scientific publications not directed to the general public.

This reflects the companies' belief that healthcare professionals should have access to information that is impartial and independent. While companies should seek to minimise any element of commercial bias in their communications and stick to the facts based on scientific evidence, it should also be incumbent upon non-Governmental organisations to minimise any inaccuracies and political bias in their communications too.

Supporting breastfeeding

UK companies work to almost identical regulations across the EU, where breastfeeding rates are universally higher. The reasons why UK breastfeeding rates are lower than comparator countries are numerous and complex, and it will require a multi-stakeholder approach to address these – such influencing factors may include insufficient paid maternity leave, embarrassment of or hostility to breastfeeding in public, and/or a cultural lack of history of breastfeeding. We are concerned that the continued focus on the formula milk industry perpetuates an ongoing failure to examine the many other factors that impact parents' feeding decisions.

For breastfeeding rates to rise, there needs to be universal recognition of the various reasons why parents make decisions about how they feed their infant; and it is important that parents receive the best possible support to ensure that they are able to do so effectively and safely. The formula milk industry would welcome the opportunity to work in partnership to improve UK feeding practice and create cultural and sustainable change, offering its expertise in, and understanding of, parent choices and behaviours.

About the British Specialist Nutrition Association

BSNA is the trade association representing the manufacturers of products designed to meet the particular nutritional needs of individuals; these include specialist products for infants and young children (including infant formula, follow on formula and complementary weaning foods), medical nutrition products for diagnosed disorders and medical conditions, including parenteral nutrition, and gluten-free foods. www.bsna.co.uk

References: **1.** World Health Assembly (2016). Ending inappropriate promotion of foods for infants and young children Available online: http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_R9-en.pdf?ua=1 (Mar 2017). **2.** House of Commons Hansard (2016). Feeding Products for Babies and Children (Advertising and Promotion). Available online: [https://hansard.parliament.uk/commons/2016-11-16/debates/552A05C8-5D1C-4BDB-BB2A-03C37A034DD4/FeedingProductsForBabiesAndChildren\(AdvertisingAndPromotion\)](https://hansard.parliament.uk/commons/2016-11-16/debates/552A05C8-5D1C-4BDB-BB2A-03C37A034DD4/FeedingProductsForBabiesAndChildren(AdvertisingAndPromotion)) (Mar 2017). **3.** Commission Delegated Regulation (EU) 2016/127 of 25 September 2015 supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding (Text with EEA relevance). Available online: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv%3AOJ.L_.2016.025.01.0001.01.ENG (Mar 2017). **4.** Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC Text with EEA relevance. Available online: <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141> (Mar 2017). **5.** World Health Organization (1981). International Code of Marketing of Breast-Milk Substitutes. Available online: www.who.int/nutrition/publications/infantfeeding/9241541601/en/ (Mar 2017). **6.** Modi N (2016). The RCPCH and funding from infant formula companies. BMJ Opinion. Available online: <http://blogs.bmj.com/bmj/2016/10/31/neena-modi-the-rpcc-and-funding-from-infant-formula-companies/> (Mar 2017). **7.** First Steps Nutrition Trust (2017). Costs of infant milks marketed in the UK. Available online: www.firststepsnutrition.org/pdfs/Costs_of_Infant_Milks_Marketed_in_the_UK_February2017.pdf (Mar 2017). **8.** European Commission (2015). Supplementing Regulation (EU) No 609/2013 of the European Parliament and of the Council as regards the specific compositional and information requirements for infant formula and follow-on formula and as regards requirements on information relating to infant and young child feeding. Available online: <http://ec.europa.eu/transparency/regdoc/rep/3/2015/EN/3-2015-6478-EN-F1-1.PDF> (Mar 2017). **9.** (2007). The Infant Formula and Follow-on Formula (England) Regulations 2007. Available online: www.legislation.gov.uk/uksi/2007/3521/pdfs/uksi_20073521_en.pdf (Mar 2017)