Policy
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Nestlé
Good Food, Good Life

Nestlé Policy and Instructions for Implementation of the WHO International Code of Marketing of Breast-milk Substitutes

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Author/issuing department
Public Affairs

Target audience
All employees, interested members of the public

Related Group Principles/Policies, Standards or Guidelines
The Nestlé Corporate Business Principles,
The Nestlé Management and Leadership Principles,
Code of Business Conduct

Repository
All Nestlé Principles and Policies, Standards and Guidelines
can be found at www.nestle.com/MediaCenter/MediaLibrary/Documents.
More information about this Policy is available at
www.babymilk.nestle.com/pages/home.aspx.

Approver
Executive Board of Nestlé S.A.

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In case of doubt or differences of opinion,
the English version shall prevail.

Design
Nestec Ltd., Corporate Identity & Design,
Vevey, Switzerland

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Introduction

Nestlé seeks to promote safe and adequate nutrition for infants by encouraging and supporting breast-feeding as the best start in life and by manufacturing high quality breast-milk substitutes for use when a safe alternative to breast-milk is needed, i. e. when mother's milk is not available to the infant or when a specially adapted formula is needed.

Nestlé has publicly stated its support for the International Code of Marketing of Breast-milk Substitutes and subsequent relevant WHA resolutions, which aims 1) to protect and promote breast-feeding, and 2) to ensure the proper use of breast-milk substitutes when these are needed. The Code recognises the importance of breast-feeding while acknowledging that there is a legitimate market for breast-milk substitutes when breast-feeding is not possible.

Purpose

The Nestlé Instructions – first issued in February 1982 and subsequently revised in October 1982 after consultation with many parties, including the World Health Organization (WHO) and UNICEF – give implementation guidelines on Company policy with regard to the WHO Code to market management and personnel at all levels who are involved with the marketing of all products marketed as breast-milk substitutes by Nestlé. Subsequent revisions have taken place based on practical experience with the WHO code and changing WHO policy. This June 2010 revision updates Nestlé policy in light of nearly three decades of experience with the WHO Code and also takes into account subsequent relevant World Health Assembly (WHA) resolutions. Nestlé regularly updates these Instructions and this revision supersedes the 2004 update.

The WHO has consistently clarified that it is governments who have the responsibility for defining implementation of the WHO Code within their countries. Thus as a matter of principle Nestlé universally follows all countries' implementation of the WHO Code.

However, because of a heightened need to protect children in countries of the developing world where there is poor sanitation, higher infant mortality and greater public health concerns, Nestlé has voluntarily issued detailed implementing instructions to align our marketing practices with the WHO Code.

Where such higher-risk countries have local codes or other national measures giving effect to the WHO Code, operating companies and agents must follow the national code/measures as well as the Nestlé Instructions, where the latter provide necessary clarity, are not in conflict with national measures, and/or include areas not covered by the national measures. In case Nestlé Instructions are more restrictive than the national code/measures, operating companies must follow the stricter rule laid down in the Nestlé Instructions, unless otherwise compulsorily required not to do so by the national code/measures. In case of doubt, direction should be sought from the Nestlé Nutrition Business and Public Affairs (PA) at Nestlé Group Headquarters in Vevey.

Developed countries such as the US, Canada and the EU, with good sanitation, low levels of infant mortality and strong public health measures are termed "lower-risk countries". In lower-risk countries, Nestlé respects national codes, regulations, and/or other applicable legislation relating to the marketing of infant formula, such as the European Union Directive 2006/141/EC on Infant Formulae and Follow-on Formulae which applies to all EU Member States.

Implementation of this Policy

All Nestlé personnel involved in the marketing and sale of products falling within the scope of this policy (see below) in higher-risk countries must be familiar with and adhere strictly to these Instructions, as must all agents and distributors of those Nestlé products. All communication materials for those products must be consistent with these rules. It is the Company's policy to discourage promotion of these products at point-of-sale and retailers are to be actively reminded of this (see Annex 6). Any queries with regard to implementation of these Instructions should be addressed to the Nestlé Nutrition Business and Public Affairs, Vevey.

In lower-risk countries all Nestlé personnel involved in the marketing and sale of products falling within the scope of these Instructions must be familiar with and adhere strictly to the national law and/or regulations.

This policy is intended for internal use. It may however be made public to provide our stakeholders with information about our practices in this area, avoid misrepresentation of Nestlé policy by third parties and facilitate monitoring and investigation of alleged complaints. Allegations may be reported directly to any Nestlé company or to the Secretariat of the International Association of Infant Food Manufacturers, IFM (see Complaint Form, Annex 4).

Geographical Scope

Countries are divided into two groupings which are referred to in these Instructions as "higher-risk countries" and "lower-risk countries". The designation of a country as a higher-risk country is based on reliable data relating to levels of mortality and morbidity of children under 5 years of age and the acute malnutrition status of those children in a country, such as the UNICEF statistics on Child Health and Development (www.childinfo.org and www.unicef.org/rightsite/sowc/statistics.php).

All other countries are designated as "lower-risk countries". Annexes 1 and 2 provide details of the two groupings. As health conditions improve or deteriorate in a country and country specific legislation is enacted to govern infant feeding, the designation of a country may be changed.

Product Scope (higher-risk countries)

a) All infant formulas designed to satisfy the nutritional requirements of healthy* infants from birth through 12 months;
b) follow-up formula products sold to the public for the feeding of healthy* infants under the age of twelve months;
c) bottles and teats, as these may be seen to undermine breast-feeding as defined by the WHO Code. These products are currently not manufactured or marketed by Nestlé.

Products mentioned under description of a) and b) will be collectively referred to as INFANT FORMULAS throughout this document, except where otherwise specified.

Unless specifically required by national legislation, these Policy and Instructions do not apply to:

a) complementary foods, including infant cereals, sterilised (or aseptically prepared) meat, vegetable, fruit and/or dairy preparations for babies, *when marketed for use after six months of age* provided they do not contain instructions for modification for use as a breast-milk substitute. This is to reinforce Nestlé's commitment to exclusive breast-feeding in the first six months of life;
b) products that are designed for infants of any age with special medical needs (such as PKU, shortened or abnormal digestive tracts or very premature births). These infants are unable to absorb, digest or metabolise breast-milk or standard infant formula, are under medical supervision and are at risk of death or abnormal development without access to these products.

Product Scope (lower-risk countries)

The product scope in lower-risk countries is determined by each national or regional legislation and norms (e.g. the European Union).

* Healthy infants are those with no medical needs and who do not require special physician supervision.

Nestlé's Support of Public Policy

The WHO Code calls on governments to give effect to the principles and aim of the WHO Code by enacting and enforcing national regulations or other suitable measures as appropriate to the social and legislative framework of their countries and to enforce those regulations or measures on the same basis against all those involved in the manufacture and marketing of breast-milk substitutes. It is therefore important that these governments develop impartial, transparent monitoring to ensure such codes/measures are enforced and complied with by all relevant parties. Nestlé supports efforts by governments to implement the WHO Code through national legislation, regulation, or other suitable measures that are designed to meet the letter and spirit of the WHO Code's recommendations concerning the marketing of breast-milk substitutes and the promotion of exclusive breast-feeding in the first six months of life and which are clearly communicated to all parties concerned and effectively monitored through impartial procedures.

Nestlé is a founding member of the International Association of Infant Food Manufacturers (IFM) which was formed to facilitate industry dialogue with WHO and governments and to encourage responsible marketing standards for the infant food industry. Nestlé also makes its positions known within the Infant Food Association and publicly.

Responsibilities for Management of the WHO Code Implementation

The Chief Executive Officer of Nestlé Nutrition, who is a member of the Nestlé S.A. Corporate Executive Board, is the person delegated by the Chief Executive Officer of Nestlé S.A. to be responsible for implementing and monitoring this policy. While the Code Management system is elaborated at corporate level, each individual country's specific legislations, guidelines or practices must be factored in at country level. Thus the Infant Nutrition Country Business Manager is the person responsible for implementing and monitoring this Policy in a country. Therefore this direct line responsibility to implement and monitor this Policy is uninterrupted and includes the relevant Regional Business Head and the Global Business Head of Nestlé Infant Nutrition. The Nestlé Market Head, who remains accountable for compliance with all policies related to the Nestlé Corporate Business Principles, continues to have oversight of this Policy as well.

The CEO of Nestlé S.A. is ultimately responsible for ensuring that this Policy is honoured. Every substantiated violation of the WHO Code is reported to the CEO of Nestlé S.A.

Nestlé's Commitment to the WHO Code and Subsequent WHA Resolutions

Nestlé fulfils its commitment to the WHO Code in higher-risk countries by:

- not advertising or promoting INFANT FORMULAS for infants below 12 months of age;
- not labelling, promoting or selling of complementary foods for infants under six months of age unless otherwise mandatorily required by local code or measures;
- issuing detailed Procedure manuals containing internal Instructions for the implementation of WHO recommendations both at the corporate level and at the regional and country level;
- aligning its marketing practices in detail on the recommendations of the WHO Code and relevant subsequent WHA Resolutions, and providing systematic training towards Code compliance to its marketing personnel;
- auditing on a regular basis its subsidiaries' INFANT FORMULA marketing practices by corporate as well as local auditors, and submitting summary reports of those audits to review by the Audit Committee of the Nestlé Board of Directors;
- putting in place an Internal WHO Code Ombudsman System allowing Nestlé employees to alert the Company on potential non-compliance with the WHO Code in a confidential way, outside line management;
- commissioning regular audits by an independent external auditor and making a summary of the audit findings publicly available;
- implementing a system for investigating all allegations of non-compliance, externally or internally reported, when sufficient information has been received, as well as taking corrective action on all substantiated non-compliance cases;
- commissioning independent external audits in case of allegations of multiple and/or serious non-compliance with the WHO Code by Nestlé;
- using results of information from Stakeholder input, as well as the recommendations deriving from internal and external audits to identify opportunities to improve our Code management system.

The Company's commitment to the WHO Code is prominently mentioned in the Nestlé Corporate Business Principles.

Nestlé Instructions to Personnel to Assist in Implementing the WHO Code Provisions in all Higher-Risk Countries

Using this Manual

The WHO Code provisions are shown on the left-hand side of the page, and the Instructions to Nestlé personnel on how to implement each of these provisions of the WHO Code in higher-risk countries are shown on the right-hand side. These Instructions do not replace the WHO Code provisions, but are intended to assist Nestlé personnel in giving practical effect to the Code.

Note: throughout these Instructions, the use of the term "mothers" includes pregnant women, mothers or members of their close families.

WHO Code	Nestlé Instructions
Article 1 **Aim of the Code** The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.	**Article 1** **Aim of the Code** This must be the aim of all our infant food marketing practices.
Article 2 **Scope of the Code** The Code applies to the marketing and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, food and beverages, including bottle-fed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast-milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.	**Article 2** **Scope of the Code** These Instructions apply to the marketing of infant formula covered by Codex (FAO/WHO Foods Standards Programme, Recommended International Standard, Codex Alimentarius Commission, 72-1981) (see Article 10.2). They also apply to follow-up formula products which are marketed for consumption by infants up to 1 year of age.
Note: *The scope is clarified in Annex 3 (p. 33) of the Code:* *"During the first four to six months of life, breast-milk alone is usually adequate to sustain the normal infant's nutritional requirements. Breast-milk may be replaced (substituted for) during this period by bona fide breast-milk substitutes, including infant formula. Any other food, such as cow's milk, fruit juices, cereals, vegetables, or any other fluid, solid or semisolid food intended for infants and given after this initial period, can no longer be considered as a replacement for breast-milk (or as its bona fide substitute)".*	*Note:* *Throughout these Instructions, all those products are referred to as "INFANT FORMULAS" except where otherwise specified.* WHA Resolution 54.2, as a global public health recommendation, recommends exclusive breast-feeding for six months. Therefore no complementary foods, including infant cereals and baby foods, should be marketed for use before six months of age unless otherwise mandatorily required by local code or national legislation.
	Note: *The following Nestlé products are not covered by the Code:* • *complementary foods when marketed for use after six months of age, including infant cereals, sterilised meat, vegetable fruit and/or dairy preparations for babies, as long as they do not contain instructions for modification and use as a breast-milk substitute;* • *sweetened condensed milk, evaporated milk, skimmed milk, UHT milk, full cream powdered milk, growing up milks. All such milk products shall not contain instructions for modification for use as a breast-milk substitute and shall bear a statement indicating that they are not suitable for use as a breast-milk substitute.*

WHO Code	Nestlé Instructions
Article 3 **Definitions** (see Annex 1)	**Article 3** **Definitions** (see Annex 1)
Article 4 **Information and Education**	**Article 4** **Information and Education**
Article 4.1 Governments should have the responsibility to ensure that objective and consistent information is provided on infant and young child feeding for use by families and those involved in the field of infant and young child nutrition. This responsibility should cover the planning, provision, design and dissemination of information, or their control.	**Article 4.1** This provision is addressed to governments (see also Art. 4.2).
Article 4.2 Informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and mothers of infants and young children, should include clear information on all the following points: (a) the benefits and superiority of breast-feeding; (b) maternal nutrition, and the preparation for and maintenance of breast-feeding; (c) the negative effect on breast-feeding of introducing partial bottle-feeding; (d) the difficulty of reversing the decision not to breast-feed; and (e) where needed, the proper use of infant formula, whether manufactured industrially or home-prepared. When such materials contain information about the use of infant formula, they should include the social and financial implications of its use; the health hazards of inappropriate foods or feeding methods; and, in particular, the health hazards of unnecessary or improper use of infant formula and other breast-milk substitutes. Such materials should not use any pictures or text which may idealise the use of breast-milk substitutes.	**Article 4.2** All infant feeding information intended for mothers, whether of a general educational nature or dealing with the explanation and instructions for the use of INFANT FORMULAS, must contain a statement regarding each of the points (a) to (e) contained in this article of the WHO Code. Specific points from Art. 4.2 will be dealt with in much greater detail in certain educational materials such as mother books and educational posters (see also Art. 4.3). Only information intended for mothers that deals with the explanation and instructions for use of a specific INFANT FORMULA may bear corporate and product brands. In order to avoid confusion with other formula products or milk products inappropriate for use as breast-milk substitutes, they may include the packshot of the specific INFANT FORMULA. These materials are intended for use by health workers in instructing mothers who have to use breast-milk substitutes and may not be given to mothers by company personnel. They are intended to complement information contained on the label, especially when catering to the needs of minority language groups or the needs of semi-literate or illiterate mothers. Such materials must include the information specified in this Article of the WHO Code. Baby pictures may only be used to enhance the educational value of information and must not idealise INFANT FORMULA feeding. The same restraint should generally be observed for pictures or texts used in those informational and educational materials. In case of doubt, the Nestlé Nutrition Business and Public Affairs must be consulted (see also note under Art. 5.1).

WHO Code	Nestlé Instructions
Article 4.3 Donations of informational or educational equipment or materials by manufacturers or distributors should be made only at the request and with the written approval of the appropriate government authority or within guidelines given by governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary product that is within the scope of this Code, and should be distributed only through the health care system.	**Article 4.3** Materials intended for pregnant women and mothers that are of a general nature related to maternal and child health, such as educational posters, educational charts, mother books, breast-feeding booklets, weight/growth charts, vaccination and health cards, height measurement charts, films or slide presentations, videocassettes, CD-ROMs, etc., must not contain illustrations of INFANT FORMULA or mention the names of individual INFANT FORMULA brands. Corporate name or logo may be used. If these materials have been edited by the company in collaboration with the health authorities or the medical profession, this may be mentioned. Such materials should be made available to health care institutions and professionals only upon their request and in accordance with any applicable government requirements or guidelines. *Note:* *Materials covered under Art. 4.2 and 4.3 may only be given or shown to mothers by health professionals, and when dealing with infant feeding must include the information required by Art. 4.2 of the WHO Code. A note on such material shall clearly indicate that the material may be given or shown to mothers by health professionals only. Mother books may include generic information on INFANT FORMULA of an educational nature which explains when the use of an INFANT FORMULA may be necessary and the precautions for correct use.*

WHO Code	Nestlé Instructions
Article 5 **The General Public and Mothers**	**Article 5** **The General Public and Mothers**
Article 5.1 There should be no advertising or other form of promotion to the general public of products within the scope of this Code.	**Article 5.1** Information relating to INFANT FORMULAS must not be communicated directly to mothers or the general public either through public media or by personal contact between company representatives and the public. This restriction also applies to information put on Nestlé web-sites. The restriction under Art. 5.1, as applied to products specified under Art. 2, includes a ban on: • participation in/sponsorship of baby shows (even when invited to participate by health workers or charitable institutions); • distribution of gift packs for mothers; • distribution to mothers of materials of a non-educational nature (whether product-related or not): birth certificates, calendars, baby albums, etc. General information on infant feeding and baby care, which includes information on the proper use of INFANT FORMULA (such as mother books and posters) may only be distributed to mothers by health workers or displayed by them in health care facilities subject to the provisions of Art. 4.2, 4.3, 6.2 and 7.2. Such information may not feature INFANT FORMULA brands and may not be used as advertising or promotion aimed at the general public.
	Note: Educational materials intended for use in instructing mothers must be consistent with these Instructions.
Article 5.2 Manufacturers and distributors should not provide, directly or indirectly, to pregnant women, mothers or members of their families, samples of products within the scope of this Code.	**Article 5.2** No samples of INFANT FORMULAS should be given to the general public. Such samples may only be given to health workers, in accordance with Art. 7.4.
Article 5.3 In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code. This provision should not restrict the establishment of pricing policies and practices intended to provide products at lower prices on a long-term basis.	**Article 5.3** Activities at the retail level aiming at promoting sales of INFANT FORMULAS directly to the consumer are not permitted, i. e. • no coupon redemption schemes; • no raffles or lotteries; • no point-of-sale promotions (i.e. deals, gifts, special displays or exhibitions, including display contests); • no in-store demonstrations; • no company-induced price offers to the consumer at the retail level (consumer discounts, loss-leaders, tie-in sales); • no incentives or discounts to the trade for the purposes of advertising or promotion at point-of-sale.

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	This does not prevent the implementation of a normal trade price structure. This policy must be communicated in writing to wholesalers and retailers of Nestlé INFANT FORMULAS products who must be reminded that it is company policy to prevent promotion of INFANT FORMULA products at the point-of-sale (see Annex 6). It is the sales staff's responsibility to maintain stock rotation and to ensure shelf-availability and clean and tidy presentation of INFANT FORMULA products at the point-of-sale where it is needed. Shelf or bin markers clearly indicating product name and price are permitted, but promotional advertising is not.
Article 5.4 Manufacturers and distributors should not distribute to pregnant women or mothers of infants and young children any gifts of articles or utensils which may promote the use of breast-milk substitutes or bottle-feeding.	**Article 5.4** See instructions above (Art. 5.1).
Article 5.5 Marketing personnel, in their business capacity, should not seek direct or indirect contact of any kind with pregnant women or with mothers of infants and young children.	**Article 5.5** Company personnel involved in the marketing of infant and baby foods, including those whose responsibilities include the provision of information to the health profession about those products, may not solicit direct contact with pregnant women or mothers of infants below six months of age, either individually or in groups, through whatever medium. This restriction applies even to contacts for the purpose of providing information or samples of products not covered by the Code, such as food supplements for expectant and nursing mothers, *if such contacts aim at indirectly promoting products covered by the Code*. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information on correct use of INFANT FORMULAS. Requests for information on health matters, or general information on INFANT FORMULAS, must be referred to a health worker (see also Art. 6.4 and 8.2).

WHO Code	Nestlé Instructions
Article 6 Health Care Systems	**Article 6 Health Care Systems**
Article 6.1 The health authorities in Member States should take appropriate measures to encourage and protect breast-feeding and promote the principles of this Code, and should give appropriate information and advice to health workers in regard to their responsibilities, including the information specified in Art. 4.2.	**Article 6.1** Addressed to the health authorities.
Article 6.2 No facility of a health care system should be used for the purpose of promoting infant formula or other products within the scope of this Code. This Code does not, however, preclude the dissemination of information to health professionals as provided in Art. 7.2.	**Article 6.2** Nestlé Instructions relating to Art. 5.1, 5.2, 5.4 and 5.5 also apply to Nestlé activities within the health care system. The distribution to health care facilities of educational materials bearing corporate identification, subject to the requirements of Art. 4, is permitted. Scientific or technical product information, and instructions intended to assist health workers in guiding mothers on the correct use of specific formula may only be distributed to health workers (see Art. 7.2).
Article 6.3 Facilities of health care systems should not be used for the display of products within the scope of this Code, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in Art. 4.3.	**Article 6.3** See above.
Article 6.4 The use by the health care system of "professional service representatives", "mothercraft nurses", or similar personnel, provided or paid for by manufacturers or distributors, should not be permitted.	**Article 6.4** Company personnel must not be used by the health care system for advising mothers or similar duties. The role of company personnel is covered in Art. 8.2.
Article 6.5 Feeding with infant formula, whether manufactured or home-prepared, should be demonstrated only by health workers, or other community workers if necessary; and only to the mothers or family members who need to use it; and the information given should include a clear explanation of the hazards of improper use.	**Article 6.5** Company personnel may not assist in this work but may provide relevant educational/ instruction material to assist health workers in guiding mothers. In case mothers request advice from company personnel, they should be referred to the medical profession or other health workers (see Art. 5.5 – see also Instructions pertaining to Art. 6.2 above).

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Article 6.6 Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institutions, this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.	**Article 6.6** INFANT FORMULAS may not be donated to health care facilities for any reason, nor may they be sold to health care facilities at a price which is merely token in nature (thus amounting to a de facto donation). Sales to health care facilities or systems may be made under normal procurement procedures for hospital supplies, at the best wholesale price. Where national rulings allow, the Company may respond to written requests from orphanages or other social welfare institutions for free or low-price supplies of INFANT FORMULAS for feeding infants who have to be fed with breast-milk substitutes, to serve social or humanitarian purposes. In such cases, the Company will ensure that such supplies will be made only to bona fide institutions and the medical and social grounds for such supplies are clearly documented in accordance with the form contained in Annex 2 hereof or any stricter requirement set forth by national authorities. The label or lid of the products donated or supplied at reduced price must be clearly marked with a sticker stating: "Free supply (or reduced-price supply) for use at the discretion of the social welfare institution, only for infants who have to be fed on breast-milk substitutes". A record of such donation or reduced-price supply must be kept for at least 36 months (see also Art. 6.7).
Article 6.7 Where donated supplies of infant formula or other products within the scope of this Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.	**Article 6.7** In cases where a social welfare institution requests free or reduced-price supplies of INFANT FORMULAS for use outside that institution, the following instructions must be respected: 1) the institution requesting the supply must inform the Company of the total quantity required for feeding the infants; 2) the Company will reserve the right to determine on a case-by-case basis whether that quantity can be supplied, and will inform the institution concerned of its decision, and the implications for meeting continued requirements; 3) obligations entered into under this heading must be confirmed in writing, and records of quantities distributed must be maintained for at least 36 months; 4) the Company will supply the requested products to the social welfare institution, not directly to the consumer, together with relevant instructions to the institution to ensure that the products are used correctly;

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	5) Nestlé will make it clear that use outside an institution of supplies that have been made available on a free or reduced-price basis, is at the discretion and under the responsibility of that institution. Donors as well as institutions or organizations concerned should bear in mind this responsibility.
Article 6.8 Equipment and materials in addition to those referred to in Art. 4.3, donated to a health care system may bear a company's name or logo, but should not refer to any proprietary product within the scope of this Code.	**Article 6.8** This refers to materials and equipment intended for professional use by health workers and institutions. As a rule donations of such materials and equipment may not be used as a sales inducement. Equipment such as incubators and audiovisual equipment (hardware and software other than CD-ROM containing educational/ instruction material on nutrition and health care) can only be given to institutions. Such equipment as well as low-cost service items, like diaries and gestation calendars, for the use of health workers may bear the Company name and logo, but no product name or logo. Equipment exceeding a value of US$ 50 may only be provided against a written request from the head of the department or institution concerned or in accordance with national regulations, with the approval of a member of the management committee of the local Nestlé company. Service items given to the medical profession but used publicly in the health institutions including: • wrist bands; • hospital health cards; • arm/head measuring tapes; • tongue spatulas; • bibs; • plates/cups/spoons; • alcohol swabs, etc. may not bear any INFANT FORMULA brand but may bear the Corporate logo. Please refer to Annex 4 for details on materials of professional utility which may be given to health workers.

WHO Code	Nestlé Instructions
Article 7 Health Workers	**Article 7 Health Workers**
Article 7.1 Health workers should encourage and protect breast-feeding; and those who are concerned in particular with maternal and infant nutrition should make themselves familiar with their responsibilities under this Code, including the information specified in Art. 4.2.	**Article 7.1** Health workers' responsibility. Nestlé will cooperate in these efforts by providing upon request, and whenever possible, copies of the official WHO Code and culturally appropriate educational materials (videos, brochures, posters) promoting breast-feeding.
Article 7.2 Information provided by manufacturers and distributors to health professionals regarding products within the scope of this Code should be restricted to scientific and factual matters, and such information should not imply or create a belief that bottle-feeding is equivalent or superior to breast-feeding. It should also include the information specified in Art. 4.2.	**Article 7.2** In their contacts with health workers, Company personnel have the responsibility to emphasise the superiority of breast-feeding, the WHO Code and to give objective information on scientific and factual matters pertaining to formula and its correct use. Information on formula intended for health professionals should avoid promotional language and content, whether textual or pictorial, aiming at idealising formula feeding over breast-feeding. These informational materials may include pictures of the product and bear corporate and product brands in order to facilitate identification of the product. They must mention the information specified in Art. 4.2 of the Code. Detailed and illustrated preparation instructions, using vernacular languages, may be given to health workers to assist them in instructing mothers who have to use breast-milk substitutes. All such informational materials should conspicuously mention that they are destined for health workers only and bear a date and a print-code for traceability purposes.
Article 7.3 No financial or material inducements to promote products within the scope of this Code should be offered by manufacturers or distributors to health workers or members of their families, nor should these be accepted by health workers or members of their families.	**Article 7.3** No financial or material inducements to promote INFANT FORMULAS may be offered to health workers or members of their families. Low-cost items of professional utility (see Annex 4), or token gifts may be given to health workers on an occasional basis if and as culturally appropriate. No such donations should be used as a sales inducement. Those items may bear the Corporate logo.
Article 7.4 Samples of infant formula or other products within the scope of this Code, or of equipment or utensils for their preparation or use, should not be provided to health workers except when necessary for the purpose of professional evaluation or research at the institutional level. Health workers should not give samples of infant formula to pregnant women, mothers of infants and young children, or members of their families.	**Article 7.4** Samples of INFANT FORMULAS may be provided to individual health workers for the purpose of professional evaluation only in the following instances: • to introduce a new INFANT FORMULA product; • to introduce a new formulation of an existing product; • to introduce our INFANT FORMULA range to a newly qualified health professional.

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	In these cases, one or two cans of INFANT FORMULA may be given to a health worker for this purpose and one time only, upon receipt of a sample request form filled in by the health worker. Samples must bear the mention "sample for professional evaluation". Sample request forms and sample distribution records must be maintained for 36 months. INFANT FORMULAS may also be provided for research or clinical validation, subject to completion of a research protocol (see Annex 6.2, Nestlé's Clinical Validation Protocol). In such cases, the INFANT FORMULAS must bear a sticker: "Formula provided for Clinical Validation – NOT FOR RESALE".
	Important note: *Clinical validations are not to be used as a sales inducement and are subject to the detailed rules specified in Annex 6.*
Article 7.5 Manufacturers and distributors of products within the scope of this Code should disclose to the institution to which a recipient health worker is affiliated any contribution made to him or on his behalf for fellowships, study tours, research grants, attendance at professional conferences or the like. Similar disclosures should be made by the recipient.	**Article 7.5** The decision to support scientific activities such as congresses, scholarships, study tours, etc. must be taken on a case-by-case basis by a member of the management committee of the local Nestlé company. In case of doubt, the Nestlé Nutrition Business and PA, Vevey, must be consulted. Financial or other support does not imply endorsement by the recipients of Nestlé's policies or activities and shall be provided in a transparent manner. Preference will be given to support for nominees of associations or institutions. Requests for support must be confirmed in writing by a responsible officer of the association/ institution (or his nominee) or by the health professional concerned. Guidelines for support of scientific activities established by the association/institution or by the authorities must be strictly complied with. Records for such support must be maintained for 36 months.

WHO Code

Article 8 Persons employed by Manufacturers and Distributors

Article 8.1 In systems of sales incentives for marketing personnel, the volume of sales of products within the scope of this Code should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it.

Article 8.2 Personnel employed in marketing products within the scope of this Code, should not, as a part of their job responsibilities, perform educational functions in relation to pregnant women or mothers of infants and young children. This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

Nestlé Instructions

Article 8 Persons employed by Manufacturers and Distributors

Article 8.1 Bonuses or incentives aimed at encouraging increased volume of sales of INFANT FORMULAS must not be paid to sales staff, medical delegates, and other marketing personnel. Remuneration for sales staff and medical delegates must be examined on a country-by-country basis in order to determine the criteria to be established for appropriate compensation, such as clean display, customer service, Code knowledge, etc.

Article 8.2 Company personnel, e.g. medical delegates whose responsibilities include the provision of information about infant and baby foods to the health profession may not perform educational functions in relation to pregnant women or mothers of infants and young children if such contacts aim at indirectly promoting products covered by the Code. However such personnel may provide information on weaning practices and complementary feeding to mothers of infants beyond six months of age, subject to their emphasizing that breast-feeding should continue for as long as possible after introduction of complementary feeding (see also Art. 6.4).

This should not be understood as preventing such personnel from being used for other functions by the health care system at the request and with the written approval of the appropriate authority of the government concerned.

WHO Code	Nestlé Instructions
Article 9 Labelling	**Article 9 Labelling**
Article 9.1 Labels should be designed to provide the necessary information about the appropriate use of the product, and so as not to discourage breast-feeding.	**Article 9.1** Individual country requirements, if any, must be respected in addition to the requirements under this WHO Code Article which are recognised as the minimum requirement. Please refer to labelling guidelines respectively issued by Nestlé Nutrition Business and by the Dairy Strategic Business Unit, Vevey.
Article 9.2 Manufacturers and distributors of infant formula should ensure that each container has a clear, conspicuous, and easily readable and understandable message printed on it, or a label which cannot readily become separated from it, in an appropriate language, which includes all the following points: (a) the words "Important Notice" or their equivalent; (b) a statement of the superiority of breast-feeding; (c) a statement that the product should be used only on the advice of a health worker as to the need for its use and the proper method of use; (d) instructions for appropriate preparation, and a warning against the health hazards of inappropriate preparation. Neither the container nor the label should have pictures of infants, nor should they have other pictures or text which may idealise the use of infant formula. They may, however, have graphics for easy identification of the product as a breast-milk substitute and for illustrating methods of preparation. The terms "humanized", "maternalized" or similar terms should not be used. Inserts giving additional information about the product and its proper use, subject to the above conditions, may be included in the package or retail unit. When labels give instructions for modifying a product into infant formula, the above should apply.	**Article 9.2** Nestlé INFANT FORMULA labels have to comply with each point contained in Article 9.2 of the WHO Code. It is important to note that the "appropriate language" will be subject to the decision of the health authorities. In cases where several languages are commonly read and understood by different population groups, it may be necessary to include additional information in the form of on-pack leaflets. In case of doubt, the national authorities should be consulted.
Article 9.3 Food products within the scope of this Code, marketed for infant feeding, which do not meet all the requirements of an infant formula, but which can be modified to do so, should carry on the label a warning that the unmodified product should not be the sole source of nourishment of an infant. Since sweetened condensed milk is not suitable for infant feeding, nor for use as a main ingredient of infant formula, its label should not contain purported instructions on how to modify it for that purpose.	**Article 9.3** In the absence of specific national requirements, labels of Nestlé milk products not adapted for infant feeding must bear a warning to that effect. Labels of condensed milks (sweetened or unsweetened) must mention: "(name of product category) is not to be used as a breast-milk substitute". Similarly, Nestlé powdered milk labels must include the following information: "However (brand name), like liquid cow's milk, has not been modified for infant feeding and is not to be used as a breast-milk substitute". In any case, the Dairy Strategic Business Unit's detailed labelling instructions should be referred to.

WHO Code	Nestlé Instructions
Article 9.4 The label of food products within the scope of this Code should also state all the following points: (a) the ingredients used; (b) the composition/analysis of the product; (c) the storage conditions required; and (d) the batch number and the date before which the product is to be consumed, taking into account the climatic and storage conditions of the country concerned.	**Article 9.4** To be implemented in accordance with individual country requirements, recognising that the requirements under this WHO Code Article are the minimum requirement.
Article 10 Quality	**Article 10 Quality**
Article 10.1 The quality of products is an essential element for the protection of the health of infants and therefore should be of a high-recognised standard.	**Article 10.1** The manufacture and distribution of all Nestlé products is based on this principle.
Article 10.2 Food products within the scope of this Code should, when sold or otherwise distributed, meet applicable standards recommended by the Codex Alimentarius Commission and also the Codex Code of Hygienic Practice for Foods for Infants and Children.	**Article 10.2** In accordance with current standards except where otherwise specified by government regulations.

WHO Code	Nestlé Instructions
Article 11 Implementation and Monitoring	**Article 11 Implementation and Monitoring**
Article 11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures. For this purpose, governments should seek, when necessary, the co-operation of WHO, UNICEF and other agencies of the United Nations system. National policies and measures, including laws and regulations, which are adopted to give effect to the principles and aim of this Code should be publicly stated, and should apply on the same basis to all those involved in the manufacture and marketing of products within the scope of this Code.	**Article 11.1** Implementation and interpretation of the Code in each country is the responsibility of the government (usually the health authorities). Nestlé Market Managers should make every effort, in co-operation with our competitors wherever possible, to encourage the development of clear and unambiguous national codes where these do not yet exist.
Article 11.2 Monitoring the application of this Code lies with governments acting individually, and collectively through the World Health Organization as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate non-governmental organizations, professional groups, and consumer organizations should collaborate with governments to this end.	**Article 11.2** See above. It is vital that impartial and effective monitoring procedures, under government responsibility, be included as part of the measures to implement the Code. Contact the Nestlé Nutrition Business and PA, Vevey, if in doubt as to how to proceed.
Article 11.3 Independently of any other measures taken for implementation of this Code, manufacturers and distributors of products within the scope of this Code should regard themselves as responsible for monitoring their marketing practices according to the principles and aim of this Code, and for taking steps to ensure that their conduct at every level conforms to them.	**Article 11.3** Internal monitoring of the correct implementation of these Instructions and/or of the national code if it exists, is an on-going responsibility of Nestlé Market Management.
Article 11.4 Non-governmental organizations, professional groups, institutions and individuals concerned should have the responsibility of drawing the attention of manufacturers or distributors to activities which are incompatible with the principles and aim of this Code, so that appropriate action can be taken. The appropriate governmental authority should also be informed.	**Article 11.4** Complaints relating to alleged non-conformity by Nestlé with the WHO Code must be properly documented to allow prompt investigation and corrective action if and as required. For this purpose, a complaint form has been established (Annex 4). Markets should immediately inform PA, Vevey, of all allegations of non-conformity directly addressed to them.
Article 11.5 Manufacturers and primary distributors of products within the scope of this Code should apprise each member of their marketing personnel of the Code and of their responsibilities under it.	**Article 11.5** As stated in the "Introduction" section, these Instructions must be communicated to all company personnel employed by companies of the Nestlé Group or by agents and primary distributors engaged in the marketing of INFANT FORMULAS.

WHO Code	Nestlé Instructions
Article 11.6 In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.	**Article 11.6** Addressed to governments.
Article 11.7 The Director-General shall report in even years to the World Health Assembly on the status of implementation of the Code; and shall, on request, provide technical support to Member States preparing national legislation on regulations, or taking other appropriate measures implementing and furtherance of the principles and aim of this Code.	**Article 11.7** Addressed to the Director-General, WHO.

Annexes

Annex 1

Lists of Lower-Risk and Higher-Risk Countries

Lower-risk countries

Andorra
Australia
Austria
Belgium
Brunei
Canada
Chile
Croatia
Cuba
Cyprus
Czech Republic
Denmark
Estonia
Finland
France
Germany
Greece
Hong Kong*
Hungary
Iceland
Ireland
Israel
Italy
Japan
Latvia
Liechtenstein
Lithuania
Luxembourg
Malaysia
Malta
Monaco
Netherlands
New Zealand
Norway
Poland
Portugal
Republic of Korea
San Marino
Singapore
Slovakia
Slovenia
Spain
Sweden
Switzerland
Taiwan
United Kingdom
United States

* Territory

Higher-risk countries

Afghanistan
Albania
Algeria
Angola
Antigua and Barbuda
Argentina
Armenia
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belize
Benin
Bhutan
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Bulgaria
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
China
Colombia
Comoros
Congo
Cook Islands
Costa Rica
Côte d'Ivoire
DPR Korea
DR Congo
Djibouti
Dominica
Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Ethiopia
Fiji
Gabon
Gambia, The
Georgia
Ghana
Grenada
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia
Iran
Iraq
Jamaica
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Lao PDR
Lebanon
Lesotho
Liberia
Libya
Macedonia
Madagascar
Malawi
Maldives
Mali
Marshall Islands
Mauritania
Mauritius
Mexico
Micronesia
Moldova
Mongolia
Montenegro
Morocco
Mozambique
Myanmar
Namibia
Nauru
Nepal
Nicaragua
Niger
Nigeria
Niue
Occupied Palestinian Territory
Oman
Pakistan
Palau
Panama
Papua New Guinea
Paraguay
Peru
Philippines
Qatar
Romania
Russian Federation
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Solomon Islands
Somalia
South Africa
Sri Lanka
Sudan
Suriname
Swaziland
Syria
Tajikistan
Tanzania
Thailand
Timor Leste
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
Ukraine
United Arab Emirates
Uruguay
Uzbekistan
Vanuatu
Venezuela
Vietnam
Yemen
Zambia
Zimbabwe

Annex 2

International Code of Marketing of Breast-milk Substitutes (Article 3) Definitions

Article 3 Definitions
For the purposes of this Code:

"Breast-milk substitute"
means: any food being marketed or otherwise represented as a partial or total replacement for breast-milk, whether or not suitable for that purpose.

"Complementary food"
means: any food, whether manufactured or locally prepared, suitable as a complement to breast-milk or to infant formula, when either becomes insufficient to satisfy the nutritional requirements of the infant. Such food is also commonly called "weaning food" or "breast-milk supplement".

"Container"
means: any form of packaging of products for sale as a normal retail unit, including wrappers.

"Distributor"
means: a person, corporation or any other entity in the public or private sector engaged in the business (whether directly or indirectly) of marketing at the wholesale or retail level a product within the scope of this Code. A "primary distributor" is a manufacturer's sales agent, representative, national distributor or broker.

"Health care system"
means: governmental, non-governmental or private institutions or organizations engaged, directly or indirectly, in health care for mothers, infants and pregnant women; and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this Code, the health care system does not include pharmacies or other established sales outlets.

"Health worker"
means: a person working in a component of such a health care system, whether professional or non-professional, including voluntary, unpaid workers.

"Infant formula"
means: a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age, and adapted to their physiological characteristics. Infant formula may also be prepared at home, in which case it is described as "home-prepared".

"Label"
means: any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on, or attached to, a container (see above) of any products within the scope of this Code.

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

"Marketing"
means: product promotion, distribution, selling, advertising, product public relations, and information services.

"Marketing personnel"
means: any persons whose functions involve the marketing of a product or products coming within the scope of this Code.

"Samples"
means: single or small quantities of a product provided without cost.

"Supplies"
means: quantities of a product provided for use over an extended period, free or at a low price, for social purposes, including those provided to families in need.

Annex 3

Request for Free or Low-Price Supplies of Formula

Please supply the following quantities of formula for use exclusively within this Institution by infants who have to be fed on breast-milk substitutes (social welfare cases, orphans, sick infants, etc.):

Supply Requested

No. of infants	Average stay (days)	Brand	Size	No. of tins

I confirm that the Company has drawn my attention to the relevant extracts overleaf, quoted from the WHO International Code of Marketing of Breast-milk Substitutes and the WHO Guidelines concerning the Main Health and Socio-economic Circumstances in which infants have to be fed on breast-milk substitutes, and this request is consistent with the same. These supplies will not be used for routine use by healthy newborn babies, nor will they be given to mothers as free samples.

Date of request: .....

Name (please PRINT): .....

Authorised signature: .....

Institution: .....

Address: .....

Date of receipt: .....

Authorised signature: .....

Name (please PRINT): .....

Position: .....

Name of Nestlé representative: .....

Note: *If the formula to be supplied is for use **outside** the Institution, please address a separate request to the Company giving the following details: name of infant, age, dependence on breast-milk substitute (e.g. 25%, 50%, 75%, 100%), how long supply will be needed, name of health worker supervising the infant, and any other relevant details.*

The Company decision will be communicated to the person responsible for the request.

Formula Supplies

Extracts from the International Code of Marketing of Breast-milk Substitutes

Article 3

Definition

"Supplies" means quantities of a product (infant formula) provided for use over an extended period free or at a low price, for social purposes, including those provided to families in need.

Article 6.6

Donations or low-price sales to institutions or organizations of supplies of infant formula or other products within the scope of this Code, whether for use in the institutions or for distribution outside them, may be made. Such supplies should only be used or distributed for infants who have to be fed on breast-milk substitutes. If these supplies are distributed for use outside the institution this should be done only by the institutions or organizations concerned. Such donations or low-price sales should not be used by manufacturers or distributors as a sales inducement.

Article 6.7

Where donated supplies of infant formula or other products within the scope of the Code are distributed outside an institution, the institution or organization should take steps to ensure that supplies can be continued as long as the infants concerned need them. Donors, as well as institutions or organizations concerned, should bear in mind this responsibility.

The World Health Organization Guidelines concerning the Main Health and Socio-economic Circumstances in which infants have to be fed on breast-milk substitutes (April 1986) state that there are a number of situations – fortunately relatively infrequent – where infants cannot, or should not, be breast-fed. The choice as to the best alternative to breast-feeding depends on the nature of the circumstances:

1) Infants who cannot be fed at the breast (e.g. sucking difficulties) but for whom breast-milk remains the food of choice. **If possible these infants should be fed expressed breast-milk provided by their own mothers or by a wet-nurse, or by milk from a breast-milk bank.**

2) Infants who should not receive breast-milk or breast-milk substitutes based on cow's milk (e.g. due to rare metabolic disorders). **Special preparations will be required in these cases.**

3) Infants for whom breast-milk is not available, for whatever reason. **Commercially-produced infant formula represents an important nutritional advance for these infants.**

The Guidelines recommend that breast-milk substitutes be made accessible and used in ways that do not interfere with the protection and promotion of breast-feeding. For this reason, Nestlé supplies formula to hospitals and other institutions, only for infants who, in the judgement of the health professionals concerned, need to be formula-fed.

From: WHO Document A39/8 Add. 1, April 1986

Annex 4

Complaint Form

These Instructions reflect the public commitment made by Nestlé to conduct its marketing of formula products in accordance with the principles and aim of the World Health Organization International Code of Marketing of Breast-Milk Substitutes. This form may be used by third parties to investigate possible violations. Complaints may be sent directly to Nestlé or to the International Association of Infant Food Manufacturers (IFM) (see address below). Use of this form will help the Company by supplying the kind of information it needs to determine whether Nestlé marketing practices are in conformity with the Code. For the sake of an efficient investigation of the apparent violation, we would request that the complaint be sent to Nestlé or IFM within ninety days of the occurrence of the apparent violation.

1) Country: City or village:

2) Description of apparent violation:

2 a) Brand name of product involved:

2 b) Place (and address if possible) where violation occurred (for example: name of particular medical institution or store, or particular newspaper, or radio or television station):

2 c) Date and time when violation was observed:

2 d) Description of violation (in as much detail as possible):

2 e) Persons responsible for violation (if known):

2 f) Part of Nestlé Company responsible (if known):

2 g) Names and addresses of any other witnesses who can be approached in investigating the complaint (if any):

3) Have you had any contact with company officials or with governmental or health authorities about this apparent violation? (Please describe and give names, if known):

4) Other information or comments:

5) Name, address, telephone number and e-mail address (if available) of person submitting form. (Please print or type if possible):

Date: Signature:

If possible, please enclose actual evidence (photos, letters, affidavits, tape, recordings, etc.) relating to the activities concerned.

Mail to:
Nearest **Nestlé Company Office** or to
International Association of Infant Food Manufacturers (IFM),
Chemin Louis Dunant 7–9,
CH-1211 Genève 20,
Switzerland,
Fax +41 22 788 39 12

Annex 5

List of Materials of Professional Utility which may be Distributed to Individual Health Workers

These materials should be inexpensive, i. e. the value would not constitute an inducement to prescribe formula products to the detriment of breast-feeding.

Material intended for health workers (including those attending congresses and conferences) will either have a clear educational purpose or be designed to render a genuine service.

The Nestlé Nutrition Business, Vevey, is not able to act as a distributor for most such materials. Markets should seek local suppliers, importers or agents, order directly and arrange payments themselves. In no case will Nestlé Nutrition Business absorb costs of materials for market requirements.

Items may not bear any product brand or message, but may include the company name or logo. Such materials are designed for and addressed to a professional audience, not to the general public.

The following list does not relate to materials, including service items that may be requested by, or donated to institutions or associations.

I In-service aids and professional educational materials:

- charts for recording weight, height or other anthropometric indications;
- wall charts, desk charts or calculators providing reference date (on subjects such as: gestation, evaluation of the newborn, stage of development of the foetus or of the child, stages of pregnancy, immunisation, child health and care, etc.);
- materials or equipment designed to assist with record keeping such as:
  - diaries, year planners and calendars, – slide storage pockets or boxes,
  - Cardex indices,
  - easybinders or boxes,
  - congress bags or document cases;
- material for the health workers' own continuing education;
- personalised non product-related prescription pads or notepads. Since these could be issued sheet by sheet to the general public, no product brand may appear.

II Materials and equipment for individual health workers:

Materials and equipment to help health workers in the diagnosis and/or treatment of obstetric, paediatric and/or nutritional problems according to the following list:

- measuring tapes (e. g. arm/head circumference);
- length measuring devices;
- weighing scales – babies and children;
- skinfold calipers;
- sphygmomanometers;
- cold light;
- reanimation lamp;
- head mirror;
- otoscope;
- stethoscopes (including obstetric and/or foetal);
- clamp for umbilical cord;
- percussion hammer;
- thermometers;
- tongue depressors;
- vacuum forceps;
- delivery mat;
- breast-milk pump.

Similar low-cost professional items may be considered after consultation with Nestlé Nutrition Business and PA, Vevey.

Clinical Validation Policy

Objectives

- monitor product performance under normal conditions of use, on a representative and on-going basis, in order to establish a solid data base;
- monitor comprehension of, and conformity with, preparation instructions, particularly among users in the lower socio-economic groups.

Principles

In conformity with our commitments under the International Code, the following principles have to be respected when clinical validations are conducted on infant formula:

- since breast-feeding is to be encouraged for all babies, only those babies who have to be fed on a breast-milk substitute may participate in trials – these may, however, include babies whose mothers, after consultation with a doctor, have chosen not to breast-feed, or chosen to discontinue breast-feeding, or chosen to complement breast-feeding;
- sufficient infant formula must be provided for infants participating in the trials, to cover their needs until they reach the age of six months (follow-up formula, from a minimum age of four months up to a maximum age of twelve months);
- clinical validations are not to be used as a sales inducement;
- all clinical validations must be conducted under medical supervision according to an agreed protocol, which is to be completed and a copy given to Nestlé for each completed study (a basic protocol and data recording sheet is enclosed – Annex 6.2 – but the protocol may be extended at the doctor's discretion);
- the health status of all babies participating in clinical validations should be checked by the supervising doctor at the beginning, during and at the end of the trial;
- both the mother and the supervising doctor must sign an agreement to the terms of the trial (enclosed text – Annex 6.1 – to be adapted according to local requirements);
- products for clinical validations are provided only on condition that the above principles are respected (the number of trials should be limited or even totally eliminated if they are not properly documented by the doctor);
- knowledge of correct preparation procedures can be tested with the help of the simple checklist shown in Annex 6.3.

Establishing the data-base

In order to establish a valid data-base, an adequate number of trials will need to be conducted by a representative cross section of doctors, covering the different social groups who use formula. Quantities of formula allocated for clinical validation purposes are to be strictly limited and subject to approval by the Nestlé Market Manager or his deputy. It is recognised that quantities required will be proportionally greater in relation to sales for new products than for well-established products. In case of doubt, Nestlé Nutrition Business must be consulted.

An annual report, summarising the results of all clinical validations by product – Annex 6.4 – must be sent to Nestlé Nutrition Business with copy to Zone Management by January 31st each year.

Administration

Products provided for clinical validation must be clearly marked with a sticker in the appropriate language(s) "Formula provided for Clinical Validation – NOT FOR RESALE".

The quantities provided for individual Clinical Validation, will vary from case to case according to the feeding pattern (e. g. exclusive formula feeding vs. mixed breast and formula feeding), the age at which the trial begins and ends, and the type of formula (e. g. special formula, routine infant formula, follow-up formula).

As an indication, exclusive formula feeding from birth to the age of six months will require approximately 20 kg (22 tins of 900 g each), while the use of follow-up formula as the liquid part of the weaning diet from the age of six months to the age of twelve months, would require approximately 15 kg.

Annex 6.1

Clinical Validation Agreement

Nestlé agrees to provide (brand) formula to (mother's name) for her baby (name) from (beginning date of trial).

Nestlé understands that during this period baby (name) will be under the care of (doctor's name) and he/she will examine baby (name) at the beginning, during and at the end of the trial.

Nestlé is providing (brand) formula for (baby's name) on the understanding that (mothers name) is aware of the superiority of breast-feeding, has chosen to use a formula after consultation with (doctor's name), and will be given full instruction for the safe use of formula.

(Doctor's name) agrees to give Nestlé a completed clinical validation protocol covering the progress of (baby's name) during the above period.

We have read and accept the above terms:

Doctor's signature: .....

Address: .....

.....

.....

Date: .....

Mother's signature: .....

Address: .....

.....

.....

Date: .....

Annex 6.2

Clinical Validation Protocol

Baby's name: .....

Sex: .....

Date of birth: .....

Birth weight: .....

Product provided: .....

Please enter following details on growth chart:
Beginning of trial (BT):

Date: .....

Age: .....

Height: .....

Body weight: .....

Head circumference: .....

Feeding pattern from birth to beginning of trial:

- Breast only B
- Breast and Formula BF
- Breast and other Foods BOF
- Formula only F
- Formula and other Foods FOF

Feeding pattern during trial: BF/F/FOF
End of trial (ET):

Date: .....

Age: .....

Height: .....

Body weight: .....

Head circumference: .....

Clinical Notes:

	Yes	No
Was formula well tolerated?	☐	☐

Remarks: .....

.....

.....

Was the trial completed?	☐	☐

Did the baby suffer any of the following symptoms during the trial?

Spitting-up	☐	☐
Vomiting	☐	☐
Colic	☐	☐
Constipation	☐	☐
Loose stools	☐	☐
Diarrhoea	☐	☐
Other (please specify)	☐	☐

Did the baby's condition require treatment during the trial? (Please specify)	☐	☐

Feeding Problems

Indicate if any of the symptoms below were observed and linked with the use of the product:

	Spitting-up	Colic	Loose stools	Constipation	Diarrhoea
0–1					
1–2					
2–3					
3–4					
4–5					
5–6					
6–9					
9–12					

Doctor's observations: .....

.....

.....

.....

Annex 6.3

Knowledge of Correct Preparation Procedures (Selected Mothers)

	Spontaneous Knowledge		**Prompted Knowledge** (comprehension of label instructions)	
	Yes	No	Yes	No
Wash bottle, teat and cap	☐	☐	☐	☐
Boil bottle, teat and cap	☐	☐	☐	☐
Boil drinking water	☐	☐	☐	☐
Pour exact amount of boiled water into feeding bottle (see feeding table)	☐	☐	☐	☐
Correct use of scoop leveller	☐	☐	☐	☐
Correct number of scoops of powder (see feeding table)	☐	☐	☐	☐
Shake bottle until powder dissolves	☐	☐	☐	☐

Annual Validation Protocol Report (Year)

Brand:

Quantity of product used for Clinical Validations (kg):

Number of babies participating:

Number of babies completing trials:

Number of doctors participating:

Average length of trial (months):

Results:

1) Brief description of general acceptance, tolerance, weight and height development.

2) Number of incidences of illness requiring treatment, and whether these were considered to be related to the infant feeding pattern:
   - diarrhoea;
   - respiratory;
   - other.

3) Knowledge of correct formula preparation procedures (number of mothers tested, spontaneous knowledge, prompted knowledge, comprehension of written and/or pictorial label instructions).

Conclusions/Recommendations:

Annex 7

Important Reminder to the Trade

Dear ...

In May 1981, the 34th World Health Assembly adopted the World Health Organization (WHO) International Code of Marketing of Breast-milk Substitutes. This Code is intended to contribute to the provision of safe and adequate nutrition for babies in particular by encouraging breast-feeding and ensuring that appropriate breast-milk substitutes are used only when necessary. Nestlé has publicly stated its support for the Code and has issued instructions to all its marketing personnel to ensure that Nestlé marketing practices are in accord with the principles and aim of the Code.

The Nestlé Instructions relate to the following formula products:

.....

(insert brand names), and are the only products Nestlé markets as suitable for use as breast-milk substitutes in:

.....

(insert name of country).

We would like to draw your attention particularly to the WHO Code Article 5.3 and the relating Instructions to Nestlé personnel:

Article 5.3

WHO Code

In conformity with paragraphs 1 and 2 of this Article, there should be no point-of-sale advertising, giving of samples, or any other promotion device to induce sales directly to the consumer at the retail level, such as special displays, discount coupons, premiums, special sales, loss-leaders and tie-in sales, for products within the scope of this Code.

Article 5.3

Nestlé Instructions

Activities at the retail level aiming at promoting sales of INFANT FORMULAS directly to the consumer are not permitted, i.e.:

- no coupon redemption schemes;
- no raffles or lotteries;
- no point-of-sale promotions (i.e. deals, gifts, special displays or exhibitions, including display contests);
- no in-store demonstrations;
- no company-induced price offers to the consumer at the retail level (consumer discounts, loss-leaders, tie-in sales);
- no incentives or discounts to the trade for the purposes of advertising or promotion at point-of-sale.

Note: *This does not prevent the implementation of a normal trade price structure.*

Nestlé communicates to all wholesalers and retailers of Nestlé formula products that it is company policy to prevent promotion of formula products at the point-of-sale. It is the sales staff's responsibility to maintain stock rotation and to ensure shelf-availability and clean and tidy presentation of formula products at the point-of-sale where it is needed. Shelf or bin markers clearly indicating product name and price are permitted, but promotional advertising is not.

Nestlé's policy is to prevent the promotion of INFANT FORMULA products at the point-of-sale, since this might have the effect of persuading a mother not to breast-feed, or to discontinue breast-feeding too early.

Nestlé is confident that in the interests of mothers and babies, retailers will respect Nestlé's policy in this regard, and that they will not carry out any advertising or sales promotion of INFANT FORMULAS, other than normal display as foreseen in the Nestlé Instructions.

Your co-operation in this matter is greatly appreciated.