

# Infant Nutrition Industry Code of Practice

FIRST EDITION

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# Chapter One: Introduction

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## Purpose and Scope

This Code of Practice (“the INI Code”) is a voluntary self-regulation standard developed by manufacturers of specialised infant foods who are members of the British Specialist Nutrition Association (“BSNA”), the trade association representing infant food manufacturers in the UK. Compliance with the INI Code is a condition of membership of BSNA.

The INI Code demonstrates the infant nutrition industry’s commitment to the World Health Organisation’s International Code of Marketing of Breastmilk Substitutes (“WHO Code” 1981), as implemented within the UK’s specific legal and economic context. It supports the principles and aims of the WHO Code, which is:

*“...to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breastmilk substitutes, when they are necessary, on the basis of adequate information and through appropriate marketing and distribution.”*

The INI Code applies to the following product types used for infants aged 0–12 months:

- **infant formula** suitable from birth (also known as ‘first infant milk’)
- **follow-on formula** suitable from 6–12 months, designed for use as part of a mixed weaning diet
- **infant foods for special medical purposes** (iFSMP), specialist formulas which are designed for infants from 0–12 months and should be used under medical supervision

In the INI Code, these products are referred to collectively as ‘formula foods’.

The INI Code covers areas of industry practice relating to the sales and promotion of formula foods in the UK including product quality, sales, marketing, and clinical research. It applies to the UK market only.

Formula foods are amongst the most strictly regulated of all foodstuffs.<sup>1</sup> Extensive UK and European law exists in relation to the promotion, composition, labelling, sale and safety of formula foods. The INI Code reflects this legislation and extends beyond it in several areas.

## Supporting Breastfeeding

Breastfeeding is the best way to feed a healthy infant and is important for both mother and baby’s health and wellbeing. The World Health Organisation recommends that infants are exclusively breastfed until six months of age, after which breastfeeding is complemented with the appropriate introduction of solid food until two years of age and beyond.

There is no question that breastmilk provides the best possible nutrition for infants. As signatories to the INI Code, we fully support initiatives to increase the rates of breastfeeding in the UK.

However, when healthy infants are not exclusively breastfed, the only food recognised by the WHO as a suitable and safe alternative to breastmilk is a scientifically developed infant formula.

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<sup>1</sup> Regulation EU No. 2016/127 and EU Directive 2006/141/EC. See also Regulation EU No. 2016/128 and Directive 1999/21/EC (in relation to iFSMPs); Regulation (EU) No. 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control; The Food for Specific Groups (Information and Compositional Requirements) (England) (Amendment) Regulations 2017 No. 62; The Medical Food (England) Regulations 2007 No. 3521

There may also be circumstances in which infants who have a particular disease, disorder or medical condition require an iFSMP, either as a sole source of nutrition or as a supplementary feed.

Infant nutrition companies, health practitioners and government all have an important role to play in ensuring that the mothers and carers of infants who are fed formula receive adequate and appropriate information, whilst also protecting and promoting breastfeeding.

## Ensuring High Standards

As signatories to the INI Code, we recognise that we have a responsibility to operate in a responsible, ethical and professional manner. We acknowledge the importance of, and commit to, the principles and aims of the WHO Code as implemented through national legislation. We also understand the importance of ensuring that our standards of behaviour are consistent and clear. Whilst the industry has a legitimate right to communicate with healthcare professionals and the public, the INI Code recognises and seeks to achieve a balance between the needs of parents, the public in general, and healthcare professionals, and the rigorous regulatory environment which controls every aspect of formula foods. The availability of accurate, representative and up-to-date information is essential to ensure that all formula foods are used appropriately.

We fully support the INI Code and commit that, as signatory companies, we will devote the necessary resources to ensure that our activities comply with it. Any complaint made against a company under the INI Code will be regarded as a serious matter both by that company and by the industry as a whole. The INI Code of Practice Authority (INICPA) will require appropriate corrective action to be taken by any company found to be in breach of the INI Code. In addition, the outcome of complaints will be published on the BSNA website.

Companies will ensure that all relevant personnel are trained appropriately and regularly in the requirements of the INI Code. Companies have operating procedures in place under which all materials and activities covered by the INI Code are reviewed to ensure compliance both with the INI Code and with the appropriate legal requirements.

This Code will be reviewed and updated on an ongoing basis, but at least every two years, and will take into account any rulings that may be made by INICPA, as well as those made by official external agencies and enforcement bodies. Further information on the INI Code's complaints procedure can be found in chapter 12.

The standards laid down in the INI Code represent a minimum for all signatory companies. Each individual company may choose to apply tighter standards or procedures.

## Signatories

The following are signatories to this Code:

Abbott Laboratories Ltd	Nestlé Health Science
Danone Early Life Nutrition	Nestlé Nutrition
HiPP UK Ltd	Nutricia Advanced Medical Nutrition
Mead Johnson Nutrition	
– part of RB Group	

The INI Code applies to infant formula, follow-on formula and infant foods for special medical purposes for infants aged 0-12 months.

# Chapter Two: Our Core Principles

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We recognise that we have a responsibility to operate in a responsible, ethical and professional manner. We acknowledge the importance of, and commit to, the principles and aims of the WHO Code as implemented through national legislation. Five core principles lie at the heart of our activities.

## Principle 1

**Superiority of Breastmilk** – *We acknowledge and support the superiority of breastmilk and breastfeeding.*

We support breastfeeding as the first and best choice to feed a baby, and recognise the superiority of breastmilk as the optimal food for healthy infants.

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## Principle 2

**Compliance** – *We comply with all relevant legislation.*

We comply with all relevant EU and UK laws and regulations.

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## Principle 3

**Accountability** – *We are responsible for our actions and legally accountable to relevant authorities.*

We have in place internal governance procedures to ensure compliance with the INI Code, and commit to taking corrective action in respect of any breaches.

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## Principle 4

**Informed Choice** – *We support the right of parents and carers to make the appropriate choices for the infants in their care.*

Healthcare professionals, parents and other carers should have all the information they need to enable them to make informed choices about their infants' nutrition.

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## Principle 5

**Quality** – *We adhere to rigorous quality standards.*

Quality is a top priority. Our ingredients are sourced, and our products manufactured, to rigorous compositional and safety specifications, meeting strict hygienic and quality control standards, as set out in relevant EU and UK legislation.

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# Chapter Three: Healthcare Organisations and Healthcare Professionals

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We support breastfeeding and recognise that breastmilk provides the best nutrition for a healthy infant. However, for those parents who cannot, or choose not to, breastfeed exclusively, bottle feeding with infant formula is the only safe alternative for an infant as a sole source of nutrition.

Healthcare professionals play an essential role in supporting appropriate early life feeding practices, including encouraging and facilitating breastfeeding, and providing consistent, objective advice to mothers and families about the superiority of breastfeeding.

Healthcare professionals are also ideally placed to recommend and supervise the use of iFSMPs for infants with a particular disease, disorder or medical condition.

To enable parents to make an informed decision about their infant's nutrition, healthcare professionals must be up-to-date and knowledgeable about all forms of infant feeding, including breastfeeding, formula feeding and using iFSMPs, and be familiar with the benefits and suitability of each feeding method. Therefore, healthcare professionals need up-to-date and evidence-based information and materials to enable them to provide accurate, objective and consistent advice to parents.

Healthcare professionals should also be familiar with their responsibility to all parents and carers as set out in national policy and strategy and the UNICEF Baby Friendly Initiative.<sup>2</sup>

We do not offer any gifts, benefits in kind, financial or other offerings to healthcare professionals or organisations as an inducement to prescribe, recommend, sell or promote any formula food.

## 3.1 Information Provided to Healthcare Organisations and Healthcare Professionals (including via traditional print and online)

Any information provided specifically for healthcare professionals is not intended for the general public and is scientific, factual and appropriately referenced. None of the information we supply will imply or create a belief that formula foods are equivalent or superior to breastmilk.

- 3.1.1 Items for healthcare professional use such as posters, growth charts, calendars or formula preparation charts, for use in hospitals or clinics where the general public might see them, will not carry a formula food product name.
- 3.1.2 Companies may disseminate specific product information/reference materials to healthcare professionals for their own use; for example, pamphlets, product data cards, posters and booklets. Any information will always be 'scientific and factual'.<sup>3</sup> Such materials may carry the name of formula foods.
- 3.1.3 Product information materials in 3.1.2 which are intended specifically for healthcare professionals will always prominently include the statement "For Healthcare Professional Use Only" (or similar wording).

<sup>2</sup> <https://www.unicef.org/babyfriendly/>

<sup>3</sup> Regulation 21 of the Infant Formula and Follow-On Formula (England) Regulations 2007 only allows infant formula to be advertised in scientific publications and trade publications, and puts in place controls on the content of such advertisements.

- 3.1.4 Companies will provide information on the safe preparation and use of formula foods to help ensure the health and safety of infants.
- 3.1.5 When requested, companies may show healthcare professionals how to prepare and use formula foods in the form of a practical demonstration.
- 3.1.6 Practice-related equipment, or small work-related items, e.g. pens or sticky note pads, that may be provided for use by healthcare professionals at their request, will not carry the product name of a formula food, but it may feature a company name or company logo.
- 3.1.7 Company websites that provide information for healthcare professionals require a dedicated area for that information. Healthcare professionals must also acknowledge that they are entering a dedicated area which is intended only for them.
- 3.1.8 Company websites must always display the name of the company, address and contact information.
- 3.1.9 Company website cookie information must provide clear and comprehensive information about the storage of personal data.
- 3.1.10 All privacy and confidentiality laws are respected and adhered to.
- 3.1.11 Personal, confidential and proprietary information is protected.
- 3.1.12 Prior to any external distribution, all company communications, whether traditional print or online, are internally validated by means of a robust and documented review and approval process involving the appropriate subject matter experts, e.g. regulatory and medical experts, nutritionists or lawyers.

### **3.2 Advertising of products to healthcare professionals (via traditional print and online)**

Companies comply with legislation controlling advertising of formula foods to healthcare professionals.

- 3.2.1 It is within the remit of Trading Standards Officers to enforce legislation controlling healthcare professional media advertising relating to formula foods.
- 3.2.2 All healthcare professional traditional print advertising clearly states: “For Healthcare Professional Use Only” (or similar wording).

### **3.3 Provision of Products for Professional Evaluation (PPE)**

We provide PPE of formula foods to healthcare professionals at their request. Any such provision must be approved and recorded by the company that provides the product.

- 3.3.1 PPE are provided specifically for the purpose of professional evaluation or demonstration purposes, and only upon the request of a healthcare professional, which is recorded by the company. The provision of PPE may include, for example:

Product information materials intended specifically for healthcare professionals will always prominently include the statement “For Healthcare Professional Use Only” (or similar wording).

- a) The introduction of a new product or new product packaging/labelling following notification to the Department of Health (DH), as required.
- b) The introduction of a new formulation/recipe of an existing product following notification to DH, as required.
- c) The introduction of a range of products to new, or recently qualified, healthcare professionals.
- d) In the case of iFSMP, (in addition to a), b) and c) above), to confirm the healthcare professional's assessment of the suitability of the product for patients.

3.3.2 PPE are typically supplied for short-term use in small quantity.

3.3.3 When distributing PPE it must always be made clear that:

- a) The product is provided solely for the purpose of professional evaluation;
- b) The product is not being provided as an incentive to prescribe, recommend, sell, promote or use any specific formula food.

3.3.4 To enable evaluation of the suitability of iFSMPs, PPE may also be sent directly to parents or carers, but only at the request of a healthcare professional. Any such request shall be approved by the company and recorded.

### **3.4 Products Provided in Urgent Situations**

We have a duty of care to help ensure continuity of supply of iFSMP to infants under the medical supervision of healthcare professionals.

3.4.1 A very limited quantity of iFSMP may be provided in urgent situations, ideally on the request of a healthcare professional. Such situations might include a failure or delay in the normal retail or hospital supply. Any such provision must be approved by the company and recorded.

### **3.5 Industry Training and Education for Healthcare Professionals**

We support continued professional development and training through the provision of activities including fellowships, speaker opportunities, attendance at professional conferences and symposia, and other informational and educational programmes. Industry funding or support for any educational or scientific meeting hosted by a professional body, including patient carer organisations, should not in any way be, or be portrayed as, an endorsement of the company's products by the individual host society or other body. Ideally, the role of the sponsor should be publicised by means of a statement in the event's promotional material and/or programme. Any such support from industry for continued professional development will be documented by the company through a contractual arrangement.

3.5.1 Events may provide a forum for the exchange of scientific and factual information, including that related to formula foods, and the healthcare professional's area of clinical expertise.

3.5.2 Company-organised events for healthcare professionals must be convened for educational purposes or for professional training. The scientific content of the event programme must be relevant to the specific interests of the delegates.



- 3.5.3 Hospitality is limited to refreshments and/or meals incidental to the main purpose of the event, and only provided to event participants, not their guests, spouse or other family members.
- 3.5.4 Any funding to support healthcare professionals in attending events is limited to the healthcare professional only, and not their guests, spouse or other family members. Payment would include reimbursement of pre-agreed travel expenses, meals, accommodation and registration fees. No payment is made for any time spent travelling, or attending an event; the same applies to any accompanying guests, spouse or other family members. Sponsorship is not conditional upon an obligation to prescribe, recommend, sell or promote any formula food.
- 3.5.5 Healthcare professionals are not incentivised to attend events on the basis of any entertainments offered. If any leisure or social activity is part of an itinerary, it will always be secondary to the scientific agenda.

### **3.6 Healthcare Professionals as Speakers, Trainers and Consultants**

Healthcare professionals providing consulting and advisory services to companies are offered reasonable, fair-market compensation and are reimbursed for reasonable travel, lodging and meal expenses incurred as part of providing those services. A legitimate business need for the services will be agreed in advance of entering into arrangements.

- 3.6.1 Reasonable fees and reimbursement of out-of-pocket expenses, including travel and accommodation, are paid to healthcare professionals who offer speaker, training or consultancy services.
- 3.6.2 All healthcare professionals must have a written contract or agreement specifying the nature of the services to be provided, the basis for payment for those services and the amount of payment (if any).
- 3.6.3 Any payment to healthcare professionals for services rendered, should ideally be made through BACS or company (not personal) cheque, and never in cash.

### **3.7 Educational Grants**

We provide funds to support independent research, the advancement of science and healthcare professional education, or patient and public education in relation to formula foods and infant feeding. No grant is made as a reward or as an inducement to prescribe, recommend, sell or promote any products or services.

- 3.7.1 Documentation is maintained by each company in respect of all educational grants made.
- 3.7.2 Educational grants are not linked in any way to past, present or potential future use or recommendation of formula foods by individual healthcare professionals.
- 3.7.3 Educational grants are only awarded to healthcare professionals, organisations or entities entitled to receive them.
- 3.7.4 Recipients of any educational grant must have a formal written contract detailing the amount of the grant, the payment terms, and the agreed scope and purpose of the work.

# Chapter Four: Industry Interaction with the General Public including Pregnant Women and Parents of Children under the Age of 12 Months

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Access to accurate, up-to-date, scientific information is essential to support parents and carers of infants in making informed feeding choices. We will provide this in accordance with the law and will encourage the general public, including pregnant women, parents and carers, to seek contact with, and information from, healthcare professionals when appropriate.

## 4.1 Information and Educational Materials

- 4.1.1 The provision of any information relating to the feeding of healthy infants and intended to reach pregnant women and mothers of infants and young children will always include or refer to the following:
- a) The benefits and superiority of breastfeeding;
  - b) Maternal nutrition;
  - c) The preparation for and the maintenance of breastfeeding;
  - d) The possible negative effect on breastfeeding of introducing partial bottle feeding;
  - e) The difficulty of reversing the decision not to breastfeed; and
  - f) Where needed, the proper use of an infant formula.
- 4.1.2 Any material which contains information about the use of an infant formula will also include information about the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and the health hazards of improper use of infant formula.
- 4.1.3 Neither infant formula nor iFSMP is advertised to the general public.
- 4.1.4 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. These materials are supplied to parents at their request or via their healthcare professional.

We never state, suggest or imply that formula foods are equivalent or superior to breastmilk.

## 4.2 Broadcast and Non-Broadcast Advertising

All advertising to the general public, including pregnant women, parents and carers of infants and young children, must comply with legislation. In addition, the Advertising Standards Authority is the UK's independent regulator of advertising across all media and it adjudicates on compliance with its advertising codes.<sup>4 5</sup> Its work includes acting on complaints and proactively checking the media to take action against misleading, harmful or offensive advertisements.

- 4.2.1 Neither infant formula nor iFSMP is advertised to the general public. When advertised, follow-on formula is always presented as only suitable for infants from six months of age as part of a mixed weaning diet.
- 4.2.2 Babies featured in advertisements for follow-on formula must be aged over six months, ideally with documented proof of age and the date of the media creation. When this is not available – for example, when using library photographs – the babies should demonstrate relevant developmental markers of age, e.g. sitting unaided, with good head control, or visible lower incisors.
- 4.2.3 All advertising, including nutrition and health claims, complies with legislation.

## 4.3 Company Websites

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 latter always in a bespoke section).

- 4.3.1 Users accessing company websites which refer primarily to the feeding of healthy infants will be prompted to read and acknowledge an 'Important Notice' before they are able to access product-specific information regarding infant formula on a company website. The 'Important Notice' will include information on the following:
  - a) The benefits and superiority of breastfeeding;
  - b) Maternal nutrition;
  - c) The preparation for and the maintenance of breastfeeding;
  - d) The possible negative effect on breastfeeding of introducing partial bottle feeding;
  - e) The difficulty of reversing the decision not to breastfeed; and
  - f) Where needed, the proper use of an infant formula.
- 4.3.2 Any material which contains information about the use of an infant formula will also include information about the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and the health hazards of improper use of infant formula.

<sup>4</sup> BCAP: The UK Code of Broadcast Advertising <https://www.asa.org.uk/asset/846F25EB-F474-47C1-AB3FF571E3DB5910.97855BAF-833F-4B75-9E10729E8807C7B8/>

<sup>5</sup> CAP: The UK Code of Non-Broadcast Advertising <https://www.asa.org.uk/codes-and-rulings/advertising-codes/nonbroadcast-code.html>

#### 4.3.3 Website content for consumers:

- a) Complies with all relevant regulations;
- b) Clearly displays all terms and conditions;
- c) Clearly displays the name of the company, address and contact information;
- d) Respects and adheres to copyright, privacy and consumer protection laws;
- e) Protects confidential and proprietary information;
- f) Does not use avatars to engage with mothers without revealing industry identity;
- g) Contains information that is supported by objective, science-based data; and
- h) Only uses nutrition and health claims that comply with legislation.

#### 4.4 Company Online Baby or Parenting Clubs

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. Data protection legislation is complied with at all times.

- 4.4.1 Only parents or carers who have specifically chosen to join a company's baby or parenting club will be registered, and they may unsubscribe or leave at any time.
- 4.4.2 Small, low-value, gifts may be provided to parents or carers when they join a company's baby or parenting club. Such gifts must be relevant to parenting or infancy, e.g. muslin cloth, baby towel, car sunscreen. They should never undermine breastfeeding or promote formula feeding, and will not carry the product name of any formula food.
- 4.4.3 Emails to parents or carers of healthy infants as part of a company baby or parenting club will:
  - a) Not include the product name of an infant formula or iFSMP; and
  - b) Not include the product name of follow-on formula unless the recipient has advised that their child is at least six months of age.

#### 4.5 Face-to-Face Contact with the General Public

We sometimes interact with parents or carers, e.g. at baby or parenting shows.

- 4.5.1 All staff interacting with the general public will be trained on the principles of UK regulations in relation to the sales and marketing of formula foods. They will also be trained on relevant aspects of the INI Code.
- 4.5.2 Advice on infant feeding may be provided by trained staff and, when appropriate, members of the general public will be directed to their local healthcare professional. Individual medical advice will not be given.
- 4.5.3 Companies do not conduct or fund any 'face-to-face' demonstrations of feeding practices on infant and follow-on formula to parents, carers and the general public, such as 'how to prepare a feed', as these 'face-to-face' demonstrations should only be conducted by healthcare professionals.

**Neither infant formula nor iFSMP is advertised to the general public.**

- 4.5.4 There will be no promotion of infant formula or iFSMP. Any questions from the general public about infant formula and iFSMP will be directed to a healthcare professional or a trained member of a company Careline team, who will address them in a factual way.

#### **4.6 Provision of Product Samples to the General Public**

We operate a strict policy on the provision of product samples to the general public. For the purposes of this Code, a sample is an appropriate and limited quantity of product provided for promotional purposes, without cost to the recipient, and not intended for sale.

- 4.6.1 Samples of infant formula are never provided to the general public.
- 4.6.2 Samples of follow-on formula may be offered, but only in circumstances where a parent or carer has advised that infants are at least six months of age.

#### **4.7 Parent Education Days Specific to iFSMP**

Healthcare professionals may prescribe an iFSMP for the dietary management of infants diagnosed with a specific disease, disorder or medical condition. Parents, carers or family members of these infants often require support and practical advice on feeding and introducing the appropriate diet during the first 12 months of life.

Healthcare professionals may encourage parents, carers or family members to share experiences and discuss management strategies and techniques at events that are specially organised for that purpose. Any industry funding to facilitate this type of activity will be limited to room hire and refreshments. Any fees or expenses which may be payable to healthcare professionals will be paid in accordance with section 3.6 and are not made as a reward, inducement to prescribe, recommend, sell or promote any products or services related to products falling under the scope of the INI Code.

Only parents, carers and family members of infants with pre-existing and diagnosed conditions are invited to such events.

- 4.7.1 A healthcare professional is always involved in the organisation of these events.
- 4.7.2 Allied patient charity representatives may also offer advice and support.
- 4.7.3 Demonstrations of feeding techniques or strategies, such as changing food texture or incorporating iFSMP into the diet, may be given to parents, carers or families by an industry representative, but only with the prior agreement of the healthcare professional or patient charity representative. Any provision of product for professional evaluation by the healthcare professional will be in accordance with section 3.3.3.

# Chapter Five: In-Store and the Retail Environment

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All parties involved in the selling and marketing of formula foods in-store or online have a responsibility to comply with the law. It is the responsibility of the retailer to sell formula foods to the public in accordance with the requirements of the legislation. Any breaches of the law will fall under the jurisdiction of local Trading Standards Officers and the Advertising Standards Authority.

- 5.1 Companies sell products through various retail outlets but do not control how the retailer presents the products for sale.
- 5.2 Companies work with retailers to help ensure that all in-store promotional activity is legally compliant. If any breach of the legislation comes to light in the retail environment, companies take swift action to alert the retailer to the breach.
- 5.3 Infant formula and iFSMP should not be promoted to the general public in retail outlets (including pharmacies and online) by any means, including:
  - a) Special displays, including in-store promotional space, e.g. end-of-aisle displays
  - b) Discount coupons
  - c) Premiums
  - d) Special sales
  - e) Loss-leaders
  - f) Tie-in sales
  - g) Loyalty schemes

It is illegal to promote infant formula to the general public. Any breaches of the law should be reported to Trading Standards or the Advertising Standards Authority.

# Chapter Six: Carelines

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Company Carelines are available for parents to use if they have questions about feeding their infant. This provides parents with an opportunity to ask questions and also to gain reassurance that any issues that they have around infant feeding are usual or, if not, to seek medical advice. As Careline contact numbers and emails are available on product packaging and websites, we expect that the majority of queries are specific to particular products rather than infant feeding choices more generally. However, Careline operators will also offer evidence-based advice about infant feeding upon request.

- 6.1 Careline services are managed by staff who understand the importance of breastfeeding and are trained on the principles and aims of the WHO Code as implemented into national legislation. Careline staff are also trained appropriately on the INI Code.
- 6.2 Careline operators are trained and knowledgeable on product usage and composition. They may provide general advice such as on preparation methods, product usage and other information, in line with what is stated on the label. When more specialised information is requested, they may refer the query to company subject matter experts, such as qualified nutritionists or dietitians.
- 6.3 If asked about infant formula or iFSMP, Careline operators will always advise that the use of these products should be discussed with a healthcare professional.
- 6.4 Careline operators may offer general information about common feeding issues or medical conditions, but will never offer personal, individual medical advice. Callers will always be referred to their healthcare professional to discuss their specific concern when it is appropriate to do so.
- 6.5 The personal data of individuals using a Careline service will be treated in accordance with legislative requirements.
- 6.6 Carelines are not used to sell or actively promote formula foods. Breastfeeding is always supported as the optimal way to feed an infant.
- 6.7 Any product information about infant formula and iFSMP must be explicitly requested by the caller.
- 6.8 All questions will be answered in a direct, non-promotional and factual manner.

Company carelines are never used to sell or actively promote infant formula. Breastfeeding is always supported as the optimal way to feed an infant.

# Chapter Seven: Labelling of Formula Foods

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Information provided on labels of formula foods is tightly regulated under relevant EU and UK legislation. All nutrition and health claims used in labelling must be positively assessed by the European Food Safety Authority and authorised by the European Commission. When infant formula and iFSMP are placed on the market, the labels must be notified to the Department of Health, which is able to review labelling and substantiation for any new ingredients.

- 7.1 Labels must be clear, easily readable and understandable. Information must be evidence-based and accurate.
- 7.2 All labels of formula foods include a very clear age indication for use, a list of ingredients and the nutrition information for the product.
- 7.3 All statements used on labels, including nutrition and health claims, comply with legislation.
- 7.4 Labels always include clear and simple instructions for the preparation, use and storage of formula foods, and information about the possible health hazards from incorrect preparation.
- 7.5 All product labels have appropriate markings to allow for full traceability, e.g. batch number, best-before date.
- 7.6 Labels of infant formula will always bear the words 'Important Notice' and a statement explaining the superiority of breastfeeding. In addition, they will not state or imply that those products are equivalent to breastmilk, and will not discourage breastfeeding.
- 7.7 Infant formula and iFSMP labels must always recommend that the formula should be used on the advice of a healthcare professional.
- 7.8 Follow-on formula is labelled for use from six months of age as part of a mixed weaning diet. Any decision to use follow-on formula before six months of age should be made only on the advice of a healthcare professional.
- 7.9 Trading Standards Officers enforce compliance with the legislation.

The nutritional content of formula food is clearly stated on product labels or packaging.



# Chapter Eight: Research

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It is important that manufacturers continually conduct clinical research, measure outcomes and innovate products. We conduct and support research in line with established guidelines on good clinical practice and local healthcare professional organisations' protocols.

## 8.1 Clinical Studies

Clinical studies are undertaken to assess the safety, clinical outcomes and efficacy of formula foods and should be designed so as not to undermine a mother's commitment to breastfeeding.

- 8.1.1 Studies are conducted according to guidelines such as the International Council for Harmonisation (ICH) Good Clinical Practice Guidelines, the Declaration of Helsinki, and other applicable codes of practice, local laws or regulations.
- 8.1.2 All research activities must be conducted in accordance with all contractual obligations agreed prior to commencement.
- 8.1.3 There is no undue or improper influence on clinical study participants, results or outcomes. Companies do not in any way influence the provision, supply, dispensing or promotion of any products during a period of investigation.
- 8.1.4 Clinical study investigators are only provided with products related to the clinical study. The quantities of product strictly correspond to study protocol and the declared number of participants. This information is documented by the company.

## 8.2 Market Research

We use market research to better understand the environment in which we operate.

- 8.2.1 Companies have policies and procedures in place which are applied when conducting market research. This ensures that any research is conducted in a responsible, ethical and appropriate manner. In addition, market research is often conducted using independent third-party market research organisations or professional bodies. Such organisations include Market Research Society (MRS) accredited members, working in accordance with the ICC/ESOMAR International Code on Market and Social Research.
- 8.2.2 Data collection during market research is in line with UK laws and regulations, e.g. complies with data protection legislation.
- 8.2.3 All market research participants are informed in advance about the scope and use of data. Documented consent is always obtained.

# Chapter Nine: Quality and Safety

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The quality and safety of our products is of the highest importance. Formula foods are amongst the most strictly regulated of all foodstuffs. The EU and UK mandate strict requirements on nutritional composition in legislation, as well as restrictions on pesticides, contaminants and microorganisms, along with packaging materials. All manufacturers are required to ensure that their food products are safe in accordance with General Food Law, and standards are in many respects even tighter for formula foods for infants.

Ingredients for formula foods are sourced, manufactured and purchased to compositional and safety specifications which meet strict hygiene and quality control standards, as set out in relevant EU and UK legislation.

- 9.1 All formula foods are manufactured under very strict hygienic and quality management procedures to help ensure the protection, health and safety of infants.
- 9.2 All ingredients must be carefully sourced to ensure compliance with company-defined quality standards and relevant EU and UK legislation.
- 9.3 All products must have appropriate markings which enable them to be tracked through the distribution chain, e.g. a batch number, best-before date.
- 9.4 All products must feature a best-before date to provide a clear indication of the period within which their quality, including their nutritional adequacy, is guaranteed.
- 9.5 All batches are validated against compliance standards prior to release into the market.
- 9.6 Products must be sold and distributed in accordance with all applicable quality and hygiene standards set by EU and UK legislation.
- 9.7 All products which clearly display a quality guarantee should also include, where required by applicable law, a disclaimer that this does not affect statutory consumer rights.

We adhere to the highest quality and safety standards.

# Chapter Ten: Humanitarian Aid

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Signatories to the INI Code recognise that emergency situations or humanitarian disasters do not call for the routine distribution and use of formula foods. The conditions prevalent during emergencies, such as a lack of clean water or poor sanitation, are likely to lead to additional health risks. For this reason, during an emergency, it is particularly important that infants continue to be breastfed. Only when this is not possible should formula foods be given to infants, and then in the safest way possible in the prevailing circumstances.

Signatories to the INI Code who are able to provide humanitarian aid when requested have internal policies regarding the provision of any formula food (whether it be infant formula, follow-on formula or iFSMP). These policies require that all product donations and other disaster relief assistance provided in response to such requests comply at all times with applicable laws and regulations. The policies of the companies that provide formula food as humanitarian aid can be viewed via the links below:

**Abbott:**

[https://dam.abbott.com/en-us/documents/pdfs/transparency/Abbott\\_Policy\\_on\\_the\\_Marketing\\_of\\_Infant\\_Formula.pdf](https://dam.abbott.com/en-us/documents/pdfs/transparency/Abbott_Policy_on_the_Marketing_of_Infant_Formula.pdf)

**Danone:**

<https://www.danone.com/content/dam/danone-corp/danone-com/about-us-impact/policies-and-commitments/en/2018/Danone%20Policy%20for%20the%20Marketing%20of%20Breast-Milk%20Substitutes%202018.pdf>

**Mead Johnson:**

<http://www.rb.com/responsibility/infant-and-child-nutrition>

**Nestle:**

<https://www.nestle.com/asset-library/documents/creating%20shared%20value/nutrition/standard-donations-low-cost-supplies.pdf>

# Chapter Eleven: Internal Governance

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As signatories to the INI Code, we fully support it and commit that we will devote the necessary resources to ensure compliance. Companies will ensure that all relevant personnel are trained appropriately in the requirements of the INI Code.

- 11.1 Internal governance procedures are in place to ensure compliance with the INI Code and that any required corrective action is taken.
- 11.2 Operating procedures within companies are in place to ensure that materials and activities covered by the INI Code comply both with it and the appropriate legislation.
- 11.3 All companies operate dedicated confidential and anonymous reporting systems for use by employees who may be concerned or unsure about company practices.
- 11.4 All relevant UK employees of companies that are signatories to the INI Code receive appropriate training on the provisions of the INI Code:
  - a) Training is mandatory
  - b) Training is recorded and renewed annually
  - c) New starters will receive training as part of their induction programmes

Internal governance procedures are in place to ensure compliance with the INI Code.

# Chapter Twelve: Complaints Procedure

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The INI Code will be administered by the Infant Nutrition Industry Code of Practice Authority (“INICPA”). INICPA is responsible for the provision of advice and guidance on the INI Code as well as for the complaints procedure. It consists of an independent Director and Panel. It is supported by a secretariat.

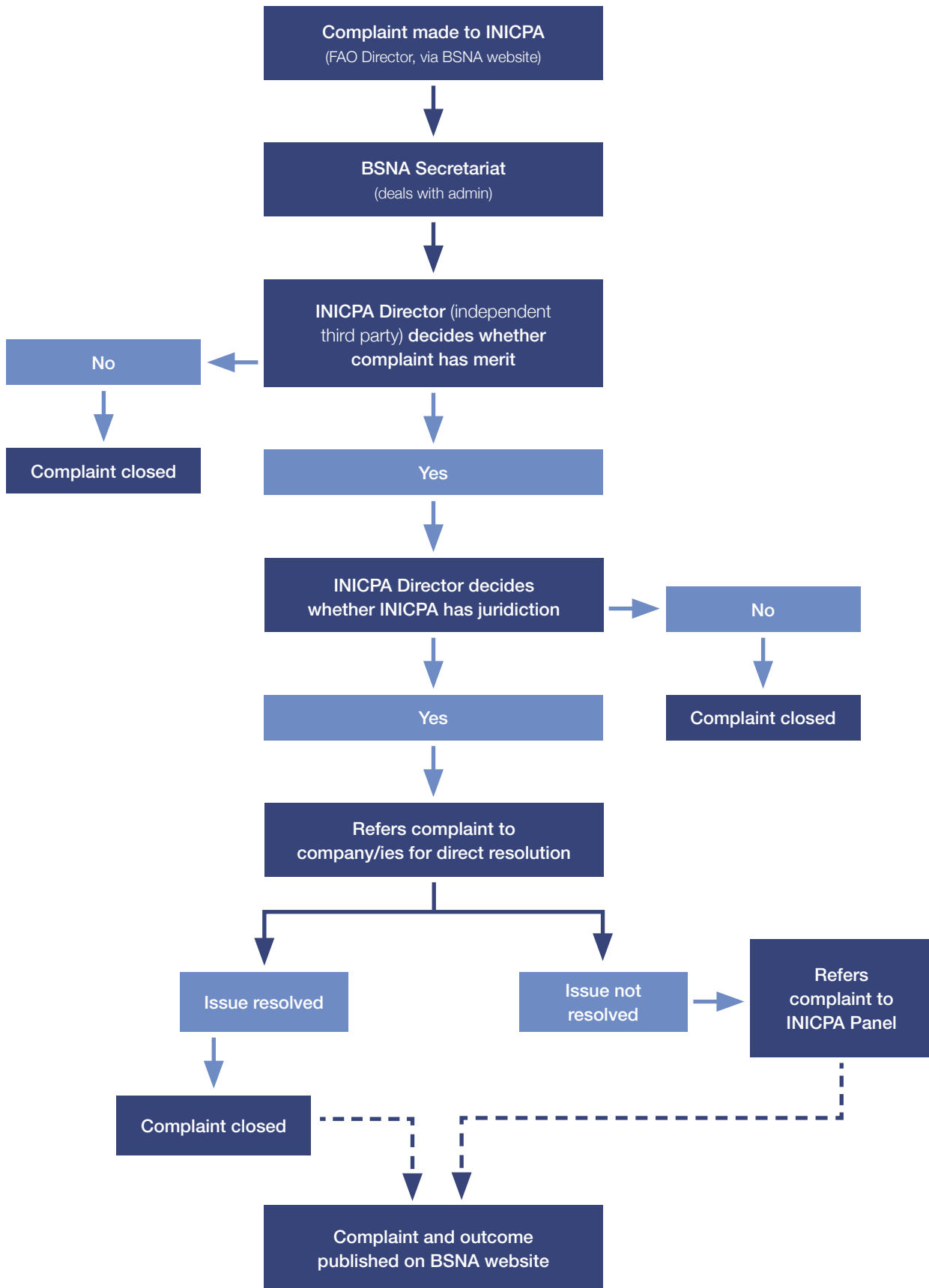
Signatory companies, healthcare professionals, healthcare professional organisations, members of Parliament, devolved Parliaments and Assemblies may lodge a complaint if they believe that the INI Code has been breached. Complaints should be submitted to the Director of Infant Nutrition Industry Code of Practice Authority by e-mail to [info@bsna.co.uk](mailto:info@bsna.co.uk).

The complaints procedure is a process in which a complainant asks the Director to investigate whether a signatory to the INI Code has acted in breach of it. The complainant will provide a name, contact details and relevant information about their interests in the matter of the complaint; identify why they believe that the INI Code has been breached and which specific clause appears to have been breached; and provide any supporting evidence. If the Director assesses that the complaint both falls under the jurisdiction of INICPA and may also have merit, he/she refers it to the company alleged to be in breach of the INI Code for swift resolution. If this is not possible, the Director will refer the complaint to the INICPA Panel. The Panel takes evidence from both sides and can seek evidence from third parties if necessary. All complaints will be judged on the evidence provided by the parties.

If the complaint is upheld, the company in breach of the INI Code will be required to take corrective action. The outcome of complaints will be published by BSNA at [www.bsna.co.uk](http://www.bsna.co.uk).

The INI Code complements, and is consistent with, existing regulations. Any complaints that fall under the jurisdiction of, or is the subject of a separate complaint, claim or other process administered by national, local or regulatory authorities (e.g. the Advertising Standards Authority (ASA), Trading Standards (TS)) will be dealt with by those authorities, and not under the INI Code procedure unless the two members consent to go through the INI Code complaints procedure where a matter could have been referred to a national, local or regulatory authority. Where a third-party initiates a complaint, the option to raise this through the INI procedure will be presented for the third-party’s consideration. If the complaint is referred to a national, local or regulatory authority, the decision of the relevant authority is final and the complaint will not be the subject of a separate investigation by INICPA.

Further information on the complaints procedure is available on a dedicated page at [www.bsna.co.uk](http://www.bsna.co.uk).



# Chapter Thirteen: Definitions

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For the purposes of the INI Code the following definitions will apply:

## **Advertising**

An unsolicited communication to the general public of a promotional message through mass media: for example, television, national or local newspapers, magazines and radio, the internet (including social media) or at point of purchase.

Price information at point of sale, infant 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, are excluded from this definition.

## **Avatar**

An icon or figure representing a particular person in a video game, internet forum, etc.

## **Baby and Parenting Shows**

Public physical displays, arrangements, exhibitions or presentations intended to appeal to the general public and covering a wide range of subject matter, e.g. baby-related equipment such as prams, infant feeding and food topics, maternal and baby clothing, baby furniture, etc.

## **Breastmilk Substitute**

Any food marketed or otherwise represented as a partial or total replacement for breastmilk, whether or not suitable for that purpose.

## **Broadcast Communication**

A term given to cover broadcast to the general public. Broadcast communication can use either the name of the product or the name of its manufacturer.

## **Company (or Companies)**

Any infant nutrition business that is a signatory to the INI Code.

## **Educational Materials**

Any materials, whether written, aural, or visual, paper-based or online, that provide education or information about such topics as nutrition, healthcare or growth and development of infants.

## Events

Events include fellowships, study tours, speaker opportunities, symposia, fora, conferences or other scientific or professional meetings organised by an infant formula manufacturer or third parties. These events provide either educational or professional training to healthcare professionals or an opportunity to exchange scientific information or professional expertise.

## Follow-on Formula

A formula product designed to meet the nutritional needs of infants from six months of age when appropriate weaning foods are introduced, and which constitutes the principal liquid element in this varied diet.

## Formula Feeding/Formula Foods

The feeding of the following products to infants aged 0–12 months:

- **infant formula** suitable from birth (also known as ‘first infant milk’)
- **follow-on formula** suitable from 6–12 months, designed for use as part of a mixed weaning diet
- **infant foods for special medical purposes (iFSMP)**, specialist formulas which are designed for infants from 0–12 months and should be used under medical supervision

## Healthcare Organisation

Any entity (1) that is a healthcare, medical or scientific association or organisation (irrespective of the legal or organisational form), such as a hospital, clinic, foundation, university or other teaching institution or learned society (except for patient organisations), or (2) through which one or more healthcare professional(s) provide services. This could include, for example, midwife associations.

## Healthcare Professional (HCP)

Any member of the medical, dental, pharmacy, midwifery, dietetic, nutrition and nursing professions, or students thereof, or any other person who, in the course of his or her professional activities, may prescribe, purchase, supply, recommend or administer a nutritional or medicinal product. For the avoidance of doubt, the definition of healthcare professional includes any official or employee of a government agency or other organisation (whether in the public or private sector).

## iFSMP

Infant Foods for Special Medical Purposes are foods specially processed or formulated and intended for the dietary management of infants, to be used under medical supervision; they are intended for the exclusive or partial feeding of patients with a limited, impaired or disturbed capacity to take, digest, absorb, metabolise or excrete ordinary food or certain nutrients contained therein, or metabolites, or with other medically-determined nutrient requirements, whose dietary management cannot be achieved by modifications of the normal diet alone.



## **Important Notice**

Mandatory information defined in legislation that must appear on websites, labels and advertising. The information may vary between product categories, and types of information materials.

## **Industry**

The companies that collectively make up the infant nutrition industry.

## **Infant**

A child under the age of 12 months.

## **Infant Formula**

A food intended for use by infants during the first months of life and satisfying by itself the nutritional requirements of such infants until the introduction of appropriate complementary feeding.

## **Label**

Any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to the packaging or container of food.

## **Labelling**

Any words, particulars, trademarks, brand name, pictorial matter or symbol relating to a food and placed on any packaging, document, notice, label, ring or collar accompanying or referring to such food.

## **Manufacturer**

A corporation or other entity in the public or private sector engaged in the business or function of manufacturing a product (whether directly, indirectly, through an agent, or through an entity controlled by or under contract with it) within the scope of this Code.

## **Marketing**

Product promotion, distribution, selling, advertising, product public relations and information services.

## **Online Communication**

A 'catch-all' term which can include communication to the general public; for example, company websites displaying product names and social media, including YouTube video. The term also includes a more defined community or those who have chosen to sign up and register for online services, such as company websites or baby clubs.

## **Product Name**

A name given by a company to identify its products distinctively from others of the same type.

## **Products for Professional Evaluation (PPE)**

Restricted supply of products to healthcare professionals, for the purpose of professional review/assessing suitability of different products for their intended use, or research at an institutional level. In general, PPE are provided in small quantity. The quantity of PPE provided by the company will depend on the specific product, e.g. infant formula, follow-on formula or iFSMP, the end user, and the professional requirements of the healthcare professional in order for them to conduct their evaluation.

## **Promotion(s)**

Promotions can provide an incentive for the consumer to buy by using a range of added direct 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” offers, 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.

## **Sample**

An appropriate and limited quantity of product provided for promotional purposes, without cost to the recipient, and not intended for sale.

## **Scientific and Factual**

Information that is accurate, evidence-based, and which is substantiated by scientific data. When possible, scientific and factual information should be based on data which has been published in peer-reviewed scientific journals. When this is not possible, the supporting evidence on which the scientific and factual information is based should always be available for scrutiny upon request,\* e.g. presentations made at scientific meetings, or reference to ‘data on file’, etc.

\*unless to do so would prejudice future publication, or breach confidentiality rights, etc.



The British Specialist  
Nutrition Association  
10 Bloomsbury Way  
London  
WC1A 2SL  
Secretariat@bsna.co.uk  
www.bsna.co.uk  
@BSNA\_UK