



## **Submission to the Select Committee on UK-US Trade Relations from First Steps Nutrition Trust.**

We are a small public health nutrition charity in the UK ([www.firststepsnutrition.org](http://www.firststepsnutrition.org)) and we would like to highlight potential risks to public health from any reduction in regulatory protection around foods for infants and children in the UK to accommodate US food trade. This is for consideration in relation to the terms of reference bullet point 5:

- *how any agreement should approach regulation, including regulatory harmonisation.*

**We believe that any agreement must ensure that the highest level of regulation to protect consumer health is considered, particularly when this relates to infant and young child health.**

We would like to highlight two areas that we work in where children's health is protected under current UK regulation, and where this could be compromised if a trade deal does not put in place regulatory harmonisation to protect our current regulations.

### **1. The use of azo-dye colours in food and drink that has been associated with hyperactive behaviour in children**

One of the key successes for families in the UK has been the reduction in the use of some colours linked to hyperactivity in children, and the need for a warning label on foods that contain them. In 2002 Research by the UK's Asthma & Allergy Research Centre, working on behalf of the UK government's Food Standards Agency (FSA) found that "*significant changes in children's hyperactive behaviour could be produced by the removal of colourings and additives from their diet*".<sup>1</sup> The additives tested were the artificial food colourings Tartrazine (E102), Quinoline Yellow (E104), Sunset Yellow (E110), Carmoisine (E122), Ponceau 4R (E124), Allura Red (E129) and the preservative Sodium Benzoate (E211).

The FSA commissioned further research<sup>2</sup> and the new study carried out by Southampton University, corroborated the findings of the first. The study found that there was a possible link between consumption of these additives and increased hyperactive behaviour. A voluntary ban was proposed by the FSA on the six colours included in the study, and in 2008, Ministers accepted the proposal. In the same year the European Parliament voted in favour of labelling food

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<sup>1</sup> Bateman B, Warner JO, Hutchinson E, *et al.* The effects of a double blind, placebo controlled, artificial food colourings and benzoate preservative challenge on hyperactivity in a general population sample of preschool children. [Archives of Disease in Childhood 2004;89:506-511](#)

<sup>2</sup> <https://www.food.gov.uk/science/research/chemical-safety-research/additives-research/t07040>

containing the six food colours E102, E104, E110, E122, E124 and E129 with the words ‘*may have an adverse effect on activity and attention in children*’.<sup>3</sup>

The response from manufacturers and retailers in the UK was swift and dramatic, with most foods becoming, and staying, free from these dyes. Major retailers and manufacturers replaced these artificial colours with natural ones including pumpkin, beetroot and spirulina. Whilst a few UK manufacturers have failed to change the colours they use, and choose to put the warning label on their foods and drinks, this is a minority of UK products. The most likely place to find these azo-dye additives now in foods marketed to children in the UK are in confectionery, drinks and other foods imported from the USA. It is important to note that in the USA recent evidence<sup>4</sup> has found that over 96% of confectionery items in US stores contained artificial colours, as well as many other items consumed by children, and there is no warning label on these products to alert families to potential risk.

The UK food supply chain made enormous efforts to remove these colours and apply labels to imported products in line with current regulations. It would be a backward and negative step for public health if the regulations were not harmonised to ensure we protect our children in the way we have been doing for the past 10 years. Harmonisation of food regulations in any trade deals with the US must therefore allow for the highest set of food standards, and not the lowest.

## **2. Infant formula regulations in the UK are stricter and more protective of infant health than those in the US.**

Here we highlight the main concerns about the import of US infant formula based on the current US regulatory framework to the UK market. A further explanation of some of the regulatory differences is attached in Appendix 1.

Infant formula is the sole source of nutrition for infants who are not breastfed in the first 6 months of life, and is the recommended main milk drink for non-breastfed babies alongside solid foods from 6 months to 1 year. Infant formula composition and labelling are regulated in both the UK (via EU directives) and the US, but there are some specific differences in ingredients permissible and in the labelling of these products. Essentially the precautionary principle is written in to regulation on foods for special groups.<sup>5</sup>

‘In order to ensure a high level of health protection in relation to the persons for whom the food referred to in Article 1(1) of this Regulation is intended, *the precautionary principle* as set out in Article 7 of Regulation (EC) No 178/2002 shall apply

<sup>3</sup> <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2008:354:0016:0033:en:PDF>

<sup>4</sup> Batada A, Jacobsen MF (2016) Prevalence of artificial food colors in grocery store products marketed to children. *Clinical Pediatrics* (online). DOI: 10.1177/00099228126651621. P1-7.

<sup>5</sup> <http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=celex%3A32013R0609>

The US opposes the precautionary principle and requires evidence of harm before regulating.

The most significant differences in composition and labelling of infant formula in the UK and US are summarised below:

- UK regulations specify lower and upper limits for carbohydrate in infant formula. They also require a large proportion of the carbohydrate present to be in the form of the milk sugar lactose. Sucrose and glucose are not permitted in infant formula made from cows' or goats' milk. Fructose is not permitted in any infant formula. The US regulations do not establish limits for the carbohydrate content of infant milks. Lactose is not mandatory and there are no limits on the use of sucrose and glucose. This means that sugar can be the main ingredient in US infant formula and ingredients such as corn syrup can be freely added.
- Infant formula in the US can have protein contents significantly higher than in the UK. Higher protein in infant formula is now linked to greater weight gain in childhood. The maximum protein content permissible in the UK is currently 3g/100kcal but this is being lowered in infant formula marketed in the EU to 2.5g/100kcal by 2020. The US maximum protein value is 4.5g/100kcal.
- Infant formula in the US does not have to be fortified with iron to an amount considered optimal in the UK, but the maximum amount permitted is much higher than allowed in the UK.
- There are fewer restrictions on the fats that can be used and trans fats are not restricted.
- Far fewer vitamins and minerals have 'upper levels' specified in US regulations.
- US formula can have ingredients not permitted in the UK such as carrageenan gum.
- There is no requirement to protect breastfeeding on infant formula labels in the US by making a statement about the superiority of breastfeeding, or restricting idealising images or words that suggest products are close to breastmilk. Health claims are regulated for Infant formula in the UK and no health claims will be allowed by 2020. US formula can make statements that compare artificial milks to breastmilk, make health claims and use images that idealise the products,. In the US infant formula can be marketed for 'newborns' despite all infant formula suitable in the first year having to meet the same compositional guidelines by law.



- In the US formula can be labelled as having non GMO ingredients, but there is no requirement to label that they have GMO ingredients. In the UK foods with GMO ingredients must be labelled as such.
- Infant formula imported from the US may well have been made from milk from cows where recombinant bovine somatotropin (rBST), a synthetic growth hormone, has been used, and this would not be identifiable on labels.

We believe that infants in the UK are currently better protected by UK regulations on the composition and labelling of infant formula, and these regulations should be strengthened, not weakened, by any trade deals. Childhood obesity is a matter of great concern to the UK Government and we are sure ministers would not wish to put the current and future health of UK infants at risk by allowing any degradation of standards in products for this our most vulnerable population group.

We would be more than happy to discuss any of these points further, and hope this submission will be of value to the Select Committee when considering the importance of high food standards for infants and young children in any future trade negotiations.

Dr Helen Crawley. 16.11.2017

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## **Appendix 1.**

### **Background Information: How do regulations for infant formula differ in the UK and US?**

Under UK law, foods intended specifically for infants and young children are considered as foods for specific groups and their safety, suitability and conditions of use are clearly defined in commission directives. A new directive encompassing all Foods for Special Groups EC609/2013 came into force in 2016, however the specific detail on composition, labelling and marketing of infant formula is held in a delegated act which accompanies this directive, and this does not come into force until 2020. Products currently marketed in the UK therefore comply with the previous EU Commission Directive 2006/141/EC on infant formula and follow-on formula and amending Directive 1999/21/EC.



In the US the laws governing food are found in the Federal Food, Drug and Cosmetics Act (FFDCA). Subchapter 9 of the Act deals with food. Additional requirements found in section 412 of the FFDCA apply to infant formula. The food laws are given effect by the Food and Drug Administrations' (FDAs') implementing regulations in title 21 of the Code of Federal Regulations parts 106 and 107 (21 CFR 106 and 107).

### **Nutritional Adequacy**

Under both UK and US legislation there are regulations specifying the nutritional composition infant products must comply with. Whilst UK and US regulations on the composition of infant formula cover the same macronutrients, vitamins and minerals, there are some fundamental differences

### **Energy**

US regulations do not establish limits for the total energy content of infant milks. EU regulations require that infant and follow-on formula milks provide between 60 and 70 kcal/100ml (250-295kJ/100ml).

### **Carbohydrates**

UK regulations specify lower and upper limits for carbohydrate in infant formula. They also require a large proportion of the carbohydrate present to be in the form of the milk sugar lactose. Sucrose and glucose are not permitted in infant formula made from cows' or goats' milk. Fructose is not permitted in any infant formula.

The US regulations do not establish limits for the carbohydrate content of infant milks. Lactose is not mandatory and there are no limits on the use of sucrose and glucose. This means that sugar can be the main ingredient in some US infant formula and ingredients such as corn syrup (glucose syrup) can be added.

### **Protein**

UK and US regulations specify the same minimum protein content for infant formula of 1.8g/100kcal. However, the US upper limit for protein of 4.5g/100kcal exceeds the UK upper limit of 3.0g/100kcal for infant formula. The new EC delegated regulation EU 2016/2017 is set to widen that gap further as it reduces the upper limit for protein in European infant and follow-on formula to 2.5g/100kcal. There has been considerable discussion in the last few years about the role of lower protein formula in managing later weight gain in formula-fed infants (Weber et al, 2014) and the protein content of most formula milks in the EU is currently at the lower end of EU regulations.



In the UK breast milk is used as the reference protein by which other protein sources are measured and cows' milk, goats' milk and soya protein are named as the only permissible protein sources for infant milks. Under US legislation, casein (the dominant protein in cows' milk) is used as the reference protein.

### **Fats**

The maximum amount of fat permitted in infant formula in the UK and US are the same but infant formula in the US can contain slightly less fat than UK formula. UK regulations also exert greater control on the types of fatty acids permitted in infant milks as they require both linoleic acid and  $\alpha$ -linolenic acid to be present where the US regulations require only linoleic acid to be present. The UK regulations impose further restrictions on fatty acids in infant formula milks including restrictions on trans fatty acids, erucic acid, lauric and myristic acids and phospholipids.

### **Docosahexaenoic acid**

Both the UK and US regulations currently permit the addition of DHA to infant formula as an 'optional' ingredient, however, under the new EC Delegated regulation 2016/127 the addition of DHA will become mandatory in all infant formula in the EU and claims of a health benefit for this ingredient will then be disallowed.

**Choline and Inositol** are required in infant formula in the UK, but must only be present in infant milks in the US which are non-milk based.

### **Minerals and Vitamins**

Under UK and US regulations minimum permissible concentrations of the same 12 minerals and 13 vitamins have been established for infant formula. The main difference between UK and US regulations is that under UK regulations maximum permissible concentrations for all 13 vitamins and 12 minerals been established whilst under US regulations, these have been established for vitamins A and D only and for 6 out of 12 minerals. The minimum requirements for minerals in infant formula in the UK are generally lower than the levels required in the US, with the notable exceptions of iron and iodine.

### **Iron and Iodine**

The permissible range of concentrations of iron and iodine in infant formula in the US are significantly wider than in the UK with lower minimum and higher maximum levels permitted than under UK legislation. Under the new EU regulations in the delegated act to come into force in 2020 (EU2016/127) the difference in permissible iodine levels will become more pronounced as the range for iodine in the EU narrows with a higher minimum limit and a lower maximum limit.



US regulations permit a minimum concentration of iron in infant formula that is half of that required for infant formula in the UK.

### **Differences in ingredients permitted in Infant formula in the US and the UK**

The regulatory differences between the US and UK have resulted in some clear differences in the ingredients used in infant formula.

**Sugars** is one area where there are clear differences in what is permissible between US and UK legislation. In the UK at least 4.5g/100kcal of a possible maximum of 14g/100kcal of carbohydrate in cows' milk and goats' milk based formula must be sourced from the milk sugar lactose. In the US, there are no such limits on the use of sugar and glucose and lactose is not mandatory. It is therefore highly possible that there are infant formula milks in the US where all of the carbohydrate is provided by sucrose, maltodextrins, corn syrup solids, rice syrup and/or other sugars. Infant formula provides roughly 40% energy from sugars. This means that a baby who is consuming a formula that contains no lactose will be consuming 40% of their energy as, for example, maltodextrins and sucrose.

**Carrageenan** is another ingredient which is not permitted in infant milk in the UK but is considered 'Generally Regarded As Safe' (GRAS) in infant formula in the US. It is not widely used but one major brand includes it in their organic RTF infant formula. The use of carrageenan has been controversial with some studies associating it with intestinal inflammation. Since 2007 the joint FAO-WHO expert committee on food additives (JECFA) has advised against its use in all infant formula, however, the results of a 2014 JECFA<sup>6</sup> review has concluded that the use of carrageenan in infant formula at concentrations up to 1000mg/litre is not of concern. This conclusion has not as yet been reflected in EU legislation.

### **Genetically Modified Organisms (GMOs)**

The US is the world's leading producer of genetically modified crops (GM) and there is no comprehensive federal legislation specifically addressing GMOs. GMOs are regulated under the general statutory authority of environment, health and safety laws. The US approach to regulating

GMOs is based on the assumption that regulation should focus on the nature of the products, rather than the process in which they were produced. There is therefore no regulatory requirement to label foods produced from GM organisms or containing GM ingredients. In a 1992 policy statement the FDA said that foods derived from GM plants would be presumptively GRAS, however where GMO products differed significantly in structure, function, or composition from

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<sup>6</sup> <http://www.who.int/foodsafety/publications/Summary79.pdf?ua=1>



substances currently found in food, pre-market approval as a food additive would be required (The Law Library of Congress, 2015).

### **Recombinant Bovine Growth Hormones (rBGH)**

Recombinant bovine somatotropin (rBST) is a synthetic growth hormone used in dairy cows to increase milk yield. Milk from cows treated with rBGH contains higher levels of the hormone insulin-like growth factor (IGF-1), which has been linked to cancer and the development of insulin-dependent diabetes mellitus in infants fed on milk containing rBGHs. The use of growth hormones is widespread in the US but is banned in the EU (1999/879/EC).

The FDA and EU policy makers have both reviewed the same evidence in respect of rBGH and have adopted different positions. The FDA position is that the consumption by infants and children of milk and edible products from rBGH treated cows is safe.

### **Antibiotics in Organic Dairy Farming**

Under EU legislation, antibiotics are permitted for use in animals used for organic food production where alternatives are inappropriate, whereas in the US antibiotics are not permitted in animals used for organic food production. Under existing organic equivalence arrangements between the EU and US, the EU recognizes the USDA National Organic Program (NOP) as equivalent to the EU Organic Programme. In order for EU products produced and handled under the EU Organic Program to be marketed as “organic” in the United States using the USDA organic logo, antibiotics must not have been administered to animals.

### **Differences arising from labelling requirements for infant formula**

Infant formula are subject to the labelling requirements of the national food legislation with additional requirements in the infant formula regulations. In the EU the European Food Information to Consumers regulations 1169/2011 (FIC) covers labelling for foods for the wider population. In the US Standard food labelling requirements are found in 21 CFR, part 101.

The information that must be displayed on food product labels is broadly similar in the EU and US. All food products must be labelled with the name of the food, the amount of the product, manufacturer details, ingredients, presence of allergens, best before/use by dates and nutritional information. In addition infant formula must carry information pertaining to the preparation and suitability of the product, warn against the hazards of improper use and indicate that the products should only be used with the advice of a healthcare professional.

US infant formula are available in concentrated liquid format which is not a format currently available in the EU. US labelling regulations therefore require an additional set of details for the safe preparation of liquid formula milks. There is a real potential for improper use of concentrated



infant formula should they be placed on the EU market as parents in the UK are not familiar with this format of milk and may not realise that concentrated infant milks differ from RTF formula milks

In the US infant formula is marketed for infants at different ages despite the regulations for all infant formula being the same. For example, infant formula is marketed for newborns (0-3 months) in the US suggesting these are specially tailored for this early period. This would not be permitted in the EU where all infant formula must state that it is suitable from birth when infants are not breastfed.

### **Protecting breastfeeding**

The EU has enacted legislation implementing some of the provisions of the WHO Code and under EU legislation some specific provisions are made to protect breastfeeding that are not made under US regulations. Infant formula labels in the EU must carry a statement concerning the superiority of breast feeding and must be designed to provide the necessary information about the appropriate use of the products without discouraging breastfeeding.

Idealising images such as pictures of infants are not allowed, and the label must not use terms such as 'humanised', 'maternalised', 'adapted', or similar suggesting the product is close in composition to breastmilk. There are also strict restrictions on any health claims that can be made. In contrast in the US a variety of health claims are made on infant formula packaging and idealising images are common.

### **How are consumers protected from unsubstantiated claims on infant and follow-on formula milks?**

The EU Commission Directive 2006/141/EC disallows health claims on infant formula (with the exception of a specific controlled claim related to protein allergenicity). The permissible nutrition claims relate to the presence (or not) of lactose, and to the presence of DHA, taurine, fructo and galacto-oligosaccharides and nucleotides, but their use is limited to certain conditions being met and no health claims can be made. The new commission delegated regulation EU 2016/127 which comes into effect in 2020 prohibits all nutrition and health claims on infant milks.

Under US regulations claims should not be made on infant formula milk labelling however, as is the case with many other areas of the US legislation, there are exemptions and exceptions. The regulations surrounding the conditions under which nutrient content, structure/function and health claims may be made are complex. In practice infant formula packaging in the US contain a wide range of nutrient and health claims that would not be permitted in the EU.



## References

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<https://www.loc.gov/law/help/restrictions-on-gmos/usa.php>

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