




## HSE Policy on the Marketing of Breast Milk Substitutes for the Public Health Services

Is this document a:

Policy  Procedure  Protocol  Guideline

*Insert Service Name(s), Directorate and applicable Location(s):*

**All HSE Directorates and Service Areas**

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## PART A: Outline of PPPG Steps - HSE Policy on the Marketing of Breast Milk Substitutes

HSE National Breastfeeding Implementation Group disseminates policy through appropriate channels



National Directors (NDs), Chief Officers (COs) of Community Healthcare Organisations (CHOs) and Chief Executive Officers (CEOs) of Hospital Groups (HGs) cascade policy to their staff



Line managers ensure staff are aware of the HSE Policy on the Marketing of Breast Milk Substitutes



- Promotion and marketing of breast milk substitutes (see 1.8.1 for definition of breast milk substitute) within HSE facilities, by HSE employees and section 38 agencies and their facilities is prohibited.
- The HSE, hospital, institution name or HSE staff job titles must not be associated with breast milk substitutes marketing events or sponsored study days. Attendance at events and study days in an official capacity using health service job titles represents a conflict of interest under *Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers (DOH,2018)*
- Health care professionals should not promote a specific brand of formula.
- Inpatient formula feeds are distributed as needed and are stored securely at all other times.
- Mothers, whether breastfeeding or formula feeding should not be given free samples on discharge from hospital or in the community.
- Where there is a clinical indication for a specific brand of product, information should be provided without marketing.
- Information produced by HSE and other reputable sources is only given to mothers, approval by senior clinician is required if company information is deemed essential in an individual circumstance.
- Information on formula feeding should explain the importance of breastfeeding and the risks of not breastfeeding so parents can make an informed decision.
- Contact between a company representative and health service staff should only be on request from the health service staff and related to the specific product, this contact should not be a marketing event. "Cold Calling" is prohibited.
- Communication to health professionals should be scientific, factual and use appropriate terms and imagery. Information on the usefulness of new ingredients and / or products must be based on published, up-to-date, scientific evidence and must reflect this evidence accurately and clearly.
- No company-paid personnel to contact or to advise mothers.
- Health service employees should not receive benefits or hospitality of any kind from breast milk substitute companies, umbrella companies or distributors, as this could reasonably be seen to compromise their personal judgement or integrity and that of the HSE/WHO infant feeding recommendations.
- Any contribution from a manufacturer or distributor to an employee, or accepted on their behalf for research grants, study etc should be disclosed by the recipient.
- Staff should be aware that support, incentives or programmes of work should not create conflicts of interest.
- The Code and relevant legislation should be considered by research ethics committees in all research on infant feeding.



Managers audit policy & keep records.

National Breastfeeding Implementation Group monitors and evaluates policy to inform policy implementation and review.

PPPG Title:

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**HSE Policy on the Marketing of Breast Milk Substitutes for the Public Health Services**

**October 2021**

## **PART B: PPPG Development Cycle**

### **1.0 INITIATION**

#### **1.1 Purpose**

The Health Service Executive (HSE) is committed to promoting and supporting breastfeeding which leads to positive health outcomes for mother and child. The Department of Health and HSE have adopted as policy World Health Organisation (WHO) guidance recommending exclusive breastfeeding for the first six months of an infant's life. Thereafter it is recommended that breastfeeding continues, in combination with appropriate complementary foods, up to two years of age and beyond (WHO/UNICEF 2003, DoH&C, 2005, HSE, 2016).

1.1.2 The aim of this policy is to implement the WHO/UNICEF Code of Marketing of breast-milk substitutes and subsequent WHA resolutions (WHO Code) within HSE facilities, by HSE employees, by HSE funded agencies and government funded health service facilities.

1.1.3 This policy aims to ensure the protection, support and promotion of breastfeeding as identified in the WHO code:

*'In view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including unnecessary and improper use of breast milk substitutes, the marketing of breast milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products'.(WHO Code)*

#### **1.2 Scope**

1.2.1 The policy applies to all staff working in the public health service (HSE and Section 38 agencies) and HSE/Section 38 agency facilities in the following roles:

- All hospital and community health service managers
- Medical doctors, midwives, nurses
- Allied health professionals
- Research and professional/practice development
- Support staff, e.g. health care assistant, catering, medical and nutrition supplies etc

1.2.2 The scope of the products covered by the WHO Code is outlined in the definition of breast milk substitute products listed in the glossary of terms (see Section 1.8.1).

### 1.3 Objective(s)

- 1.3.1 To prohibit the marketing of breast milk substitutes within HSE/section 38 agency facilities and by HSE/section 38 agency employees.
- 1.3.2 To provide guidance to managers, staff and other stakeholders on their role in implementing the policy.
- 1.3.3 The World Health Assembly Resolution 58.32 calls for action to 'ensure that financial and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest'.

Health care professionals should consider *Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers, (DOH 2018)* and other professional codes of practice that contain clauses that need to be considered in the context of the marketing of breast milk substitutes and conflicts of interest.

- 1.3.4 Recognising what forms this marketing can take, and where it may breach this HSE policy and the WHO code, is crucial for health workers looking to make sure that families have access to unbiased information.

### 1.4 Outcome(s)

- 1.4.1 The statutory regulations in Ireland are outlined in the 2018 National Implementation of the International Code Status Report, (WHO, 2018).

**While the current EU legislation does not mirror the WHO Code it does intend to conform to the principles and aims of the code. The legislation does not completely eliminate marketing practices and the HSE is adopting a policy to promote and protect breastfeeding by eliminating marketing practices in HSE facilities, by HSE employees, including Section 38 agencies and their employees.**

- 1.4.2 The policy will ensure that the HSE meets its responsibilities in relation to Irish legislation and the WHO Code thereby protecting parents and health workers from inappropriate marketing practices and protecting breastfeeding.
- 1.4.3 There is a requirement for full implementation of the WHO Code within HSE facilities in order to achieve baby friendly status.

### 1.5 PPPG Development Group

The PPPG Development Group is the HSE National Breastfeeding Implementation Group.

See Appendix I for Membership of the PPPG Development & Governance Group.  
See Appendix II for PPPG Conflict of Interest Declaration Form template.

## 1.6 PPPG Governance Group

The PPPG governance group is the HSE National Breastfeeding Implementation Group (appendix 1).

## 1.7 Supporting Evidence

1.7.1 Breastfeeding is unparalleled in providing the ideal food for infants and young children. There is considerable evidence to demonstrate the importance of breastfeeding for the health of both mothers and children and the negative influence of breast milk substitute marketing, which can be aggressive and inappropriate, (Victora et al, 2016).

1.7.2 This policy aims to ensure the protection, support and promotion of breastfeeding as identified in the WHO code (see Appendix III and IV for information on the code and subsequent World Health Assembly Resolutions):

*'In view of the vulnerability of infants in the early months of life and the risks involved in inappropriate feeding practices, including unnecessary and improper use of breast milk substitutes, the marketing of breast milk substitutes requires special treatment, which makes usual marketing practices unsuitable for these products'.(WHO Code 1981)*

1.7.3 The Department of Health and HSE have adopted as policy World Health Organisation guidance recommending exclusive breastfeeding for the first six months of an infant's life. Thereafter it is recommended that breastfeeding continues, in combination with appropriate complementary foods, up to two years of age and beyond (WHO/UNICEF 2003, DoH&C, 2005, HSE, 2016).

1.7.4 The World Health Assembly Resolution 58.32 calls for action to 'ensure that financial and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest'. Health care professionals should consider the various professional codes of practice that contain clauses that need to be considered in the context of the marketing of breast milk substitutes and conflicts of interest.

1.7.5 ` The Department of Children and Youth Affairs early years strategy - First 5 A Whole-of-Government Strategy for Babies, Young Children and their Families 2019-2028 (DCYA 2018) sets out a number of goals that support breastfeeding. There are specific actions identified under these:

*Goal B: Optimum Physical and Mental Health Strategic Action 4.1: Promote and support positive health behaviours among pregnant women, babies, young children and their families.*

*Continue progress towards the breastfeeding target rate set out in the National Breastfeeding Action Plan (i.e. annual 2% increase in*

*breastfeeding duration rates over the period 2016–2021). To meet this target, continue to support mothers to breastfeed through the PHN service, implement standardised breastfeeding policies and provide clinical specialist posts in both primary care and maternity hospitals as per the key actions of the National Breastfeeding Action Plan. Extensions to this target will be considered at the end of year three review of First 5 in 2021.*

- 1.7.6 The HSE Breastfeeding in a Healthy Ireland Health Service Breastfeeding Action Plan 2016 – 2021 (HSE, 2016) includes the action to ‘Strengthen compliance with the International Code of Marketing of Breast Milk Substitutes and subsequent WHA resolutions’. Calling for the International Code & WHA resolutions to be policy for all Government departments, the HSE & contracted agencies.
- 1.7.7 The National Maternity Strategy 2016-2026: Creating a Better Future Together (DoH, 2016) outlines the responsibilities of the Department of Health, HSE and the National Women & Infants Health Programme in relation to the promotion, support and protection of breastfeeding.
- 1.7.8 The Irish health strategy, Healthy Ireland – A Framework for Improved Health and Wellbeing 2013-2025 (DOH, 2013), commits to addressing risk factors and promoting protective factors at every stage of life, including pre-natal and through early childhood. Breastfeeding is integral to supporting child health and development in the context of evidence-based prevention and early intervention initiatives working with children and families.



### 1.7.9 Relevant legislation

EU legislation	Given effect in Ireland by:
1. Commission Directive 2006/141/EC of 22 December 2006 on infant formula and follow-on formulae and amending Directive 1999/21/EC	1. S.I. No. 852 of 2007 of 21 December 2007 European Communities (Infant Formula and Follow-on formulae) Regulations 2007, as amended.
2. Regulation (EC) No. 1924/2006 of the EP and of the Council of 20 December 2006 on nutrition and health claims made on food, as amended.	2. S. I. No. 11 of 2014 signed 21 January 2014 European Union (Nutrition and Health Claims made on Food) Regulations 2014
The European Court of Justice Ruling (Case C-19/15) regarding the scope of Regulation 1924/2006 on nutrition and health claims	The FSAI have produced Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020) <a href="https://www.fsai.ie/makeacomplaint/">https://www.fsai.ie/makeacomplaint/</a>  <a href="https://www.fsai.ie/CommunicatingwithHealthProfessionalsAboutInfantformula/">https://www.fsai.ie/CommunicatingwithHealthProfessionalsAboutInfantformula/</a>
3. Commission Directive 2013/46/EC of 28 August 2013 adapting Directive 2006/141/EC with regard to protein requirements for infant formulae and follow-on formulae	3. S.I. No. 92 of 2014 of 11 February 2014 European Communities (Infant Formula and Follow-on formulae) (Amendment) Regulations 2014
4. Commission Delegated Regulation (EU)2016/127 of 25 September 2015  Supplementing Regulation (EU) No. 609/2013 as regards the specific compositional and information requirements for infant formula and follow-on formulae and as regards requirements on information relating to infant and young child feeding  5. Commission Delegated Regulation (EU) 2019/828 of 14 March 2019 amending Commission Delegated Regulation (EU)2016/127 with regard to vitamin D requirements for infant formula and erucic acid requirements for infant formula and follow-on formula  6. Commission Delegated Regulation (EU) 2016/128 supplementing Regulation (EU)	4. S.I. No. 425/2019 - European Union (Food Intended For Infants And Young Children, Food For Special Medical Purposes, And Total Diet Replacement For Weight Control) Regulations 2019  (Applies with effect from 22 February 2020 except for product manufactured from protein hydrolysates, to which it shall apply from 22 February 2022)

609/2013 regards the specific compositional and information requirements for foods for special medical purposes

7. Commission Delegated regulation (EU) 2021/572 of 20 January 2021 amending Delegated Regulation (EU) 2016/127 as regards the date of application of certain of its provisions.

### 1.7.10 Relevant Professional Codes of Conduct

- *Code of Professional Conduct and Ethics for Registered Nurses and Registered Midwives*. Nursing and Midwifery Board of Ireland (NMBI, 2021) <https://www.nmbi.ie/NMBI/media/NMBI/Code-of-Professional-Conduct-and-Ethics.pdf?ext=.pdf>
- *Guide to Professional Conduct and Ethics for Registered Medical Practitioners 8th Edition* (Irish Medical Council 2016) <https://www.medicalcouncil.ie/News-and-Publications/Reports/Guide-to-Professional-Conduct-and-Ethics-8th-Edition-2016-.pdf>
- *CORU members: Code of Professional Conduct and Ethics* [http://www.coru.ie/en/registration/code\\_of\\_professional\\_conduct\\_and\\_ethics1](http://www.coru.ie/en/registration/code_of_professional_conduct_and_ethics1)
- *The Pharmaceutical Society of Ireland, Code of Conduct for Pharmacists* [https://www.thepsi.ie/gns/Pharmacy\\_Practice/code-of-conduct.aspx](https://www.thepsi.ie/gns/Pharmacy_Practice/code-of-conduct.aspx)
- *Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers*, Dept of Health (2018) <https://www.gov.ie/pdf/?file=https://assets.gov.ie/11437/db8d44e1132f460db25c86603c87da62.pdf#page=1>

1.7.11 There are no existing PPPGs that are being replaced by this PPPG.

1.7.12 Related PPPGs. – The following PPPGs refer to the *International Code of Marketing of Breast-Milk substitutes* and responsibilities of health workers and:

- Infant Feeding Policy for Maternity & Neonatal Services (HSE, 2019)
- Infant feeding Policy for Primary Care Teams and Community Health Organisations (HSE, 2018)

## 1.8 Glossary of Terms

**1.8.1 Breast milk substitutes:** means any food being marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose. This includes:

- Infant formulae, including follow up formula and growing up milks.
- Special formulas for infants with specific medical or nutritional needs;
- Other products marketed or otherwise represented for use **before six months** such as baby teas, juices and waters, as well as cereals, processed baby meals represented for use before six months;

- Any milk product shown to be substituting for the breast milk part of the child's diet between six months and three years, such as follow-on formula and growing up milks;
- The Code also applies to feeding bottles, teats, soothers and other aids or products marketed to parents that could be used to replace milk.

**1.8.2 The WHO Code:** The WHO Code is a set of recommendations to regulate the marketing of breast milk substitutes, feeding bottles and teats. The code aims to stop the aggressive and inappropriate marketing of breast milk substitutes.

The 34th session of the World Health Assembly (WHA) adopted the *International Code of Marketing of Breast-milk Substitutes* in 1981 as a minimum requirement to protect and promote appropriate infant and young child feeding.

The Code aims 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 breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution" (Article 1).

The Code advocates that babies be breastfed. If babies are not breastfed, for whatever reason, the Code also advocates that they be fed safely on the best available nutritional alternative. Breast milk substitutes should be available when needed, but not be promoted.

**1.8.3 Promotion and Marketing** The terms "promotion" and "marketing" mean those marketing and informational activities coming under the control or authority of the company (e.g. infant formula company, umbrella companies and processed milk distributors), the purpose of which is to induce the prescribing, supply, sale or consumption of the company's products.

Promotion includes, for example, the activities of company representatives; various aspects of sales promotion such as:

- events for health workers, sponsorship of research, conference attendance including travel costs, education etc.,
- provision of samples, gifts or hospitality,
- journal and direct mail advertising, press releases, posters,
- the use of mail (including post, telephone, email, and other electronic means of communication),
- the use of the internet & sponsored websites,
- the use of audio-visual materials such as films, video recordings, data storage services.

#### **1.8.4 Commercial Communication**

‘Commercial communication’ is any form of communication designed to promote, directly or indirectly, the goods, services or image of a company, organisation or person pursuing a commercial, industrial or craft activity or exercising a regulated profession.

Providing clarity on the application of Commission Regulation 1924/2006, the European Court of Justice Ruling C-19/15 decided that commercial communications between food companies and health professional’s falls within the scope of communications referred to and governed by Commission Regulation 1924/2006. It also means that while there is provision for information pertaining to new scientific developments to be given to health professionals from infant formula companies, any and all information disseminated should be objective, scientific and factual.

There is a standard for the type and nature of nutrition and health claims that can be provided to healthcare professionals on infant formula, defined by EU law. The FSAI has produced *Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020)*

<https://www.fsai.ie/CommunicatingwithHealthProfessionalsAboutInfantformula>

Some key issues are outlined in more detail in sections 2.7.3 and 2.7.4.

#### **1.8.5 WHA: World Health Assembly**

**WHO:** World Health Organisation

### **2.0 DEVELOPMENT OF PPPG**

#### **2.1 List the questions (clinical/non-clinical)**

Information was gathered on new and emerging evidence in relation to the marketing of breast milk substitutes and products covered in the scope of the Code related to infant and young child feeding.

#### **2.2 Describe the literature search strategy**

The review of the literature relating to breastfeeding and WHO International Code of Marketing included a search of journals in the fields of human lactation, health promotion, medicine, nursing and the social and behavioural sciences. A number of online databases were examined including EBSCO, MEDLINE, PubMed, CINAHL, ISI Web of Science, PsycINFO. In addition a search of relevant websites, e.g. WHO, UNICEF UK and IBFAN was

undertaken.

### 2.3 Describe the method of appraising evidence

WHO International Code of Marketing of Breast milk Substitutes and subsequent relevant WHA Resolutions, and related policies were reviewed. When considering the literature, the following three questions were borne in mind:

- What are the results and are they valid?
- What are the recommendations and are they feasible?
- Are the results applicable/generalisable to the health service?

### 2.4 Describe process PPPG Development Group used to formulate recommendations

The recommendations were developed by appraising the evidence and legislation and balancing the challenges and opportunities with such a policy. The following was considered:

- What is the Code?
- How will it apply in practice in Irish hospital and community settings?
- What is the potential benefit verses harm to the employee?
- What are the potential challenges to the employer?

### 2.5 Provide a summary of the evidence from the literature

There is considerable evidence to demonstrate the short and long term benefits of breastfeeding to both mothers and infants. The Irish health strategy, *Healthy Ireland – A Framework for Improved Health and Wellbeing 2013-2025* (DoH, 2013), commits to addressing risk factors and promoting protective factors at every stage of life, including pre-natal and through early childhood. Appropriate infant young child feeding is integral to supporting child health and development.

The Lancet breastfeeding series in 2016 highlights the negative influence of breastmilk substitute marketing, which can be aggressive and inappropriate. Commenting on the impact of the breastmilk substitute industry, the Lancet series author Professor Cesar Victora from the Federal University of Pelotas in Brazil states:

*“There is a widespread misconception that breastmilk can be replaced with artificial products without detrimental consequences. The evidence outlined in the Series, contributed by some of the leading experts in the field, leaves no doubt that the decision not to breastfeed has major long-term negative effects on the health, nutrition and development of children and on women’s health.”*

(see <http://www.evidentlycochrane.net/lancet-breastfeeding-series/>).

The Global Strategy for Infant and Young Child Feeding (WHO, 2003) describes essential interventions to protect, promote and support appropriate infant and young child feeding. In relation to protection this includes implementing and monitoring the

*International Code of Marketing of Breast-milk Substitutes* and to subsequent relevant World Health Assembly resolutions.

The *National Maternity Strategy 2016-2026: Creating a Better Future Together* (DoH, 2016) outlines the responsibilities of the Department of Health, HSE and the National Women & Infants Health Programme in relation to the promotion, support and protection of breastfeeding. Actions include the following 'The Department of Health will ensure that the WHO International Code of Marketing of Breast-Milk Substitutes and subsequent relevant WHA resolutions are implemented' (DoH, 2016).

The HSE *Breastfeeding in a Healthy Ireland Health Service Breastfeeding Action Plan 2016 – 2021* (HSE, 2016) includes the action to 'Strengthen compliance with the International Code of Marketing of Breast milk Substitutes and subsequent WHA resolutions'. Calling for the International Code & WHA resolutions to be policy for all Government departments, the HSE & contracted agencies.

The HSE Infant Feeding Policy for Maternity & Neonatal Services (HSE, 2019 ) and the HSE Infant Feeding Policy for PCTs and Community Healthcare settings (HSE, 2018) include sections on the importance of protecting breastfeeding because of its significance for long-term infant and maternal health, and impacts on normal weight, protection against obesity, family finances and the environment. The policies outline the responsibilities of healthcare staff and facilities within Maternity & Neonatal Services and Community Healthcare organisations in relation to the WHO *International Code of Marketing of Breast-milk Substitutes*, subsequent relevant WHA resolutions and related Irish legislation to protect infants, their families and hospital staff, and assist safe feeding.

The International Code of Marketing of Breast milk Substitutes aims 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 breast milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

The WHO/UNICEF/IBFAN report *Marketing of Breast milk Substitutes: National Implementation of the International Code -Status Report- 2020* states that: "Every country needs to improve its implementation of the Code. Essential for this improvement is the presence of sustained, high-level political will and accountability. Specific recommendations for countries include:

1. Legislators and policy-makers should recognize their obligations to promote and protect breastfeeding, and to eliminate inappropriate marketing practices.
2. Countries should analyse and address weaknesses or gaps in their existing legislation and act accordingly.
3. Legislation must be supported by allocation of adequate budgets and human resources.
4. Governments should establish robust and sustainable monitoring and enforcement mechanisms.
5. Governments should apply deterrent sanctions in the case of violations of national Code legislation.

6. Health care workers should be educated on their responsibilities under the Code and national legislation to avoid conflicts of interest and fully protect, promote and support breastfeeding”.

The WHO/UNICEF/IBFAN report (2016). *Marketing of Breast milk Substitutes: National Implementation of the International Code Status Report* states that countries should in particular ensure the inclusion of provisions that:

- broaden the range of designated products under the scope of their legislation to include all milk products intended and marketed as suitable for feeding young children up to the age of 36 months; (*Ireland as part of the EU can only give effect to Regulations adopted within the EU*).
- requires inclusion of all necessary messages in informational and educational materials on infant and young child feeding, as specified under article 4.2 of the Code;
- explicitly prohibit all advertising and other forms of promotion of designated products to the general public, including contact with pregnant women and mothers, promotion through the internet, social media and other electronic means of communication, as well as within the health system;
- prohibit the provision of free or low-cost supplies to health facilities by manufacturers or distributors, and any other financial or material inducements to health workers to promote designated products, taking into consideration resolutions WHA 49.15, WHA 58.32 and WHA 61.20 to ensure avoidance of conflicts of interest;
- include all necessary requirements for labelling of designated products, as indicated in Code Article 9.2 and resolution 58.32; and
- specify government obligations to establish robust and sustainable monitoring and enforcement mechanisms.’

## **2.6 Detail resources necessary to implement the PPPG recommendations.**

### **2.6.1 Policy, support & information for employees**

- User friendly information for employees on the *HSE Policy on the Marketing of Breast Milk Substitutes* and their responsibilities under this policy.
- Support/direction for employees who identify breaches or potential breaches of the Code and this HSE policy.

### **2.6.2 Inclusion in training in infant and young child feeding**

- Inclusion of this HSE policy, the WHO Code of Marketing and WHA Resolutions in infant and young child feeding training for HSE staff.
- Sufficient time should be made available for all staff to appraise themselves of their responsibilities and considerations in their role in adhering to this policy.



## 2.7 Outline of PPPG Steps/Recommendations

### Promotion and Marketing

- 2.7.1 The promotion and marketing of breast milk substitutes is prohibited.
- 2.7.2 No part of the health facility is used for the promotion or marketing of breast milk substitutes. No service provided within a health service facility is used to promote breast milk substitutes either directly or through cross promotion.
- 2.7.3 The health facility is not used for the display of products within the scope of the Code, or for other promotional materials such placards or posters concerning such products, baby clubs, carelines, pens, post-its, lanyards etc. including logos of manufacturers.
- 2.7.4 No member of staff is engaged in the promotion or marketing of breast milk substitutes. Where there is a clinical indication for a specific brand of product, information on this product should be provided without marketing.
- 2.7.5 If a mother makes an informed decision not to breastfeed health care workers will not promote a specific brand of formula, and are not involved in the promotion of products used for infant feeding.
- 2.7.6 World Health Assembly Resolution 58.32 calls for action to 'ensure that financial and other incentives for programmes and health professionals working in infant and young child health do not create conflicts of interest'. Therefore, materials provided by manufacturers or distributors of breast milk substitutes should not be used within the health care sector. Materials provided by manufacturers or distributors of breast milk substitutes promoting baby clubs, websites, carelines, phone apps, weaning information, recipe books & parent handbooks etc. should not be provided by health care professionals or displayed in the HSE or in funded organisations, e.g. GP surgeries.

### Supply and Samples

- 2.7.7 The procurement of non formula branded teats is preferred within HSE services.
- 2.7.8 Stocks of formula feeds are not on display in hospital ward areas including maternity hospitals and units & children's hospitals.
- 2.7.9 In-patient infants who are formula feeding should be given feeds as needed and stocks of formula feeds should be stored securely and accessed only by staff.
- 2.7.10 Mothers, whether breastfeeding or formula feeding, are not given bottles of ready-to-feed or any formula products on discharge from maternity hospital or in the community.

## **Nature and Availability of Information to Parents & Families**

- 2.7.11 Healthcare staff do not promote any brand of formula or feeding equipment. Where there is a clinical indication for a specific brand of product, information on this product should be provided without marketing.
- 2.7.12 Where specific instruction materials produced by a commercial company on the use of a specialised feeding product is deemed essential in an individual circumstance, approval for its use should be sought from medical practitioners, dieticians, midwifery managers, hospital management or Public Health Nurse management, as appropriate.
- 2.7.13 All information prepared by health workers on formula feeding explains the importance of breastfeeding, and the health risks of formula feeding.
- 2.7.14 Article 4.2 of the Code states that 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 the following points:
- The benefits and importance of breastfeeding.
  - Maternal nutrition, and the preparation for and maintenance of breastfeeding.
  - The negative effect on breastfeeding of introducing partial formula feeding.
  - The difficulty of reversing the decision not to breastfeed.
  - Where needed, the proper use of formula.

When such material contains information about the use of formula, the information should include the social and financial implications of formula use; the health risks of inappropriate foods or feeding methods; and in particular, the health risks of the unnecessary or improper use of formula.

- 2.7.15 Information and educational materials should not use pictures or text that may idealise the use of formula.
- 2.7.16 All materials used to provide information on new scientific developments should be factual, accurate, up to date and in full and evidence based.
- 2.7.17 Health care professionals give accurate, objective and consistent information and educational material on breastfeeding.
- 2.7.18 Health care professionals should discuss the importance of breastfeeding and risks of not breastfeeding so parents can make an informed decision.
- 2.7.19 Child Health Information provided by the HSE, Government agencies and government funded agencies, and other reputable sources approved by HSE **is only used** e.g. HSE Breastfeeding – A good start in Life, [www.mychild.ie](http://www.mychild.ie), My Pregnancy- Expert advice for very step, My Child 0-2 year and My Child 2-5 years, HSE Nutrition Reference Pack for Health Care Professionals, UNICEF; Baby Friendly UK, La Leche league and Cuidiú.

## **Nature and Availability of Information to Health Care Professionals**

- 2.7.20 Information on breast milk substitutes should be provided by companies on request only, from relevant health care professionals such as Consultant Neonatologists, Consultant Paediatricians, HSE Dieticians, Directors of Nursing, Directors of Midwifery, Directors of Public Health Nursing.
- 2.7.21 HSE Dieticians provide information to relevant health care professionals through training and information updates and on request.
- 2.7.22 Information on any new products should be provided by companies only to relevant health care professionals such as Consultant Neonatologists, Consultant Paediatricians, HSE Dieticians, Directors of Nursing, Directors of Midwifery and Directors of Public Health Nursing.
- 2.7.23 Information about breast milk substitute products and any new products must be up-to-date, scientific, factual, verifiable, accurately reflects current knowledge and must not mislead either directly or indirectly. The HSE Nutrition reference Pack for Infants is the primary source for information for use by Health Care professionals in community settings.
- 2.7.24 Scientific information on breast milk substitute products should be appropriately referenced in communications to healthcare professionals. Referencing should be in accordance with normal scientific citation. The full name of the paper must be provided. To allow a healthcare professional to assess the weight of evidence referenced in support of a breast milk substitute product, the type of study e.g. case study, observational study, randomised controlled trial should be clearly stated in descriptive passages. Study aims and objectives, population studied, study results and study conclusions, including study limitations must be presented in a clear and precise manner.

In situations where the study findings have not been submitted for publication in a scientific journal, this should be made known to the healthcare professional. For example, if the findings of the study have been presented at a scientific conference but there are no accepted peer-reviewed publications on the study, this should be acknowledged.

References to 'data on file' should not be used. Instead such supporting information should be referenced as 'unpublished data on file' which clarifies that these data have not been peer reviewed and published in a scientific journal. Appropriate information should be provided to the healthcare professional to fully describe such data, i.e. type of study, population studied, study limitations, results and study conclusions. Should the healthcare professional request the unpublished data or study referenced within a material, such information/studies should be provided within four weeks.

Materials aimed at healthcare professionals

<b>Acceptable Sources of Scientific and Factual Information</b>	<b>Unacceptable Sources of Scientific and Factual Information</b>
<ul style="list-style-type: none"> <li>• Publications from national and international public health agencies, research bodies/academic institutes or nutrition associations</li> <li>• Peer-review articles</li> <li>• Text books</li> <li>• Conference proceedings</li> <li>• Conference abstracts</li> <li>• Consensus scientific publications</li> <li>• Compositional laboratory data</li> <li>• Unpublished data on file</li> </ul>	<ul style="list-style-type: none"> <li>• Company information such as national/international sales, usage or market trend analysis data</li> <li>• Unreferenced information</li> <li>• Influencers and bloggers</li> <li>• Non-academic media personalities</li> </ul>

2.7.25 Communication to health professionals should be scientific and factual and use appropriate terms and imagery. Information on the usefulness of new ingredients and / or new breast milk substitute products must be based on an up-to-date evaluation of all the evidence and must reflect this evidence accurately and clearly. Exaggerated claims must not be made and all-embracing claims and superlatives avoided. Claims must not imply that a breast milk substitute, or an active ingredient it contains is equivalent or superior to breast milk.

<b>Commercial communication must</b>	<b>Communication should not</b>
<p>Use appropriate terms and imagery such as:</p> <ul style="list-style-type: none"> <li>• intended to</li> <li>• suitable for</li> <li>• provides</li> <li>• imagery that enables a clear distinction to be made between infant formula and follow-on formula</li> </ul>	<p>Use terms and imagery such as:</p> <ul style="list-style-type: none"> <li>• optimal, maximum</li> <li>• exceptional, excellent, the best</li> <li>• unparalleled,</li> <li>• secure</li> <li>• ‘humanised’, ‘maternalised’, ‘adapted’ or similar terms,</li> <li>• pictures of infants</li> <li>• pictures that may idealise the use of infant formula</li> </ul>

## Company Representatives

- 2.7.26 Contact between a company representative, manufacturer or distributor of a Code related product and Health service staff is restricted to providing information that is accurate, scientific and factual and related to a new specific product and / or ingredient. This contact should not be used as a marketing event.
- 2.7.27 Contact between company representative, manufacturer or distributor of a breast milk substitute / Code related product and the HSE should only be on request from senior managers in the health service. The exception is information on new products which should only be provided to relevant health care professionals such as Consultant Neonatologists, Consultant Paediatricians, HSE Dieticians, Directors of Nursing, Directors of Midwifery, Directors of Public Health Nursing. The HSE Nutrition Reference Pack for Health Care Professionals which is updated regularly should be the first reference point for information on products available.
- 2.7.28 'Cold calling' (meeting without prior appointment) from company representative, manufacturer or distributor of a Code related product is prohibited.
- 2.7.29 Health service staff or staff in government funded healthcare facilities should not accept gifts or hospitality from company representatives, manufacturer or distributor of a breast milk substitute / Code related product.
- 2.7.30 No direct or indirect contact is permitted or facilitated between employees of manufacturers or distributors of breast milk substitutes, feeding bottles, teats, dummies or other feeding equipment and pregnant women, mothers or members of their families.
- 2.7.31 The provision of company branded, any branded, or unbranded materials informational or educational materials to pregnant women, mothers or members of their families is not permitted.
- 2.7.32 The provision of company branded, any branded, or unbranded materials to health care professionals is not permitted. This includes pens, paper pads, mouse pads, mugs, torches /lights, gestation wheels, weight conversion charts, measuring tapes and any other materials.
- 2.7.33 The provision of materials for use with patients/clients is not permitted.
- 2.7.34 The provision of free or low cost samples to health service staff or facilities is prohibited.
- 2.7.35 Company representatives, manufacturers and distributors of a breast milk substitute / Code related product must abide by the WHO International Code of Marketing of Breast-milk Substitutes, Infant Formulae and Follow on Formulae Regulations, Foods for Special Medical Purposes and Nutrition and Health Claims Regulations.

### **Gifts and Hospitality**

- 2.7.36 Health service employees should not receive benefits or hospitality of any kind from breast milk substitutes companies, umbrella companies or distributors, which could reasonably be seen to compromise their personal judgement or integrity and that of the HSE/WHO Infant Feeding recommendations and the WHO Code.
- 2.7.37 Any contribution made by a manufacturer or distributor to an employee, or accepted on their behalf, for fellowships, research grants, study, or the like should be disclosed by the recipient to management.

### **Events and Study Days**

- 2.7.38 The health service environment does not facilitate marketing events by manufacturers of breast milk substitutes, including advertising of sponsored events and study days.
- 2.7.39 The HSE, hospital, institution name or HSE job titles must not be associated with breast milk substitutes marketing events or sponsored study days. Attendance at events and study days in an official capacity using health service job titles represents a conflict of interest under *Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service providers* (DOH, 2018) and is no longer permitted.
- 2.7.40 HSE and health service staff should be aware that support, other incentives or programmes for health professionals working in infant and young child health should not create conflicts of interests.

### **Research Studies**

- 2.7.41 The WHO Code of Marketing of Breast milk Substitutes, and relevant subsequent WHA resolutions, EU Directives, regulations and Irish Statutory Instruments on infant formulae and relevant HSE National Infant Feeding Policies should be considered in all research and by research ethics committees on infant feeding.
- 2.7.42 Article 10.3 of Commission Delegated Regulation (EU) 2016/127 regards the specific compositional and informational requirements for infant formula and follow-on formula states that:
- ‘Manufacturers and distributors of infant formulae shall not provide to the general public, or to pregnant mothers or members of their families, free or low priced products, samples or any other promotional gifts, either directly or indirectly via the health care system or health workers.’
- Therefore the provision of free or low priced infant formulae or other products, samples or any other promotional gifts should not be used as an incentive to recruit participants to research studies.
- 2.7.43 Article 5 of the International Code relates to the general public and mothers. Companies are prohibited from seeking contact with pregnant mothers and must not promote products covered by the Code to them or

the general public in any way, for research or any other purposes.

- 2.7.44 Health workers should disclose to the institution any contribution made towards fellowships, research grants, attendance at professionals conferences and the like.
- 2.7.45 WHA resolution 49.15 and WHA resolution 58.32 require that financial support and other incentives for programmes and health professionals working in infant and young child health do not create conflict of interest. Research on infant and young child feeding, which may form the basis for public policies, should always contain a declaration relating to conflicts of interest and be subject to peer review.
- 2.7.46 The HSE National Infant Feeding Policy for Maternity and Neonatal services, in relation to providing information to pregnant women, states:  
*“It should be assumed that all women will breastfeed. Women should not be asked to state their infant feeding intention antenatally, unless there is a specific medical reason why a decision needs to be made during pregnancy”, (HSE, 2019 – 2.7.4).*

Therefore health professionals should not agree to participate in or facilitate any research proposals which require women to state a feeding intention in the antenatal period.

- 2.7.47 In research studies / proposals breastfeeding mothers whose babies require a supplement of infant formula for clinical reasons or who request a supplement of infant formula should not be prospectively designated “formula feeding” or “partially breastfeeding”, rather such mothers should be given every help to breastfeed fully. It is HSE policy that no food or drink other than breast milk be given unless medically indicated. If a supplement is indicated, the first and optimal choice of supplement should be the mother’s own expressed breast milk. Artificial formula should only be given when medically indicated and when own mother’s milk or donor milk is not available. Research proposals should adhere to the policy.
- 2.7.48 Research proposals should not exclude mothers and babies from the care outlined in HSE infant feeding policy, including care in relation to keeping mother and baby together, promoting exclusive breastfeeding, providing clear evidence-based information to enable them to make fully informed decisions, supporting early contact and initiation of breastfeeding, showing mothers how to breastfeed and maintain lactation, information on discharge etc.

### **3.0 GOVERNANCE AND APPROVAL**

#### **3.1 Outline Formal Governance Arrangements**

Refer to Appendix III for Membership of the Approval Governance Group.

### **3.2 List method for assessing the PPPG in meeting the Standards outlined in the HSE National Framework for developing PPPGs.**

3.2.1 The draft PPPG was developed and reviewed by the HSE National Breastfeeding Implementation Group and other relevant stakeholders including;

- HSE Corporate Employee Relations who were consulted on the content of the policy and supported the internal consultation process with the health service trade unions through the National Joint Council Policies and Procedures subgroup
- Food Safety Authority of Ireland
- Department of Health

3.2.2 All feedback and subsequent changes have been accompanied by supporting evidence.

3.2.3 The intention to develop the national policy was highlighted in the HSE Breastfeeding Action Plan (2016).

3.2.4 The final PPPG document is signed by the chairperson of the HSE National Breastfeeding Implementation Group (Appendix I).

3.2.5 The final version will be converted to a PDF document to ensure the integrity of the PPPG.

3.2.6 A signed and dated master copy will be retained in an agreed central location with written or electronic signatures. This will ensure document control before dissemination.

### **3.3 Attach any copyright/permission sought.**

Not applicable.

### **3.4 Insert approved PPPG Checklist.**

See Appendix V.

## **4.0 COMMUNICATION AND DISSEMINATION**

### **4.1 Communication and dissemination plans**

Each National Director, Hospital Group CEO and Community Healthcare Organisation's Chief Officer will cascade the policy to all managers for implementation. Implementation of the policy will be supported by resources and information for managers to help them comply with policy.



#### 4.1.2 Communicating the Policy

- It will be the responsibility of each National Director, Hospital Group CEO and Community Healthcare Organisation CO to cascade the policy to all managers for implementation.
- Managers will have a responsibility to communicate with their staff on this policy and disseminate this policy to all of their staff (see Appendix VI for Employee Signature Page).
- All new relevant staff will be orientated to the policy by line managers as soon as their employment begins.
- All staff will have ready access to a copy of this policy through the forthcoming PPPG repository.

### 5.0 IMPLEMENTATION

#### 5.1 National Implementation Plan

- 5.1.1 HSE policy and supporting resource *Working within the code – HSE Policy on the Marketing of Breast milk substitutes - A guide for staff* recommended for approval by National Breastfeeding Implementation group.
- 5.1.2 Policy approved by HSE Executive Management Team.
- 5.1.3 The National Breastfeeding Implementation will commence implementation by initiating a communication and dissemination plan. This will include using existing channels of communication to promote this policy with all public healthcare providers.
- 5.1.4 Advice for managers and employees on the implementation of this policy will be provided by the National Breastfeeding Co-ordinator, the Assistant National Breastfeeding Co-ordinator & local lactation consultants (IBCLCs).
- 5.1.5 The National Breastfeeding Implementation Group will review the policy and its implementation as needed.

#### 5.2 Local Implementation Plan

- 5.2.1 Manager ensures that all relevant staff are aware of the provisions contained in the policy according to their role.
- 5.2.2 Breaches of Irish law, including inappropriate communication with health professionals under new FSAI Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020) should be reported to the Food Safety Authority of Ireland at <https://www.fsai.ie/makeacomplaint/>
- 5.2.3 Line manager addresses and stores records relating to breaches of this policy.
- 5.2.4 Breaches of the policy may be dealt with under the HSE Disciplinary

Procedure or other relevant procedure for section 38 agencies.

### **5.3 Barriers and facilitators and timelines**

- 5.3.1 As per the evidence (section 2.5), the protection and promotion of breastfeeding as the optimal source of nutrition for infants and young children may be undermined if there is a lack of support for the Code.
- 5.3.2 The new guidance on the interpretation of the European Court of Justice ruling (case C-19/15), published by the FSAI in 2020, sets out clear parameters for how breast milk substitute companies may communicate information to health care professionals.
- 5.3.3 It is hoped that by HSE leaders, managers and employees recognising and valuing the significant role of the FSAI Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020) and the WHO code in delivering excellent care to mothers and babies and protecting staff from unethical marketing practices will facilitate successful implementation of this policy.
- 5.3.4 A facilitating factor for implementation of this policy is its overall ethos, that it is focussed on supporting evidence based care for optimal child and maternal health now and in the future. Indeed, there is a desire for such a policy from staff, as evidenced by on-going queries from HSE staff regarding on-going unethical marketing practices in Ireland and the role of health care professionals in implementing and adhering to the code.

### **5.4 Describe education/training plans required to implement the PPPG**

- 5.4.1 This policy will be incorporated into existing breastfeeding training provided for front line staff in maternity and community services.
- 5.4.2 All new relevant staff will be orientated to the policy by line managers as soon as their employment begins.
- 5.4.3 Advice for managers and employees on the implementation of this policy will be provided by the National Breastfeeding Co-ordinator, the Assistant National Breastfeeding Co-ordinator & lactation consultants (IBCLCs) working in maternity and community services.

### **5.5 Identify lead person(s) responsible for the implementation of the PPPG.**

Complete.

## 5.6 Roles and responsibilities.

### 5.6.1 Employees

Employees have responsibility to:

- Comply with policy provisions as outlined in section 2.7 above.
- Report any breaches in policy to DOM, DPHN, Hospital/primary care management and clinical lead manager as appropriate.
- Report non-conformance with FSAI Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020) regarding inappropriate communication to health care professionals by breast milk substitute companies <https://www.fsai.ie/makeacomplaint>

### 5.6.2 Line Managers

Line managers have responsibility to:

- Ensure all relevant staff are informed of the organisation's policy supporting breastfeeding and are given access to a copy of the policy.
- Ensure that all new relevant staff, as part of their induction, have information on the provisions contained in the policy according to their role and know what to do if there is a breach in policy.
- To lead by example and address any breaches of this policy in conjunction with *Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers* and/or professional bodies codes of conduct. Breaches of the policy may also be dealt with under the HSE disciplinary procedure or other relevant procedure for section 38 agencies.
- To report breast milk substitute companies providing inappropriate communication to health care professionals not conforming with FSAI Guidance For Compliance with Food Law When Communicating With Health Professionals About Infant Formula Products (2020) <https://www.fsai.ie/makeacomplaint/>
- Retain a record of any breaches or comments from staff in relation to the policy.

### **5.6.3 National Directors (NDs), Chief Officers (COs) of Community Healthcare Organisations (CHOs) and Chief Executive Officers (CEOs) of Hospital Groups (HGs)**

National Directors, Chief Officers of the Community Healthcare Organisations and Chief Executive Officers of the Hospital Groups, are responsible for:

- Overseeing the development, provision and communication of resources and supports locally to assist the implementation of this policy, in conjunction with appropriate personnel.
- Endorsing and supporting local implementation of the policy and ensure compliance through agreed monitoring process.
- Ensuring this policy is brought to the attention of all staff.
- Aligning appropriate resources to support the implementation of this policy.
- Including actions aligned to this policy in CHO, HG, Hospital, service Healthy Ireland Implementation plans.

### **5.6.4 The Chief Executive Officer**

The CEO has responsibility for:

- Ensuring compliance with the HSE Policy on the Marketing of Breast milk substitutes.
- Ensuring that all staff are aware of this policy.
- Facilitating conformance with the FSAI Guidance for Compliance With Food Law When Communicating With Health Professionals About Infant Formula Products (2020).

## **6.0 MONITORING, AUDIT AND EVALUATION**

Describe the plan and identify lead person(s) responsible for the following processes:

### **6.1 Monitoring**

This policy will be reviewed by the National Breastfeeding Implementation group one year after its introduction in the HSE and thereafter every three years or more frequently as circumstances or legislation require.

A review process will be agreed and will incorporate obtaining feedback on local implementation of the policy.

New evidence may emerge by audit, evaluation, serious incident, organisational structural change, advances in technology or significant changes in international evidence or legislation.

Evidence which has immediate and significant implications for the policy will trigger a policy update. Emerging evidence which does not have significant implications for the policy will be used to amend and update the original policy at the review period.

## **6.2 Audit & Evaluation**

The National Breastfeeding Implementation Group monitors effectiveness of policy to inform policy implementation and review.

## **7.0 REVISION/UPDATE**

### **7.1 Describe procedure for the update of the PPPG**

Initial review will take place one year following approval and every three years thereafter or as warranted.

### **7.2 Identify method for amending PPPG if new evidence emerges.**

Amend policy through PPPG development group and Approval group.

### **7.3 Complete version control update on PPPG Template cover sheet**

## 8.0 REFERENCES

HSE HR Circular 062 2020, <https://www.hse.ie/eng/staff/resources/hr-circulars/hr-circular-062-2020-department-of-health-code-of-conduct.pdf>

Department of Health (2018) Supporting a Culture of Safety, Quality and Kindness: A Code of Conduct for Health and Social Service Providers. Government Publications: Dublin.

Department of Health (2013) *Healthy Ireland – A Framework for Improved Health and Wellbeing 2013-2025* Government Publications: Dublin.

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Food Safety Authority of Ireland, (2020) *Guidance for Compliance with Food Law When Communicating with Health Professionals about Infant Formula*  
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HSE, (2009) *Framework for the Corporate and Financial Governance of the Health Service -Executive Codes of Standards and Behaviour*  
<https://www.hse.ie/eng/staff/resources/codeofstandards.pdf>

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HSE (2016) *Breastfeeding in a Healthy Ireland* Health Service Breastfeeding Action Plan 2016 – 2021. Health Service Executive: Tullamore.

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<https://www.hse.ie/file-library/infant-feeding-policy-for-maternity-neonatal-services-2019.pdf>

HSE (2018) *Infant Feeding Policy for Primary Care Teams and Community Healthcare settings*. <https://www.hse.ie/file-library/infant-feeding-policy-for-pcts-and-chos.pdf>

IPHA (2015) *Code of Practice for the Pharmaceutical Industry Edition 8.1*. Irish Pharmaceutical Healthcare Association: Dublin.

Victoria et al (2016) Breastfeeding in the 21st century: epidemiology, mechanisms, and lifelong effect; *The Lancet* VOLUME 387, ISSUE 10017, P475-490.  
<http://www.evidentlycochrane.net/lancet-breastfeeding-series/>

WHO. (1981). *International Code of Marketing of Breast-Milk Substitutes*. Geneva: World Health Organization.

WHO. (2003). *Global Strategy for Infant and Young Child Feeding*. Geneva: World Health Organization.

WHO, (2005) *Fifty - eighth World Health Assembly*. Geneva: World Health Organisation [https://www.who.int/nutrition/topics/WHA58.32\\_itycn\\_en.pdf?ua=1](https://www.who.int/nutrition/topics/WHA58.32_itycn_en.pdf?ua=1)

WHO, UNICEF, IBFAN (2020) *Marketing of Breast- milk Substitutes: National Implementation of the International code status report*. Geneva: World Health Organization <https://www.who.int/publications/i/item/9789240006010>

WHO, UNICEF, IBFAN (2018) *Marketing of Breast- milk Substitutes: National Implementation of the International code status report*. Geneva: World Health Organization  
[https://www.who.int/nutrition/publications/infantfeeding/code\\_report2018.pdf?ua=1](https://www.who.int/nutrition/publications/infantfeeding/code_report2018.pdf?ua=1)

WHO. UNICEF. IBFAN.(2016) *Marketing of Breast-milk Substitutes: National Implementation of the International Code*. Status Report 2016. Geneva: World Health Organization; 2016.

## 9.0 APPENDICES

Appendix I Membership of the PPPG Development & Governance Group

Appendix II Conflict of Interest Declaration Form Template

Appendix III WHO International Code of Marketing of Breast-milk Substitutes

Appendix IV Summary of WHA Resolutions adopted subsequent to the Code

Appendix V PPPG Checklist for Developing Clinical PPPGs

Appendix VI Signature Sheet

## Appendix I: Membership of the PPPG Development and Governance Group

### **Chairperson**

#### **Anne Pardy**

Programme Lead – Nurture Programme

#### **Carmel Brennan**

Programme Manager-National Healthy Childhood Programme, until Aug 2021

#### **Angela Dunne**

Lead Midwife, National Women and Infants Health Programme

#### **Dr Melissa Canny**

Specialist in Public Health Medicine,

#### **Cara O' Neill**

Head of Service., H&W, CHO 1

#### **Ellen O'Dea**

Head of Service, H&WB CHO 9

#### **Helen Murphy**

Director of Midwifery, University Hospital Galway

#### **Joanna Mc Carthy**

Interim Director of Public Health Nursing, West Cork

#### **Laura McHugh**

National Breastfeeding Coordinator

#### **Sarah O'Brien**

Lead, Healthy Eating & Active Living Programme

#### **Margaret O'Neill**

National Dietetic Adviser until Aug 2021

#### **Meena Purushothoman**

Asst. National Breastfeeding Coordinator

#### **Siobhan Hourigan**

National Breastfeeding Co-ordinator until January 2018

#### **Rebecca O'Donovan**

Asst. National Breastfeeding Co-ordinator until December 2018

#### **Jacinta Egan**

Project support, The Nurture Programme - Infant Health and Wellbeing



## Appendix II: Conflict of Interest Declaration Form



### CONFLICT OF INTEREST DECLARATION

This must be completed by each member of the PPPG Development Group as applicable

**Title of PPPG being considered:**

**HSE Policy on the Marketing of Breast milk Substitutes**

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**Please circle the statement that relates to you**

**1. I declare that I DO NOT have any conflicts of interest.**

**2. I declare that I DO have a conflict of interest.**

**Details of conflict (Please refer to specific PPPG)**

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**(Append additional pages to this statement if required)**

**Signature**

**Printed name**

**Registration number (if applicable)**

**Date**

The information provided will be processed in accordance with data protection principles as set out in the Data Protection Act. Data will be processed only to ensure that committee members act in the best interests of the committee. The information provided will not be used for any other purpose.

PTO

A person who is covered by this PPPG is required to furnish a statement, in writing, of:

(i) The interests of the person, and

(ii) The interests, of which the person has actual knowledge, of his or her spouse or civil partner or a child of the person or of his or her spouse which could materially influence the person in, or in relation to, the performance of the person's official functions by reason of the fact that such performance could so affect those interests as to confer on, or withhold from, the person, or the spouse or civil partner or child, a substantial benefit.

## **Appendix III: WHO International Code of Marketing of Breast-milk Substitutes**

### **What is the Code?**

The Code was adopted in 1981 by the World Health Assembly (WHA) to promote safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when these are necessary.

One of the main principles of the Code is that health care facilities should not be used for the purpose of promoting breast milk substitutes, feeding bottles or teats. Subsequent WHA resolutions have clarified the Code and closed some of the loopholes.

### **Which products fall under the scope of the Code?**

The Code applies to breast milk substitutes when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk. This includes:

- Infant formulae, including follow up formula and growing up milks.
- Special formulas for infants with specific medical or nutritional needs;
- Other products marketed or otherwise represented for use **before six months** such as baby teas, juices and waters, as well as cereals, processed baby meals represented for use before six months;
- Any milk product shown to be substituting for the breast milk part of the child's diet between **six months and three years**, such as follow-on formula and growing up milks;
- The Code also applies to feeding bottles, teats, soothers and other aids or products marketed to parents that could be used to replace milk.

### **What are a hospital and health service staff's responsibilities under the Code?**

- No promotion and marketing of breast milk substitutes (pg 9: definition of Breast milk substitutes) within HSE facilities, by HSE employees and by HSE funded agencies.
- Health care professionals do not promote a specific brand of formula.
- Inpatient formula feeds are distributed as needed and are stored securely at all other times.
- Mothers, whether breastfeeding or formula feeding are not given free samples on discharge from hospital or in the community.
- Where there is a clinical indication for a specific brand of product, information should be provided without marketing.
- Information produced by HSE and other approved reputable sources are only to be given to mothers, approval needed if company information is deemed essential in an individual circumstance.
- Information on formula feeding should explain the importance of breastfeeding and the risks of not breastfeeding so parents can make an informed decision.
- Contact between a company representative and health service staff should only be on request from the health service staff and related to the specific product, this contact should not be a marketing event. "Cold Calling" is prohibited.

- Information given to health workers is scientific, complete, up to date and factual.
- No company-paid personnel to contact or to advise mothers.
- No gifts or personal samples to health workers or facilities is permitted.
- Any contribution from a manufacturer or distributor to an employee, or accepted on their behalf for research grants, study etc should be disclosed by the recipient.
- The HSE, hospital or institution name or HSE staff job titles must not be associated with marketing events or sponsored study days.
- Staff should be aware that support, incentives or programmes of work should not create conflicts of interest.
- The Code should be considered by research ethics committees in all research on infant feeding.

### **Who is a “health worker” for the purposes of the Code?**

According to the Code, any person working in the health care system, whether professional or non-professional, including voluntary and unpaid workers, in public or private practice, is a health worker. Under this definition, ward assistants, health care assistants, housekeeping, nurses, midwives, social workers, dieticians, physiotherapists in-hospital pharmacists, doctors, administrators, clerks, etc. are all health workers.

***Be aware that support and other incentives for programmes and health professionals working in infant and young-child health should not create conflicts of interests.***

## Appendix IV: Summary of WHA Resolutions adopted subsequent to the Code

Year	Number	Resolutions
1981	WHA 34.22	Code overwhelmingly adopted by WHA (118 in favour, 1 no, 3 abstentions)  Stresses that adoption and adherence to the Code is a minimum requirement. Member States are urged to implement the Code into national legislation, regulations and other suitable measures.
1982	WHA 35.26	Recognises that commercial promotion of breastmilk substitutes contributes to an increase in artificial feeding and calls for renewed attention to implement and monitor the Code at national and international levels.
1985	WHA37.30	Requests that the Director General work with Member States to implement and monitor the Code and to examine the promotion and use of foods unsuitable for infant and young child feeding.
1986	WHA39.28	Urges Member States to ensure that small amounts of breastmilk substitutes needed for the minority of infants are made available through normal procurement channels and not through free or subsidized supplies.  Directs attention of Member States to the following: <ul style="list-style-type: none"> <li>Any food or drink given before complementary feeding is nutritionally required may interfere with breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period.</li> <li>Practice of providing infants with follow up milks is “not necessary”.</li> </ul>
1988	WHA41.11	Requests the Director General to provide legal and technical assistance to Member States in drafting or implementing the Code into national measures.
1990	WHA43.3	Highlights the WHO/UNICEF statement on “protection, promoting and supporting breastfeeding: the special role of maternity services” which led to the Baby-Friendly Hospital Initiative in 1992.  Urges Member States to ensure that the principles and aim of the Code are given full expression in national health and nutrition policy and action.

1994	WHA47.5	<p>Reiterates earlier calls in 1986, 1990 and 1992 to end “free or low cost supplies” and extends the ban to all parts of the health care system; effectively superseding the provisions of Art.6.6 of the Code.</p> <p>Provides guidelines on donation of breastmilk substitutes in emergencies.</p>
1996	WHA49.15	<p>Calls on Member States to ensure that:</p> <ul style="list-style-type: none"> <li>• Complementary foods are not marketed for or used to undermine exclusive and sustained breastfeeding;</li> <li>• financial support to health professionals does not create conflicts of interests;</li> <li>• Code monitoring is carried out in an independent, transparent manner free from commercial interest.</li> </ul>
2001	WHA 54.2	<p>Sets global recommendation of “6 months” exclusive breastfeeding, with safe and appropriate complementary foods and continued breastfeeding for up to two years or beyond.</p>
2002	WHA55.25	<p>Endorses the Global Strategy on Infant and Young Child Feeding which confines the baby food companies’ role to 1. Ensure quality of their products and 2. Comply with the Code and subsequent WHA resolutions, as well as national measures.</p> <ul style="list-style-type: none"> <li>• Recognizes the role of optimal infant feeding to reduce the risk of obesity.</li> <li>• Alerts that micronutrient interventions should not undermine exclusive breastfeeding.</li> </ul>
2005	WHA58.32	<p>Asks Member States to:</p> <ul style="list-style-type: none"> <li>• Ensure that nutrition and health claims for breastmilk substitutes are not permitted unless national/regional legislation allows;</li> <li>• Be aware of the risks of intrinsic contamination of powdered infant formulas and to ensure this information be conveyed through label warnings;</li> <li>• Ensure that financial support and other incentives for programmers and health professionals working in infant and young child health do not create conflicts of interest</li> </ul>
2006	WHA59.11	<p>Member States to make sure the response to the HIV pandemic does not include non-Code compliant donations of breastmilk substitutes or the promotion</p>

		thereof.
2006	WHA 59.21	Commemorates the 25th anniversary of the adoption of the Code; welcomes the 2005 Innocenti Declaration and asks WHO to mobilize technical support for Code implementation and monitoring
2008	WHA61.20	<ul style="list-style-type: none"> <li>• Urges Member States to scale up efforts to monitor and enforce national measures and to avoid conflicts of interest.</li> <li>• Investigate the safe use of donor milk through human milk banks for vulnerable infants, mindful of national laws, cultural and religious beliefs</li> </ul>
2010	WHA 63.14	Member States to implement recommendations to reduce the impact on children of the marketing of 'junk' foods (foods high in saturated fats, trans-fatty acids, free sugars, or salt) by restricting marketing, including in settings where children gather such as schools and to avoid conflicts of interest.
	WHA 63.23	<ul style="list-style-type: none"> <li>• Member States to strengthen implementation of the International Code of Marketing of Breastmilk Substitutes and relevant WHA Resolutions, The Global Strategy on Infant and Young Child Feeding, the Baby Friendly Hospital Initiative, Operational Guidance for Emergency Relief Staff and Programme Managers on infant and young child feeding in emergencies.</li> <li>• End to all forms of inappropriate promotion of foods for infants and young children and that nutrition and health claims should not be permitted on these foods .( i.e. claims about IQ, eyesight or protection from infection)</li> </ul>
2012	WHA 65.6	WHA 65.6 requested the Director-General “to provide clarification and guidance on the inappropriate promotion of foods for infants and young children cited in resolution WHA 63.23, taking into consideration the ongoing work of the Codex Alimentarius Commission. In response, the WHO convened a Scientific and Technical Advisory Group (STAG) to define what constitutes inappropriate promotion of foods for infants and young children. Further consultations and revisions resulted in the final report, which was presented to the sixty-ninth World Health Assembly in 2016 and provides guidance on the inappropriate promotion of foods for infants and young children.
2016	WHA 69.9	WHA 69.9 urges Member States, manufacturers and

		<p>distributors, health care professionals and the media to implement new WHO Guidance recommendations that contain a number of implications for the Code:</p> <ol style="list-style-type: none"> <li>1. Clarification that “follow-up formula” and “growing-up milks” fall under the scope of the Code and should not be promoted.</li> <li>2. Recommendation that messages on complementary foods should always include a statement on the need for breastfeeding to continue through 2 years and that complementary foods should not be fed before 6 months.</li> <li>3. Recommendation that the labels and designs on products other than breast milk substitutes need to be distinct from those used on breast milk substitutes to avoid cross-promotion.</li> <li>4. Recognition that any donations to the health care system (including health workers and professional associations) from companies selling foods for infants and young children represent a conflict of interest and should not be allowed.</li> <li>5. Recommendation that sponsorship of meetings of health professionals and scientific meetings by companies selling foods for infants and young children should not be allowed.</li> </ol>
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**Adapted and expanded from Code & Resolutions and Code Essentials 3; Responsibilities of Health Workers under the *International Code of Marketing of Breast-milk Substitutes and subsequent WHA resolutions*. IBFAN Penang, 2011.**



## Appendix V: PPPG Checklist for Developing Clinical PPPGs

Standards for developing Clinical PPPG	Checklist
<b>Stage 1 Initiation</b>	
The decision making approach relating to the type of PPPG guidance required (policy, procedure, protocol, guideline), coverage of the PPPG (national, regional, local) and applicable settings are described.	<input checked="" type="checkbox"/>
Synergies/co-operations are maximised across departments/organisations (Hospitals/Hospital Groups/Community Healthcare Organisations (CHO)/National Ambulance Service (NAS)), to avoid duplication and to optimise value for money and use of staff time and expertise.	<input checked="" type="checkbox"/>
The scope of the PPPG is clearly described, specifying what is included and what lies outside the scope of the PPPG.	<input checked="" type="checkbox"/>
The target users and the population/patient group to whom the PPPG is meant to apply are specifically described.	<input checked="" type="checkbox"/>
The views and preferences of the target population have been sought and taken into consideration (as required).	<input checked="" type="checkbox"/>
The overall objective(s) of the PPPGs are specifically described.	<input checked="" type="checkbox"/>
The potential for improved health is described (e.g. clinical effectiveness, patient safety, quality improvement, health outcomes, quality of life, quality of care).	<input checked="" type="checkbox"/>
Stakeholder identification and involvement: The PPPG Development Group includes individuals from all relevant stakeholders, staff and professional groups.	<input checked="" type="checkbox"/>
Conflict of interest statements from all members of the PPPG Development Group are documented, with a description of mitigating actions if relevant.	<input checked="" type="checkbox"/>
The PPPG is informed by the identified needs and priorities of service users and stakeholders.	<input checked="" type="checkbox"/>
There is service user/lay representation on PPPG Development Group (as required).	<input type="checkbox"/> N/A
Information and support is available for staff on the development of evidence-based clinical practice guidance.	<input type="checkbox"/> N/A
<b>Stage 2 Development</b>	
The clinical question(s) covered by the PPPG are specifically described.	<input checked="" type="checkbox"/>
Systematic methods used to search for evidence are documented (for PPPGs which are adapted/adopted from international guidance, their methodology is appraised and documented).	<input checked="" type="checkbox"/>
Critical appraisal/analysis of evidence using validated tools is documented (the strengths, limitations and methodological quality of the body of evidence are clearly described).	<input checked="" type="checkbox"/>
The health benefits, side effects and risks have been considered and documented in formulating the PPPG.	<input checked="" type="checkbox"/>
There is an explicit link between the PPPG and the supporting evidence.	<input checked="" type="checkbox"/>

PPPG guidance/recommendations are specific and unambiguous.	<input checked="" type="checkbox"/>
The potential resource implications of developing and implementing the PPPG are identified e.g. equipment, education/training, staff time and research.	<input checked="" type="checkbox"/>
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input checked="" type="checkbox"/>
Budget impact is documented (resources required).	<input checked="" type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based clinical practice guidance (as appropriate).	<input type="checkbox"/> N/A
<b>Three additional standards are applicable for a small number of more complex PPPGs:</b> Cost effectiveness analysis is documented. A systematic literature review has been undertaken. Health Technology Assessment (HTA) has been undertaken.	<input type="checkbox"/> N/A <input type="checkbox"/> N/A <input type="checkbox"/> N/A
<b>Stage 3 Governance and Approval</b>	<b>Checklist</b>
Formal governance arrangements for PPPGs at local, regional and national level are established and documented.	<input checked="" type="checkbox"/>
The PPPG has been reviewed by independent experts prior to publication (as required).	<input type="checkbox"/> N/A
Copyright and permissions are sought and documented.	<input type="checkbox"/> N/A
<b>Stage 4 Communication and Dissemination</b>	<b>Checklist</b>
A communication plan is developed to ensure effective communication and collaboration with all stakeholders throughout all stages.	<input checked="" type="checkbox"/>
Plan and procedure for dissemination of the PPPG is described.	<input checked="" type="checkbox"/>
The PPPG is easily accessible by all users e.g. PPPG repository. <i>(when this becomes available)</i>	<input checked="" type="checkbox"/>
<b>Stage 5 Implementation</b>	<b>Checklist</b>
Written implementation plan is provided with timelines, identification of responsible persons/units and integration into service planning process.	<input checked="" type="checkbox"/>
Barriers and facilitators for implementation are identified, and aligned with implementation levers.	<input checked="" type="checkbox"/>
Education and training is provided for staff on the development and implementation of evidence-based PPPG (as required).	<input type="checkbox"/> N/A
There is collaboration across all stakeholders in the planning and implementation phases to optimise patient flow and integrated care.	<input checked="" type="checkbox"/>
<b>Stage 6 Monitoring, Audit, Evaluation</b>	<b>Checklist</b>
Process for monitoring and continuous improvement is documented.	<input checked="" type="checkbox"/>
Audit criteria and audit process/plan are specified.	<input checked="" type="checkbox"/>
Process for evaluation of implementation and (clinical) effectiveness is specified.	<input checked="" type="checkbox"/>

Stage 7 Revision/Update	Checklist
Documented process for revisions/updating and review, including timeframe is provided.	<input checked="" type="checkbox"/>
Documented process for version control is provided.	<input checked="" type="checkbox"/>

I confirm that the above Standards have been met in developing the following:

**Title of Policy: Breastfeeding Policy for HSE Employees**

**Name of Person(s) signing off on the PPPG Checklist:**

<p><b>Name: <u>Carmel Brennan</u></b></p> <p><b>Title: <u>Programme Manager National Healthy Childhood Programme – (Chairperson National Breastfeeding Implementation Group)</u></b></p>	
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**This signed PPPG Checklist must accompany the final PPPG document in order for the PPPG to be approved.**

