



BFLG-UK draft submission to Department of Health and Social Care (DHSC) Open consultation on Nutrition and health claims on food: proposed legislative reforms

Submission closing date: 31 October 2023 (submitted on 31 October 2023).

<https://www.gov.uk/government/consultations/nutrition-and-health-claims-on-food-proposed-legislative-reforms/nutrition-and-health-claims-on-food-proposed-legislative-reforms>

Consultation description/summary:

The government is proposing to assimilate the majority of the NLCS REUL, while reforming nutrition and health claims enforcement in England and removing redundant tertiary legislation from the statute book. This consultation sets out the proposed changes in relation to NLCS REUL.

The government wants to ensure that consumers can have confidence in the food they buy, and any health benefits promoted on the label. The nutrition and health claims regulations ensure that claims made about a food or drink are accurate and not misleading so that consumers can make informed choices to meet their lifestyle and nutritional needs.

The reform proposals contained within this consultation are largely technical in nature, and are not related to the healthfulness of foods and drinks that feature nutrition and health claims. The government is proposing changes in relation to nutrition labelling, composition and standards (NLCS) retained EU law.

The proposals discussed in this consultation would:

- reform the nutrition and health claims enforcement procedure in England by introducing an improvement notices regime
- remove redundant tertiary legislation from the statute book (by revoking 60 Commission Regulations (tertiary legislation) which approved or rejected health claims)

The government is determined to realise the benefits of EU exit by ensuring that smarter regulation supports the UK's ambitions of creating the best regulated economy in the world, and stimulating economic growth, innovation and job creation.

The government wants to ensure that consumers can have confidence in the food they buy, and any health benefits promoted on the label. The nutrition and health claims regulations ensure that claims made about a food or drink are accurate and not misleading so that consumers can make informed choices to meet their lifestyle and nutritional needs. These regulations ensure that nutrition and health claims have been scientifically assessed and supported by evidence.

Although the consultation is being conducted by the UK government, the proposals for revocation would, if taken forward, be implemented via a Great Britain-wide statutory instrument (SI) which would be subject to the consent of ministers in Scotland and Wales.

Proposal 1

It is a criminal offence to use an unauthorised nutrition or health claim - for example, one that is not included in the legislation. However, the current enforcement procedure does not align with other food labelling enforcement which is less bureaucratic, more proportionate, and largely welcomed by businesses and enforcement agencies alike.

An improvement notice regime enables a consistent and low-resource enforcement approach to labelling offences.

Do you agree or disagree to the introduction of an improvement notice regime for nutrition and health claims as an additional step for enforcement authorities in England?

- Agree
- Disagree
- Don't know

Please explain your answer.

We would like to start our submission by saying that this consultation could be highly misleading if read by someone not familiar with the legislation. For example, the introduction to the consultation states that the legislation is designed to ensure that claims made about a food or drink are accurate and not misleading so that consumers can make informed choices to meet their lifestyle and nutritional needs.

While this statement could only be true for those foods and drinks that are covered by the regulations, it is now out-dated. The assumption that health and nutrition claims could be an appropriate way to inform the public about products needs to be reassessed and the health claims regulations revised, simplified and strengthened to take into account the evidence and growing consensus that health, nutrition or any promotional claims for a vast range of ultra-processed products are not only inappropriate, but essentially misleading. Indeed, the BFLG-UK is of the view that ideally there should be no claims on commercially produced foods and drinks marketed for infants and young children (6-36 months) (1) and that rather, the public would be better served by warnings for these products and has maintained this position for many years. We also hold the strong view that commercial formulas for pregnant and nursing women should not carry health, nutrition, or other promotional claims.

(1. In line with WHA Resolution 63.23 and Codex Guidelines for use of Nutrition and Health claims (CAC/GL 23-1997) that states: *Nutrition and health claims shall not be permitted for foods for infants and young children except where specifically provided for in relevant Codex standards or national legislation.*)

The introduction also portrays that the regulations ensure that nutrition and health claims have been scientifically assessed and supported by evidence. We have seen no evidence that this is true. In our experience, the legislation is poorly enforced and there is no mechanism to enforce the legal requirement that formula advertisements to health care professionals be scientific and factual.

We accept that the proposal to introduce improvement notices is considered by many as a more proportionate and feasible step in the enforcement for labelling offences however, we have not as yet seen evidence that this will result in greater efficiency in how reports of labelling offences are managed. We would support a mechanism that would reduce the burden on enforcement agencies (i.e., Trading Standards), only if it results in increased compliance with the nutrition and health claims regulations.

We support the response that is being submitted from the Obesity Health Alliance (OHA). If current enforcement in England, whereby breaches are punishable by a criminal prosecution (fine or imprisonment), is not acting as a deterrent to potential law-breakers, we agree that the system needs improvement. It is our understanding that the current policy is not adequately acting as a deterrent because

reported offences are not carried through to prosecution, due to time pressures on the enforcement officers, and the costly and burdensome court proceedings. Improvement Notices should have deadlines, must lead to criminal prosecutions, and must be public.

As we say above, we would like to see the evidence that the use of improvement notices have indeed provided sufficient incentives for business to make appropriate changes in order to comply with regulations. Our understanding, in the example of the implementation and enforcement of legislation regulating the marketing of infant and follow-on formula, (where an enforcement notice regime has been in place for some time) is that a report of non-compliance is first dealt with informally. When we have tried to find out what improvement notices had been issued for reports of non-compliance – with the infant and follow-on formula laws, we could not find any. We do not believe that improvement notice regimes are a consistent and low-resource method of enforcement, unless they are appropriately used.

We are uncertain whether the current lack of compliance is due to lack of clarity and limitations of the current policy, a lack of enforcement staff to follow up on potential offences, or a lack of human, financial and legal resource. The lack of legal support is available to enforcement staff to take offences through to legal proceedings, let alone prosecution and issues within the Trading Standards Services workforce are not included in the Impact Assessment, and so we are unsure where the root of the issues lies.

We worry that the regulation changes are stated solely to ‘benefit businesses and enforcement agencies’. Legislation should be to the benefit of the public. The fact that benefit to the public is not included in the Impact Assessment illustrates the urgent need to revise the impact assessment. E.g., Our prior understanding was that if there is a case where the offence could pose a risk to health, there should be a mechanism where an enforcement officer could still progress immediately to prosecution. In line with its many public commitments, the UK should also widen the scope of impact assessments following a One Health Approach.

Do you agree or disagree with allowing a 3 month notice period to bring in improvement notices?

- Agree
- Disagree
- Don't know

Please explain your answer.

If improvement notices are being brought in, 3 months seems a reasonable period of adjustment. We also agree that the changes should come into force a maximum of 3 months from when the Statutory Instrument is made This gives industry and trading standards time to prepare.

Proposal 2

Revoking redundant tertiary legislation would allow us to tidy up the UK NLCS statute book, making it simpler to navigate.

Do you agree or disagree with removing redundant tertiary legislation relating to the authorisation of health claims?

- Agree
- Disagree
- Don't know

Please explain your answer.

We agree that the UK NLCS statute book should be easier for enforcement officers to use. We also support getting rid of unnecessary tertiary legislation. We note that revoking this legislation has no legal impact as the legislation either rejected claims or the authorised claims are retained in the annex to Commission Regulation EU (No) 432/2012.

A simple way to improve, simplify and speed up the system further, as regards to food and drink products marketed for infants and young children 6-36 months is to completely outlaw claims.

However, WHO recommendations and global guidance in the form of Codex and WHA resolution 63.23 state "... nutrition and health claims shall not be permitted for foods for infants and young children, except where specifically provided for, in relevant Codex Alimentarius standards or national legislation..."

WHA resolution 63.23: https://apps.who.int/gb/ebwha/pdf_files/WHA63/A63_R23-en.pdf

One way of complying with this would be that if a product were to pass a suitable profiling assessment, such as using the Nutrient and Promotion Profile Model (WHO Europe, 2022).

WHO Europe. 2022. Nutrient and promotion profile model: supporting appropriate promotion of food products for infants and young children 6–36 months in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2022. <https://www.who.int/europe/publications/i/item/WHO-EURO-2022-6681-46447-67287>

Impacts and benefits

As these proposals either maintain existing standards or streamline enforcement processes, it is proposed that no new burdens for businesses would be created.

Through these reforms we believe that we will achieve the right balance between safeguarding the public health needs of consumers and the burden on industry through robust and proportionate regulation.

Do you agree or disagree with the impacts that have been identified as resulting from proposals set out within this consultation?

- Agree
- Disagree
- Don't know

Please explain your answer.

We note no new burdens for businesses would be created from the proposals set out within this consultation. The only cost impact appears to be related to familiarisation of business and enforcement authorities. This would be the total wage costs, on a per business or per local authority basis, for the time needed for an employee and manager or director within the company to read and understand how the changes will affect business and the enforcement regime.

Are you aware of any impacts that have not been identified in this consultation?

- Agree
- Disagree
- Don't know

Please explain your answer.

The systemic lack of resources for enforcement officers, together with an increase in enforcement duties, may cause further compliance issues. If an improvement notice regime facilitates a consistent and low-resource enforcement approach to labelling offences, that will result in increased compliance with the regulations, we will support this approach. However, there is insufficient evidence provided in the consultation to be able to state this with certainty.

Do you agree or disagree with the benefits these proposals would have which are referred to in the consultation?

- Agree
- Disagree
- Don't know

Please explain your answer.

Our previous exploration of enforcement of compliance with legislation for labelling infant and follow-on formulas has found that there is very little formal reporting of cases of suspected non-compliance to Trading Standards. In the absence of systematic monitoring of compliance, enforcement is non-functional, regardless of how the mechanism is meant to work in theory. Part of the reason for this could be that the burden of submitting a complaint lies with the complainant and it is therefore time-consuming and resource-intensive. The matter is one of a lack of systematic monitoring of compliance by authorities. It should not be down to the public, civil society or non-governmental organisations (NGOs) to raise formal complaints when observed. Evidence of systematic poor compliance with labelling requirements for infant formula and follow on formula raises a serious question about functionality of the enforcement system. We feel that simpler legislation could aid compliance.

The BFLG-UK and its members would like to see a much more systematic and transparent approach to monitoring compliance (meaning systematic process of assessing compliance over time, as distinct from investigation of one-off complaints):

- All inspections to be logged
- Type of company should be reported e.g., primary producers, manufacturer and packers, importers/exporters, distributors and packers, retailers and restaurants/caterers
- Outcomes of investigations (including where no further action has been taken) to be reported
- For the reporting to be transparent, published on e.g., the Food Standard Agency website

It seems that there is a framework for the application, assessment, and decision-making regarding the approval of nutrition and health claims, which are required to be based on scientific evidence and may only be used if they have first been approved by a UK appropriate authority following relevant risk assessment and risk management.

We would like the framework to include a requirement for a product to pass following a nutrition profiling assessment, such as using the Nutrient Profile Model. Although as stated above, a simpler and safer strategy would be to completely prohibit any claims on foods and drinks marketed for infants and young children (6-36 months). The BFLG-UK position is that ideally there should be no health, nutrition or other claims on commercial milk formula/breast-milk substitutes, foods or drinks marketed for infants and young children 6-36 months, supplements for infants and young children or formulas for pregnant or lactating women. Application of the WHO Europe (2022) nutrient and promotion profile model would be a practical means of dealing with the issue of inappropriate claims on foods and drinks marketed for infants and young children 6–36 months.

WHO Europe. 2022b. Nutrient and promotion profile model: supporting appropriate promotion of food products for infants and young children 6–36 months in the WHO European Region. Copenhagen: WHO Regional Office for Europe; 2022. <https://www.who.int/europe/publications/i/item/WHO-EURO-2022-6681-46447-67287>

If it is important to this government that nutrition and health claims used are accurate, and consumers are not misled by marketing statements that make foods appear healthier or more nutritionally beneficial than they are, we would like to see a further consultation on the use of nutrition and health claims on foods deemed to be less healthy.

What classifies as a health or nutrition claim

DHSC Guidance Notes to assist with interpretation of the UK nutrition laws states the following about nutrition and health claims for infant formula (DHSC, 2022) which is relevant to all foods/drinks:

Article 8 of the Commission Delegated Regulation states: Nutrition and health claims are prohibited on infant formula.

The following definitions, which are set out in Regulation (EC) No 1924/2006 on nutrition and health claims made on foods, apply for the purposes of the Commission Delegated Regulation:

‘Claim’ means any message or representation, which is not mandatory under any enactment, including pictorial, graphic or symbolic representation, in any form, which states, suggests or implies that a food has particular characteristics.

‘Nutrition claim’ means any claim which states, suggests or implies that a food has particular beneficial nutritional properties due to:

- (a) the energy (calorific value) it:
 - Provides
 - provides at a reduced or increased rate, or
 - does not provide

And/or:

- (b) the nutrients or other substances it:
 - Contains
 - contains in reduced or increased proportions, or
 - does not contain

‘Health claim’ means any claim that states, suggests or implies that a relationship exists between a food category, a food or one of its constituents and health.

‘Reduction of disease risk claim’ means any health claim that states, suggests or implies that the consumption of a food category, a food or one of its constituents significantly reduces a risk factor in the development of a human disease.

Currently, the legislation on processed cereal-based foods and baby foods for infants and young children (Commission Directive 2006/125/EC) provides the following provision on claims, which is inadequate: ‘(23) Whilst claims not specifically prohibited may generally be made for the products in question in conformity with the rules applicable for all foodstuffs, such claims should, where appropriate, take into account the compositional criteria specified in this Directive.’

There are certain foods that have specific composition and labelling requirements. These include:

- infant formula and follow-on formula (IF and FOF)
- commercial baby and toddler foods and drinks marketed for use from 6 to 36 months
- foods for special medical purposes (FSMP) (for the dietary management of disease, disorder or medical conditions), including infant milks marketed as FSMP
- total diet replacement (TDR) for weight control products
- the composition and labelling of food supplements including the vitamins and minerals which can be added to them and the restrictions and prohibitions on the sale of these products

The NLCS REUL protects some of the most vulnerable people in society, including infants, young children and people who have specific nutritional needs for health reasons. As well as ensuring that accurate nutritional information is provided to consumers, NLCS legislation ensures robust compositional standards to help maintain high standards of quality and safety. This helps consumers to make informed choices about their diet and have trust in the food they consume.

Currently, the FSMP category is being misused by the commercial milk formula industry (BFLG-UK, 2022). Companies choose which set of regulations (infant and follow-on formula / EU Commission Delegated Regulation 127 of 2016) or the foods for special medical purposes EU Delegated Regulation 128 of 2016) to market their products under and the companies are not always categorising their products appropriately.

For example, there are some products (e.g., comfort or anti-colic milks) which do not have scientific evidence for effectiveness but are being marketed as FSMP. Other products (e.g., lactose free or soya-based formulas) are being marketed as IF & FoF, when should be marketed as FSMPs. These specialised products are therefore being widely sold in supermarkets, pharmacies, online and are being bought and used without medical supervision, because they are not appropriately categorised (BFLG-UK, 2022).

Infant milks

Since there are currently separate provisions in legislation, we need to treat the following categories of products differently:

- **Infant formula (IF):** Designed for healthy infants from birth to one year, meeting their nutritional needs in the first 6 months of life, and in the second 6 months alongside complementary foods. Products marketed as infant formula are subject to compositional, safety and marketing regulations for infant formula. Nutrition and health claims are currently not allowed on infant formula (EU Delegated Regulation 2016/127).
- **Follow-on formula (FoF):** Milks marketed for feeding infants from six months to a year. Products marketed as FoF are subject to compositional and safety regulations for FoF. Claims are currently permitted on FoF.
- **Growing-up milks or toddler milks (GUM/TM):** Many infant formula companies extend their product range into the second and third year of life by marketing products as 'growing-up' and 'toddler' milks labelled as stage 3 and stage 4 'formula'. There are no specific compositional, marketing or labelling regulations for these products, which are considered unnecessary.

The DHSC Guidance Notes (2022) provide the following Examples of 'claims' on infant formula that could be considered as 'non-permitted' claims include:

- 'contains all the nutrients your baby needs to grow strong and healthy'
- 'easy to digest'
- 'gentle'
- highlighting the addition or exclusion of any ingredients such as:
 - taurine
 - fructo-oligosaccharides and galacto-oligosaccharides (GOS/FOS)
 - nucleotides
 - DHA without accompaniment of either of the statements in Article 9

Examples of claims according to each category:

The following examples from IF and FoF come from data collected during July and August 2022, as part of research that evaluated all IF and FoF labels in the UK (paper currently in preparation for peer-reviewed publication). The example from the GUM comes from Conway, et al., 2023.

All **Infant Formula** labels contain claims, despite health and nutrition claims not being allowed by law since February 2020:

- Cow & Gate First infant milk: 'nutritionally complete'; examples of specific nutrients such as 'Contains DHA (Omega-3)' in bold on the front of the pack.
- SMA Advanced First Infant Milk: 'easy to digest', 'protein broken into smaller pieces', 'nutritionally complete with Omega 3 (DHA)'. 'Did you know that a 6 month old baby's iron needs per kg/day are 2 times higher than a teenage girls?'
- HiPP Organic 1 First Infant Baby Milk Ready to feed Starter pack from birth: 'contains all the nutrients your baby needs to grow if they are not being breastfed'.
- SMA PRO First Infant Milk: 'We have been leading research in baby nutrition for over 100 years and have produced brand X First Infant Milk, a nutritionally complete breast milk substitute, expertly created with nature in mind to support babies' unique nutritional needs'.

Follow on Formula labels contain claims, which are legally allowed by law:

- Cow & Gate Follow-on milk: 'No artificial preservatives', text stating 'Calcium', 'DHA (Omega 3)', 'Vitamin D', 'Iron' in bold on the front of the pack.
- Aptamil Stage 2 Follow-on milk powder: 'Nutri Fibres (GOS/FOS)', 'Vitamins A, C, D', 'DHA (Omega 3)', 'Iron', 'Contains Vitamin D to support the normal function of the immune system', Iron supports normal cognitive development
- Kendamil Organic Follow-on milk: 'As identified with human breast milk, MFGM = Milk Fat Globule Membrane'.

Growing up milk labels contain claims, for which there are no specific legal controls:

- 'SMA PRO Growing Up Milk now contains 2'FL which is structurally identical to the most abundant oligosaccharide found in breast milk'.
- HiPP growing up milk probiotic 2+ years (stage) 4: 'Vitamin C & D', 'iron', 'which contribute to the normal function of the immune system'.

Our findings above are similar to those found among surveyed products for sale on the UK market in the summer of 2020: Conway et al (2023) found that 18% of all infant, follow-on, growing-up and specialist formula contained health claims that may be considered non-permitted, according to current DHSC guidance.

Examples of health claims on infant and baby food:

- Marketing claims and statements on **commercial infant and toddler foods** (marketed for use from 4-36 months of age) on the market in 2023 (from: FSNT, 2023)
- "Provides 2 of your little one's 5-a-day" Little Dish Cottage pie
- "Perfectly balanced for growing babies" Ella's Kitchen Organic Peach & Banana Melty Sticks
- "Our Veggie Plus recipes are created with a natural source of iron from amaranth, to provide your little ones with 18% of their daily iron requirement in one quick & easy meal" HiPP Organic Baby Food Jar Veg & Mozzarella Potato Bake
- "Enriched with calcium, iron and vitamins. Nutritionally tailored for your baby's needs" HiPP Organic Summer Berry Multigrain Porridge Baby Cereal

Example of claims on **foods for special medical purposes (FSMPs)** and infant formula that should be marketed as FSMP (BFLG-UK, 2022):

- Aptamil Comfort 'for the dietary management of Colic & Constipation' From birth to 12 months: 'Our blend of Galacto- and Fructo-oligosaccharides GOS:FOS (9:1)', 'reduced lactose', 'partially Hydrolysed Protein (pHP) & fat blend with beta-palmitate'. 'Aptamil Comfort is a Food for Special Medical Purposes'.
 - Note that all of this content is available on the label, and manufacturers categorise these products as FSMP, despite there not being scientific evidence for their effectiveness.
- SMA Soya Infant Formula From Birth to 12 months: 'for babies with a cow's milk intolerance', 'suitable for vegetarians', 'nutritionally complete and contains Omega 3 DHA (as required by the legislation for all infant formula)'.
- SMA LF Lactose Free Infant Milk From Birth to 18 Months: 'for babies with lactose intolerance', 'nutritionally complete and enriched with Omega 3 DHA (as required by the legislation for all infant formula)'.
 - Note that these soya-based, lactose free products are marketed as an IF and therefore widely sold and available, but should actually be categorised as a FSMP.

BFLG-UK recommendations

While there is some legislation restricting claims on formula milks in the UK, we would advocate that legislation needs to be strengthened so that restriction on nutrition and health claims that currently exist only for infant formula (and formula milks marketed as FSMPs) is extended to follow on formula and growing up and toddler milks marketed to children up to the age of 36 months, in line with WHO

recommendations (WHO & UNICEF, 2018). The current existence of a barrage of unregulated nutrition and health claims on products is a marketing tactic that is harmful to maternal, infant and young child health.

At the moment, the UK scores just 40 out of 100 on the Code Status report from 2022 (WHO, UNICEF and IBFAN, 2022). We would therefore advocate for the implementation of the full International Code of Marketing of Breastmilk Substitutes and all subsequent World Health Assembly resolutions to be in law (WHO Europe, 2022a; WHO, 2023). The UN Committee on the Rights of Child (CRC) has called three times, in 2002, 2008 and 2016, for the UK government to fully implement the International Code of Marketing of Breastmilk Substitutes and subsequent, relevant Resolutions of the World Health Assembly after noting that aggressive marketing is common in the UK. The Government could have used this Statutory Instrument to make these changes, but has failed to do so once again.” Therefore, the Government needs to guarantee that these safeguards will not only be retained but strengthened so that the marketing that has misled parents and turned the UK into an obesogenic environment is ended.

The WHA resolution 69.9 of 2016 (a part of the Code) recommended that “Foods for infants and young children that are not products that function as breast-milk substitutes should be promoted only if they meet all the relevant national, regional and global standards for composition, safety, quality and nutrient levels and are in line with national dietary guidelines” and that “Nutrient profile models should be developed and utilized to guide decisions on which foods are inappropriate for promotion”. (WHA, 2016). We therefore also advocate for the full implementation into legislation of the Nutrient and Promotion Profile Model Supporting more appropriate promotion of food products for infants and young children 6–36 months in the WHO European Region (WHO Europe, 2022b). The application of this model would result in the removal of most nutrition, health, and marketing claims.

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Email to: nlcs-reul-consultation@dhsc.gov.uk

The consultation is open until 11:59pm on Tuesday 31 October 2023

<https://www.gov.uk/government/consultations/nutrition-and-health-claims-on-food-proposed-legislative-reforms/nutrition-and-health-claims-on-food-proposed-legislative-reforms#survey-questions>

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Association of Breastfeeding Mothers (ABM), Association for Improvements in the Maternity Services (AIMS), Baby Milk Action, Best Beginnings, the Breastfeeding Network (BfN), Breastival, Code Monitoring Northern Ireland, the Community Practitioners' and Health Visitors' Association (CPHVA), Doula UK, The Fatherhood Institute, First Steps Nutrition Trust, GP Infant Feeding Network (GPIFN), HENRY, Hospital Infant Feeding Network (HIFN), the Human Milk Foundation, Institute of Health Visiting, Lactation Consultants of Great Britain (LCGB), La Leche League GB (LLLGB), Leicester Mammias, Centre for Lactation, Infant Feeding and Translational research (LIFT), Local Infant Feeding Information Board (LIFIB), Midwives Information and Resource Service (MIDIRS), National Breastfeeding Helpline, NCT (National Childbirth Trust), Royal College of Midwives (RCM), Save the Children, UK Association of Milk Banking (UKAMB), Unicef UK Baby Friendly Initiative, Unison, Women's Environmental Network (WEN), World Breastfeeding Trends Initiative (WBTi) UK, Dr Robert Boyle, Natasha Day, Dr Clare Patton, Dr Ernestine Gheyoh Ndzi (independent members).