IFA

Infant Feeding Association

Rules for Responsible Conduct

CONFIDENTIAL FOR IFA MEMBERS ONLY

FINAL DOCUMENT AMENDED JULY 2018

Infant Feeding Association of South Africa, Rules for Responsible conduct

1.0 Introduction

1.1 The IFA and its members are committed to the responsible and ethical marketing of products for infants and young children. Responsible and ethical marketing enables health workers to obtain accurate, science-based information, supports caregivers' decisions to choose nutritious and healthy foods for their children, and promotes safe and appropriate use of nutritional products in a manner that protects breast feeding.

1.2 The IFA and its members support the recommendations of the World Health Organisation (WHO) for exclusive breast feeding for the first six months of life, where indicated, and the introduction of safe and appropriate complementary foods thereafter to supplement continued breast feeding.

1.3 The IFA and its members comply with the Regulation Relating to Foodstuffs for Infants and Young Children, R991 of 6 December 2012, promulgated under the Foodstuffs, Cosmetics and Disinfectants Act, (Act 54 of 1972), and any subsequent amendments. The IFA and its members respect the aims and principles of the 1981 World Health Organisation's International Code for the Marketing of Breastmilk Substitutes (The WHO code) and its subsequent resolutions.

1.4 The IFA and its members recognise that when mothers do not adopt breast feeding or only do so partially, that there is a legitimate market for infant formula and accessories. These products 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 complex and multi-factorial. The IFA 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 Healthcare personnel and health establishments play an essential role in guiding and influencing infant and young child feeding practices and providing scientific, objective advice about appropriate feeding options. Such advice is independent of undue influence from manufacturers, and other parties with a commercial interest in the process of bringing a product to the consumer. Appropriate marketing and distribution practices are important in ensuring that health workers have access to truthful science-based and balanced information.

1.7 Breast milk substitutes are recognised by the WHO as the only safe and nutritious alternative to breastmilk for feeding infants through to six months of age. The IFA member companies also develop a range of specially formulated products to address specific nutritional requirements of premature babies and infants who suffer from medical disorders. Theses formulas are intended for infants with special medical requirements are helping to improve treatments, survival rates and long term outcomes.

1.8 Through the adoption of these Rules, the IFA and its members seek to establish industry standards that

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- Help advance infant and young child nutrition, by the provision of factual and scientific information to healthcare professionals
- Are clear, unambiguous and transparent
- Encourage best practices by all, with a commercial interest, involved in the process of bringing feeding products to the consumer, and

- Promote consistent compliance across its members.

1.9 The Rules set a base standard for IFA members

1.10 Acceptance of these Rules as a minimum standard of conduct is a condition of membership of the IFA. Acceptance of these Rules by an IFA member does not preclude an IFA member from adopting additional approaches to compliance.

1.11 A full list of IFA members that have agreed to follow these Rules may be obtained from the IFA

1.12 In order to keep the Rules current, they will be reviewed at least annually by the IFA Executive and Regulatory Committees and amended or added to as necessary. Suggestions for amendments or additions may be submitted to the IFA.

2.0 Scope

These Rules apply to the designated products as defined by the Regulations Relating to Foodstuffs for Infants and Young Children, R991 of 6 December 2012, which has been promulgated under the Foodstuffs, Cosmetics and Disinfectants Act,(Act 54 of 1972), of South Africa and any subsequent amendments. Currently published amendments to R991/2012 are R365/May 2013 Correction Notice; R433/June 2013 Extension Notice; R434/ June 2013 Schedule.

A draft amendment has been published for comment on 7 July 2015. Comments are due by 7 October 2015 and this document will be amended on promulgation of that draft amendment

Designated products are defined within R991/ 2012 are as follows:

(a) Infant formula
(b) Follow up formula
(c) Infant or follow-up formula for special dietary management for infants with specific medical conditions
(d) Complementary foods
(e) Liquid milks, powdered milks, modified powdered milks or powdered drinks marketed or otherwise represented as suitable for infants or young children
(f) Feeding bottles, teats and feeding cups with spouts, straws or teats and
(g) Any other products marketed or represented as suitable for feeding infants and young children that the Minister may so designate by notice published in the Gazette.

It should be noted that for the Regulation 7: Sales and Promotion, the following definition of designated products applies (Regulation 7(1)):

(a) Infant formula
(b) Follow up formula
(c) Infant or follow-up formula for special dietary or medical purposes
(d) Liquid milks, powdered milks, modified powdered milks or powdered drinks marketed or otherwise represented as suitable for infants or young children
(e) Feeding bottles, teats and feeding cups with spouts, straws or teats and
(f) Any other products that the Minister may publish by notice in the Gazette.

These Rules apply to infants and young children up to the age of 36 months as defined in the South African Regulations (R991/2012). R991/2012 relates to the labelling, manufacture, distribution, sales and promotion of all designated products.

These Rules do not apply to products that are not designated under R991/2012 and consequently exclude, for example, breast pumps, breast milk storage containers, spoons, bowls, maternal supplements, special dietary or medical supplements for children over the age of 1 year, adult medical supplements or other foods and drinks not captured in the designated products definitions above.

The Department of Health of South Africa has published a question and answer document in February 2014, entitled Guidelines to Industry and Healthcare Personnel: The Regulations relating to Foodstuffs for Infants and Young Children, R991 of 6 December 2012 ("Regulations"). This document has been used in the development of the IFA Rules for Responsible Conduct document, of which the relevant sections are clearly marked.

There is on-going communication between the Department of Health (DoH) and the IFA and its members, with respect to clarification where there is a mis-alignment between the interpretation of the Regulations and the Guidance Document. The IFA Rules will uphold the IFA's understanding of the legal interpretation of those areas of R991/2012 until such time as either the Department of Health's Guidance Document or the Regulation is amended. These areas are clearly identified within this document.

3.0 **Definitions**

The definitions outlined in R991/2012 apply. The definitions given below provide further clarity on meaning that is not included in the Regulation.

Breast milk substitute means any food that is marketed or otherwise represented as partial or total replacement for breastmilk, whether or not suitable for that purpose. (WHO code definition)

Claim in relation to a foodstuff, means any written, pictorial, visual, descriptive on verbal statements, communications or representation that cannot be referenced from a reputable source document and/or one where a brand name is inserted into or associated with a fact that confers a benefit to that brand. Claims might be health, medicinal or nutritional in nature. Medicinal claims are not permitted for foodstuffs.

Colic is persistent, unexplained crying in a healthy baby between two weeks and five months of age. Colic, which is not a disease, affects 10 -20% of all infants.
References: *http://*pediatrics.aappublications.org/content/18/5/829 & https://medical-dictionary.thefreedictionary.com/colic

Fact is a true statement that can be referenced from a clinical paper, medical or nutrition text book or can be quoted from another reputable source.

Non- designated product is any product that does not fall into the classifications given above and in R991/2012.

Nutrition is defined as the process by which living organisms take in and use food for the maintenance of life, growth and functioning as part of normal physiology to generate a healthy state of mind and body [1,2,3].

References: 1. Merriam-Webster Online Dictionary. www.merriam-webster.com/dictionary/nutrition 2. Oxford Reference. www.oxfordreference.com/view/10.1093 nutrition 3. Dictionary.com. www.dictionary.reference.com/browse/nutrition

Rebates are discounts off retail price offered to the consumer. [Q6, DoH Guidance Document]

Sales device is any method or activity that encourages any person to purchase or use a designated product as defined in Regulation 7 (1), which may include advertising designated products, special displays, additional kickbacks, discounts or incentives or gifts specifically targeted designated products. [Q5, DoH Guidance Document].

Technical Aspects relate to scientific and factual matters regarding the composition, indications for use, suggested feeding schedules, direction for preparation and method of use, storage instructions and shelf life. [Q71, DoH Guidance Document]

4.0 Labelling, Composition, Packaging and Manufacturing Matters

4.1 **General Labelling requirements:** All designated products shall observe the labelling requirements as outlined in Regulation 2, General Labelling, Composition, Packaging and Other Manufacturing Matters of designated products, except where the category of the designated product has been specifically exempted.

4.2 **Graphic representation:** Regulation 2(a) graphic representation is defined in these regulations as being illustrations, photographs, drawings or pictures of infants, young children, child characters, cartoons or any other forms that resemble them, human or not, such as humanised fruits, vegetables, animals and/or flowers, among others. Graphics that do not fall under this definition are acceptable on the labels of designated products. [NB. There is an outstanding question with the Department of Health over trademarked humanised graphics and the acceptability of their inclusion]

4.3 **Sweeteners, correction notice:** Regulation 2 (17) has been corrected to state ' Table 1 of the general standard for food additives'. Correction notice R365/ May 2013.

4.4 **Sterility statement, modification:** Regulation 3 (1) (a) (iii)(b) and Regulation 3 (2) (a) (iv). This statement has been modified by the Department of Health to state 'This product is not always sterile. It must be prepared and used appropriately.' The amendment to the Regulation has not yet been promulgated. The IFA has supporting documents and agreement to proceed with the above statement. Documents available on request.

4.5 **Nutrient table:** Regulation 3 (8) There is currently a discrepancy between the labelling requirements of R991/2012 and R146/ 2010. The amendment to the Regulation has not yet been promulgated. The DoH has agreed that this discrepancy will be corrected.

4.6 **Complementary food graphics:** Regulation 4 relates to complementary foods and other products marketed as suitable for infants or young children. Please note that for graphics on the labels of these products both R991/2012 and Regulation relating to the Labelling and Advertising of Foodstuffs, R146/ March 2010, Regulation 34 apply.

4.7 **Accessories graphics.** Regulation 6 (3) prohibits the use of graphic representation, except for those used in the illustration of cleaning and sterilisation of the product on the label,

package or container of the feeding bottle, teat or feeding cup. This does not prohibit the use of graphics on the bottle, teat or cup itself.

4.8 **Anti-colic statement for use on accessory packaging.** Regulation 4(a) (i) and (ii) prohibit the use of health, medicinal or nutrition claims for any designated product. A statement using the words 'anti-colic' on accessory packaging is not considered to be in contravention of this regulation. Feeding bottles, teats and feeding cups cannot make nutrition or health claims in accordance with the definitions within the Regulations. The prohibition of a medical claim may apply but this would require the accessory to be treating, preventing or curing a human disease. Colic is not considered to be a disease.

5.0 Sale and Promotion

5.1 **Complementary foods:** Regulation 7 does not apply to complementary foods. However, other regulations do apply to the sale and promotion of these products. Within R991, Regulation 2 (4) (a) which states 'no health, medicinal or nutrition claims shall be permitted……' applies as does Regulation 3 of R146/ 2010. For reference, Regulation 3 of R146/2010 stipulates that no person shall advertise a foodstuff in any manner, which contains any information, claim, reference or declaration not permitted on the label in accordance with the regulation.

5.2 **Sales Devices:** Regulation 7 (2) (a) stipulates that sales devices must be avoided. The definition further defines sales devices and the activity. It should be noted that highlighting the price of a designated product, even when not discounted, is considered to be a sales device.

The following are not considered to be sales devices

5.2.1 Permanent displays of designated products are permitted. Temporary or 'special displays' are considered to be a sales device

5.2.2 Inclusion of designated products as a contributor towards total basic point allocations in loyalty programmes is permitted. Designated products may not be allocated their own associated loyalty points or any additional points. [Q5, DoH guidance document]

5.3 **Retailers**; An IFA document for use by retailers on 'The Do's and Don'ts' as they relate to the R991 is attached in Appendix 1.

5.3.1 In addition, front shop pharmacy staff and/or retail staff must be suitably trained to ensure that consumers know what they are buying, who the product is intended for, how to use it correctly, where to find ingredients and nutritional and or other technical information with respect to the use of all designated products. Manufacturers or suppliers of designated products may provide this training, provided that the training is NOT promotional in nature and includes only information that is factual, technical and scientific in nature.

This will ensure that manufacturers, importers and distributors are in compliance with the Consumer Protection Act,2008 which states that instructions for use are critical. Failure to provide this could lead to a claim of liability against anyone in the supply chain.

5.4 **Rebates:** Regulation 7 (2) (a) stipulates that rebates are a promotional practice and are therefore prohibited. Trading Terms, as negotiated between supplier and retailer, are not considered to be rebates and consequently are not prohibited under R991 except where

the expenditure directly relates to activities which are prohibited such as advertising [Q6, DoH guidance document]

5.5 **Social Media:** Regulation 7(2)(b) prohibits the interaction of the company and the consumer through direct & indirect methods, such as the internet, mother and baby clubs. Social media platforms are considered to be internet sites and are designed to encourage direct interaction between the designated brand and the consumer. These are not permitted for designated products.
[The IFA and its members are in discussion with the Department of Health to gain further clarity.]

5.6 **Educational information and educational material:** Regulation 7 (4) prohibits the production and/or distribution of material that promotes any designated product whilst providing guidance to the **general public** on the use of designated products (educational material) i.e. No product branding is allowed. 7 (5) prohibits manufacturers, retailers, distributors or persons contracted on behalf of the aforementioned from producing, distributing or presenting any educational information (designed to impart knowledge, facts, information and skills) about infant and young child nutrition. Since material directed to the healthcare professional is referred to in Regulation 11, the IFA interprets Regulation 7 (5) to relate to the provision of educational information by companies to the general public. Healthcare personnel are not prohibited from writing generic educational information and material, provided it is in their own right and not on behalf of a company.

6.0 Prohibition of the distribution of free or low cost designated products or samples

6.1 **Low Cost clarification:** Regulation 9 (1) prohibits the sale of designated products at low cost. Low cost is clarified by the use of an example e.g. if the usual retail price is R100 including VAT, than the designated product may not be sold at less than R80 including VAT. [Q4, DoH Guidance Document]

6.2 **Additional regulation, correction notice:** Regulation 9 (3) has been added through Correction Notice R434/ June 2013 to state 'No person in a health establishment shall accept or give to any other person free or at low cost supplies or samples of designated products.'

6.3 **Tenders.** Are not exempt from the Regulations. However, requests for samples of designated products is not prohibited for tender purposes, as the samples are not distributed at free will but it is a tender requirement of application. [Q44, Department of Health Guidance Document]

6.4 **Emergency Relief Operations.** This is only permitted on written permission from the Director General of Health. The amendment to this regulation has not yet been promulgated.

7.0 Healthcare personnel interactions

7.1 **Research Grants**: Regulation 7 (2) (h) prohibits research grants and other financial assistance to healthcare personnel or establishments in the field of infant and young child nutrition, unless prior approval from the Director- General of the Department of Health has been obtained.

7.2 **Financial Contributions**: Regulation 7 (2) (i) relates to financial contributions or sponsorship (financial or in-kind assistance) to individual healthcare personnel working in

infant and young child nutrition. The IFA's interpretation of this is that it applies to those health care personnel whose primary healthcare role is to offer advice on feeding normal, healthy infants and young children, such as those in primary care/ community practice.

7.3 **Events:** Regulation 7 (2) (j) relates to sponsorship of **meetings** targeting healthcare personnel (HCP) where infant and young child nutrition is the sole or partial topic of discussion. Sponsorship of CPD/CNE meetings for HCPs is allowed provided that the sole or partial discussion topic is NOT infant and young child nutrition or on a designated product brand.

7.3.1 **Topics and Products:** HCP meetings that relate to an abnormal state of health (e.g. disease states/ entities) and nutrient functions (e.g. role of lutein in the human body) and for topics unrelated to infant and young child nutrition may be held. If the company hosting the meeting has designated products within their portfolio, additional care should be taken to ensure that other aspects of R991/2012 are not inadvertently contravened.

The IFA proposes that the following questions should be asked by meeting organisers to ensure that R991/2012 is not inadvertently contravened:

1. Are there topics on the agenda or is the focus of the meeting infant and young children nutrition?
   No, normal company/ internal rules should apply
   Yes, proceed to question 2
2. Is the product to which this meeting relates designated?
   Yes, proceed to question 3
   No & also not related to infant & young children nutrition, then meeting should proceed under normal company/ internal rules. If related to infant and young child nutrition proceed to question 3.
3. Is the information scientific & factual in nature?
   Yes, this meeting may be held, but within the constraints of R991/2012.
   No, this meeting should not be held without revision to focus/ agenda as may contravene R991/2012.

HCPs should be given the opportunity to determine for themselves whether or not they wish to attend such sponsored meetings. To support HCP in their decision making, the IFA recommends that a statement is included in the invitation. This statement may be worded as the example below, but can be modified.

'This meeting relates to products that do not fall under R991/2012, Regulations relating to foodstuffs for infant and young child nutrition. Companies are permitted to hold HCP meetings for non-designated products and topics that are outside of infant and young child nutrition'.

If the topic does relate to infant and young child nutrition then a statement could be added to the invitations:

'X company is a member of the Infant Feeding Association of South Africa and consequently abides to R991/2012 as well as the IFA's Rules of Responsible Conduct'.

None of the above statements are mandatory & are for guidance only.

7.3.2. **Audience**: Healthcare personnel working in infant and young child nutrition applies to those healthcare personnel whose primary healthcare role is to offer advice on feeding normal, healthy infants and young children, such as those in primary care/ community practice.

7.3.2 **Funding:** Where the sole or partial topic of the meeting for healthcare personnel is infant and young child nutrition the following may occur:

7.3.2.1 funding may be given to the event organiser as part of a pool of funds. A single company may provide that pool of funds.

7.3.2.2 event organisers may acknowledge the company/ies providing the funds through use of their logo & company name

7.3.2.3 funding must not be dependent on a delegate list provided by the company

7.3.3 **Stands:** Stands are permitted at events attended by healthcare personnel provided that the following regulations are observed.

7.3.3.1 Regulation 11, material directed at healthcare providers. All material must be of a factual and scientific nature and preclude all unsubstantiated claims. This includes literature, stand panels, etc. (Refer to definition of a claim)

7.3.3.2 Samples of any designated product, limited to one for each brand, may be available at the stand, to aid healthcare personnel understanding of instructions for use.

[Q 51 DoH Guidance Document, gives an alternative interpretation of this. However, the reference to display samples within the regulation relates to retail & healthcare establishments and not to healthcare personnel. The IFA and its members understand that sample designated products are being used to inform and educate the healthcare personnel on the technical aspects of the product and not to promote and are consequently separate from the DoH interpretation. This has been raised with them]

7.3.3.3 A single stand may provide information relating to designated and non-designated products. Care should be taken when distributing gifts associated with non-designated products to ensure that no association can be made between the gift being offered and a designated product. Verbal presentations and/or discussions must be limited to discussions around either the designated products or the non-designated product. Combining information in respect to designated and non-designated products into one conversation must be avoided.

7.3.3.4 Gifts are not permitted for designated products – see below.

7.3.4 **Speakers.** Personnel from manufacturers, retailers or distributors may not engage speakers on the topic of infant and young child nutrition as this

contravenes Regulation 7 (5). However, speakers may be engaged and honorariums paid for educational meetings on other topics.

7.4 **Gifts**: Regulation 7 (3) (a) and (b) relate to the provision of gifts to healthcare personnel, this includes hospitality and refreshments, not being offered. However, should an event be held, then it would be reasonable in South Africa's climate, to provide water.

8.0 Material directed at healthcare personnel

8.1 **General requirements:** Regulation 11 outlines the requirements of all materials directed to healthcare personnel. It is easy however to confuse scientific facts and claims. These are defined under 'Definitions' in this document. Unsubstantiated claims are prohibited in regulation 11 (2), as are medical claims (prevent, treat, cure).

8.2 **International studies:** Scientific material may include information from international studies as well as local studies.

8.3 **Probiotic claims**: These claims require special attention as they are listed in the schedules of 20 March 2015, R234 GN 38586, to the Medicines and Related Substances Control Act (Act 101 of 1965). Claims are only allowed if the minimum dose is 1 x 10^9 CFU. At these levels, only a general health claim with respect to maintaining digestive health is allowed. If such a claim is made, the product must indicate a S0 status and be labelled in accordance with the requirements for the labelling of medicines as required by Act 101/1965. Enhanced immunity is a registerable claim in terms of Act 101/1965. Should a product contain <1 x 10^9 CFU then the product is categorised as a food and currently no probiotic health claims are allowed for foods. If a probiotic claim should be made, the claim should be referenced and supported by an appropriate scientific reference that aligns the health benefits claimed to both the levels of and the strains of probiotics that are made in the claim.

Specific strains can be mentioned by name in the ingredient list and nutritional table without any reference to the term "probiotic", in foods for infants and young children as regulated by R991.

8.4 **Inclusions:** The IFA and its members recommend that material intended for healthcare professionals is clearly marked, using the words 'For HCP use only' or 'HCP material' or similar wording, preferably on every page. All scientific facts are carefully referenced to ensure no confusion between a fact and a claim. Design and creative teams need to be particularly careful when placing a brand logo, pack shot or picture of the product to ensure that no inferred claim can be made as a result of the positioning of the graphic.

All material must include the date and/or a code number identifying when the material was drawn up or last revised.

9.0 Commencement

9.1 Implementation of all the regulations with exception of Regulation 17 are in effect.

Regulation 17 states that on 6 December 2015 all designated products, on shelf, that do not comply with the labelling requirements of R991/2012 must be removed. The IFA and its members are in discussed with the DoH to have this time period extended.

10.0 Monitoring and Enforcement

10.1 IFA members are responsible for monitoring their compliance with these Rules.

10.2 Genuine, timely and adequately documented complaints from IFA members and non- IFA members relating to non-compliance with these Rules are encouraged. It is expected that IFA members will have attempted to resolve the complaint between themselves through dialogue and intercompany conciliation. If this has been unsuccessful, then the involvement of the IFA can be requested. Detailed procedures for complaints are set out in Appendix 2 attached.

10.3 The IFA will maintain a log of all complaints received to support the further development of these Rules.

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