

How does legislation on infant formula composition and labelling differ in the UK and US?

Summary

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. The most significant differences relate to:

- Sugar can be the main ingredient in US infant formula and sucrose, glucose syrups and other sugars can be added to infant formula based on animal milks, with no requirement for a minimum lactose content. Lactose is the sugar found in animal milk and most infant formula in the UK have this as the predominant source of sugar.
- 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. US formula must specify if they are, or are not, iron fortified.
- 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. US formula can be marketed for 'newborns' despite all infant formula suitable in the first year having to meet the same compositional guidelines by law.
- There are a large numbers of nutrition and health claims made on infant formula labels in the US which are not permitted in the UK.
- 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.

What is infant formula?

When infants are not breastfed, infant formula will be the sole source of nutrition during the first 6 months of life. For non-breastfed babies infant formula is also recommended alongside solids as the main milk drink throughout the first year. The nutritional adequacy and safety of infant milks are regulated everywhere in the world, but how different can infant formula be under US and UK regulations? In this paper we compare standards for infant formula, but it is important to remember that a range of other breastmilk substitutes are marketed globally for infants and young children and these may also vary in composition.

How do the UK and US differ in principles to protect citizens from risk?

UK regulation is currently based on EU directives. In the EU the 'precautionary principle' (explained in article 191 in the Lisbon treaty on the functioning of the European Union) seeks proactively to regulate risks, particularly where the potential risks are not completely known. In the EU you don't have to prove harm if there is not sufficient data to evaluate risk fully.

The US opposes the precautionary principle and requires evidence of harm before regulating. However, in reality there are some areas where the EU is more precautionary than the US and others where the US is more precautionary than the EU (Wiener and Rogers 2002) and the precautionary principle needs to be supported by good regulation.

How do the UK and the US build the WHO Code of Marketing of Breastmilk Substitutes (the WHO Code) into regulation?

In the UK, the WHO Code has been considered in both the current and new regulations, and in the new delegated acts that come into force in 2020 greater consideration will be given to protecting families from inappropriate labelling and marketing of infant milks. The UK regulations do not bring the full Code and subsequent relevant WHA resolutions into law, so there remain loopholes which allow products to be marketed. Currently UK legislation does not allow direct marketing of infant formula to families, but does allow the marketing of follow on formula, and there are specific rules relating to infant formula labelling. More detail of these differences will be given later.

The US does not bring any aspects of the WHO Code into legislation. This may in part explain why follow on formula is not a regulated product in the US since there has been no need to market a product for infants that can be advertised since infant formula can be freely marketed.

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).

How do the regulations define infant formula?

One of the fundamental differences between the regulations covering infant milks in the US and UK is the definition of infant formula. The Federal Food, Drug, and Cosmetic Act (FFDCA) defines infant formula as "a food which purports to be or is represented for special dietary use solely as a food for infants by reason of its simulation of human milk or its suitability as a complete or partial substitute for human milk" (FFDCA 201(z)).

FDA regulations define infants as persons not more than 12 months old (Title 21, Code of Federal Regulations 21 CFR 105.3(e)).

The EU regulations on which UK regulation is based give the following definitions: (a) 'infants' means children under the age of 12 months; (c) 'infant formulae' means foodstuffs intended for particular nutritional use by infants during the first months of life and satisfying by themselves the nutritional requirements of such infants until the introduction of appropriate complementary feeding.

d) 'follow-on formulae' means foodstuffs intended for particular nutritional use by infants when appropriate complementary feeding is introduced and constituting the principal liquid element in a progressively diversified diet of such infants

Infant formula in the US describes all infant milks marketed for infants in the first year of life, whilst the EU differentiate between infant formula (suitable for the first year of life) and follow-on formula (only suitable after 6 months of age). The term follow-on formula is not recognised under US legislation. It is agreed by all health departments in the UK (NHS Choices, 2017) and the WHO (WHO, 2013) that follow on formula is not a necessary product.

This paper will focus on infant formula in the two regulatory systems.

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. Table 1 shows the compositional requirements for infant formula in the UK and US. Table 2 in Appendix 1 shows nutrient differences required in mandatory nutrition labelling in both the US and the UK. In the UK we provide information per 100ml of infant formula, in the US they provide information per 100kcal of milk (approximately 150ml).

Table 1: Macro and micronutrient requirements for infant formula in the UK and US.

	Infant Formula UK		Infant Formula US	
	Min/100ml	Max/100ml	Min/100ml	Max/100ml
Energy kJ	250	295		
kcal	60	70	N/S	N/S
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Protein g	1.8	3.0	1.8	4.5
Carbohydrate g	9.0	14.0	N/S	N/S
of which lactose g	4.5	N/S	N/S	N/S
Fat g	4.4	6.0	3.3 (30% e)	6.0 (54% e)
Linoleic acid mg	300	1200	300mg (2.7% calories)	N/S
Linolenic acid mg	50	N/S	N/S	N/S
Prebiotic fibre g	N/S	0.8 ¹	N/S	N/S
VITAMINS				
Vitamin A µg-RE	60	180	250 IU (75 µg-RE)	750 IU (225 µg- RE)
Vitamin C mg	10	30	8.0	N/S
Vitamin E mg	0.5 ²	5.0	0.7(IU) (with at least 0.7IU/gm linoleic acid)	N/S
Vitamin D µg	1.0	2.5	40 (IU) (1µg)	100 (IU) (2.5µg)
Vitamin K µg	4	25	4d	N/S
Thiamin (B₁) µg	60	300	40	N/S
Riboflavin (B₂) µg	80	400	60	N/S
Niacin µg	300	1500	250	N/S
Vitamin B₆ µg	35	175	35	N/S
Vitamin B₁₂ µg	0.1	0.5	0.15	N/S
Folic acid µg	10	50	4.0	N/S
Biotin µg	1.5	7.5	1.5e	N/S
Pantothenic acid µg	400	2000	300	N/S
MINERALS				
Calcium mg	50	140	60f	N/S
Chloride mg	50	160	55	150
Copper µg	35	100	60	N/S
Fluoride µg	N/S	100	N/S	N/S
Iodine µg	10	50	5.0	75
Iron³ mg	0.3	1.3	0.15	3.0
Magnesium mg	5.0	15	6.0	N/S
Manganese µg	1.0	100	5.0	N/S
Phosphorus³ mg	25	90	30f	N/S
Potassium mg	60	160	80	200
Selenium µg	1.0	9.0	2.0	7.0g
Sodium mg	20	60	20	60
Zinc mg	0.5	1.5	0.5	N/S
Choline mg	7	50	7.0e	N/S
Taurine mg	N/S	12	N/S	N/S
Nucleotides mg	N/S	5.0	N/S	N/S
Inositol mg	4.0	40	4.0e	N/S
L-carnitine mg	1.2 ⁴	N/S	N/S	N/S

N/S = not specified

Footnotes UK columns

¹ Fructo-oligosaccharides and galacto-oligosaccharides (prebiotic fibre) may be added to infant formula. In that case their content shall not exceed 0.8g/100ml in a combination of 90% oligogalactosyl-lactose and 10% high molecular weight oligofructosyl-saccharose.

- 2 Vitamin E: 0.5mg/g of polyunsaturated fatty acids expressed as linoleic acid as corrected for the double bonds but in no case less than 0.5mg per 100kcal, maximum 5.0mg/100kcal.
- 3 For products manufactured from soya protein isolates or in a mixture with cows' milk, minimum and maximum values for iron for infant formula are 0.45mg and 2.0mg respectively and for follow-on formula 0.9mg and 2.5mg respectively. For phosphorus, minimum and maximum values for both infant and follow-on formula are 30mg and 100mg respectively.
- 4 The L-carnitine concentration is only specified for formula containing protein hydrolysates or soya protein isolates.

Footnotes US columns

d - Any vitamin K added shall be in the form of phylloquinone

e -required to be included in this amount only in formulas which are not milk-based

f - calcium to phosphorus ratio must be no less than 1.1 nor more than 2.0

g - established by FDA Final Rule effective from 22/06/2016 at: <https://www.federalregister.gov/documents/2015/06/23/2015-15394/infant-formula-the-addition-of-minimum-and-maximum-levels-of-selenium-to-infant-formula-and-related>

In addition for the US regs:

Any vitamin K added shall be in the form of phylloquinone.

Vitamin B6 shall be present at a level of at least 15 micrograms of vitamin B6 for each gram of protein in excess of 1.8 grams of protein per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container.

The ratio of calcium to phosphorus in infant formula in the form prepared for consumption as directed on the container shall be no less than 1.1 and not more than 2.0.

Protein shall be present in an amount not to exceed 4.5 grams per 100 kilocalories regardless of quality, and not less than 1.8 grams per 100 kilocalories of infant formula in the form prepared for consumption as directed on the container when its biological quality is equivalent to or better than that of casein. If the biological quality of the protein is less than that of casein, the minimum amount of protein shall be increased proportionately to compensate for its lower biological quality. For example, an infant formula containing protein with a biological quality of 75 percent of casein shall contain at least 2.4 grams of protein (1.8/0.75). No protein with a biological quality less than 70 percent of casein shall be used.

Sources:

Infant Formula and Follow-on Formula (England) Regulations 2007

Code of Federal Regulations Title 21 Chapter 1, Subchapter B, Part 107 Infant Formula at:
<https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=107&showFR=1>

The main differences between the UK and US compositional regulations are:

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. It is unclear from the regulations whether high fructose corn syrup could be added to infant formula, but a recent paper looking at the sugars content of a range of US infant formula did not detect fructose in 20 common brands analysed (Walker & Goran, 2015).

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. The regulations do not name specific permissible protein sources but stipulate only that the protein used is at least of a biological quality 70% of that of casein.

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 α -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. US labelling laws do however, require infant formula labels to declare that they are "**Infant Formula with Iron**" if they contain more than 1mg/100kcal iron or a statement to the effect that "**Additional Iron May Be Necessary**" if they contain less than 1mg/100kcal iron in the reconstituted product. There is no distinction in the EU for infant formula with and without iron, all products must contain a minimum amount.

Table 1: Iron and Iodine requirements for infant and follow-on formula in the UK and Infant Formula in the US

	Infant Formula UK		Infant Formula US	
	Min/100kcal	Max/100kcal	Min/100kcal	Max/100kcal
Iron¹ mg	0.3	1.3	0.15	3.0
Iodine	10 (15 ²)	50 (29 ²)	5.0	75
Linolenic acid mg	50	N/S	N/S	N/S

¹For products manufactured from soya protein isolates or in a mixture with cows' milk, minimum and maximum values for iron for infant formula are 0.45mg and 2.0mg respectively

²New values for this mineral when delegated acts within the EU Directive for Foods for Specific Groups come into force in 2020.

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. An example of an infant formula milk which is permitted in the US but would not be permitted in the UK is shown below:



Ingredients Similac For Spit-Up

Corn Syrup, Modified Rice Starch, Milk Protein Isolate, High Oleic Safflower Oil, **Sugar**, Soy Oil, Coconut Oil, Galactooligosaccharides. Less than 2% of: C. Cohnii Oil, M. Alpina Oil, Beta-Carotene, Lutein, Lycopene, Calcium Phosphate, Potassium Citrate, Potassium Chloride, Potassium Phosphate, Calcium Carbonate, Magnesium Chloride, Ascorbic Acid, Choline Chloride, L-Cystine Dihydrochloride, Ascorbyl Palmitate, Salt, Ferrous Sulfate, Choline Bitartrate, Taurine, m-Inositol, Mixed Tocopherols, Zinc Sulfate, L-Carnitine, Niacinamide, d-Alpha-Tocopheryl Acetate, Calcium Pantothenate, Vitamin A Palmitate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Riboflavin, Pyridoxine Hydrochloride, Folic Acid, Potassium Iodide, Phylloquinone, Biotin, Sodium Selenate, Vitamin D3, Cyanocobalamin, Potassium Hydroxide, and Nucleotides

(Adenosine 5'-Monophosphate, Cytidine 5'-Monophosphate, Disodium Guanosine 5'-Monophosphate, Disodium Uridine 5'-Monophosphate).

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 JECFA¹ 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.

Ingredients:

Water, Organic Nonfat Milk, Organic Maltodextrin, Organic Sugar, Organic High Oleic Sunflower Oil, Organic Soy Oil, Organic Coconut Oil; Less than 0.5% of: C. Cohnii Oil, M. Alpina Oil, Beta-Carotene, Lutein, Lycopene, Fructooligosaccharides, Potassium Citrate, Calcium Carbonate, Ascorbic Acid, Organic Soy Lecithin, **Carrageenan**, Magnesium Chloride, Salt, Ferrous Sulfate, Choline Chloride, Choline Bitartrate, Taurine, m-Inositol, d-Alpha-Tocopheryl Acetate, L-Carnitine, Zinc Sulfate, Niacinamide, Calcium Pantothenate, Riboflavin, Vitamin A Palmitate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Pyridoxine Hydrochloride, Folic Acid, Manganese Sulfate, Phylloquinone, Biotin, Potassium Iodide, Sodium Selenate, Vitamin D3, Cyanocobalamin, Potassium Hydroxide and Nucleotides (Adenosine 5'-Monophosphate, Cytidine 5'-Monophosphate, Disodium Guanosine 5'-Monophosphate, Disodium Uridine 5'-Monophosphate).



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

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

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

The use of GMOs in food in the EU is more controversial. Compared to the US the EU imposes strict regulations on GM foods. Maize is the only crop that has been approved for cultivation in the EU and some member states have adopted safeguarding clauses to prohibit cultivation on their territory. A further 58 GM crops have been approved for sale and consumption in the EU, they include maize, cotton, soybean, oilseed rape and sugar beet. Most genetically modified soya and maize entering the EU is used as animal feed. Under EU regulations, GM ingredients or ingredients made from cows fed on GM feed are permitted in non-organic infant milks in the UK, however the EU regulations require foods containing or consisting of GMOs or containing ingredients produced from GMOs to indicate this on the label. Products produced with GM technology or products from animals fed on GM feed do not have to be labelled and GM labelling is not required for products containing 0.9% or less GM ingredients.



Some manufacturers choose to use non-GM ingredients as a marketing tool, voluntarily labelling their products as non-GMO. Some EU countries have introduced schemes where products can be labelled as 'GM-free' or 'without GM'. However, the rules of these schemes tolerate some GM materials (low level accidental presence, use of certain GM additives etc). The UK has not introduced any scheme to indicate the absence of GM.

In the UK, a lack of EU regulation would mean that unlabelled products containing GM could conceivably enter the UK market.

This situation may make products labelled as non-GMO more attractive to UK parents. Nestlé make some of their Gerber Good Start products in the US without GM ingredients. The company say that their decision not to use GM ingredients in products was based on parental feedback. They also state that their infant formula products labelled as non-GMO meet with their 'internal definition' which is consistent with the definitions of the European Union and the state of Vermont, the only U.S. state with GMO legislation. It is however, not clear whether or not the micronutrients in these products are derived from genetically engineered materials.

Bisphenol A (BPA)

BPA is a synthetic compound found in many plastics, as well as in the lining of canned food containers. Its use is controversial as the available evidence suggests that it can bind to oestrogen receptors and influence growth and other processes including cell repair, foetal development and reproduction. It may also have the ability to interact with other hormone receptors, such as thyroid hormone receptors, thereby altering their function (Diamanti-Kandarakis et al, 2009).

The use of BPA in the manufacture of baby bottles has been banned in the US and EU for a number of years, however, there are now concerns over its use in packaging materials used to line food containers as small amounts can migrate into the contents. In the US the FDA state that based on their ongoing safety review of scientific evidence, the available information '*continues to support the safety of BPA for the currently approved uses in food containers and packaging currently allowed*' (FDA, 2014). It has however, amended its food regulations to no longer provide for the use of certain BPA-based materials in baby bottles, sippy cups and infant formula packaging. This action was taken in response to a food additive petition from industry demonstrating that its use had been permanently and completely abandoned by industry.

In the EU commission regulation EU No. 10/2011 on plastic materials and articles intended to come into contact with food limits, but does not prohibit, the migration of BPA from packaging materials coming into contact with infant formula. Updated draft legislation is set to prohibit any migration of BPA from food contact materials into infant formula, effectively banning its use.

The current status is therefore that BPA is not a permitted substance under US legislation but in the EU some infant formula may contain BPA from packaging materials, but future regulations are likely to change this.

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).

A report by the FAO/WHO Joint Committee on Food Additives evaluating the evidence for residues of veterinary drugs concluded that the available evidence suggests that the milk from rBST treated cows would not pose an additional risk for the development of diabetes and the carcinogenicity risk of rBSTs themselves was considered negligible (JECFA, 2013).

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.

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm>

There are currently no trade barriers to prevent milk products from cows injected with rBST in the US from entering the European Union, therefore, no trade barriers exist to milk products from US dairy cattle treated with rBST. When the UK leaves the EU, infant formula made from milk from cows treated with rBST may therefore become increasingly available on the UK market.

Organic infant formula

Differences between organic regulations in the US and EU mean that some US infant formula contain substances that are not present in organic infant formula in the EU. The regulations around organic

products in the EU and US appear to be similar in that they both specify that in order for a processed food to be labelled as organic at least 95% of its ingredients of agricultural origin must be organic. Non-organic substances may be added where specific compositional criteria must be met and organic alternatives are not available.

Under EU regulations non-organic substances that are considered optional may not be added to infant formula whereas US regulations prohibit the addition of non-organic ingredients to organic foods **unless they have been reviewed and approved by the National Organic Standards Board (NOSB)**, a federal advisory committee under the United States Department of Agriculture. The NOSB have recommended that the following ingredients are not added to organic infant formula: L-carnitine, lycopene, lutein, taurine, nucleotides, ascorbyl palmitate, beta-carotene, DHA and ARA extracted using hexane.

The FDA have, as yet, not adopted or implemented these recommendations from the NOSB and so they will continue to be added to some organic infant formula in the US until the FDA create a rule that may be enforced.

DHA and ARA extracted using hexane can also be found legitimately in organic infant formula in the EU where they are included as the 5% of non-organic products of agriculture permitted in products labelled as organic. Under the new EU directive DHA will become a compulsory ingredient in infant formula in the EU.

Contains milk ingredients.



Organic Nonfat Milk, Organic Maltodextrin, Organic Sugar, Organic High Oleic Sunflower Oil, Organic Soy Oil, Organic Coconut Oil. Less than 2% of: C. **Cohnii Oil, M. Alpina Oil**, Beta-Carotene, Lutein, Lycopene, Fructooligosaccharides, Potassium Citrate, Calcium Carbonate, Ascorbic Acid, Ascorbyl Palmitate, Ferrous Sulfate, Salt, Choline Chloride, Choline Bitartrate, Taurine, m-Inositol, Magnesium Chloride, Zinc Sulfate, Mixed Tocopherols, d-Alpha-Tocopheryl Acetate, Niacinamide, Calcium Pantothenate, L-Carnitine, Vitamin A Palmitate, Cupric Sulfate, Thiamine Chloride Hydrochloride, Riboflavin, Pyridoxine Hydrochloride, Folic Acid, Manganese Sulfate, Phylloquinone, Biotin, Sodium Selenate, Vitamin D3, Cyanocobalamin, Potassium Iodide, Potassium Hydroxide, and Nucleotides (Cytidine 5'-Monophosphate,

Disodium Guanosine 5'-Monophosphate, Disodium Uridine 5'-Monophosphate, Adenosine 5'-Monophosphate).

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 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.



Similac Pro-advance (manufactured by Abbott) claims the ‘human milk oligosaccharides’ it contains offer immune support.

No health claims are permitted in the EU for the use of oligosaccharides in infant formula and they are deemed unnecessary ingredients by the European Food Safety Authority with no proven benefit for supporting the immune system.

Gerber Good Start (manufactured by Nestlé) has an image of a baby on the packaging and makes claims such as

‘inspired by breastmilk’,
‘immune support’
‘comfort proteins advantage’



Enfamil Enspire (Manufactured by Mead Johnson) claims to Be

‘our closest to breast milk’
and makes claims for
‘cognitive function’ and the ‘immune system’

Parent's Choice infant formula (made by Wyeth and sold in Walmart)

Has a picture of a teddy bear with a bottle on the label and makes numerous claims for ingredients and health benefits including that the formula is 'neuro complete' offering social, motor and cognitive benefits.



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 but allows for 'statements' related to lactose and DHA only, provided that certain conditions are met.

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. A critical assessment of US policies and practices in respect of the regulation of health claims suggests that the FDA seldom question manufacturer's claims regarding nutrient content, issuing warning letters where products are considered to be in violation of the Food, Drugs and Cosmetics Act (Kent, 2014). 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.

The FDA has permitted the use of a very qualified health claim in respect of the relationship between the consumption of 100% whey-protein partially hydrolyzed infant formula and a reduced risk of atopic dermatitis, if conditions are met, This means a statement reporting that the evidence for any benefit is weak, little evidence is available or the relationship between using this formula and eczema development is uncertain. Unlike the EU position, the FDA have not affirmed that the addition of DHA to infant formula is beneficial and it has not authorized the manufacturers to make claims regarding their benefits, but many labels highlight DHA content.

In September 2016 the FDA produced a draft guidance document for manufacturers to outline the quality of evidence required before claims can be made on infant formula. Final guidance has not yet been issued.

How is the safety of new ingredients added to infant formula regulated?

Under both EU and US legislation the basic composition of infant formula is strictly defined and provision is also made for the addition of some specified optional ingredients, for example, taurine and fructo and galacto-oligosaccharides, however, under both sets of regulations there is plenty of scope for manufacturers to add substances not covered by the specific requirements of the regulations. The EU and US regulators have developed different approaches to evaluate the safety and suitability of new ingredients.

EU regulations allow for the addition of new ingredients in infant formula provided that their suitability for particular use by infants from birth had been established by generally accepted scientific data. Suitability and safety must be demonstrated through systematic review of the available data relating to expected benefits as well as safety and if necessary, appropriate studies. This work must be performed following expert guidance on the design and conduct of these studies. In the EU several expert committees have published such guidance.

Under US regulations ingredients or 'substances' can legitimately be added to foods including infant formula as either a food additive, a listed exception, or as a GRAS substance. GRAS substances are those which are "generally recognised among qualified experts, as having been adequately shown to be safe under the conditions of its intended use". Only the food additives route requires premarket approval by the FDA therefore most additional ingredients are added to infant formula following the GRAS route. The GRAS process allows companies rather than the FDA to determine whether a substance meets the definition of GRAS or not.

The FDA state that achieving GRAS status requires the same quantity and quality of scientific evidence as is required to obtain approval of the substance as a food additive and that:

"achieving GRAS status through scientific procedures is based upon the application of generally available and accepted scientific data, information, or methods, which ordinarily are published, as well as the application of scientific principles, and may be corroborated by the application of unpublished scientific data, information, or methods." There are however no definitions of what is meant by "Qualified experts", what "adequately shown", "safe" or "intended use" means.

Notification

When placing a new infant formula on the market, manufacturers must 'notify the competent authority' in the case of EU regulations or notify the FDA in the case of US regulations. The US notification procedure requires manufacturers to provide a much more rigorous account of their products than is required by manufacturers in the EU who must forward only a model of the label. Under both EU and US regulations manufacturers should also be ready to produce the required evidence for safety and suitability, however, the competent authorities in EU member states and the FDA are not obligated to ask for, review, or approve this evidence and pre market approval is not implied.

Appendix 1

Table 2 compares the nutrients that must be declared under EU and US legislation. **Red** denotes nutrients missing from either set of regulations, **blue** denotes differences in units between the regulations and **green** denotes conditional inclusion. For the US data only, the order and units of expression are mandatory.

Table 2 : Mandatory nutrient information for labelling purposes:

EU 2006/141/EC	US CFR Title 21 Part 107 Subpart B
Per 100ml*	Per 100kcal,
Energy kcal &kJ	Fl. oz
Protein g	Protein g
Fat g	Fat g
Carbohydrate g	Carbohydrate g
	Water g
	Linoleic acid mg
Vitamin A µg-RE	Vitamin A IU
Vitamin D µg	Vitamin D IU
Thiamin (B ₁) µg	Vitamin E IU
Riboflavin (B ₂) µg	Vitamin K µg
Niacin µg	Thiamin (B ₁) µg
Pantothenic acid µg	Riboflavin (B ₂) µg
Vitamin B ₆ µg	Vitamin B ₆ µg
Biotin µg	Vitamin B ₁₂ µg
Folic acid µg	Niacin µg
Vitamin B ₁₂ µg	Folic acid (Folacin) µg
Vitamin C mg	Pantothenic acid µg
Vitamin K µg	Biotin µg¹
Vitamin E mg α-TE	Vitamin C (Ascorbic acid) mg
Sodium mg	Choline mg¹
Potassium mg	Inositol mg¹
Chloride mg	Calcium mg
Calcium mg	Phosphorus mg
Phosphorus mg	Magnesium mg
Magnesium mg	Iron mg
Iron mg	Zinc mg
Zinc mg	Manganese µg
Copper µg	Copper µg
Iodine µg	Iodine µg
Selenium µg	Selenium µg
Manganese µg	Sodium mg
Fluoride µg	Potassium mg
Choline mg	Chloride mg
Inositol mg	
L-carnitine mg	

¹. Biotin, choline and inositol content shall be declared except when they are not added to milk-based infant formulas (these substances are required only for non-milk based formulas.)

Appendix 3

US and UK/EU legislation referred to in the text

US legislation

Nutrient Content Claims - General Principles (21 CFR.101.13)
Health Claims - General Requirements (21 CFR.101.13)
Infant Formula Quality Control Procedures (21 CFR.106),
Records and Reports Regulations (21 CFR.106.100),
Infant Formula Labelling Requirements (21 CFR. 107.10–107.30),
Exempt Infant Formulas (21 CFR. 107.50),
Nutrient Requirements for Infant Formulas (21 CFR. 107.100),
Infant Formula Recall Requirements (21 CFR. 107.200–107.280).

Petitioned substances for consideration by NOSB for inclusion in organic foods can be found here:

<https://www.ams.usda.gov/rules-regulations/organic/national-list/b>

US Regulation on Bisphenol A

<https://www.fda.gov/newsevents/publichealthfocus/ucm064437.htm#regulations>
Update on Bisphenol A (BPA) for Use in Food Contact Applications
January 2010; March 30, 2012; Updated March 2013; July 2014; November 2014

Lists of different food additives and their regulatory status can be found here:

<https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/IngredientsAdditivesGRASPackaging/ucm082463.htm>

It includes a list of substances prohibited from use in human food.

FDA conclusion on the safety and use of rBST can be found here:

<https://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm130321.htm>

FDA draft guidance on health claims September 2016

<https://www.fda.gov/downloads/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/UCM514642.pdf>

US-EU Organic Equivalency Arrangement

<http://www.usda-eu.org/trade-with-the-eu/trade-agreements/us-eu-organic-arrangement/>

EU legislation

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
<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32016R0127>



Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae and amending Directive 1999/21/EC 20

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0141>

COMMISSION DIRECTIVE 2006/125/EC of 5 December 2006 on processed cereal-based foods and baby foods for infants and young children

<http://eur-lex.europa.eu/legal-content/EN/ALL/?uri=CELEX%3A32006L0125>

European Food Information to Consumers Regulation No.1169/2011 (FIC) Available at:

https://ec.europa.eu/food/safety/labelling_nutrition/labelling_legislation_en

EU Register of nutrition and health claims made on foods Available at:

http://ec.europa.eu/food/safety/labelling_nutrition/claims/register/public/?event=register.home

Council Regulation (EC) No 834/2007 of 28 June 2007 on organic production and labelling of organic products and repealing Regulation (EEC) No 2092/91 available here:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32007R0834&from=EN>

REGULATION (EC) No 1829/2003 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 22 September 2003 on genetically modified food and feed, available here:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32003R1829&qid=1509372387120&from=EN>

Commission Regulation (EU) No 10/2011 of 14 January 2011 on plastic materials and articles intended to come into contact with food Text with EEA relevance available here:

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32011R0010&from=EN>

may be replaced by:

'The migration into or onto food of 2,2-bis(4-hydroxyphenyl)propane ('BPA') (CAS No 0000080-05-7) from varnishes or coatings applied to materials and articles shall not exceed a specific migration limit of 0,05 mg of BPA per kg of food (mg/kg).

2.By derogation from paragraph 1, no migration of BPA shall be permitted from varnishes or coatings applied to materials and articles specifically intended to come into contact with infant formula, follow-on formula, processed cereal-based food, baby food or food for special medical purposes developed to satisfy the nutritional requirements of infants and young children, as referred to in Regulation (EU) No 609/2013. '

COMMISSION REGULATION (EU) .../... on the use of bisphenol A in varnishes and coatings intended to come into contact with food and amending Regulation (EU) No 10/2011 as regards the use of that substance in plastic food contact materials available at:

[http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509366145604&uri=PI_COM:Ares\(2017\)4140854](http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1509366145604&uri=PI_COM:Ares(2017)4140854)

1999/879/EC: Council Decision of 17 December 1999 concerning the placing on the market and administration of bovine somatotrophin (BST) and repealing Decision 90/218/EEC available here:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:31999D0879:EN:HTML>

EU Regulation on livestock

https://ec.europa.eu/agriculture/organic/eu-policy/eu-rules-on-production/livestock_en

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