Centre for Food Safety

"Food Claims: Truth and Myth"

Regional Symposium, Hong Kong, Oct. 29, 2012

Managing benefit messaging on foods: An industry point of view

Mead Johnson
PEDIATRIC NUTRITION
INSTITUTE

Peter Van Dael, PhD
Global Regulatory & Nutrition Science
Mead Johnson Nutrition
Evansville, Indiana, USA

AGENDA

01 Introduction

02 Regulatory environment

03 Case studies

04 Conclusion

Introduction

A common goal

Offering safe, trusted and nutritionally adequate foods to all consumers is a common goal for all stakeholders!

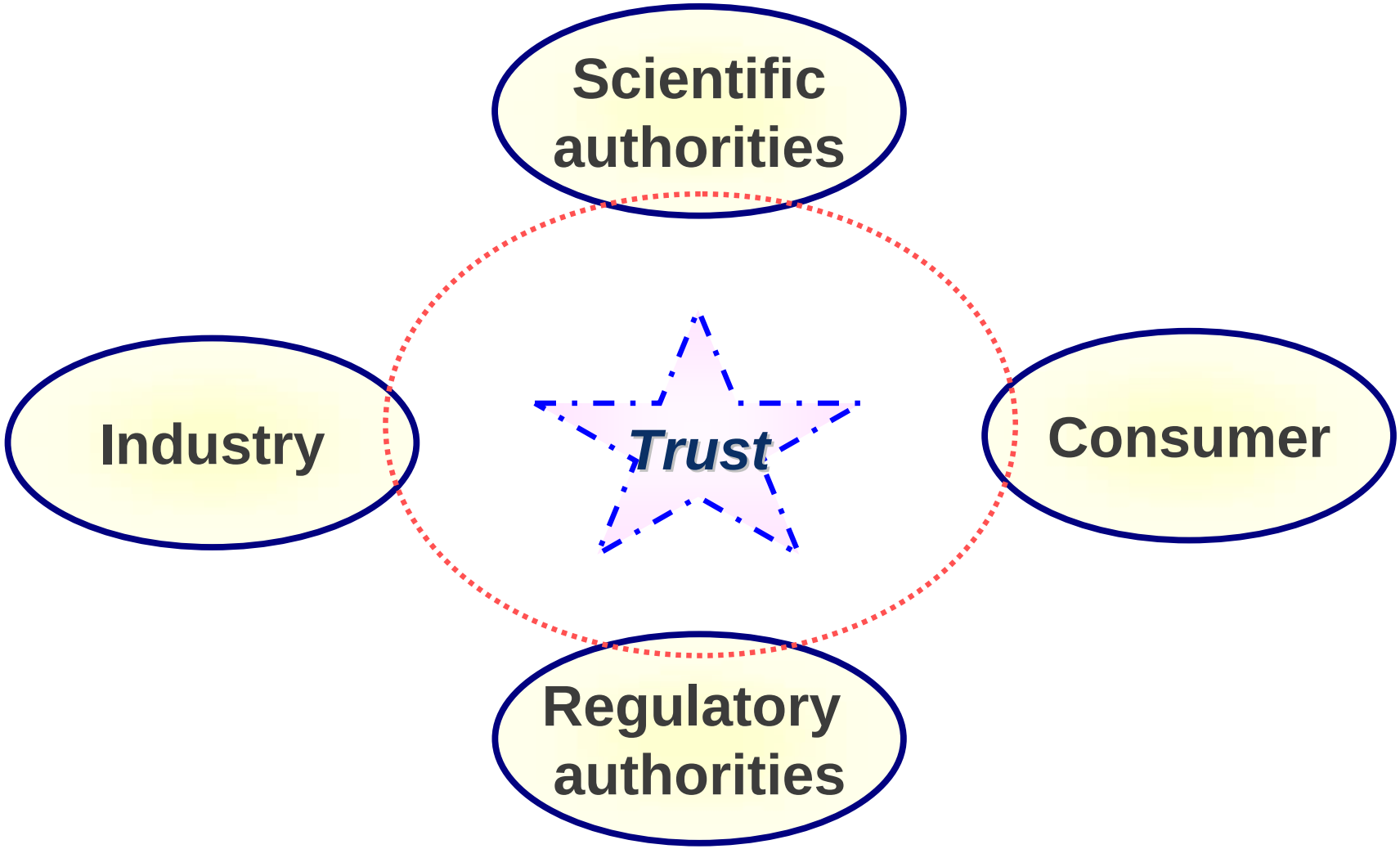
Introduction

Benefit messaging on food: Looks challenging

- **Nutrition policies:**
  - Focus on the critical role of diet and physical activity
  - Restrictions around benefit messaging and claims on foods
  - Marketing restrictions for infant nutrition products
- **Consumers need information:**
  - Communication on critical role of diet for health is important for consumers
  - Clear and truthful information on nutritional value of foods is indispensable to make right choices
  - Trust in information is key
  - Information overload makes the task of a consumer not easy (e.g., internet, newspapers, magazines, ...)
- **Regulations define messaging:**
  - Regulations aim to safeguard truthful character of information
  - Labeling defines on-pack and off-pack communication
  - Claims have to be scientifically substantiated and approved (e.g., EU)
  - A regulated environment can increase consumers trust
- **Benefit messaging is complex:**
  - Competitive environment
  - Food manufacturers are challenged regarding claimed benefits
  - Messages are to be scientifically substantiated
  - Changing consumer behavior (e.g., internet, Facebook)

Introduction

Benefit messaging: Collaboration and trust among stakeholders is indispensable!



AGENDA

01 Introduction

02 Regulatory environment

03 Case studies

04 Conclusion

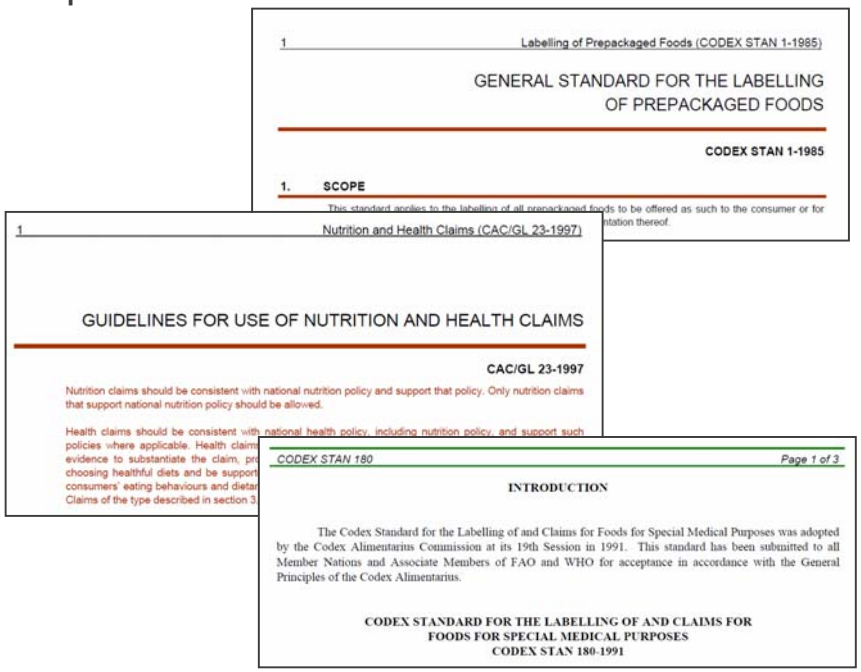
Regulations

Regulatory provisions manage product information

- **Scope of regulations:**
  - Provide info to consumers enabling them to make good choices
  - Encourage use of sound nutrition principles for public health benefits
  - Convey nutrient info on label
  - Ensure nutrient info is truthful and correct

- **Regulated messages:**
  - Label: info/pictorial presented or attached to the food container
  - Labeling: label and any info/pictorial that is displayed near the food, including promotional material
  - Claim: statement that implies the food has particular qualities, such as nutritional/health benefits

- **Codex Alimentarius:**
  - Joint food standards program of FAO/WHO is the global reference
  - Several Codex standards and guidelines lay down provisions for the labeling and claims on foods in general and foods for special dietary uses in particular



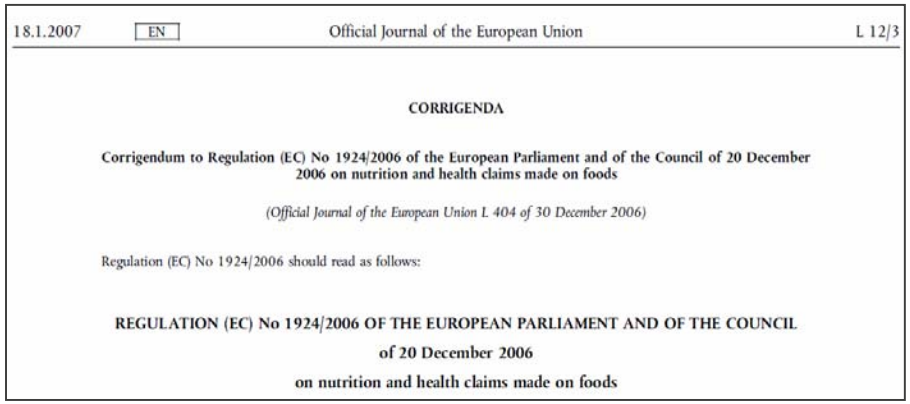
Regulations

Regulatory provisions manage product information

- **European Commission (EC):**
  - Food regulation for the 27 Member States of the European Union
  - Several directives and regulations lay down provisions for labeling and claims on foods

- **US Food and Drug Administration (FDA):**
  - Code of Federal Regulations (CFR) defines the regulatory provisions for labeling and claims in the USA

- **Food Standards Australia New Zealand (FSANZ):**
  - Joint food standards program for Australia and N. Zealand lays down provisions for labeling and claims



18.1.2007 EN Official Journal of the European Union L 12/3

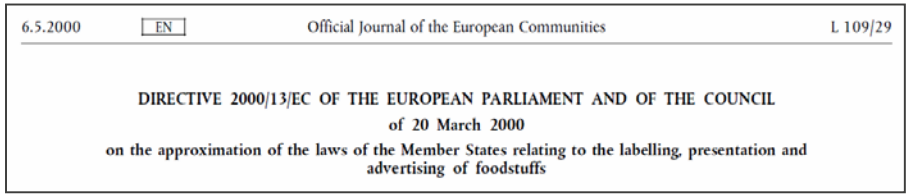
CORRIGENDA

Corrigendum to Regulation (EC) No 1924/2006 of the European Parliament and of the Council of 20 December 2006 on nutrition and health claims made on foods

(Official Journal of the European Union L 404 of 30 December 2006)

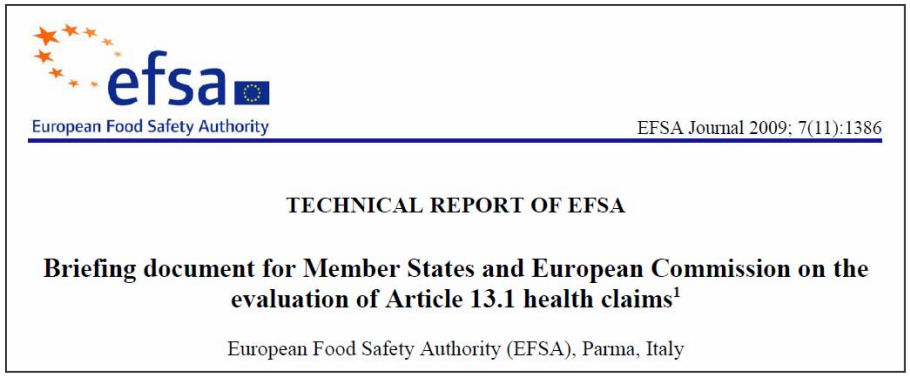
Regulation (EC) No 1924/2006 should read as follows:

REGULATION (EC) No 1924/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 December 2006
on nutrition and health claims made on foods



6.5.2000 EN Official Journal of the European Communities L 109/29

DIRECTIVE 2000/13/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 20 March 2000
on the approximation of the laws of the Member States relating to the labelling, presentation and advertising of foodstuffs



efsa
European Food Safety Authority
EFSA Journal 2009; 7(11):1386

TECHNICAL REPORT OF EFSA

Briefing document for Member States and European Commission on the evaluation of Article 13.1 health claims[1]

European Food Safety Authority (EFSA), Parma, Italy

Regulations

Regulatory provisions manage product information

efsa
European Food Safety Authority
Committed *since 2002* to ensuring that Europe's food is safe

About EFSA | News & events | Topics A-Z | Publications | Panels & units | Cooperation | Applications helpdesk | Calls & consultations

Home > News & events > News & features > EFSA further assesses health claims and pu... Print

efsa
European Food Safety Authority

The EFSA Journal (2007) 530, 1-44

Parma, 23 July 2007
SP/NDA/CLAIMS/WD/1, Rev 4-Final

SCIENTIFIC AND TECHNICAL GUIDANCE FOR THE PREPARATION AND PRESENTATION OF THE APPLICATION FOR AUTHORISATION OF A HEALTH CLAIM

Opinion of the Scientific Panel on Dietetic Products, Nutrition and Allergies

Adopted on 6 July 2007

efsa
European Food Safety Authority

EFSA Journal 2011;9(4):1984

SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to gut and immune function[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

efsa
European Food Safety Authority

EFSA Journal 2012;10(7):2816

SCIENTIFIC OPINION

Guidance on the scientific requirements for health claims related to functions of the nervous system, including psychological functions[1]

EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA)[2, 3]

European Food Safety Authority (EFSA), Parma, Italy

AGENDA

01 Introduction

02 Regulatory environment

03 Case studies

04 Conclusion

Case studies

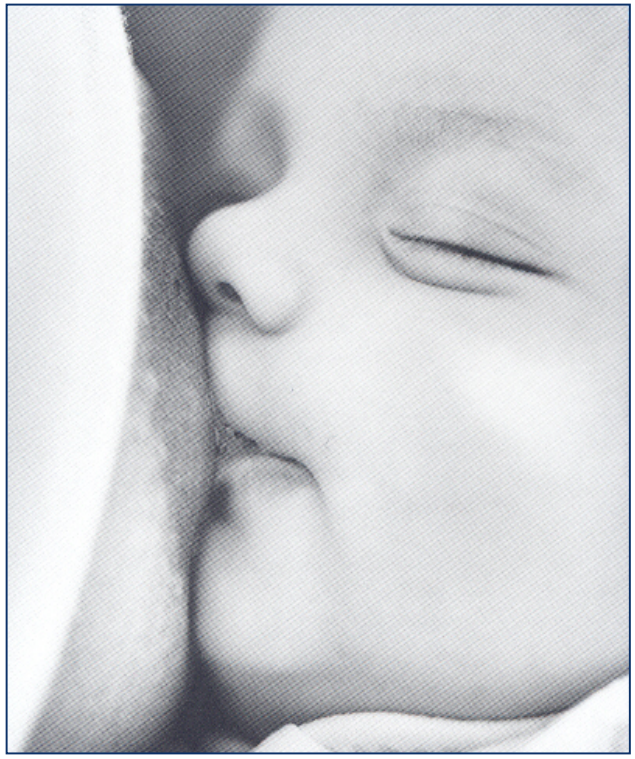
Messaging on infant & children nutrition products

- **Nutrition is critical during early life:**
  - Breastfeeding is reference
  - Sole source of nutrition, breast milk or breast milk substitute (infant formula)
  - Rapid growth and development
  - Emerging science indicates that early nutrition has long-term health effects
  - Best researched period in life
- **Health policies promote feeding choices and nutritional education:**
  - WHO recommends exclusive breastfeeding for 6 months
  - WHO Code provides guidance on marketing of breast milk substitutes
  - WHO Strategy for diet, physical activity and health
  - National nutrition policies (e.g., USA)
- **Highly regulated food category:**
  - Infants >> Young children >> Children
  - Strict requirements (e.g., composition, labeling) for infant and follow-on formulas
  - Benefit messages to consumers are regulated on foods for infants (0-1 year) and young children (1-3 years) in most countries and prohibited in others
- **Emotionally loaded food category:**
  - Promotion of breastfeeding
  - All mothers have right on truthful, science-based information
  - Consumers desire information that is easily available
  - Food safety requirements are becoming stricter every day

Case study 1

Messaging on infant & children nutrition products

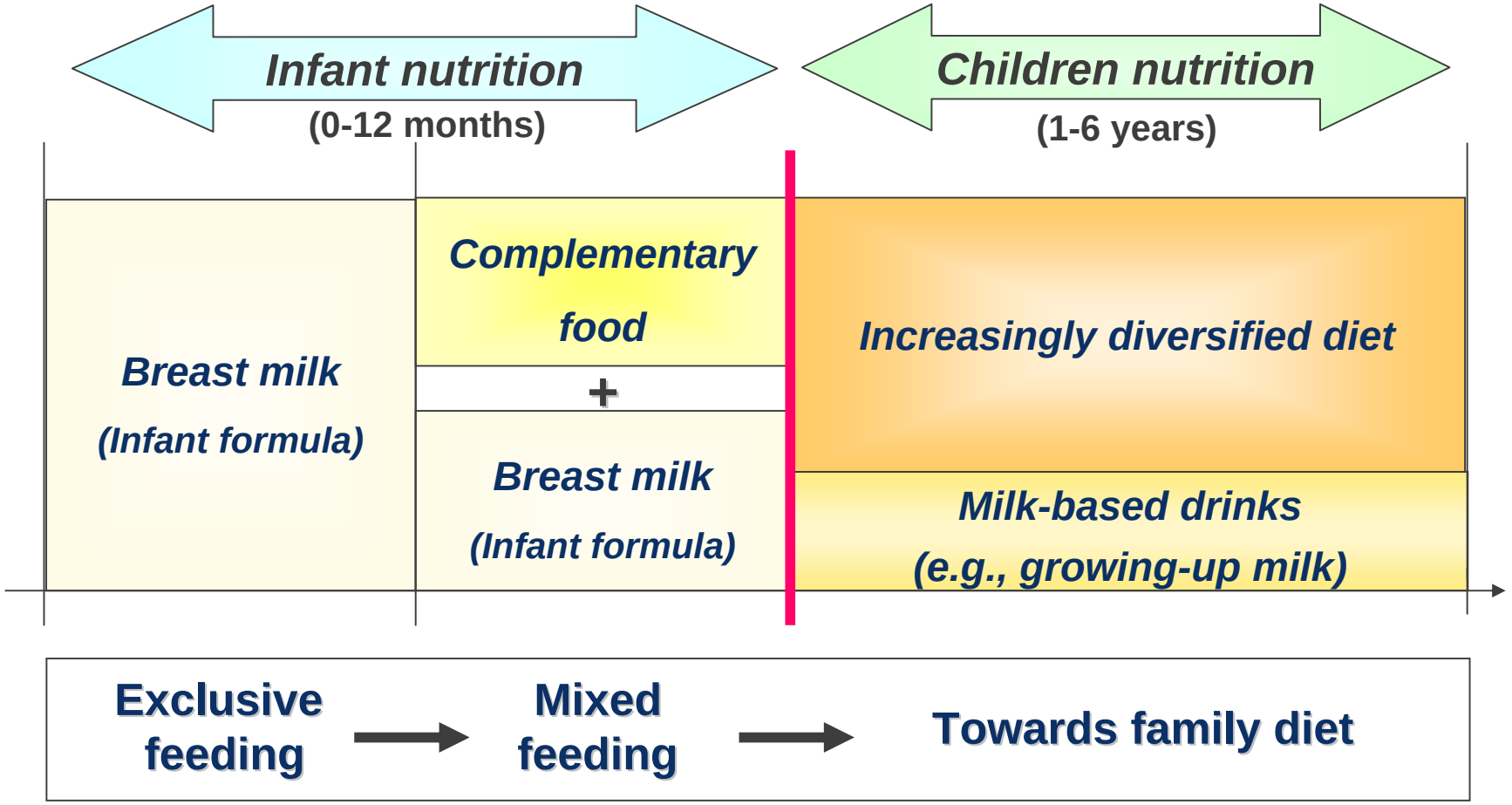
Breastfeeding* = *Reference for infants



Case study 1

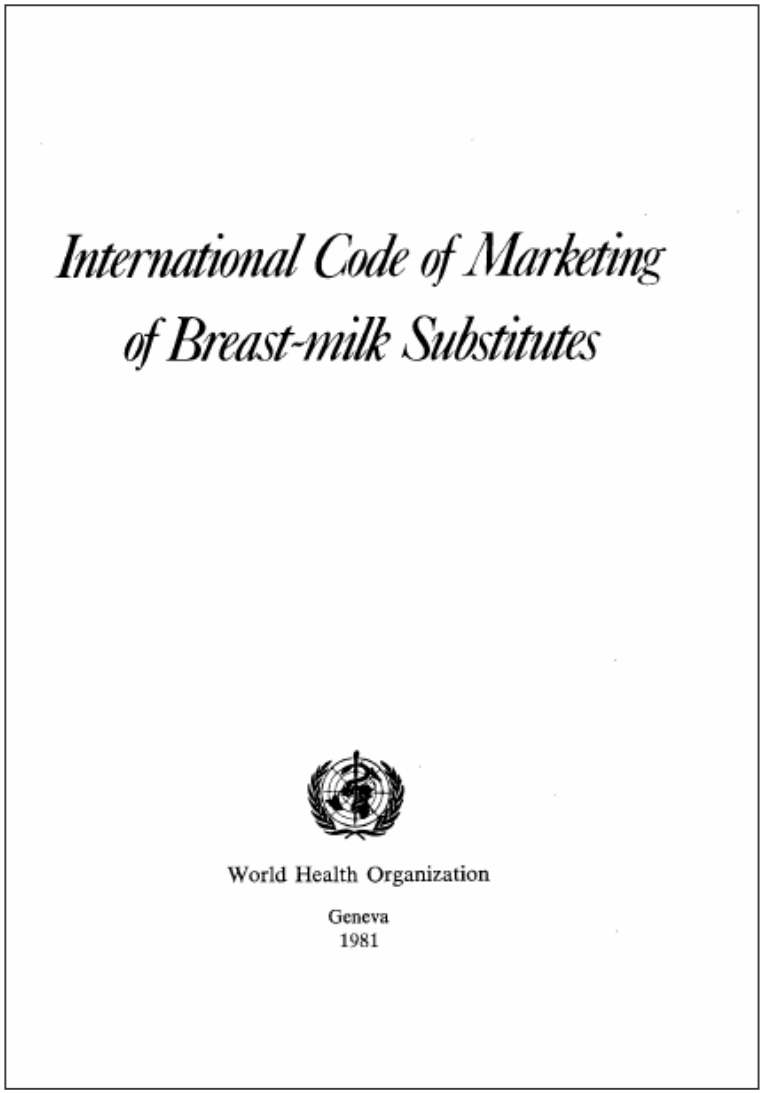
Messaging on infant & children nutrition products

Breastfeeding *is the reference during early life*



Case study 1

Messaging to support appropriate choices



International Code of Marketing of Breast-milk Substitutes

World Health Organization

Geneva
1981

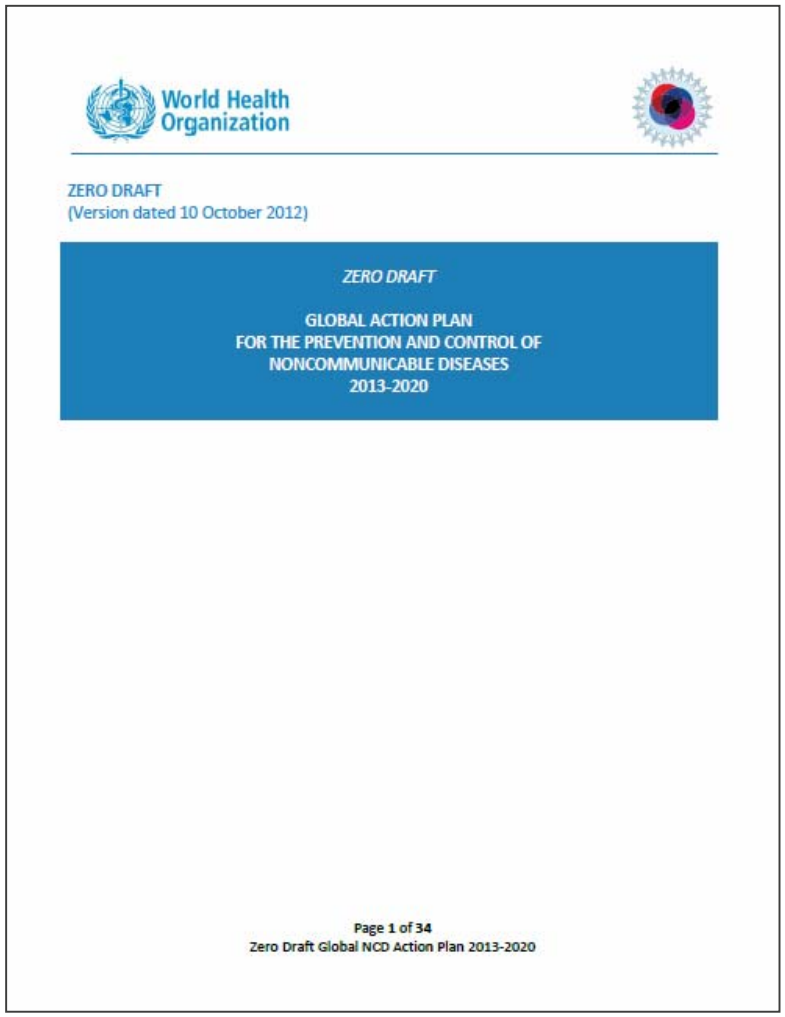
Conscious that breast-feeding is an unequalled way of providing ideal food for the healthy growth and development of infants; that it forms a unique biological and emotional basis for the health of both mother and child; that the anti-infective properties of breast milk help to protect infants against disease; and that there is an important relationship between breast-feeding and child-spacing;

Recognizing that the encouragement and protection of breast-feeding is an important part of the health, nutrition and other social measures required to promote healthy growth and development of infants and young children; and that breast-feeding is an important aspect of primary health care;

Considering that when mothers do not breast-feed, or only do so partially, there is a legitimate market for infant formula and for suitable ingredients from which to prepare it; that all these products should accordingly be made accessible to those who need them through commercial or non-commercial distribution systems; and that they should not be marketed or distributed in ways that may interfere with the protection and promotion of breast-feeding;

Case study 1

Messaging to support appropriate choices



World Health Organization

ZERO DRAFT
(Version dated 10 October 2012)

ZERO DRAFT

GLOBAL ACTION PLAN
FOR THE PREVENTION AND CONTROL OF
NONCOMMUNICABLE DISEASES
2013-2020

Page 1 of 34
Zero Draft Global NCD Action Plan 2013-2020

Overarching principles

The Global NCD Action Plan 2013–2020 relies on the following overarching principles:

- **Life-course approach**
  A life-course approach is key to prevention and control of NCDs. It starts with maternal health, including preconception, antenatal and postnatal care and maternal nutrition. In addition, proper infant feeding practices, including promotion of breastfeeding and health promotion of children, adolescents and youth, followed by promotion of a healthy working life, healthy ageing and care of NCDs for people in later life are integral components of a life-course approach.

Proposed action for Member States: Promoting healthy diet

Advance the implementation of global strategies and recommendations: Member States should consider developing or strengthening national nutrition policies and action plans and implementation of the Global Strategy on Diet, Physical Activity and Health, the Global Strategy for Infant and Young Child Feeding, the implementation of the WHO set of recommendations on marketing of foods and non-alcoholic beverages to children and other relevant strategies, including the introduction of policies and actions aimed at promoting WHO best buys and emerging good buys for healthy diets in the entire population in order to:

a. ***Promote and support exclusive breastfeeding*** for the first six months of life, continued breastfeeding until two years old and beyond and adequate and timely complementary feeding.

Case study 1

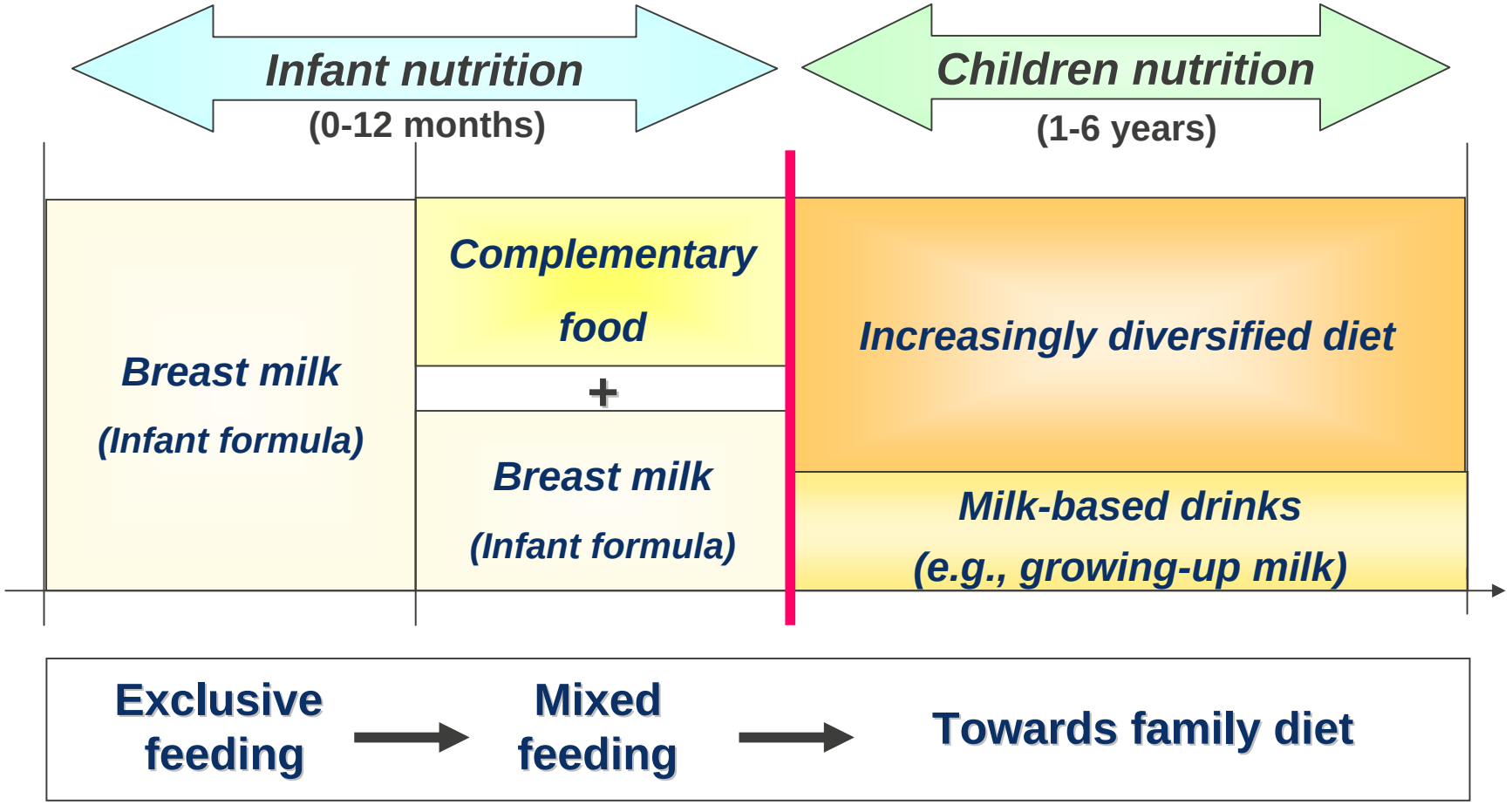
Conclusion

- **Promotion of breastfeeding and exclusive breastfeeding for 6 months**
- **Infant formulas are defined as safe, nutritionally suitable substitutes to breast milk by WHO**
- **Regulations may help manage messaging**
- **Messaging needs to assure that all breast- and formula feeding mothers feel supported in their feeding choices**
- **Collaboration of stakeholders is important to achieve the common goal offering the best start in life for all infants**

Case study 2

Messaging on infant & children nutrition products

*Introduction of **complementary feeding** diversifies the diet*



Case study 2

Messaging to support appropriate choices

Journal of Pediatric Gastroenterology and Nutrition
46:99–110 © 2008 by European Society for Pediatric Gastroenterology, Hepatology, and Nutrition and
North American Society for Pediatric Gastroenterology, Hepatology, and Nutrition

Medical Position Paper

Complementary Feeding: A Commentary by the ESPGHAN Committee on Nutrition

ESPGHAN Committee on Nutrition: *Carlo Agostoni, †Tamas Decsi, ‡[3]Mary Fewtrell, §Olivier Goulet, ¶Sanja Kolacek, ||[1]Berthold Koletzko, **[3]Kim Fleischer Michaelsen, ††Luis Moreno, ‡‡John Puntis, §§Jacques Rigo, ¶¶Raanan Shamir, ||||[2]Hania Szajewska, ***Dominique Turck, and †††Johannes van Goudoever

ABSTRACT

This position paper on complementary feeding summarizes evidence for health effects of complementary foods. It focuses on healthy infants in Europe. After reviewing current knowledge and practices, we have formulated these conclusions: Exclusive or full breast-feeding for about 6 months is a desirable goal. Complementary feeding (ie, solid foods and liquids other than breast milk or infant formula and follow-on formula) should not be introduced before 17 weeks and not later than 26 weeks. There is no convincing scientific evidence that avoidance or delayed introduction of potentially allergenic foods, such as fish and eggs, reduces allergies, either in infants considered at increased risk for the development of allergy or in those not considered to be at increased risk. During the complementary feeding period, >90% of the iron requirements of a breast-fed infant must be met by complementary foods, which should provide sufficient bioavailable iron. Cow's milk is a poor source of iron and should not be used as the main drink before 12 months, although small volumes may be added to complementary foods. It is prudent to avoid both early (<4 months) and late (≥7 months) introduction of gluten, and to introduce gluten gradually while the infant is still breast-fed, inasmuch as this may reduce the risk of celiac disease, type 1 diabetes mellitus, and wheat allergy. Infants and young children receiving a vegetarian diet should receive a sufficient amount (~500 mL) of breast milk or formula and dairy products. Infants and young children should not be fed a vegan diet. ***JPGN 46:99–110, 2008.***

Case study 2

Messaging to support appropriate choices

Infant & Child foods
Strictly regulated
Messaging restrictions

Family foods
Less regulated
Less messaging restrictions

Case study 2

Conclusion

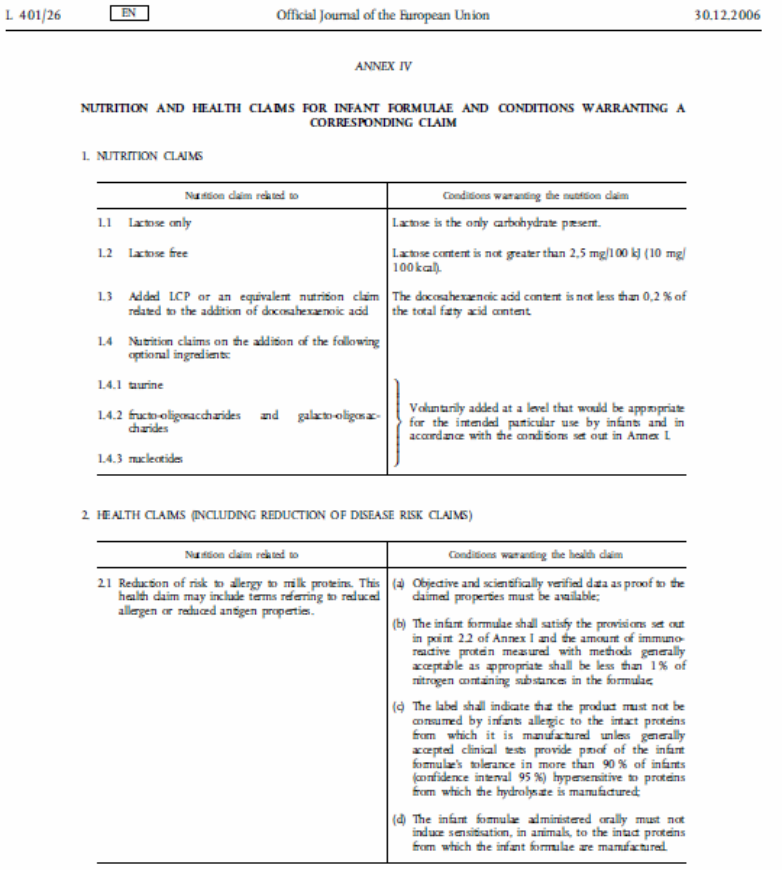
- Introduction of complementary feeding beyond 6 months of life diversifies the diet
- Family foods compete with special infant and children nutrition products, with the latter being more strictly regulated
- Regulations may help manage messaging
- Messaging needs to assure that mothers make appropriate choices regarding complementary feeding and feel supported in their choices
- Nutrition and health policies are to be accompanied by education and information efforts to help consumers make good choices
- Collaboration of stakeholders is important to achieve the common goal offering the best start in life for all infants and children

Case study 3

Messaging: Nutrition and health claims

Scientific substantiation *and* ***regulatory approval*** *are key trust factors for benefit messaging!*

COMMISSION DIRECTIVE 2006/141/EC



L 401/26 EN Official Journal of the European Union 30.12.2006

ANNEX IV

NUTRITION AND HEALTH CLAIMS FOR INFANT FORMULAE AND CONDITIONS WARRANTING A CORRESPONDING CLAIM

1. NUTRITION CLAIMS

Nutrition claim related to	Conditions warranting the nutrition claim
1.1 Lactose only	Lactose is the only carbohydrate present.
1.2 Lactose free	Lactose content is not greater than 2,5 mg/100 kJ (10 mg/100 kcal).
1.3 Added LCP or an equivalent nutrition claim related to the addition of docosahexaenoic acid	The docosahexaenoic acid content is not less than 0,2 % of the total fatty acid content.
1.4 Nutrition claims on the addition of the following optional ingredients:	
1.4.1 taurine	Voluntarily added at a level that would be appropriate for the intended particular use by infants and in accordance with the conditions set out in Annex I.
1.4.2 fructo-oligosaccharides and galacto-oligosaccharides	
1.4.3 nucleotides	

2. HEALTH CLAIMS (INCLUDING REDUCTION OF DISEASE RISK CLAIMS)

Nutrition claim related to	Conditions warranting the health claim
2.1 Reduction of risk to allergy to milk proteins. This health claim may include terms referring to reduced allergen or reduced antigen properties.	(a) Objective and scientifically verified data as proof to the claimed properties must be available; (b) The infant formulae shall satisfy the provisions set out in point 2.2 of Annex I and the amount of immunoreactive protein measured with methods generally acceptable as appropriate shall be less than 1 % of nitrogen containing substances in the formulae; (c) The label shall indicate that the product must not be consumed by infants allergic to the intact proteins from which it is manufactured unless generally accepted clinical tests provide proof of the infant formulae's tolerance in more than 90 % of infants (confidence interval 95 %) hypersensitive to proteins from which the hydrolysate is manufactured; (d) The infant formulae administered orally must not induce sensitisation, in animals, to the intact proteins from which the infant formulae are manufactured.

REGULATION (EC) No 1924/2006

Article 14

Reduction of disease risk claims and claims referring to children's development and health

1. Notwithstanding Article 2(1)(b) of Directive 2000/13/EC, reduction of disease risk claims and claims referring to children's development and health may be made where they have been authorised in accordance with the procedure laid down in Articles 15, 16, 17 and 19 of this Regulation for inclusion in a Community list of such permitted claims together with all the necessary conditions for the use of these claims.

2. In addition to the general requirements laid down in this Regulation and the specific requirements of paragraph 1, for reduction of disease risk claims the labelling or, if no such labelling exists, the presentation or advertising shall also bear a statement indicating that the disease to which the claim is referring has multiple risk factors and that altering one of these risk factors may or may not have a beneficial effect.

Case study 3

Messaging: Nutrition and health claims

EU approval of benefit messages is based on rigorous EFSA assessment of scientific substantiation

EU Register on nutrition and health claims
(August 2012)

	Authorized	Non-authorized
Nutrition claims	213	1710
Health claims	18	51

EU Register on nutrition and health claims

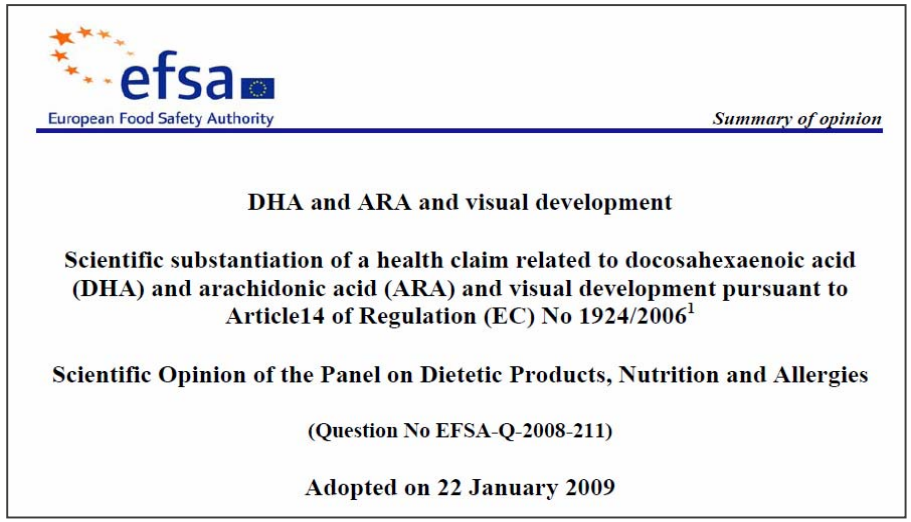
Claim type	Nutrient, substance, food or food category	Claim	Conditions of use of the claim / Restrictions of use / Reasons for non-authorisation	Health relationship	EFSA opinion reference	Commission regulation	Status	Entry Id
Art.13(1)	Iron	Iron contributes to normal oxygen transport in the body	The claim may be used only for food which is at least a source of iron as referred to in the claim SOURCE OF [NAME OF VITAMIN/S] AND/OR [NAME OF MINERAL/S] as listed in the Annex to Regulation (EC) No 1924/2006	oxygen transport	2009;7(9):1215, 2010;8(10):1740	Commission Regulation (EU) 432/2012 of 16/05/2012	Authorised	250, 254, 255, 256

Case study 3

Messaging: Nutrition and health claims

EU approval of benefit messages is based on rigorous EFSA assessment of scientific substantiation

- **Rigorous EFSA review considers:**
  - Nutrient and dose clearly defined
  - Health relationship needs to be clear
  - Message/claim has to be appropriate
  - Thorough scientific substantiation
  - Scientific consensus



efsa
European Food Safety Authority

Summary of opinion

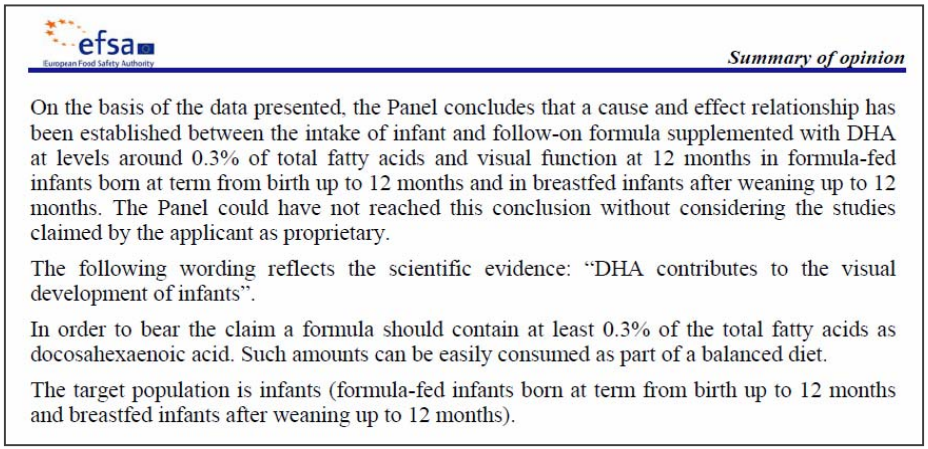
DHA and ARA and visual development

Scientific substantiation of a health claim related to docosahexaenoic acid (DHA) and arachidonic acid (ARA) and visual development pursuant to Article14 of Regulation (EC) No 1924/2006[1]

Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies

(Question No EFSA-Q-2008-211)

Adopted on 22 January 2009



efsa
European Food Safety Authority

Summary of opinion

On the basis of the data presented, the Panel concludes that a cause and effect relationship has been established between the intake of infant and follow-on formula supplemented with DHA at levels around 0.3% of total fatty acids and visual function at 12 months in formula-fed infants born at term from birth up to 12 months and in breastfed infants after weaning up to 12 months. The Panel could have not reached this conclusion without considering the studies claimed by the applicant as proprietary.

The following wording reflects the scientific evidence: "DHA contributes to the visual development of infants".

In order to bear the claim a formula should contain at least 0.3% of the total fatty acids as docosahexaenoic acid. Such amounts can be easily consumed as part of a balanced diet.

The target population is infants (formula-fed infants born at term from birth up to 12 months and breastfed infants after weaning up to 12 months).

Case study 3

Messaging: Nutrition and health claims

Approved EU claims are based on rigorous EFSA assessment of scientific substantiation

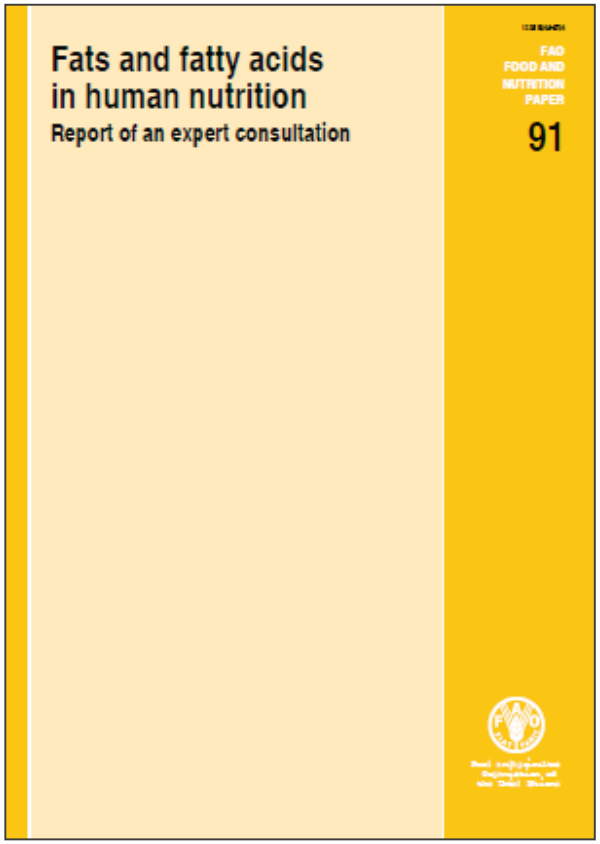
Examples of approved nutrition and health claims

Nutrient	Claim	Health relationship
DHA	DHA contributes to maintenance of normal brain function	Maintenance of normal brain function
Iodine	Iodine contributes to normal cognitive development	Contribution to normal cognitive and neurological function
Iron	Iron contributes to normal cognitive development	Cognitive function
DHA	DHA intake contributes to the normal visual development of infants up to 12 months of age	

Case study 3

Messaging: Nutrition and health claims

Scientific expert bodies recognize importance of nutrition during early life, but consensus on benefits is a challenge



RECOMMENDATIONS FOR FATTY ACID INTAKE OF INFANTS 0-24 MONTHS

There is convincing evidence that LA and ALA be considered essential and indispensable since they cannot be synthesized by humans and that DHA plays a critical role in normal retinal and brain development. There is probable evidence that although DHA can be synthesized from ALA given its limited and highly variable formation (1-5%) it should be considered conditionally essential for the first 6 months of life.

0-6 months

Fatty acid requirements for normal growth and development of this age group can be expressed as %E and when done so are consistent with the expressions of the other age groups. However, since the primary food source for this age group is human milk, it is conventional to base the amount on human milk composition and thus express the value as %FA. Since it is assumed that half of the energy in human milk comes from fat, the value expressed as %FA is double the value for %E. Both expressions are presented here. There is convincing evidence that the AI for DHA is 0.1–0.18%E or 0.2–0.36%FA and for AA and ALA is 0.2–0.3%E or 0.4–0.6%FA. However, because the DHA content of human milk approaches the level of 1.5%FA (or 0.75%E) there is no UL up to 1.5%FA if it is used at the criterion for setting the AI.

6-12 months

There is convincing evidence that the AI for the EFA for optimal growth and development of this age group are 3–4.5%E for LA and 0.4-0.6 %E for ALA. The U-AMDR for LA is < 10%E and for ALA is < 3%E at a probable level of evidence. The AI for DHA is 10-12 mg/kg at a probable level of evidence.

12-24 months

Due to limited data concerning this age group the experts decided to use the same recommendations as given for the age group 6-12 months.

Case study 3

Messaging: Nutrition and health claims

Scientific expert bodies recognize importance of nutrition during early life, but consensus on benefits is a challenge

American Academy of Pediatrics

FROM THE AMERICAN ACADEMY OF PEDIATRICS

Guidance for the Clinician in Rendering Pediatric Care

Clinical Report—Probiotics and Prebiotics in Pediatrics

Dan W. Thomas, MD, Frank R. Greer, MD, and COMMITTEE ON NUTRITION, SECTION ON GASTROENTEROLOGY, HEPATOLOGY, AND NUTRITION

KEY WORDS
probiotics, prebiotics, pediatrics, supplements, nutrition

ABBREVIATIONS
LGG—*Lactobacillus rhamnosus* GG
FOS—fructo-oligosaccharide
IBD—inflammatory bowel disease
RCT—randomized controlled trial
CI—confidence interval
RR—relative risk
OR—odds ratio
NEC—necrotizing enterocolitis
CUC—chronic ulcerative colitis
IBS—irritable bowel syndrome
GOS—galacto-oligosaccharide
FDA—Food and Drug Administration

The guidance in this report does not indicate an exclusive course of treatment or serve as a standard of medical care. Variations, taking into account individual circumstances, may be appropriate.

www.pediatrics.org/cgi/doi/10.1542/peds.2010-2548

doi:10.1542/peds.2010-2548

All clinical reports from the American Academy of Pediatrics automatically expire 5 years after publication unless reaffirmed, revised, or retired at or before that time.

PEDIATRICS (ISSN Numbers: Print, 0031-4005; Online, 1098-4275).

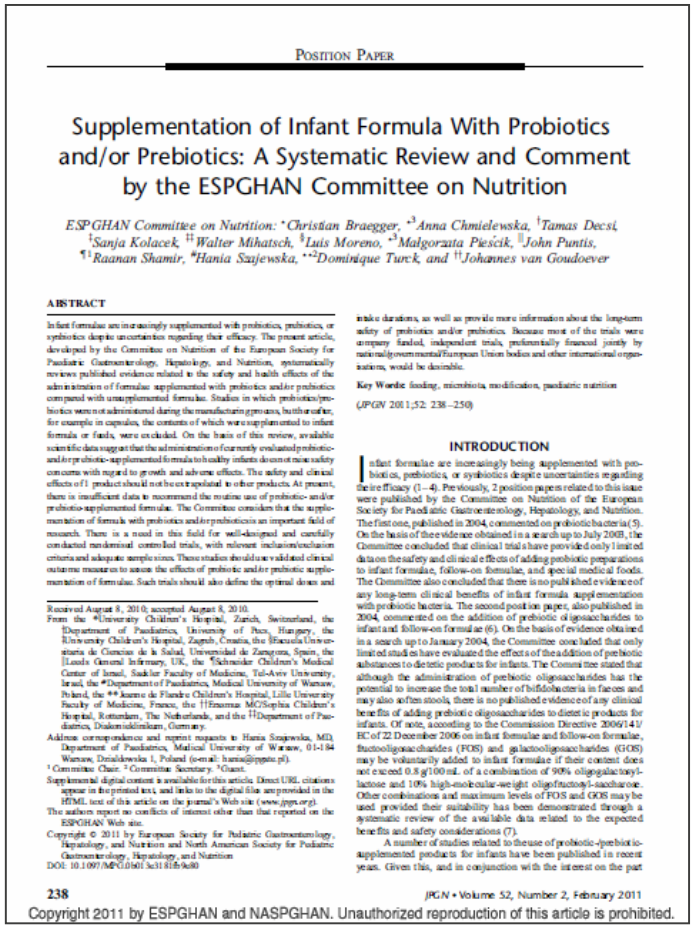
abstract

This clinical report reviews the currently known health benefits of probiotic and prebiotic products, including those added to commercially available infant formula and other food products for use in children. Probiotics are supplements or foods that contain viable microorganisms that cause alterations of the microflora of the host. Use of probiotics has been shown to be modestly effective in randomized clinical trials (RCTs) in (1) treating acute viral gastroenteritis in healthy children; and (2) preventing antibiotic-associated diarrhea in healthy children. There is some evidence that probiotics prevent necrotizing enterocolitis in very low birth weight infants (birth weight between 1000 and 1500 g), but more studies are needed. The results of RCTs in which probiotics were used to treat childhood *Helicobacter pylori* gastritis, irritable bowel syndrome, chronic ulcerative colitis, and infantile colic, as well as in preventing childhood atopy, although encouraging, are preliminary and require further confirmation. Probiotics have not been proven to be beneficial in treating or preventing human cancers or in treating children with Crohn disease. There are also safety concerns with the use of probiotics in infants and children who are immunocompromised, chronically debilitated, or seriously ill with indwelling medical devices.

Prebiotics are supplements or foods that contain a nondigestible food ingredient that selectively stimulates the favorable growth and/or activity of indigenous probiotic bacteria. Human milk contains substantial quantities of prebiotics. There is a paucity of RCTs examining prebiotics in children, although there may be some long-term benefit of prebiotics for the prevention of atopic eczema and common infections in healthy infants. Confirmatory well-designed clinical research studies are necessary. *Pediatrics* 2010;126:1217–1231

INTRODUCTION

Microbes are ubiquitous and are important factors in the overall health of humans as well as the Earth. Efforts to optimize the intestinal microbial milieu have increased the interest in adding probiotics and prebiotics to nutritional products. As with antibiotics, the use and efficacy of probiotics and prebiotics should be supported by evidenced-based medicine. The purpose of this clinical report is to review the medical uses of probiotics and prebiotics and to summarize what is currently known about their health benefits as dietary supplements added to food products marketed to children, including infant formula. The guidance in this report will help pediatric health care providers to make appropriate decisions regard-



POSITION PAPER

Supplementation of Infant Formula With Probiotics and/or Prebiotics: A Systematic Review and Comment by the ESPGHAN Committee on Nutrition

ESPGHAN Committee on Nutrition: *[3]*Christian Braegger*, *[3]*Anna Chmielewska*, [†]*Tamas Decsi*, [‡]*Sanja Kolacek*, [‡‡]*Walter Mihatsch*, [§]*Luis Moreno*, *[3]*Malgorzata Pieścik*, [‖]*John Puntis*, [¶]*Raanan Shamir*, [#]*Hania Szajewska*, **[2]*Dominique Turck*, and [††]*Johannes van Goudoever*

ABSTRACT

Infant formulae are increasingly supplemented with probiotics, prebiotics, or synbiotics despite uncertainties regarding their efficacy. The present article, developed by the Committee on Nutrition of the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition, systematically reviews published evidence related to the safety and health effects of the administration of formulae supplemented with probiotics and/or prebiotics compared with unsupplemented formulae. Studies in which probiotics/prebiotics were not administered during the manufacturing process, but rather only, for example in capsules, the contents of which were supplemented to infant formula or feeds, were excluded. On the basis of this review, available scientific data suggest that the administration of currently evaluated probiotic- and/or prebiotic-supplemented formula to healthy infants does not raise safety concerns with regard to growth and adverse effects. The safety and clinical effects of 1 product should not be extrapolated to other products. At present, there is insufficient data to recommend the routine use of probiotic- and/or prebiotic-supplemented formulae. The Committee considers that the supplementation of formula with probiotics and/or prebiotics is an important field of research. There is a need in this field for well-designed and carefully conducted randomized controlled trials, with relevant inclusion/exclusion criteria and adequate sample sizes. These studies should use validated clinical outcome measures to assess the effects of probiotic and/or prebiotic supplementation of formulae. Such trials should also define the optimal doses and intake durations, as well as provide more information about the long-term safety of probiotics and/or prebiotics. Because most of the trials were company funded, independent trials, preferentially financed jointly by national/governmental/European Union bodies and other international organizations, would be desirable.

Key Words: feeding, microbiota, modification, paediatric nutrition

(*JPGN* 2011;52: 238–250)

INTRODUCTION

Infant formulae are increasingly being supplemented with probiotics, prebiotics, or synbiotics despite uncertainties regarding their efficacy (1–4). Previously, 2 position papers related to this issue were published by the Committee on Nutrition of the European Society for Paediatric Gastroenterology, Hepatology, and Nutrition. The first one, published in 2004, commented on probiotic bacteria (5). On the basis of the evidence obtained in a search up to July 2003, the Committee concluded that clinical trials have provided only limited data on the safety and clinical effects of adding probiotic preparations to infant formulae, follow-on formulae, and special medical foods. The Committee also concluded that there is no published evidence of any long-term clinical benefits of infant formula supplementation with probiotic bacteria. The second position paper, also published in 2004, commented on the addition of prebiotic oligosaccharides to infant and follow-on formulae (6). On the basis of evidence obtained in a search up to January 2004, the Committee concluded that only limited studies have evaluated the effects of the addition of prebiotic substances to dietetic products for infants. The Committee stated that although the administration of prebiotic oligosaccharides has the potential to increase the total number of bifidobacteria in faeces and may also soften stools, there is no published evidence of any clinical benefits of adding prebiotic oligosaccharides to dietetic products for infants. Of note, according to the Commission Directive 2006/141/EC of 22 December 2006 on infant formulae and follow-on formulae, fructooligosaccharides (FOS) and galactooligosaccharides (GOS) may be voluntarily added to infant formulae if their content does not exceed 0.8 g/100 mL of a combination of 90% oligogalactosyl-lactose and 10% high-molecular-weight oligofructosyl-saccharose. Other combinations and maximum levels of FOS and GOS may be used provided their suitability has been demonstrated through a systematic review of the available data related to the expected benefits and safety considerations (7).

A number of studies related to the use of prebiotic-/probiotic-supplemented products for infants have been published in recent years. Given this, and in conjunction with the interest on the part

Received August 8, 2010; accepted August 8, 2010.
From the [#]University Children's Hospital, Zurich, Switzerland, the [‡]Department of Paediatrics, University of Pecs, Hungary, the [‡]University Children's Hospital, Zagreb, Croatia, the [§]Facultad Universitaria de Ciencias de la Salud, Universidad de Zaragoza, Spain, the [‖]Leeds General Infirmary, UK., the [¶]Schneider Children's Medical Center of Israel, Sackler Faculty of Medicine, Tel-Aviv University, Israel, the [#]Department of Paediatrics, Medical University of Warsaw, Poland, the [**]Jeanne de Flandre Children's Hospital, Lille University Faculty of Medicine, France, the [††]Erasmus MC/Sophia Children's Hospital, Rotterdam, The Netherlands, and the [††]Department of Paediatrics, Diakonissenkrankenhaus, Germany.

Address correspondence and reprint requests to Hania Szajewska, MD, Department of Paediatrics, Medical University of Warsaw, 01-184 Warsaw, Dzialdowska 1, Poland (e-mail: hania@ipczp.pl).

[1] Committee Chair. [2] Committee Secretary. [3] Guest.

Supplemental digital content is available for this article. Direct URL citations appear in the printed text, and links to the digital files are provided in the HTML text of this article on the journal's Web site (www.jpgn.org).

The authors report no conflicts of interest other than that reported on the ESPGHAN Web site.

DOI: 10.1097/MPG.0b013e3181fb9e80

Case study 3

Conclusion

- Benefit messaging must be truthful in order to generate trust among consumers
- Scientific substantiation has to be the basis for benefit messaging
- EFSA assessment considered the scientific substantiation for many claims insufficient
- Regulatory provisions governing approval may be needed in order to better manage substantiated messages
- Scientific experts support the key role of nutrition during early life, but struggle with consensus on benefits
- Collaboration of stakeholders is important to achieve the common goal offering the best start in life for all infants and children

Conclusion

Messaging is important, needs to be adequately substantiated and need to generate trust for all stakeholders, most importantly mothers/parents!

"Good feeding choice happens when women have access to the education, the means, the knowledge and the support to make the decision that they feel is best!"

- A mother's quote -

Conclusion

- **Promotion of breastfeeding and exclusive breastfeeding for 6 months are recommended**
- **Infant formulas are defined as a safe, nutritionally suitable substitutes to breast milk by WHO**
- **Introduction of complementary feeding beyond 6 months of life diversifies the diet**
- **Family foods compete with special infant and children nutrition products, with the latter being more strictly regulated**
- **Messaging needs to assure that mothers feel supported in their feeding choices**
- **Nutrition and health policies are to be accompanied by education and information efforts to help consumers make good choices**

Conclusion

- **Benefit messaging must be truthful in order to generate trust among consumers**
- **Regulatory provisions governing approval may be needed in order to better manage substantiated messages**
- **Scientific substantiation has to be the basis for benefit messaging**
- **Scientific substantiation was assessed by EFSA and proven sufficient for selected nutrition and health claims**
- **Scientific experts support the key role of nutrition during early life, but struggle with consensus on benefit messages**
- **Collaboration of stakeholders is important to achieve the common goal offering the best start in life for all infants and children**

Conclusion