

EU Regulation 609/2013 on Foods for Specific Groups Baby Milk Action – IBFAN UK response to the Informal consultation on a draft Statutory Instrument to enforce the legislation in England



Consultation Questions

General comment:

While we welcome the proposals to introduce provisions for enforcement of the Delegated Acts, the 'intended effect' of the SI should be protecting children's rights to health not "... removing unnecessary rules and burdens on business."

The UK and all nations that have ratified the Convention on the Rights of Child are bound to it by international law and have clear obligations. Indeed the Delegated Acts and Regulation 609/2013 refer to these fundamental rights. Para No.44 reads: *"This Regulation does not affect the obligation to respect fundamental rights and fundamental legal principles, including the freedom of expression, as enshrined in Article 11, in conjunction with Article 52, of the Charter of Fundamental Rights of the European Union, and in other relevant provisions."*

Precautionary Principle Article 5 of Regulation 609/2013 also clearly calls for the Precautionary Principle (PP)

Applying these principles across all relevant provisions should allow the UK to make several important clarifications in the Statutory Instrument (SI), in relation to the advertising of infant formula, the rules for placing products on the market, and the labelling and marketing of Foods for Special Medical Purposes.

Advertising: In addition to the comments below and in order to prevent further lowering of consumer protection, the wording of the Draft Statutory Instrument must, at the very least, restate the current UK position on advertising.¹ It must clearly emphasise that advertising, health claims and other marketing practices have an important impact on parents perceptions and decisions regarding infant and young child feeding (as specified in Paras 22-24 of the Delegated Act). The SI in focusing mainly on composition and labelling glosses over the importance of marketing. Figure 2 implies that only the promotion of infant formula constitutes an offence.

Article 10 of the delegated *Regulation on Infant Formula and Follow-on Formula* specifically allows Member States to go further to restrict or prohibit Infant Formula (IF) advertisements in baby care or scientific publications: *"Advertising of infant formula shall be restricted to publications specialising in baby care and scientific publications. Member States may further restrict or prohibit such advertising. Such advertising shall contain only information of a scientific and factual nature. Such information shall not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding."*

The International Baby Food Action Network (IBFAN) and Baby Feeding Law Group (BFLG)

¹ *The Infant Formula and Follow-on Formula (England) Regulations 2007 Restrictions on advertising infant formula 21 (1)*
(i) in a scientific publication, or
(ii) for the purposes of trade prior to the retail stage, in a publication of which the intended readership is other than the general public; or
(b) where the advertisement contravenes or fails to comply with the provisions of regulation 17(1)(e), (2), (3) or (4), regulation 19 or paragraph (2) or (3).

(2) Advertisements for infant formula shall only contain information of a scientific and factual nature.

position is that all advertising of infant formula and follow-on formula should be prohibited – and that only scientific and factual information be allowed in communications to health workers.

Question 1 Is it helpful to specify in the SI particularly important requirements that would attract criminal sanction if they are breached, or should all requirements potentially attract a criminal sanction if breached so that an authorised officer can make a judgement in each case as to the appropriate enforcement action?

It is essential that all requirements should attract a criminal sanction if breached.

The Department of Health is proposing moving to a system of “Improvement Notices”, which it states “*effectively decriminalises regulatory offences in appropriate cases*”. The justification for allowing breaches of criminal law to go unpunished is given as, “*It is a more flexible approach giving industry additional time and support to resolve the problem identified in the Improvement Notice, enabling them to comply before it is escalated to a criminal offence.*”

Adopting a two-stage process with Improvement Notices would only be acceptable if it had the opposite effect to that stated, in other words, if it provided a faster way to prompt company compliance than embarking on legal action. For this to be effective, it must be clear that there will be the back up of a criminal prosecution if Improvement Notice deadlines are not respected. In addition, these notices and correspondence relating to them must be placed in the public domain. Failure to do this would provide corporations that have global reach to falsely claim that they are complying with UK regulations.

Companies have already had many years to bring their practices into compliance with current and past Regulations and failed to do so. The Department of Health is long overdue in investigating why enforcement in the UK as a whole is so lacking, leading to widespread and recurring violations of the *Infant Formula and Follow-on Formula Regulations (2007)*.

Baby Milk Action has reported many cases to Trading Standards officers of illegal activities, with no demonstrable impact. We have also submitted monitoring reports to the Department of Health with examples of this evidence on behalf of the Baby Feeding Law Group. These reports also set out how the Guidance Notes issued by DH to aid enforcement officers and companies in interpreting the Regulations are disregarded by companies. Trading Standards is reluctant to bring cases to court for definitive rulings on interpretation.

Companies have been breaking the regulations for many years and in some cases have been warned by Trading Standards already and even admitted to offences. Accordingly, the Department of Health should investigate why long-overdue prosecutions have not been brought and rectify this situation as a matter of urgency, rather than decriminalise offences and give companies even more time to comply.

The Guidance Notes on interpreting the Regulations developed by the Food Standards Agency through public consultation and now under the auspices of Department of Health have proved useful in our monitoring. The principles contained in the Guidance Notes should be updated and incorporated into the new SI.

Monitoring: Paragraph 25 of the Delegated Act calls on Member States to: “*enforce food law, and monitor and verify that the relevant requirements of food law are fulfilled by food*”

and feed business operators at all stages of production, processing and distribution.”

The following aspects of the Delegated Regulations are covered by the existing Regulations and are routinely violated.

Infant formula and follow-on formula Delegated Regulation

Article 6(6) of the Delegated Regulations (requirements as to the labelling, presentation and advertising of infant formula and follow-on formula)

Infant formula branding and styling is used routinely for packaging follow-on formula products in violation of article 19 of the 2007 regulations (and more recently on so-called growing-up milks).

While these breaches are self-evident from looking at the packaging, we also note that the Department of Health guidance on complying with article 19 is simply ignored. For example, the Guidance Notes suggest that the terms “Infant Milk” and “Follow-on Milk” should be at least as large as the brand name on products.

Follow-on milks are widely advertised and promoted to cross-promote the similarly packaged infant formula, violating article 21 of the 2007 regulations. Practices specifically described as contravening the regulations in Guidance Notes paragraph 48 and frequently used.

Infant formula labels routinely use idealising text and images. The Department of Health guidance in paragraph 31 of the Guidance Notes is ignored.

Companies were given a grace period to bring labels into compliance after the 2007 Regulations replaced the 1995 version (even though the labels then on the market violated the 1995 regulations). They failed to do so and have relaunched products several times with labelling that breaks the law.

Prosecution for these offences is long overdue and should not be delayed by the introduction of a new regime. Decriminalising them is a totally inappropriate response.

Any Improvement Notice regime introduced in future should seek immediate changes, with criminal prosecutions if deadlines are not met.

Article 12(1) (notifying the competent authority about placing infant formula on the market)

Regulation 609/2013 Article 11 2 d gives the Commission power to set (d) the notification requirements for the placing on the market of food referred to in Article 1(1), in order to facilitate the efficient official monitoring of such food, and on the basis of which food business operators shall notify the competent authorities of Member States where that food is being marketed;

Article 3(3) of the Delegated Act leaves the task of checking that companies use suitable ingredients to Member States (MS): Suitability must be 'demonstrated by the food business operator through a systematic review of the available data related to the expected benefits and to safety considerations as well as, where necessary, appropriate studies, performed following generally accepted expert guidance on the design and conduct of such studies'.

This is risky because once an ingredient appears on sale in one country it can then be marketed throughout the EU. In order to protect child health the UK must use the Precautionary Principle (specified in Article 5 of Regulation 609/2013) and ensure that the SI specifies that:

- a) all ingredients are pre-authorized following rigorous independent scrutiny (with particular care over new technologies, such as nanotechnologies;
- b) systematic reviews of all available evidence are carried out *independently* of the manufacturers and distributors of the products in question;
- c) evidence is reviewed on a regular basis to ensure infants are not exposed to levels of nutrients that might put a burden on their metabolism, (a concern already raised by EFSA)
- d) there is regular post market surveillance indicating the frequency of such reviews;
- e) food ingredients not listed as essential are kept to the bare minimum;

Mandatory addition of DHA Given the lack of post-market surveillance and the weakness and inconsistency of the available evidence - especially in relation to its efficacy for older babies – steps must be taken to limit the risks of the mandatory addition of DHA. If the statement on IF has to be permitted (and it is the BFLF and IBFAN position that it should not) – it should not be on the front of the package or be a de facto promotional claim. There should also be clear nutrition labelling (specifying what the DHA is made from) and warnings that some babies may not tolerate synthetic DHA.

Article 12(2) (notifying the competent authority about placing follow-on formula on the market)

The above comments relating to Article 12 (1) also apply to Follow-on formula.

Given the failure of companies to bring labels into compliance with the existing regulations, it is entirely inappropriate to downgrade the requirement to submit labels in advance. An appropriate response would be to enhance this requirement so that products cannot be placed on the market until labels have been submitted and any failure to meet the requirements as set out in the Guidance Notes addressed. If such labels are not submitted or are used without confirmation that they meet the requirements of the Guidance Notes then prosecution should result.

Food for special medical purposes (FSMPs) Delegated Regulation

FSMPs are often the sole food for children at a vulnerable stage of growth and development when the energy and nutrient intake per kilo bodyweight is greater. Their manufacturing and marketing requires more - not less - care.

The concerns given above in 12 (1) regarding labelling, advertising, product composition, placing on the market and promotion of foods must also apply.

In addition, there should be clear guidance that product names that are de facto health claims such as *Staydown*, *Anti-Reflux*, *Comfort*, *Easy Digest* are not permitted. These terms medicalise common feeding occurrence and are highly misleading and

The requirement to submit a label in advance should remain and it should be a criminal offence to place a product on the market without confirmation that it meets the requirements set out in the Guidance Notes.

The SI should state that FSMP labelling and information should be at least as strong, and ideally stronger, than Art 6.2c of the Infant formula Delegated Act that calls for a *“.. a statement recommending that the product be used only on the advice of independent persons having qualifications in medicine, nutrition or pharmacy, or other professionals responsible for maternal and child care.”* Ideally the last part of the sentence *“or other professionals responsible for maternal and child care “* should be deleted.

Proposal to review of existing approach of Trading Standards liaison with companies for “corrective action” and the lack of criminal prosecutions

As mentioned above, companies have labelled products in breach of the violations for many years. There were some improvements when the Food Standards Agency reminded companies and Trading Standards authorities of the regulations regarding use of prohibited claims (such as “closer to breastmilk”) in 2006, but companies did still not bring their revised labels into line with the requirements. No prosecutions resulted. This proves the point that Improvement Notices without criminal sanctions that are automatically and robustly applied are doomed to failure.

Promotion of infant formula in retail outlets continues to be widespread, despite the regulations. There is currently widespread concern that Tesco and other retailers are promoting Nestle SMA infant formula in clearance sales and special displays as a prelude to the roll out of Nestle SMA Pro infant formula. There is not even a pretence that the promotion is for the similarly labelled follow-on formula.

Tesco has been responsible for price promotions on infant formula across its chain on other occasions, such as 2011 and 2015, and advertising infant formula in 2009. These are criminal offenses.

Trading Standards were informed of the above cases. The Trading Standards Primary Authority for Tesco informed Baby Milk Action in the case of the price promotion on Nestle SMA infant formula in 2015 that its role was to liaise with Tesco to encourage corrective action. This was ineffective at the time as Tesco continued to place point-of-sale promotion items in store three weeks after it had pledged to remove them. It has also proven ineffective in changing Tesco’s attitude to the regulations as a year later it is repeating the same prohibited activity. Baby Milk Action has raised this with Trading Standards, Department of Health and Tesco, but we continue to receive photographic evidence of illegal promotion.

It is our view that the liaison approach has clearly failed, and that prosecutions and fines will be more effective in both the immediate and longer term.

The fact that companies are not prosecuted when there is widespread public awareness that such practices are illegal leads to questions being asked (on social media, for example) about why Trading Standards and the Department of Health do not act. Decriminalising activities will do nothing to enhance the reputation of the enforcement and health authorities.

Question 2 If only breaches of particularly important requirements are to attract criminal sanction, have the right requirements been identified in Figures 2, 3 and 4?

As explained above, it is totally inappropriate to decriminalise provisions that are routinely breached. Instead an urgent investigation should be conducted into why criminal activities have continued for so long unpunished and no corrective action taken.

Question 3 Are criminal sanctions an appropriate enforcement mechanism for this SI on foods for specific groups or would a system of civil fines be better, i.e. the back-stop non-custodial criminal offence which exists for a failure to comply with an improvement notice (Section 10(2) Food Safety Act) would be replaced by a civil sanction in the form of a fine?

Criminal sanctions have never been tested due to the failure of Trading Standards to bring prosecutions, the failure of Department of Health to encourage observance of its Guidance Notes and the failure to bring of test cases to definitively resolve any challenges to its interpretation.

Executives have demonstrated their contempt for the current system. Reducing the seriousness of the offenses and the applicable penalties is unlikely to make them more willing to comply. Marketing strategies that breach the regulations are intended to increase sales and civil fines could easily be disregarded as a business cost, just as the repeated rulings against misleading promotion by the Advertising Standards Authority (ASA) do not prevent repeat offenses as there are no fines and no requirement to publish corrections.

The robust prosecution of repeat offenses is required, with the ultimate sanction of imprisonment for responsible officers for treating the law with contempt.

There should also be a mechanism to monitor and prosecute breaches related to health professional publications.

Question 4 If you have answered yes to Question 3, should civil sanction fines for failure to comply with an improvement notice be fixed or variable/unlimited?

See the above comments on the expectation that civil fines will be disregarded as a business cost.

Fines would likely only have an impact if linked to business turnover. For example, a fine at 10% of income from sales of the product that has been promoted in breach of the law may have an impact, particularly if repeated for each recurrence, and if there is the ultimate sanction of imprisonment for responsible officers for treating the law with contempt.

As mentioned above if the UK is to adopt the proposed two-stage process with Improvement Notices, these notices and correspondence relating to them must be placed in the public domain and a specific reasonable time frame imposed. Failure to meet the deadline should result in criminal prosecution and sanctions. The aim of any new regime should be to speed compliance, not to give companies additional time as stated in the proposals. Failure to take these steps would enable corporations that have global reach to falsely claim that they are complying with UK regulations.