



The Infant Nutrition Industry (INI) Code of Practice

Summary

On November 5th 2018 the Infant Nutrition Industry Code of Practice (INI code) was launched in the UK. This code of practice, published by the British Specialist Nutrition Association (BSNA) claims to reflect and extend UK and EU law relating to the marketing of breastmilk substitutes and provide explanation of how the industry believes that compliance to legislation should be interpreted.

Whilst the INI code claims to demonstrate a commitment to the WHO International Code of Marketing of Breastmilk Substitutes, there are a number of key areas where this industry code is at odds with the International Code (which includes all relevant WHA resolutions). The UK is a signatory to the International Code as a Member State of the UN, and we currently have some, but not all, of the International Code in UK law. The International Code is an integral part of the Unicef UK Baby Friendly standards in the UK, and many organisations would like to see the International Code brought fully into UK law. There are significant areas where the INI code does not reflect the breadth and detail of the current interpretation of UK law by the Departments of Health in the UK. We believe that this industry-focused version of the code will encourage companies to claim 'code compliance' when in fact they may be in breach of both the Department of Health interpretation of UK regulation and the International Code.

The INI code allows current inappropriate practices that are used to market breastmilk substitutes to continue. It does not represent any advancement in promotion of the International Code or UK law and it does not protect health workers from conflict of interest. Ultimately it does not serve to improve the protection of breastfeeding or the support for appropriate and safe formula feeding when this is necessary. In addition, the complaints procedure proposed by the industry has no purpose since it is the Advertising Standards Authority, Trading Standards Officers and regulatory civil servants who are responsible for handling breaches in UK regulations.

In this document we highlight some of the ways in which this INI code differs from the International Code, and outline where important elements of UK law, as interpreted by the Department of Health Guidance notes,¹ have not been included.

The Guidance notes to the legislation were produced to help industry, enforcement officers and other interested parties interpret the provisions of the Infant Formula and Follow on Formula (England) Regulations 2017, as amended, and equivalent regulations in Scotland, Wales and

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https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/204314/Infant_formula_guidance_2013_-_final_6_March.pdf

Northern Ireland. *The guidelines reflect the Department of Health (now Department of Health and Social Care) view on how the regulations should be interpreted, and they were produced to provide advice on the legal requirements of the Regulations.* It would be expected therefore that the INI interpretation of the regulations should be included in any code of conduct that purported to comply with all relevant legislation.

Chapter 1 introduces the INI code.

The context is set, describing ‘breastfeeding is the best way to feed a *healthy* infant...’.

It is stated that the INI code only covers infant formula, follow-on formula and infant milks marketed as foods for special medical purposes marketed to infants under 12 months of age.

The International Code states that ‘breastfeeding is an unequalled way of providing ideal food for the healthy growth and development of infants...’ No distinction on the basis of health is required or appropriate when qualifying the value of breastfeeding.

The International Code is clear that all breastmilk substitutes that are specifically marketed for feeding infant and young children up to the age of 3 years, including follow-on formula and growing up milks, are covered by the Code. Other foods and beverages promoted to be suitable for feeding a baby during the first 6 months of life such as baby teas, drinks and purees are also included, as are feeding bottles and teats.

The INI code makes no mention of milk products for children over the age of 1 year, baby food or bottles and teats.

Chapter 2 outlines five core principles of the INI code, including:

Principle 1 inappropriately limits its suggestion of ‘the superiority of breastmilk as the optimal food’ to ‘*healthy* infants’

Principle 2 states ‘we comply with all relevant legislation’ citing EU and UK laws. However many aspects of the interpretation of the UK law as described by the Department of Health are not included as we show later.

Chapter 3 of the INI code deals with healthcare organisations and healthcare professionals.

Within, it is stated that information provided by breastmilk substitute manufacturers must always be scientific and factual. The definition of ‘scientific and factual’ in chapter 13 of the INI code is considerably weaker than that suggested in the Department of Health guidance notes.

Regulation 21 in UK law provides that infant formula can be advertised only in scientific or trade publications which do not target the public and must contain only information which is scientific and factual. In the Department’s view, to comply, it must be possible to support any further information that is not an approved nutrition and health claim, with an article from a peer reviewed scientific journal.

The INI code allows manufacturers to provide weak supporting evidence such as presentations and 'data on file' and provides companies a loophole to avoid sharing this data on request.

In section 3.16 of the INI code it states '*practice-related equipment or small work related items such as pens or sticky note padsmay feature a company name or company logo*'.

Regulation 23(2) in UK law states that manufacturers and distributors should not give any free or discounted sample or gift for promotional purposes to any member of the public directly or indirectly through the healthcare system or health workers.

The International Code states that healthcare authorities should promote the principles of the Code and that there should be no promotion of breastmilk substitutes in health care services.

In section 3.2 of the INI code it is stated that it is within the remit of Trading Standards Officers to enforce legislation controlling healthcare media advertising relating to formula foods. In section 7.9 it also says that Trading Standards Officers enforce compliance with labelling legislation.

Notwithstanding the redundancy of the proposed INI complaints procedure in the context of the existing and mandated regulatory structure in place, this procedure does not therefore appear to propose to address legislation related to advertising in the health professional literature or product labelling.

Section 3.3.4 states that to enable evaluation of the suitability of infant milks marketed as foods for special medical purposes (FSMP), products for professional evaluation may be sent directly to parents and carers at the request of a healthcare professional.

In chapter 4, section 4.6 it also allows for product samples to be given to the general public and states in 4.6.2 that samples of follow-on formula may be offered in circumstances when a parent or carer has advised that infants are at least six months of age.

The International Code is clear that manufacturers and distributors of breastmilk substitutes should not provide samples of their products to pregnant women, mothers or members of their families.

Section 3.5 of the INI code deals with industry training and education for healthcare professionals funded by the breastmilk substitute industry and states:

(3.5.1) 'Events may provide a forum for the exchange of scientific and factual information, including that related to formula foods'.

3.5.2 Company organised events for healthcare professionals must be convened for educational purposes or for professional training.

3.5.3 Hospitality is limited to refreshments and/or meals incidental to the main purpose of the event.

3.5.4 Any funding to support healthcare professionals in attending events is limited to the healthcare professional only ...payment would include reimbursement for pre-agreed travel expenses, meals and accommodation and registration fees.

The International Code is clear that:

‘Any donations to the healthcare system (including health workers and professional associations) from companies selling foods for infants and young children represent a conflict of interest and should not be allowed’

And recommends that:

‘Sponsorship of meetings of health professionals and scientific meetings by companies selling foods for infants and young children should not be allowed’.

Additional wording in the resolutions ‘urges member states to ensure that financial support to health professionals does not create conflict of interest’, and that ‘Member States should ensure that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflict of interest.’

The INI code therefore does not represent the restrictions within the International Code on the sponsoring of events and donations made to health workers, who should be protected from conflict of interest.

Section 3.6 of the INI code deals with healthcare professionals as speakers, trainers and consultants and lays out their terms of engagement with the breastmilk substitute industry, including details of remuneration.

As above, the International Code urges avoidance of conflict of interest through financial support to health professionals. It also states that company funding must be declared by the company and the recipient. The INI code does not include a stipulation to declare company funding.

Section 3.7 of the INI code deals with educational grants for research, the advancement of science and healthcare professional education and public education in relation to formula foods.

This fails to highlight that the International Code requires ‘that information is objective and consistent and that it must clearly state the benefits and superiority of breastfeeding, the social as well as financial costs of using infant formula, the health hazards associated with artificial feeding and instructions for proper use.’

Chapter 4 of the INI code deals with industry interaction with the general public including pregnant women and parents of children under the age of 12 months.

This chapter suggests that it is the role of breastmilk substitute companies to provide information to families directly.

The International Code states that governments are responsible for provision of information on infant and young child feeding and that materials supplied by companies upon request must be approved by government. The International Code also states that marketing personnel should make no direct contact with pregnant women or mothers of infants and young children.

Sections 4.1.3, 4.2.1 and 4.5.4 of the INI code states that neither infant formula nor infant milks marketed as FSMP are advertised or promoted to the general public and 4.2.1 states that follow-on formula advertising is always presented as only suitable from six months of age as part of a mixed weaning diet.

The International Code covers all breastmilk substitutes including follow-on formula and does not permit advertising of any of these products.

The INI code does not acknowledge or provide the full details of the many restrictions that are in the Department of Health interpretation of the law, outlined as follows:

UK Law regulations 18, 19, 20, 21, 22/Guidance Note 47

Advertisements should not promote either directly or indirectly infant formula, formula milks or bottle feeding in general.

Formula advertising should not:

- Promote a range of formula products by making the brand the focus of the advert rather than specific products.**
- Feature text or images which relate to pregnancy or the feeding or care of infants under 6 months.**
- Include pictures or text which directly or indirectly relate or compare products to breastmilk.**
- Focus on carer's emotions in relation to the feeding or care of infants under 6 months.**
- Focus primarily on the promotion of ingredients, or the effect of ingredients, which are common to both follow on formula and infant formula.**

Companies also need to ensure that carelines, websites or mother and baby clubs and any advertisements for these means of communication supply only factual information to consumers and healthcare professional, and where they constitute advertising they should comply with all the controls above.

Guidance note 64 says that consumers may understand that generic references to a 'brand' of formula milk in advertisements refer to a number of formula products including infant formula. To achieve compliance companies will need to ensure that such terms are not used in advertising.

None of these points are included in the INI code.

Section 4.1.4 of the INI code states that materials aimed at parents or carers intended to provide instructions for the use of formula foods and general education and support e.g. recipe books, may include the name of the formula food.

The International Code is clear there should be no advertising of breastmilk substitutes to the public (this includes all products as defined in the Code including bottles and teats).

Guidance notes 77 and 78 which interpret UK Regulation 24, make it clear that if information materials are provided by companies for pregnant women or mothers of infants and young children (such as CDs, DVDs, wallcharts, posters, booklets, leaflets or e-information that can be downloaded from websites) that this requires approval from the Secretary of State for health before it can be given to third parties, that materials must not be marked or labelled with a proprietary brand of infant formula and materials must only be distributed through the healthcare system.

Regulation 24(3) also states that when the material contains information about infant formula that it shall not use any pictures which idealise the use of infant formula.

These points are not included in the INI code.

Section 4.3 of the INI code deals with company websites and states that company websites offer the general public a valued and readily accessible source of accurate, science based information on relevant topics; for example the importance of good maternal and infant nutrition and product information.

The International Code states that governments are responsible for provision of information on infant and young child feeding and UK Regulation 24, and its interpretive guidance notes outlined above, are also relevant in this regard.

Section 4.4 of the INI code deals with company on-line baby or parenting clubs and states that some companies provide online baby or parenting clubs which offer expectant mothers, parents or carers of healthy infants up-to-date and accurate information relating to their baby and /or parenting.

Section 4.4.2 says that small low-value gifts may be provided to parents or carers when they join a company's baby or parenting club.

UK regulation 23(2) prohibits manufacturers or distributors from providing any gift designed to promote the sale of an infant formula to the general public, pregnant women, mothers and their families. In the Department's view this would prohibit any gifts being provided by baby clubs or similar activities.

Section 4.5 of the INI code is on face to face contact with the general public stating 'we sometimes interact with parents and carers e.g. at baby or parenting shows'.

Section 4.5.2 states that advice on infant feeding may be provided by trained staff and section 4.7 provides further information on parent education days specific to infant milks marketed as FSMP, allowing these to be organised with industry funding and permitting demonstrations of feeding techniques or strategies to parents by industry representatives. Section 4.5.4 states that members of the public with questions about infant formula or iFSMP may be directed to trained staff on a company care line.

The International Code states that marketing personnel should make no direct contact with pregnant women or mothers of infants and young children.

The International Code also states that only healthcare personnel should demonstrate how to prepare breastmilk substitutes.

Chapter 5 of the INI code deals with in-store and the retail environment. It states that retailing practices must comply with the law, but puts the onus on retailers, with companies asked to alert retail environments if breaches are exposed.

Section 5.1 of the INI code states that companies sell products through various retail outlets but do not control how the retailer presents the products for sale.

Section 5.3 highlights promotion that is not allowed for infant formula and infant milks marketed as FSMP but restricts these to special displays, discount coupons, premiums, special sales, loss-leaders, tie-in sales and loyalty schemes.

The guidance notes that accompany the UK law also include the following additional guidance:

Regulation 20/Guidance Note 53:

Companies must ensure that follow on formula are clearly differentiated to avoid the risk of confusion and avoid shelf talkers or other in store promotional material for follow on formula in the vicinity of infant formula. Labelling of follow on formula must follow specific rules to ensure there is no confusion and the product is clearly not to be used for infants under 6 months.

Regulation 23(3) notes that for the purposes of regulation presentation also refers to the way in products are displayed. Guidance note 53 specifies that this includes:

That follow on formula should be located in a different part of the store to infant formula (or clearly separated by physical location).

The INI code fails to include this additional guidance.

Chapter 6 of the INI code deals with company carelines, stating ‘company carelines are available for parents to use if they have questions about feeding their infant’.

The International Code states that marketing personnel should make no direct contact with pregnant women or mothers of infants and young children and that Governments are responsible for provision of information on infant and young child feeding.

Chapter 7 of the INI code deals with labelling of formula foods.

Section 7.4 states that labels include clear and simple instructions for the preparation, use and storage of formula foods and information about the possible health hazards from incorrect preparation.

Whilst this chapter highlights some of the restrictions relating to labelling on breastmilk substitute products, the INI code does not mention that in Regulations 17(1)(d) and 18 (1)(d) instructions are required for the appropriate preparation, storage and disposal of products and that the Department recommends that these include:

- Information that powdered infant formula and follow-up formula are not sterile and as such can contain harmful bacteria.**
- All equipment used for feeding and preparing feed must be thoroughly cleaned and sterilised before use and bottles should be made up fresh for each feed as storing made-up formula milk may increase the chance of a baby becoming ill.**
- A warning about the health hazards of inappropriate preparation and storage. This statement should stress the importance to the baby's health of the correct preparation of infant formula without which there is an increased risk of the baby suffering from serious stomach upsets, diarrhoea, constipation etc. The statement should appear on the label in a conspicuous place and include wording such as 'failure to follow instructions may make your baby ill'.**

Regulation 17(e) requires a statement on the label recommending that the product be only used on the advice of independent persons having qualifications in medicine, nutrition or pharmacy or other professionals responsible for maternal and child care.

Regulation 17(2) and 18(2) seek to ensure that labelling does not discourage breastfeeding and does not use terms such as 'humanised', 'maternalised', 'adapted' or any similar term. Non-mandatory text or pictures on infant formula and follow on formula must not make reference to 'breastmilk' 'breastfeeding' 'moving on from breastfeeding' or closer to/inspired by breastmilk'

Non-mandatory text or pictures on infant formula labelling must not make reference to items such as 'the best' or 'the ideal method' of infant feeding.

Regulation 17(3) provides that the labelling of infant formula shall not include and picture of an infant or any other picture or text which may idealise the use of the product. Idealising images include pictures of infants, young children or carers, graphics that represent nursing mothers, pictures or text which imply infant health, happiness or well-being, baby or child related items (toys, cots or young animal) and anthropomorphic characters, pictures and logos.

Regulation 19 requires that there is avoidance of risk of confusion between infant formula and follow on formula. Regulations 20(1), 20(2), 21(1)(b) and 22 makes it a requirement that there should be a clear distinction in the presentation and advertising of infant formula and follow on formula. This is suggested to include:

- The terms infant formula and follow on formula should be in a font size no smaller than the brand name
- Infant formula and follow on formula should have different labels, pictures and blocks of text should differentiate between them
- The colour scheme used for infant formula packaging should be clearly different to the colour scheme for follow on formula packaging. Using different shades of the same colour is not acceptable/

None of these points are mentioned in the INI Code.

In addition, Section 7.7 states that the labels of infant milks marketed as FSMP must always recommend that the formula should be used on the advice of a health care professional.

Regulation 3(a) of Regulation 1999/21/EC states that infant milks marketed as FSMP should state on the label that they 'must be used under medical supervision.'

Chapter 13 of the INI code provides definitions of key terms.

Advertising is described as an unsolicited communication to the general public of a promotional message through mass media. This however 'excludes formula product composition and usage information for consumers and healthcare professionals published by or under the local control of infant nutrition companies on the internet'

Promotion(s) are described as 'provid[ing] an incentive to buy using a range of added or indirect benefits usually on a temporary basis to make the product more attractive. A non-exhaustive list of promotional marketing techniques includes two for the price of one offer, money-off offers, text-to-wins, instant-wins, competitions and prize draws Promotional marketing does not include routine, non-promotional distribution of products or product extensions'

Whereas the WHO² defines **promotion** as:

'The communication of messages that are designed to persuade or encourage the purchase or consumption of a product, or raise awareness of a brand. Promotional messages may be communicated through traditional mass communication channels the internet and other marketing media using a variety of promotional methods. In addition to promotional techniques aimed

² http://apps.who.int/gb/ebwha/pdf_files/WHA69/A69_7Add1-en.pdf?ua=1

directly at consumers measures to promote products to health workers through other intermediaries are included. There does not have to be a reference to a brand name of a product for the activity to be considered as advertising and promotion’.

The INI code also fails to mention **cross-promotion**, interpreted by WHO as:

‘**Cross-promotion** is a form of marketing where customers of one product or service are targeted with promotion of a related product. This can include packaging, branding and labelling of a product to closely resemble that of another. It can also refer to use of particular promotional activities for one product and/or promotion of that product in particular settings to promote another product’.

The definition of **Scientific and Factual** allows manufacturers to make claims without evidence from a peer reviewed journal, as is required in the UK Guidance Notes, and to withhold data that is stated to be ‘on file’.

We are pleased, however, to see that infant milks marketed as FSMP are described as ‘foods specially processed or formulated and intended for the dietary management of infants, to be used under medical supervision’ highlighting that companies and retailers should, as a matter of urgency remove any products marketed under these regulations from the shelves of supermarkets, shops and pharmacies for purchase where individual medical advice cannot be given.