
ifm
International Association of Infant Food Manufacturers

# Infant Food Manufacturers' Commitment and Rules for Responsible Conduct

## OUR COMMITMENT

The International Association of Infant Food Manufacturers (IFM) is a non-profit, non-governmental organization representing the leading global manufacturers of nutritional products for infants and young children. IFM members continually invest in research, product innovation, quality and safety, and engage in global public health partnerships to advance the science of nutrition and the standards of health and well-being of infants and young children worldwide.

Consumers, policymakers and other stakeholders have a legitimate interest in the way IFM members conduct their business. IFM members and employees are committed to comply with the laws of the countries in which they operate, to respect local social and cultural practices, and to conduct their business with integrity.

### Commitment to Nutrition

Scientific evidence supports the understanding that good nutrition in pregnancy and during the first few years of life have a major impact on long-term health outcomes of an individual. It is well recognised that breast milk and breastfeeding play a vital nutritional role during this period.

For more than a century, the infant nutrition industry has been supporting nutrition during this crucial period of life, providing vital nutrition for infants and young children and promoting healthy growth and development. We are dedicated to providing high-quality, nutritious and safe food for the best nutritional start in life. When children do well, families thrive. That is why our industry's products include all the essential nutrients for healthy growth and support the key areas of development in early childhood.

### Commitment to Appropriate Feeding

We support the WHO's recommendation for exclusive breastfeeding during the first six months of life when possible along with the introduction of timely, safe, and appropriate complementary feeding thereafter.

Global data continue to show that a majority of mothers use infant formula and/or follow on formula at some point during the first year of their babies' lives. Infant formula is the only safe, science-supported, nutritious and recommended alternative to breastfeeding. With an increasing number of women in the workforce worldwide, access to safe, scientifically-developed, high-quality infant feeding options is needed more than ever.

We also recognize that every family is unique and that a myriad of factors play a role in a mother's decision to exclusively breastfeed, supplement with formula, or use only infant formula to nourish their babies as their needs and circumstances warrant. We are proud to contribute to the nutritional well-being of babies and to provide education on good nutrition in all its forms.

### Commitment to Empowering Mothers to Make Informed Decisions

We believe that mothers are best positioned to make feeding decisions that meet the needs of their babies and families and support their aspirations for full participation in economic life. Well-informed

mothers make better nutrition decisions for their infants, and every mother has the right to be informed about all infant feeding options, including infant formula, and to be supported in her decisions.

**Commitment to Research and Scientific Advancement**

Nutrition is a science and IFM members take their commitment to this science seriously. The infant and young child nutrition industry supports more research on infant nutrition than any other entity. Several hundred clinical studies have demonstrated the safety of use and normal health outcomes that infant formulas provide.

At the same time, we view advancing the science of nutrition as a multi-stakeholder effort, which is why our industry partners with leading scientific institutes, universities, government entities and medical experts.

Our commitment to world-class research and development and continual investment in product innovation, quality and safety has driven hundreds of clinical trials and extensive testing. Our products are proven through clinically-validated outcomes, which is visible in the regular publication of our studies in leading peer-reviewed journals.

Our industry has also worked tirelessly to meet the needs of infants who are born with more complex nutritional needs, such as pre-term babies and those with inborn errors of metabolism, by developing specialty infant formula products.

Nutrition science is complex, but our reason for pursuing it is simple: We want the best possible health outcomes for infants and young children.

**Commitment to a World-class Supply Chain**

In the early stage of their development, infants are a vulnerable and sensitive population. IFM member companies produce products such as infant formulas that are specially formulated to be used as a sole source of nutrition for this vulnerable group and we take this responsibility seriously. All IFM member companies have in place stringent supplier requirements, state-of-the-art manufacturing plants and rigorous testing programs similar to those used in pharmaceutical plants and medical device industries.

The source of our ingredients is critical to the quality and safety of all food products, and this is at the heart of everything we do. It is critical that products are safe and manufactured with accuracy. We take this responsibility very seriously.

**Commitment to a Multi-Stakeholder Effort**

IFM member companies are proud to be part of an innovative industry that provides routine and specialty infant and toddler solutions, enables excellent health outcomes, empowers mothers to make safe, nutritious decisions for their young families, and contributes to healthier generations around the globe.

Our industry is dedicated to providing infant and young child nutrition products in an ethical manner, which is why we are implementing these Rules of Responsible Conduct.

We look forward to working with other stakeholders as a trusted partner for decades to come to improve infant and young child nutrition around the world.

**OUR RULES FOR RESPONSIBLE CONDUCT**

## 1.0 PREAMBLE

**1.1.** IFM and its members are committed to the ethical Marketing and distribution of nutritional products for infants and young children. Ethical Marketing and distribution enables Health Workers to obtain accurate, science-based information; supports caregivers' decisions to choose nutritious and healthful foods for their children; and promotes safe and appropriate use of nutritional products in a manner that protects breastfeeding.

**1.2.** IFM and its members support the recommendation of the World Health Organization (WHO) and global health practitioners of exclusive breast-feeding during the first six months of life and the introduction of safe and appropriate Complementary Foods thereafter to supplement continued breast-feeding.

**1.3.** IFM and its members acknowledge the importance and respect the aim and principles of the World Health Organization's 1981 International Code of Marketing of Breast-Milk Substitutes (the "WHO Code"), the stated aim of which is "to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution."

**1.4.** The WHO Code also recognizes 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.

**1.5.** Decisions by caregivers about feeding infants and young children are highly complex. They are influenced by a range of factors, including advice from health professionals and family, cultural traditions, educational and economic opportunities, the availability of objective information, workplace support, and the time spent by the mother away from the home. IFM and its members firmly believe that caregivers have the right to make feeding choices that are best for their families in light of their individual and often complex living and working conditions.

**1.6.** Health Workers and healthcare institutions play an essential role in guiding and influencing infant and young child feeding practices and providing objective, science-based advice about appropriate feeding options. Such advice should be independent of, and be viewed as independent of, undue influence from manufacturers and other parties with a commercial interest involved in the process of bringing a product to the consumer. Appropriate Marketing and distribution practices help fulfill this important aim by ensuring Health Workers have access to truthful, science-based, and balanced information. IFM is committed to advancing the science of nutrition. Through a continual process of research and development, IFM members work to innovate safe, nutritious and scientifically advanced foods to meet the special needs of growing children.

**1.7.** Breast-Milk Substitutes are recognized by the WHO as the only safe and nutritious alternative to breast-milk for infants from birth through six months of age without mothers or whose mothers cannot or choose not to breast-feed. IFM members also develop specially formulated products to address specific nutritional requirements which are helping to improve treatments, survival rates and long-term outcomes of premature babies and infants who suffer from medical disorders.

**1.8.** IFM and its members respect the role and sovereign right of national governments to develop health policies and to offer health and nutrition programs that are appropriate to their social and legislative framework and overall development objectives. IFM members shall comply with applicable laws and regulations in the countries where they do business. IFM and its members work with governments to promote science-based policies, regulations and standards governing infant and young child nutrition.

**1.9.** The Marketing of Breast-Milk Substitutes is subject to relevant national laws and regulations or government-issued codes: these Rules are not a substitute for such laws. To the extent there is a conflict, the national laws and regulations will prevail. The Rules represent an act of self-discipline by IFM members as applied to countries where there are high levels of infant mortality and morbidity as well as a high risk of child malnutrition.

**1.10.** Through adoption of these Rules, IFM and its members seek to establish industry standards that:

- help advance infant nutrition and health;
- are clear, unambiguous, and transparent ;
- encourage best practices by all manufacturers and other parties with a commercial interest involved in the process of bringing of infant formula and follow-up-formula and related products to the consumer; and
- promote consistent compliance across its members.

**1.11.** These Rules set the base standard for IFM members.

**1.12.** Acceptance of these Rules as a minimum standard of conduct is a condition to membership in the IFM. IFM members acknowledge that the Rules are to be applied broadly, to cover both the written words and the spirit of the Rules. Acceptance of these Rules by an IFM member does not preclude that IFM member from adopting additional approaches to compliance.

**1.13.** A full list of IFM members that have agreed to follow these Rules may be obtained from IFM.

**1.14.** In order to keep them current, the Rules will be reviewed at least annually by the IFM Board of Directors to ensure changes can be incorporated and improvements made. Suggestions for amendments or additions may be submitted to IFM.

## 2.0 SCOPE

These Rules apply to the Marketing of Breast-Milk Substitutes and Follow-on Formula for infants from birth up to the first twelve months of life ("Covered Products"), unless applicable law prescribes a different age (whether higher or lower). These Rules also apply to the quality of those foods and beverages, to bottles and teats, and to the dissemination of Informational and Educational Material concerning their use. These Rules apply to those countries identified in Appendix 1, which represent the countries classified as priority by UNICEF and the WHO.

These Rules do not apply to Excluded Products or in countries where application of the Rules would be prohibited by applicable law.

## 3.0 DEFINITIONS

***Birthing Facility Supplies*** means a quantity of Covered Products routinely provided in non-emergency circumstances to a Health Care Facility where labor, delivery and/or post-partum care is provided. Birthing Facility Supplies are intended to fulfill all or substantially all of the consumption requirements of one or more infants primarily during their stay at the Health Care Facility.

***Breast-Milk Substitute*** means any infant formula that is marketed up to the first six months of life, and any other food or beverage that is otherwise presented to be suitable as a total or partial replacement for breast-milk during that period, whether or not suitable for that purpose.

***Complementary Food*** means any food suitable as a complement to breast milk or to a Breast-Milk Substitute or a Follow-on Formula when either becomes insufficient to satisfy the nutritional requirements of the infant; provided that Complementary Foods are not considered to be Breast-Milk Substitutes if they are not marketed as such but are intended to and are marketed to supplement, rather than replace, breast-milk or Breast-Milk Substitutes.

***Excluded Products*** means those products and product categories excluded from the scope of these Rules, *i.e.* (i) foods for special medical purposes, including, but not limited to products to address metabolic conditions, such as PKU or Maple Syrup Urine Disease; (ii) human milk fortifier; (iii) pre-mature formulae; and (iv) extensively hydrolyzed hypoallergenic allergy formulae for special medical purposes.

***Follow-on Formula*** means, for the purposes of these Rules, any formula that is marketed from six to twelve months of life.

***Health Care Facility*** means any facility where health care is provided to pregnant women, new mothers, infants or young children. This includes facilities where Health Workers provide health care in private practice but does not include private homes or pharmacies or other established sales outlets.

***Health Worker*** means a person providing health care services in a Health Care Facility, including voluntary unpaid workers.

***Infant*** means a person from 0 to 12 months of age.

***Informational and Educational Materials*** means any material, whether written, aural, or visual, that provides information about such topics as nutrition, healthcare or growth and development of infants but is not intended to reference a specific brand of a product.

***Label*** means any written or graphic material printed, marked, embossed or impressed upon, or attached to, a container of a product, including wrappers. For purposes of this definition, a container is any form of packaging intended for sale.

***Marketing*** means any activity intended to encourage the recommendation, sale or purchase of a specific brand of a product, including promotion, distribution, selling, advertising, and public relations.

***Marketing Material*** means any material, whether written, aural, or visual, intended to encourage the recommendation, sale or purchase of a specific brand of product and shall include, but not be limited to, point-of-sale advertising, special displays, materials placed in hospital/clinic settings, Labels, and television, radio, internet, social media, or print advertisements.

***Marketing Personnel*** means any persons whose job responsibilities include the Marketing or sales of Covered Products.

***Product for Professional Evaluation (PPE)*** means a single container with a small quantity of Covered Products (maximum of 500 grams or the smallest container offered by a manufacturer for a particular market) provided at no cost to the recipient. The Label or container of the PPE shall clearly bear the indication that it is a "Sample for Professional Evaluation" or "Not for Resale" or a similar indication.

## 4.0 GENERAL

**4.1.** Written Policies – IFM members shall establish written policies and procedures governing the Marketing of Covered Products. These policies shall comply with both applicable legal requirements and these Rules. These documents should be periodically reviewed and updated; communicated to all relevant employees; and cover, at a minimum, quality, Marketing practices for the Covered Products, compliance monitoring, internal auditing, complaint investigation, and disciplinary procedures. Responsibility for implementing and monitoring these policies shall be clearly defined.

**4.2.** Formal Training Program – IFM members shall provide training to all relevant staff about company policies that govern the Marketing of Covered Products. Training should be conducted routinely during employment and updated, when necessary, to reflect revisions

or modifications to applicable policies. Training activities should be documented and available for internal audit.

**4.3.** Routine Internal Audits – IFM members shall establish procedures for conducting routine, systematic, internal audits of compliance with company policies that govern the Marketing of Covered Products.

**4.4.** Complaint Handling – IFM members shall establish procedures that enable the reporting of known or suspected violations of company policies, including those that govern the Marketing of Covered Products. Complaints received from both within and outside the company should be reviewed and investigated in accordance with written procedures, and, if a violation is discovered, appropriate corrective and/or disciplinary action shall be taken. Procedures to allow employees to report potential non-compliance with company policies shall be implemented. Genuine, timely, and adequately documented complaints from IFM members and external parties relating to non-compliance with these Rules are encouraged.

**4.5.** Transparency

4.5.1. IFM members shall make publicly available their company's written policy governing the Marketing of Covered Products. IFM members shall also ensure that their policies are communicated to their employees, and those other parties, acting on their behalf, involved in bringing the Covered Products to market and ultimately to the consumer.

4.5.2. IFM members shall provide the written certification set out in Appendix 3, confirming that:

4.5.2.1. the Member shall abide by and act in accordance with these Rules as a minimum;

4.5.2.2. written policies required by and that align with the Rules have been implemented;

4.5.2.3. appropriate employee training has occurred; and

4.5.2.4. each Member has a process to monitor and audit compliance with their policies and these Rules as well as a mechanism to review compliance, investigate complaints and, where necessary, remediate violations.

4.5.3. IFM members shall complete the written certification process on an annual basis. Certifications shall be signed by the most senior person with direct responsibility for that Member's global nutrition business or a member of their executive management team or the Board of Directors and submitted to the office of the IFM Secretariat along with their annual dues.

## 5.0 PROTECTION OF BREAST FEEDING

**5.1.** IFM members shall not make claims or suggest in Marketing Materials, Informational and Educational Materials, or elsewhere that Covered Products are equivalent or superior to breast-milk.

**5.2.** Marketing Materials, Informational and Educational Materials for Covered Products shall not be presented in such a way as to discourage caregivers from breast-feeding or feeding breast-milk to their infants.

**5.3.** IFM members shall not market Complementary Foods as Breast-Milk Substitutes, and, unless applicable law prescribes otherwise, Complementary Foods shall not be marketed for infants up to six months of age.

## 6.0 QUALITY STANDARDS

**6.1.** To ensure the safety of their Covered Products, IFM members shall implement strict hygienic and quality control procedures compliant with national standards or those deemed to be equivalent by governments, such as international guidelines developed by *Codex Alimentarius*.

**6.2.** IFM members will continue to engage governments and standard-setting bodies on a range of critical safety issues, including best practices in food safety, harmonization of science-based standards, food safety monitoring, supplier education, and capacity building through, *e.g*., public campaigns, professional training, and the strengthening of relevant institutions.

## 7.0 COMMUNICATION STANDARDS

**7.1.** IFM members shall ensure that all Marketing Materials and Informational and Educational Materials regarding Covered Products are supported by sound science, balanced, and accurate, in accordance with relevant applicable law.

**7.2.** IFM members shall establish an internal review process to ensure that Marketing Materials and Informational and Educational Materials regarding Covered Products are supported by sound science and comply with these Rules and all applicable regulatory and legal requirements prior to dissemination.

**7.3.** Clinical studies, clinical assessments and market research and surveys regarding Covered Products must not be carried out for the purposes of promotion or Marketing of Covered

Products. They must be conducted with a primarily scientific or educational purpose. None of the above shall prevent data generated from clinical studies, clinical assessments and market research and surveys from being used for the promotion and marketing of Covered Products in accordance with relevant applicable law.

## 8.0 LABELING STANDARDS FOR COVERED PRODUCTS

**8.1.** Labels for Covered Products should be designed to provide all necessary information about their safe and appropriate use in accordance with national laws and applicable provisions contained in *Codex Alimentarius*.

**8.2.** Labels for Covered Products should not include picture or text or be presented in such a way as to discourage caregivers from breast-feeding or feeding breast-milk to their infants, such as by incorporating pictures of babies.

**8.3.** Unless otherwise required by applicable law, Labels for Covered Products should contain a clear, conspicuous, and easily readable and understandable message in the appropriate language(s) which includes all the following points:

- The words “Important Notice” or their equivalent;
- A statement of the superiority of breast-milk;
- A statement on the proper method of use of the Covered Products; and
- Instructions for appropriate preparation, use and storage of the Covered Products, and information about the possible health hazards of inappropriate preparation.

## 9.0 INTERACTIONS WITH HEALTH WORKERS

**9.1.** No gift, benefit-in-kind, or pecuniary advantage shall be offered to Health Workers or their families as an inducement for the supply, recommendation or sale of Covered Products or for the purpose of promoting Covered Products.

**9.2.** IFM members may provide Health Workers with practice-related items, such as pens or notepads, provided such items are relevant to the Health Worker’s practice and are of a minimal value that cannot be considered as an inducement in the local context. These items may not bear Covered Product brands. In some countries, if allowed under applicable law and in accordance with local practice, an inexpensive gift not related to the Health Worker’s practice may be given on an infrequent basis in acknowledgment of significant national, cultural or religious events.

**9.3.** IFM members may enter into *bona fide* consulting arrangements with Health Workers. It is appropriate for Health Workers who provide genuine advisory services under *bona fide* consulting arrangements to be offered reasonable, fair-market compensation for those services and reimbursement for reasonable travel, lodging, and meal expenses incurred as part of providing those services.

**9.4.** In order to facilitate continuing professional development and training, and subject to relevant laws and regulations, IFM members may make a contribution to or on behalf of a Health Worker for fellowships, study tours, research grants, attendance at professional conferences and symposia. Such contributions shall be communicated to the institute to which the Health Worker is affiliated.

## 10.0 EVENTS

**10.1.** Scientific and Educational Objectives. The purpose and focus of all symposia, congresses and other, scientific or professional meetings ("Events") for Health Workers organized or sponsored by an IFM member shall be to inform Health Workers about Breast-Milk Substitutes, Follow on Formula and Complementary Foods and/or to provide balanced and accurate scientific or educational information.

**10.2.** Such Events will comply with all relevant aspects of applicable codes of conduct of health care professionals and their institutions.

**10.3.** Events Involving Foreign Travel. No IFM member may organize or sponsor an Event for Health Workers (including sponsoring individuals to attend such Events) unless the following requirements are met:

10.3.1. The Event complies with the hospitality requirements in these Rules as described in 11.6;
10.3.2. Sponsorship of Health Workers is limited to the payment of travel, meals, accommodation and registration fees;
10.3.3. No payments are made to compensate Health Workers for time spent in attending the Event; and
10.3.4. Any sponsorship provided to individual Health Workers must not be conditional upon an obligation to prescribe, recommend, sell or promote any Covered Products.

**10.4.** Guests. IFM members may not pay any costs associated with individuals accompanying invited Health Workers, unless such individuals independently qualify for payment of such costs.

**10.5.** Payments for Speakers and Presenters. Payments of reasonable fees (as considered in the context of the Health Worker's home market) and reimbursement of out-of pocket expenses, including travel and accommodation, may be provided to Health Workers who are providing genuine services as speakers or presenters on the basis of a written contract with the IFM member at the Event.

**10.6.** Hospitality

10.6.1. Appropriate Venue. All Events shall be held in an appropriate venue that is conducive to the scientific or educational objectives and the purpose of the Event or meeting. IFM members shall avoid using extravagant venues. The additional requirements set forth in Article 15.0 of these Rules also apply accordingly.

10.6.2. Limits of Hospitality. Hospitality shall be limited to refreshments and/or meals incidental to the main purpose of the Event and shall only be provided to participants of the Event and not their guests if to do so is moderate and reasonable under local standards. As a general rule, the hospitality provided may not exceed what Health Worker recipients would normally be prepared to pay for themselves.

**10.7.** Entertainment. No stand-alone entertainment or other leisure or social activities shall be provided or paid for by IFM members. At Events, entertainment which is secondary to refreshments and/or meals is allowed, provided it is modest and not considered lavish or extravagant in the local context.

## 11.0 EDUCATIONAL GRANTS

**11.1.** IFM members may provide funds to support genuine independent research, advancement of science or education, or patient and public education in relation to the Covered Products. However, it is important that support of these programs and activities by IFM members is not viewed as a price concession, reward to favored Health Workers or inducements to recommend, prescribe or purchase IFM members' products or services. Therefore, IFM members should ensure that they maintain appropriate documentation in respect of all educational grants made in relation to the Covered Products.

**11.2.** Educational grants will comply with all relevant aspects of codes of conduct of Health Workers and their institutions.

**11.3.** Educational grants shall not be tied in any way to past, present or potential future use of the IFM member's Covered Products.

**11.4.** Educational grants may be made preferably to organizations or entities entitled to receive them under applicable laws and regulations and should not be made to individual Health Workers unless permitted under applicable laws.

## 12.0 RETAIL TRADE AND DISTRIBUTORS

**12.1.** IFM members shall make retail customers and those other parties, acting on behalf of IFM members, involved in bringing the Covered Products to market aware of the importance of abiding by relevant laws and these Rules, and the importance of complying with their requirements.

## 13.0 GENERAL PUBLIC AND MOTHERS

**13.1.** Marketing Personnel, in their business capacity, shall not seek contact of any kind with pregnant women or with mothers of infants about Covered Products. This is not intended to prevent IFM members from responding to unsolicited questions from consumers about Covered Products via, for instance, telephone help lines, nor is it intended to prevent IFM members from participating in government organized health and/or nutrition programs.

**13.2.** IFM members shall not engage in the Marketing of Covered Products directly to the general public. This includes Marketing practices such as television, radio, internet, social media or print advertisements; discounts; point-of-sale advertising or special displays such as in hospital/clinic settings; promotional samples, items or trinkets; coupons; premiums; special sales; loss-leaders; and tie-in sales.

**13.3.** IFM members shall not use Covered Products or their specific brand names in any Informational or Educational Material about the feeding of infants intended for distribution to or use by consumers, except when such materials are intended to provide instructions for use for a specific Covered Product and are disseminated through a Health Worker upon his request or as part of a government organized health and/or nutrition program, or are materials clearly related to products which are not Covered Products.

## 14.0 SUPPLIES OF COVERED PRODUCTS TO BIRTHING FACILITIES

**14.1.** Birthing Facility Supplies at full or below full price shall be made only to and on request of a Health Care Facility and in accordance with a Health Care Facility's and IFM member's transparent, established and *bona fide* procurement, invoicing and, if applicable, payment process.

**14.2.** Birthing Facility Supplies shall be provided in quantities determined by an established process to be reasonable and intended for primary use at the requesting Health Care Facility only by infants who, pursuant to medical advice, have to be fed with Covered Products during their stay at the facility.

**14.3.** Birthing Facility Supplies shall not be provided as an incentive to Health Workers, or accompanied by other incentives, to purchase or use a particular brand of Covered Products or to purchase or use other products offered by the same IFM member whether or not those other products are covered under the scope of these Rules.

## 15.0 PRODUCTS FOR PROFESSIONAL EVALUATION (PPE)

**15.1.** PPE of Covered Products must never be used to discourage a caregiver from feeding breast-milk to an Infant.

**15.2.** IFM members shall not distribute PPE of Covered Products directly to the general public, including pregnant women and mothers of infants.

**15.3.** IFM members may only distribute PPE of Covered Products to Health Workers for purposes of evaluating a patient's tolerance and acceptability and not for personal use. PPE of Covered Products are not intended for repeat or extended consumption by the infant and distribution of PPE shall be strictly limited in regularity and quantity to avoid excessive allocation of PPE to a Health Worker.

**15.4.** PPE of Covered Products shall not be distributed to Health Workers as an incentive to purchase or resell or recommend a particular brand of Covered Products. The PPE should bear a Label stating that it is a "Sample for Professional Evaluation" or "Not for Resale", or bear a similar indication.

**15.5.** All distribution of PPE of Covered Products shall be in response to an authorized, written request from the Health Worker setting forth the Health Worker's certification that:

15.5.1. The requested PPE is solely for purposes of evaluating tolerance and acceptability;

15.5.2. The amount of PPE required;

15.5.3. They are aware of the obligations set forth under the relevant laws of the country;

15.5.4. The PPE is not being provided as an incentive to purchase or resell or recommend a particular brand of Covered Products; and

15.5.5. The PPE provided is not to be resold or taken for personal use by the Health Worker or its staff.

**15.6.** PPE of Covered Products shall never be given to pregnant women and mothers of infants directly.

**15.7.** IFM members must ensure appropriate controls and audit mechanisms for the use of PPE. These should include written policies, tracking mechanisms, training and an internal audit mechanism.

**15.8.** IFM members should also ensure that the above protocols are communicated to all of their employees, agents, contract workers who perform related activities, as well as other parties acting on their behalf, involved in bringing the Covered Products to market and ultimately to the consumer.

## 16.0 HUMANITARIAN AID

**16.1.** Supplies for Humanitarian Relief Aid in Emergency and Disaster Situations. IFM members may provide aid donations of Covered Products in emergency and disaster situations only through government channels or internationally recognized aid agencies and only in response to a specific written request by the government or appropriate aid agency that clearly documents the medical and social grounds for the request. IFM members must deliver humanitarian relief aid shipments of Covered Products to the requesting government or aid agency for distribution for use with infants who, pursuant to medical advice, have to be fed with Covered Products. IFM members may not deliver humanitarian relief aid shipments of Covered Products directly to caregivers.

**16.2.** Supplies to Orphanages or Other Social Welfare Institutions. IFM members may respond to written requests from orphanages or other social welfare institutions for free or low-priced supplies of Covered Products for feeding infants who have to be fed with Covered Products in order to serve humanitarian purposes. The Label or container of Covered Products distributed under this section shall clearly indicate that the specific Covered Product is a donation for use at the discretion of the receiving government or institution and only for infants who, pursuant to medical advice, have to be fed with Covered Products.

## 17.0 MONITORING AND ENFORCEMENT

IFM members are responsible for monitoring their compliance with these Rules.

Genuine, timely, and adequately documented complaints from IFM members and non-IFM members relating to non-compliance with these Rules are encouraged. Detailed procedures for complaints, the handling of complaints, and potential sanctions are set out in Appendix 2.

Appendix 1 – Countries within the scope of the IFM Rules of Responsible Conduct*

Afghanistan
Albania
Algeria
Angola
Antigua and Barbuda
Argentina
Armenia
Azerbaijan
Bahamas
Bahrain
Bangladesh
Barbados
Belarus
Belize
Benin
Bhutan
Bolivia
Bosnia and Herzegovina
Botswana
Brazil
Bulgaria
Burkina Faso
Burundi
Cambodia
Cameroon
Cape Verde
Central African Republic
Chad
China
Colombia
Comoros
Congo
Cook Islands
Costa Rica
Côte d'Ivoire
Democratic People's Republic of Korea
Democratic Republic of the Congo
Djibouti
Dominica
Guatemala
Guinea
Guinea-Bissau
Guyana
Haiti
Honduras
India
Indonesia
Iran (Islamic Republic of)
Iraq
Jamaica
Jordan
Kazakhstan
Kenya
Kiribati
Kuwait
Kyrgyzstan
Lao People's Democratic Republic
Lebanon
Lesotho
Liberia
Libya
Madagascar
Malawi
Malaysia
Maldives
Mali
Marshall Islands
Mauritania
Mauritius
Mexico
Micronesia (Federated States of)
Moldova
Mongolia
Montenegro
Morocco
Paraguay
Peru
Philippines
Qatar
Romania
Russian Federation
Rwanda
Saint Kitts and Nevis
Saint Lucia
Saint Vincent and the Grenadines
Samoa
Sao Tome and Principe
Saudi Arabia
Senegal
Serbia
Seychelles
Sierra Leone
Solomon Islands
Somalia
Sri Lanka
Sudan
Republic of South Sudan
Suriname
Swaziland
Syrian Arab Republic
Tajikistan
Thailand
The former Yugoslav Republic of Macedonia
Timor-Leste
Togo
Tonga
Trinidad and Tobago
Tunisia
Turkey
Turkmenistan
Tuvalu
Uganda
United Arab Emirates
United Republic of Tanzania
Uruguay
Uzbekistan
Vanuatu
Venezuela (Bolivarian Republic of)
Vietnam
Yemen
Zambia
Zimbabwe

* See '2.0 SCOPE'.

Dominican Republic
Ecuador
Egypt
El Salvador
Equatorial Guinea
Eritrea
Ethiopia
Fiji
Gabon
Gambia
Georgia
Ghana
Grenada
Mozambique
Myanmar
Namibia
Nauru
Nepal
Nicaragua
Niger
Nigeria
Niue
The Occupied Palestinian Territories
Oman
Pakistan
Panama
Papua New Guinea

Appendix 2 – Compliance Procedure

## 1.0 Introduction

As stipulated in Article 17 of the Rules, this Appendix sets out the detailed procedures for the handling of complaints and potential sanctions in cases of non-compliance with the Rules. All terms used in this Appendix but not already defined in the Rules shall have the meaning given to them in Section 3 below.

## 2.0 Scope of the Compliance Procedure

The Rules and the Compliance Procedure are open to complaints from Rules Members.

A Complainant may use this Compliance Procedure for:

a) complaints relating to alleged violations of the Rules in Covered Countries;

b) where an attempt at resolution of the complaint through dialogue and inter-company conciliation directly between the Respondent and Complainant involved has been unsuccessful; and

c) where the complaint could not be addressed through the complaints procedure of the relevant trade association at a national or regional level either due to the absence of such complaints procedure and/or due to the Respondent or the Complainant not being a member of the trade association concerned.

This Compliance Procedure may not be used for:

a) appealing decisions already adjudicated by trade associations at the regional or national level; or

b) resolving questions of compliance with national laws and regulations in Covered Countries.

If a complaint is received by the Authority that is not covered by this Compliance Procedure or that is not within the scope of the Rules, the Authority will revert the complaint back to the Complainant.

## 3.0 Definitions

***Administrative Charge*** means the fee as set out in the Schedule of Administrative Charges, which is to be paid by a Complainant to the Authority whenever a complaint is brought before the Authority.

***Authority*** means the body established by the IFM to administer this Compliance Procedure, which consists of a Secretariat, a Legal Representative, and one or more Rules Panels.

***Case Report*** means the report drafted by the Legal Representative after conclusion of a case summarising the details of a case on an anonymous basis.

***Complainant*** means a Rules Member bringing a complaint under this Compliance Procedure.

Decision means the conclusion reached by the Rules Panel after considering a complaint under this Compliance Procedure.
***Legal Representative*** means a lawyer appointed by the IFM Board in charge of conducting a legal screening of a complaint, convening the Rules Panel and assisting with the adjudication of complaints under this Complaints Procedure.

***Rules Panel*** means the body convened from time to time in charge of adjudicating complaints under this Compliance Procedure.

***Respondent*** means a Rules Member against which a complaint is brought under this Compliance Procedure.

***Rules Members*** means (i) IFM members and (ii) non-IFM member manufacturers or distributors of Covered Products who have agreed to abide by the Rules and this Compliance Procedure by signing the written certification set out in Appendix 3.

***Schedule of Administrative Charges*** means a list of Administrative Charges determined and annually published by the IFM Board.

***Secretariat*** means the legal assistant in charge of facilitating the Compliance Procedure.

**4.0 Compliance Procedure**

4.1. Organization

4.1.1. The Authority

The Authority administers this Compliance Procedure on behalf of IFM and the Rules Members. The Authority is an administrative and adjudicative body. The Compliance Procedure is a process in which the evidence to be taken into account comes from the Complainant and the Respondent. Although the Authority, through the Secretariat, may ask either party for further clarifications or may seek additional evidence from third parties, it is not an investigative body.

4.1.2. Secretariat

The Secretariat's role is to facilitate the Compliance Procedure by supporting the Legal Representative and the Rules Panel. The Secretariat receives complaints, notifies complaints validated by the Legal Representative to the Respondent, receives a Respondent's response to a complaint and ensures that the requisite information is available for, and submitted to, the Rules Panel. At the request and on behalf of the Legal Representative or the Rules Panel, the Secretariat may request copies of any relevant material from either party, including copies of the certificates authorizing marketing and other promotional material or copies of other relevant briefing material used by the Respondent. At the request and on behalf of the Legal Representative or the Rules Panel, the Secretariat may also seek evidence from third parties.

4.1.3. Legal Representative

The Legal Representative's role is, to facilitate the Compliance Procedure and to participate with the other Rules Panel members in reaching a decision. The Legal Representative ensures that the complaint is within the scope of these Rules and, if it is, convenes the Rules Panel. The Legal Representative should be the first point of contact for the IFM Board.

#### 4.1.4. Rules Panel

The Rules Panel's role is to adjudicate the complaint and give a decision.

The Rules Panel consists of three (3) members: the Legal Representative and two (2) other individuals selected from a list of experts recognized as knowledgeable in the industry and independent from the companies involved. The list of experts is approved by the IFM Board and the Rules Members on an annual basis.

The Legal Representative will select the two other Rules Panel members to adjudicate individual complaints on the basis of the approved list of experts.

The Rules Panel meets as required, and in the most expeditious fashion, to consider complaints.

### 4.2. Complaints Filing Process

#### 4.2.1. Precondition for Filing a Complaint

A complaint shall only be brought under this Compliance Procedure if a complaint could not be resolved between the Complainant and Respondent through intercompany dialogue, conciliation or the complaints procedure of a national or regional trade association and no other alternative dispute resolution mechanism exists.

#### 4.2.2. The Complaint

All complaints must be submitted to the Secretariat. They must be in writing and signed or authorized in writing by the Complainant's managing director, chief executive officer or legal counsel. The complaint shall include:

a) the name of the Complainant;

b) the name of the Respondent;

c) the Covered Country where the alleged conduct occurred;

d) a complete description of the alleged conduct and specific clauses of the Rules which are alleged to have been violated, including dates or timeframes of the alleged conduct, whether it is ongoing, and any supporting materials; and

e) a statement confirming that:
   i. direct resolution between the parties was attempted, but failed;

ii. resolution through a national or regional trade association was attempted but failed or that there is no complaints procedure of a national or regional trade association; and
iii. the matter is not pending before a court or regulatory body in the Covered Country concerned.

The complaint need not include a statement required under Section 4.2.2(e), above, if the allegation is that a Rules Member has failed to comply with an undertaking that it has given to the Authority as a result of a prior Decision.

#### 4.2.3. Payment of Administrative Charges

An Administrative Charge is payable whenever a complaint is brought before the Authority.
The Administrative Charge is comprised of the administrative cost of adjudicating a complaint as well as any costs related thereto. The Administrative Charge is determined by the IFM Board and published by the IFM on an annual basis in the Schedule of Administrative Charges. The Administrative Charge is calculated on a "per clause" basis and relates to the number of Rules provisions alleged to have been violated. The number of Administrative Charges which apply in a case is determined by the Legal Representative.

No new complaint may be submitted by the Complainant, or accepted for adjudication by the Rules Panel, until such Administrative Charge is paid in full.

#### 4.2.4. Respondents who are not Rules Members

If a complaint is received about a Respondent that is not a Rules Member, it is invited by the Secretariat to agree to comply with the Rules and accept the jurisdiction of the Authority (unless it has previously declined to do so). In the absence of such agreement, the complaint is dismissed and the Complainant is notified.

### 4.3. Adjudication Process

#### 4.3.1. Receipt of a Complaint and Verification

Within five (5) calendar days from the date of receipt of a complaint, the Secretariat shall verify that:

a) the complaint is complete and meets the requirements set forth in Section 4.2.2, above; and

b) the complaint has been submitted by a Rules Member.

If the complaint cannot be verified, it will not be processed, but reverted back to the Complainant.

#### 4.3.2. Legal Screening

Within five (5) calendar days after receiving a verified complaint from the Secretariat, the Legal Representative:

a) determines whether the complaint should be brought before the Rules Panel and, if not, provides the Complainant and Respondent with the reason for such dismissal;

b) may delay processing a complaint if the facts are essentially similar to those that are pending in another proceeding; and

c) may amalgamate a complaint with another, ongoing complaint or complaints where they are based on essentially the same alleged facts.

#### 4.3.3. Notice to Parties

Within five (5) calendar days after verification of the complaint, the Secretariat provides a copy of the complaint together with details of the process to the Respondent with a request that the Respondent's managing director or chief executive officer or legal counsel provide a complete response to the matters of complaint.

#### 4.3.4. Response

Upon receipt of a copy of the complaint, the Respondent has twenty (20) calendar days to submit its response in writing to the Secretariat. An extension of up to five (5) calendar days may be granted at the discretion of the Legal Representative. To the extent that the Respondent's response includes confidential or competitively sensitive information, the Respondent may be allowed to redact such information.

#### 4.3.5. Rules Panel Establishment and Hearing

Upon receipt of the Respondent's response, the Secretariat coordinates with the Legal Representative to convene a Rules Panel and schedule a hearing within twenty (20) calendar days. The Legal Representative shall select the other two Rules Panel members from the list of experts.
Upon Rules Panel establishment, the Secretariat provides the Rules Panel members with a copy of all written submissions. At the same time, the Secretariat notifies the parties that the complaint has been referred to the Rules Panel. The Secretariat provides the parties with copies of all written submissions and informs the parties of the date of the hearing.

Within twenty (20) calendar days of receipt of all written submissions, the Rules Panel hearing shall take place.

The Rules Panel hearing can be by video conference, teleconference or in person depending on what is most convenient, practical and expeditious to ensure the complaint is heard in good time.
The meeting is private and only open to Rules Panel members, the Complainant and the Respondent. The Complainant and Respondent are allowed to participate in the Rules Panel meeting only for the purpose of answering Rules Panel members' questions.

The merit of a complaint is assessed based on the arguments and evidence contained in the written submissions, and any oral answers provided by the parties at the hearing.

The Legal Representative will be responsible for taking minutes of the meeting.

4.3.6. Decision

Within five (5) calendar days after the hearing, the Rules Panel adopts a Decision by unanimous vote. The Legal Representative drafts the Decision, including the reasoning provided by the Rules Panel, and any remedial actions and penalties imposed pursuant to Section 5, below.
The Legal Representative communicates the Decision to the Secretariat. Within five (5) calendar days of its adoption, the Secretariat provides the Decision to the parties involved.

The Decision will be confidential to the parties and the Authority. It shall not be published or otherwise distributed.

4.3.7. Adoption of Case Reports

At the conclusion of a case under this Compliance Procedure, the Legal Representative prepares a Case Report summarizing the details of the case on an anonymous basis. The information given must not be such as to identify any individual nor any individual company.

A copy of the draft Case Report is sent to both the Complainant and the Respondent at the end of the case. Any amendments to the report suggested by these parties are considered by the Secretariat and the Legal Representative, and are decided at the sole discretion of the Legal Representative, in consultation with the Complainant and Respondent, where appropriate.

A summary of all Case Reports is shared with the IFM Board of Directors and Rules Members on an annual basis.

4.4. Appeals

4.4.1. A Respondent may, within five (5) calendar days, appeal:

a) Verification of a complaint by the Legal Representative under section 4.3.2; and

b) Any ruling of a violation of this Compliance Procedure.

4.4.2. The Secretariat shall refer the matter to an ad hoc group composed of two members of the IFM Board of Directors and the Legal Representative (other than the Board members from the companies that participated in the first instance ruling).

4.4.3. Within ten (10) days, the ad hoc group shall meet, either in person or by phone/video conference, to deliberate the appeal. A decision to uphold the verification of a Complaint or a ruling of a violation must be unanimous; otherwise the Complaint shall be dismissed.

4.4.4. Within five (5) calendar days of a decision being made, the Legal Representative drafts the decision and reasons for it.

4.4.5. The Secretariat will contact the parties with details of the decision.

## 5.0 Penalties and Remedial Actions

5.1. Where the Rules Panel finds that there is a violation of the Rules, the Rules Panel decides on appropriate penalties and remedial actions set forth in this Section.

5.2. Where the Rules Panel finds that there is a violation of the Rules, within thirty (30) calendar days of the Decision, the Respondent must also pay the Administrative Charge to the Authority for reimbursement to the Complainant, as well as any penalties determined by the Rules Panel.

5.3. In the event of a Decision of a violation of the Rules, within five (5) calendar days of the Decision, the Rules Panel shall require the Respondent to provide a written undertaking that the promotional activity or use of the material in question and any similar material (if not already discontinued or no longer in use) will cease forthwith and that all possible steps will be taken to avoid a similar violation of the Rules in the future. This undertaking must be signed by the Respondent's managing director or chief executive officer or legal counsel and must be accompanied by details of the actions taken by the Respondent to implement the undertaking, including the date on which the promotional material was finally used or appeared and/or the last date on which the activity took place. In exceptional circumstances, an extension in the time allowed to provide the written undertaking may be granted at the discretion of the Rules Panel.

5.4. In addition to the written undertaking, depending on the severity of the violation, the Rules Panel may also (either singly or combined):

a) require the Respondent to issue corrective materials and to take steps to recover items given in violation of the Rules. Written details of the steps to recover such items, and details of the proposed content of the corrective materials and mode and timing of dissemination must be provided to the Rules Panel for approval prior to use.

In the event the Respondent fails to take appropriate steps as required by the Rules Panel, the Rules Panel may (either singly or combined):

b) recommend to the IFM Board of Directors to consider requiring an audit of the Respondent's compliance with the Rules Panel's decision to be carried out by the Authority or by a third party on behalf of the Authority and, following that audit, decide whether to impose further sanctions based on the Respondent's non-compliance with the Rules Panel's decision. All of the costs of audit and additional sanctions shall be borne by the Respondent. The results of such an audit shall remain confidential to the Respondent and the Authority unless there are

repeated violations of the Rules in which case the results may also be shared with the IFM Board of Directors for consideration of a request to resign. The results of the audit and request to resign are only shared with the Board of Directors and shall otherwise remain confidential. In the case a Respondent resigns, the Respondent remains liable for the payment of the costs of the audit, the Administrative Charge and any additional sanctions imposed by the Panel.

## 6.0 General Provisions

### 6.1. Withdrawal of Complaints

A complaint may be withdrawn at any time by a Complainant, subject to payment by the Complainant of any additional costs incurred by the Authority and without refund of the Administrative Charge.

### 6.2. Failure to Pay Administrative Charges

Failure to pay the Administrative Charges must be reported by the Secretariat to the Rules Members.

### 6.3. Return or Destruction of Documents

Subject to national laws and regulations, after the conclusion of the case, within a period to be fixed by the Rules Panel, any documentation submitted by the Complainant and Respondent shall be destroyed or returned to the submitting party. At the same time, any electronic material submitted by a Complainant or Respondent shall be destroyed.

### 6.4. Unilateral Corrective Actions

A Rules Member may advise the Authority of any unilateral corrective action it has implemented.

Appendix 3 – Written Certification

**Written Certification Regarding Implementation of the IFM Rules of Responsible Conduct in 2013**

I, [name of most senior person with direct responsibility for that members' global nutrition business or a member of their executive management team or the Board of Directors], certify and confirm that, for the year ended 31 December 2013, [company name] (the "Company") had:

1) Implemented written policies to foster compliance with the Rules;

2) Conducted appropriate employee training; and

3) Taken steps to monitor compliance with the Company's written policies referenced above.

By signing below, I certify that the above is true and accurate to the best of my knowledge

[Signature]

[Name]

[Date]