BFLG-UK feedback on the DRAFT DHSC Guidance Notes on Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013)

Submitted on 16/08/2021 by Victoria Sibson, Secretariat of the BFLG-UK on behalf of the group's member organisations (please see https://www.bflg-uk.org/aboutus/#members)

Contact: vicky@firststepsnutrition.org

Address: Studio 3.04, Food Exchange, London, SW8 5EL

These Draft Guidance Notes are welcomed by BFLG UK members as a means to improve understanding and adherence to the regulations they are stated to accompany, and thereby to afford some, but very limited and insufficient protection to formula-fed and breastfed infants under 12 months of age in the UK. We remain disappointed that the UK Government continues to limit itself to the provisions of the delegated acts of the EU, particularly post-BREXIT given that regulation is now an autonomous matter for both GB and the EU as two separate legal and regulatory systems. We remain hopeful that the UK Government will take steps to enact stronger legislation with a more appropriate scope, i.e. covering all breastmilk substitutes marketed from 0-36 months of age with similar restrictions on how they are marketed, offering the potential of more meaningful protection against commercial influences on how, what and when babies and young children are fed, particularly as new trade deals are negotiated. We also remain concerned that as a non-statutory document, these Guidance Notes will be of limited utility in addressing unlawful practices by the baby food industry, and it would be preferential to provide clarity in the statutory instruments.

We would like to emphasize that in providing the following specific feedback on the Draft Guidance Notes, we are **NOT** endorsing the UK regulations as they stand. We consider the current regulations to be insufficient to provide the level of protection infants, young children and their parents need to enable optimal feeding practices in the early years in the UK. We wish to see UK laws fully reflect the International Code of the Marketing of Breastmilk Substitutes, including all subsequent World Health Assembly resolutions, and for adherence to the laws to be properly monitored and enforced.

Since 1981 the UK has strongly endorsed the adoption of the International Code and all subsequent WHA resolutions in international fora, and in 1990 the UK ratified the *Convention on the Rights of the Child* (CRC), Article 24 of which recognizes the contribution that breastfeeding makes to the fulfillment of the right of the child to the highest attainable standard of health. CRC General Comments Nos. 15 and 16 stress the obligation for States to protect, promote and support breastfeeding through the implementation of the World Health Assembly *Global Strategy for Infant and Young Child Feeding* (GSIYCF) and set a direct obligation that companies abide by the International Code and WHA resolutions universally '*in all contexts.*' Nations that have ratified the CRC are therefore bound to it by international law and have clear obligations, that should not be undermined or misinterpreted.

The International Code and WHA resolutions are embedded in many global declarations, standards

and strategies, including the *Codex Code of Ethics,*[1] the *EU Action Plan of Childhood Obesity*[2] and the *Political Declaration and Framework for Action* adopted in the 2nd International Conference on Nutrition in November 2014. Breastfeeding is one of the EUs *CORE Health Indicators for Determinants of Health*. It follows that these Guidance Notes should at the very least refer to the UK's obligation to implement the International Code and WHA resolutions in addition to the EU Regulations, and refrain from inappropriately suggesting that the regulations "give effect to the principles and aims of the Code", given their limited scope.

The UK claims to recognize the importance of promoting high quality public health principles, standards and legislation in its relations with States and international organisations in the field of public health, and there is no legal obstacle to the UK fulfilling its obligations in relation to this basic protection of child health, framing its law in line with IBFAN's Model Law. [3,4,5]

The BFLG UK looks forward to the UK government taking this clear step forward in child protection in all international fora, including during the forthcoming Codex deliberations that a reaching conclusion and the COP26. Such a move would not only have long-term advantages for human health, but would also mitigate against some of the risks associated with the global trade of industrially produced commercial milk formulas. Breastfeeding contributes to the reduction of greenhouse gasses and to water conservation; is a natural and renewable food, environmentally safe, produced and provided without pollution, unnecessary packaging and no waste.

Specific comments on the document: "DHSC Guidance Notes on Commission Delegated Regulation (EU) 2016/127 (supplementing Regulation (EU) No 609/2013)"

Intended audience

- We request that the intended audience includes interested members of the public and third sector organisations (such as the BFLG UK). We also suggest that a plain language, accessible version of the Guidance Notes is made available, alongside a plain language summary of the regulations, covering all articles.

Executive Summary

- We request that the opening sentence makes it clear that the purpose of the Guidance Notes should be to facilitate adherence to and assessment of adherence to the legislation

[1] Codex CODE OF ETHICS FOR INTERNATIONAL TRADE IN FOOD INCLUDING CONCESSIONAL AND FOOD AID TRANSACTIONS CAC/RCP 20-1979 *4.4 National authorities should be aware of their obligations under the International Health Regulations (2005) with regard to food safety events, including notification, reporting or verification of events to the World Health Organization (WHO). They should also make sure that the international code of marketing of breast milk substitutes and relevant resolutions of the World Health Assembly (WHA) setting forth principles for the protection and promotion of breast-feeding be observed*.

[2] http://ec.europa.eu/health/nutrition_physical_activity/docs/childhoodobesity_actionplan_2014_2020_en.pdf

[3] http://www.babymilkaction.org/wp-content/uploads/2021/05/201802-CE2-2nd-Edition-Final.pdf

[4] EU in the World http://ec.europa.eu/health/eu_world/policy/index_en.htm

[5] Public Health (17-09-2015) *Commission and WHO Europe scale up cooperation* http://ec.europa.eu/dgs/health_food-safety/dyna/enews/enews.cfm?al_id=1620

that the Guidance Notes address, whilst seeking to optimize the extent to which this legislation protects infants and young children.

- We request that the Executive Summary outlines the content of the Guidance Notes.

1. Introduction

- Point 2: As for the executive summary, we request that it is made clear that the purpose of the Guidance Notes should be to optimize protection to children afforded by current legislation, and where ever possible going further that the regulation. The UK has the sovereign right and obligation to take this approach. In our opinion, the use of the phrase 'interpret provisions' lacks clarity and calls in to question the potential that the Guidance Notes could have. In addition we suggest that the Guidance Notes outline what members of the public can do should they suspect that a breach of the legislation.

2. Background:

- Point 8: In order to maximize the utility of the Guidance Notes given the sale of infant milks marketed as Food for Special Medical Purposes alongside infant formula and follow-on formula in retail settings and online and with similar advertising and labelling, we request that the Guidance Notes are extended in scope to cover Food for Special Medical Purposes.
    - More specifically, we request that the scope of the Guidance Notes is extended to cover articles 5-9 of delegated regulation 2016/128, the provisions of which relate to Food for Special Medical Purposes and more specifically, the labelling, notification, avoidance of risk of confusion between FSMPs and infant and follow-on formula, advertising and promotion. As with infant formula and follow-on formula, the Guidance Notes should provide a means to ensure that FSMPs are not branded and designed in a way that facilitates cross promotion of infant formula from the same manufacturer.
    - We also suggest that the scope of the Guidance Notes is widened to incorporate articles 1-5 of the delegated regulation 2016/127, each of which include terms which may benefit from further clarification.

- Point 8, Grey box: We suggest that the word 'baby' is considered synonymous with 'infant', i.e. a child under the age of 12 months.

- Point 8, Grey box: The definition of infant formula lacks the necessary specificity to be useful, and should therefore be amended to reflect the NHS definition, which clarifies that it is suitable as the sole source of nutrition (or to supplement breastmilk) up to 6 months of age and then, alongside complementary foods, up to 12 months of age, after which infant formula (and any commercial formula milks) are not required. https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/bottle-feeding/types-of-formula/

- Point 8, Grey box: The definition of follow-on formula lacks the necessary specificity to be useful, and should therefore be amended to reflect the NHS definition, which clarifies that it is suitable only from 6 months of age (although also unnecessary). https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/bottle-feeding/types-of-formula/

- Point 8, Grey box: For clarity, the content on appropriate complementary feeding should include reference to the recommendation of SACN that infants should not start solid foods until around the age of 6 months, having achieved developmental readiness.

3. Commission Delegated Regulation (EU) 2016/127

- Point 16: This sentence is factually incorrect and needs amending: "The Commission Delegated Regulation and the overarching FSG Regulation together give effect to the principles and aims of the 1981 WHO Code on the Marketing of Breastmilk Substitutes covering marketing, information and responsibilities of health authorities…". The CDR and the FSG Regulation give effect to a small proportion of provisions in the Code and subsequent World Health Assembly Resolutions, and indeed only a small proportion of provisions related to marketing, information and responsibilities of health authorities, not least because they only cover infant formula and follow-on formula (and the Code covers all breastmilk substitutes marketed for 0-36 month olds, including bottles and teats and baby foods), and because legal restrictions for the marketing of follow-on formula in the UK fall short of those for infant formula. We request that this sentence is corrected to address the misleading messages it conveys. In addition we object to the use of the weblink to the 1981 Code document, without any explicit mention of the World Health Assembly resolutions, all of which subsequent to the 1981 document are considered a part of the Code.

- Point 17: For consistency with Article 6(3)(a) on labelling requirements for follow-on formula (Point 21), we request that the statement on infant formula be clarified in line with NHS guidance which states that *"First infant formula (first milk) should always be the first formula you give to your baby.. Unless a midwife, health visitor or GP suggests otherwise, first infant formula is the only formula your baby needs. Your baby can stay on it when you start to introduce solid foods at around 6 months and drink it throughout their 1st year.* https://www.nhs.uk/conditions/baby/breastfeeding-and-bottle-feeding/bottle-feeding/types-of-formula/

- Point 18: We welcome the recommendation that formula preparation and storage instructions reflect NHS guidance in order to protect those infants consuming the formula, and suggest that the Guidance Notes further highlight that consumers should be discouraged from using formula preparation devices and kettles which are not recommended in the NHS guidance.

- Point 19: The terms 'conspicuous' and 'clearly visible' need to be clarified and specific guidance given. We suggest that the Guidance Notes stipulate the size of the text to ensure that it is the largest text on the package, standing out from the surrounding text by the use of a contrasting font in respect of both size and colour. It may also be beneficial to advise that the text be included with the instructions for preparation (see Section 6 of the IBFAN Model law: 201802-CE2-2nd-Edition-Final.pdf (babymilkaction.org)).

- Point 20: The term 'a high degree of prominence on the label ' needs to be clarified to avoid any ambiguity. We request that the Guidance Notes state what this means in respect of where on the pack this should feature and what the relative font size and colour should be relative to other text (see IBFAN Model law for clear suggestions: 201802-CE2-2nd-Edition-Final.pdf (babymilkaction.org)). The 'Important Notice' requirement should also be required for Follow-on Formula (and all other commercial formula milks).

- Point 23: The description of article 6(6) first suggests the distinction between infant formula and follow-on formula is to prevent confusion, and latterly to prevent indirect marketing of infant formula. We suggest that the two reasons for greater distinctions between product types are given in the first sentence as prevention of cross-promotion (see: information-note-cross-promotion-infant-formula.pdf (who.int)) and to ensure appropriate product use. Currently this point misrepresents why companies market their products the way they do; i.e. to enable cross-promotion.

- Point 23: Whilst the Guidance Notes state that there should be clear product distinction between infant formula and follow-on formula (and the law also requires the same for Food for Special Medical Purposes) currently the brand and product range are more identifiable on packaging than the formula type. This serves to cross promote products, circumventing the prohibition on infant formula advertising. We welcome the guidance on how infant formula and follow-on formula should be visibly distinct from one another, but request that this guidance should be made more explicit to be useful, and to optimise the extent to which it protects infants and young children. See comment on Appendix IV below.

- Point 24: We request that the term 'idealise' is further clarified. Although some examples have been provided, the meaning has not been clarified. Idealising in this context might mean representing formula feeding as perfect, better than or equivalent to breastfeeding or the optimal way to feed infants.

- Point 24, Grey box: Specific requirements on the nutrition declaration includes a sentence on Article 7(1) which is long so the meaning is unclear. Suggested alternative wording: ''…(EU) No 1169/2011 states that food information should not be misleading. In particular, any suggestion that the food possesses special characteristics, when in fact all similar foods possess such characteristics, is misleading and should not be permitted. This is most likely to arise when the presence or absence of certain ingredients and/or nutrients is emphasized.'

- Points 26, 28, 29, 30 and 31: Instead of the vague word 'amount', we suggest using 'weight' or 'quantity'.

- Point 33: We strongly suggest that claims are not permitted on follow-on formula (or for commercial formula milks marketed for 12-36 month olds, or baby foods). Whilst the legislation governing the marketing of follow-on formula is weaker than that for infant formula (and growing up milks and toddler milks are not subject to any specific legislation pertaining to composition, advertising or labelling), consumers will be misled in to purchasing unnecessary infant milks which will undermine appropriate and optimal infant and young child feeding practices.

- Point 33, Grey box: (page 12), (b)(ii) – add 'd' to correct typo, so 'reduce' reads 'reduced'.

- Point 33: "Examples of 'claims' on infant formula that could be considered as 'non-permitted" include the highlighting of some non-mandatory ingredients. We request that this list of ingredients includes *all* non-mandatory ingredients or is reworded to say 'any non-mandatory ingredients' to avoid these ingredients being used in a way that suggests a relationship between them and any health-related outcomes.[6]

[6] If an ingredient is shown to be safe, important for child health or reduces the inadequacies of breastmilk substitutes it should be mandatory, in line with the opinion of the UK Government's Scientific Advisory Committee on Nutrition (SACN) :"*We find the case for labelling infant formula or follow-on formula with health*

- Point 36: We remain concerned that there is no reliable evidence that the DHA which manufacturers add to formula has any health or developmental benefit, e.g. Effect of long-chain polyunsaturated fatty acids in infant formula on long-term cognitive function in childhood: A systematic review and meta-analysis of randomised controlled trials (plos.org). Notwithstanding this issue, and as DHA is now classified as a mandatory ingredient, we believe highlighting it on the label of infant formula or follow-on formula, with or without either of the approved statements in article 9, serves as a claim. On this basis, we request DHA is treated in the same way as other mandatory ingredients and the Guidance Notes state that it should not be highlighted on product labels. If this request is not acted on, we suggest that the approved statement is not only in close proximity to the area of packaging highlighting the presence of DHA, but is also highly visible i.e., in a font size equal to that of the words highlighting the presence of DHA.

- Point 40: This is the only reference to the 'presentation' of infant formula and follow-on formula in the retail setting that appears in these updated Guidance Notes. Particular aspects of the word 'presentation' of foods, as defined by Regulation (EC) No 178/2002, specifically 'the manner in which they are arranged and the setting in which they are displayed' requires further clarification. Where products are displayed, what products they are displayed with, how they are arranged on shelves and where other in-store promotional devices for follow-on formula appear are all aspects of 'presentation', which are included in the current version of the Guidance Notes and which need to be addressed in this updated draft. To avoid any risk of confusion, retail settings require clearer guidance on 'presentation' of products, and we suggest that photographic examples of breaches would both assist companies adhere to the laws and enforcement officers assess their compliance (See also the IBFAN Model Law: 201802-CE2-2nd-Edition-Final.pdf (babymilkaction.org)).

- Point 40: In order for the Guidance Notes to be as useful as possible, and to optimise the extent to which they protect infants and young children, we request the addition of detail on what the marketing restrictions specified mean in practice (e.g. what is meant by a free standing display. Does end of aisle positioning qualify. What qualifies as a shelf-talker. What qualifies as a promotional gift).

- Point 40, Grey box: (page 14), add 'Includes….' before sentence starting 'text or images'

- Points 42-44: We understand that there is no precedent for the DHSC approving information materials provided by baby food companies. We suggest this information is included in the Guidance Notes and reference made to the 8 WHA resolutions which forbid such sponsorship.

- Point 48: The term 'place on the market' requires further clarification. The current Guidance Notes refer to Regulation 178/2002 which states: *'placing on the market' means the holding of food or feed for the purpose of sale, including offering for sale or any other form of transfer, whether free of charge or not, and the sale, distribution, and other forms of transfer themselves'.* This detail should be retained in the updated Guidance Notes.

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or nutrition claims entirely unsupportable. If an ingredient is unequivocally beneficial as demonstrated by independent review of scientific data it would be unethical to withhold it for commercial reasons. Rather it should be made a required ingredient of infant formula in order to reduce existing risks associated with artificial feeding. To do otherwise is not in the best interests of children, and fails to recognise the crucial distinction between these products and other foods."

- Point 49: In the case in which the Guidance Notes are expanded to encompass infant milks marketed as Food for Special Medical Purposes, we would like to request that these products are subject to a similar pre-market regulatory assessment to the one which will be developed for hydrolysates, to ensure that their stated role is supported by significant scientific agreements, free of conflict of interest.

Appendix II: 'Advertising'

We welcome the inclusion of guidance on what may be considered advertising in these updated Guidance Notes, and recognise that the dynamic nature of advertising precludes a more prescriptive approach. We request that the Guidance Notes outline what members of the public or healthcare professionals should do if they suspect that a specific representation of information is in breach of the regulations.

Appendix III: Guidance on website information relating to infant formula, follow-on formula and infant feeding

Given the expansion of on-line advertising to both parents and healthcare professionals since the publication of the current Guidance Notes, we welcome the additional guidance on this communications channel in this updated version. We strongly suggest that these updated Guidance Notes clarify which body is responsible for ensuring the compliance of pop-up advertisements by infant milk manufacturers that appear on third party websites.

Appendix IV: Differentiating infant formula and follow-on formula

Rather than relying on industry to meaningfully differentiate the packaging of their product types, we suggest that a plain packaging approach to all breastmilk substitutes, including infant formula and follow-on formula, would better avoid confusion by consumers, aid in their informed decision-making and prevent the undermining of breastfeeding. In the absence of such an approach, we request that this appendix is more fully developed to be useful, and to optimise the extent to which it protects infants and young children, providing a more prescriptive illustrative graphic with accompanying explanatory text that addresses more of the issues affecting current packaging styles.

We request that the following issues are addressed:

- Brand names often take the form of logos, in which case, specifying equal sized fonts in relation to the words 'infant formula' and 'follow-on formula' may be less useful than stipulating that the logo should be less prominent on the packaging than the formula type. It should be specified that prominence refers to both the colour, size and positioning of the text/logo.

- The background colour of the packaging for infant formula and follow-on formula should differ, and different shades of the same colour should not be used.

- Stage numbers are confusing and misleading and should not be used.

- The age range specified on infant formula should clarify that it is 'Suitable from birth to 1 year' and not as is typical of current labelling 'Suitable from birth' without clarity on the age at which the product becomes unnecessary.

- All faces of the different/common formula packaging types should be included in the guidance provided in this Appendix. This would permit further clarification of where the 'important notice' should be displayed and formatted in order to comply with the requirement for it to be 'clearly visible'/ 'afforded a high degree of prominence on the label'; we suggest front of pack.

- Further clarification of where and in what format the required warning (article 6 (2)(b) 3(b)) about the health hazards of inappropriate preparation and storage should appear on the label in order to satisfy the criteria that it be in a conspicuous place and be clearly visible and easily understandable; we suggest directly above the instructions for preparation and in a contrasting font colour to the surrounding text and background.

- Dietary suitability should be clearly displayed on front of pack.

- The legal requirement for follow-on formula labels to carry further information as outlined in article 6 (3)(a) would also be supported with guidance of where and how this may appear.

Appendix V: Guidance on scientific publications and information of a scientific or factual nature

Supporting information given by reference to research from peer-reviewed scientific journals does not guarantee that the information given is scientific and factual, and the cited science is usually weak or non-existent. We suggest that advertising of breastmilk substitutes should not be permitted at all, to the public or to health care professionals. But if advertising of infant formula is allowed to health care professionals, we suggest that prior to publication, for an impartial judgement of what constitutes 'scientific and factual' this is independently assessed by an independent body of experts (i.e. the UK Nutrition and Health Claims Committee for a nutrition or health claim or another government committee for assessing safety and suitability of a new product, e.g. the SMCN subgroup of SACN) so that there is pre-market authorisation for any claims or claim-like information related to the product. Furthermore, given the current flouting of this legislation, who is responsible for enforcement of this aspect of the legislation should be made clear in these updated Guidance Notes.