Regulations relating to Foodstuffs for Infants and Young Children: perspectives from South African dietitians

by
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ABSTRACT

Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations): Perspectives from South African dietitians.

Introduction: Knowledge surrounding the importance of breastfeeding is ever increasing and authorities have long since realised that the inappropriate marketing of breastmilk substitutes (BMS) undermines optimal breastfeeding practices. Many countries have legislated the International Code of Marketing of Breast-milk Substitutes (The World Health Organization [WHO] Code) drafted by the World Health Alliance (WHA) in 1981. South Africa adopted its own legislation (that is, The Regulations Relating to Foodstuffs for Infants and Young Children [R991] [The Regulations]) in December 2012. The perspectives of health care providers (HCPs) on the Regulations are an important factor to consider as they play a pivotal role in the implementation of such Regulations.

Objective: The study aimed to determine the knowledge, perceptions, behaviours and practices of dietitians in South Africa regarding the Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).

Methodology: A mixed method, cross-sectional design was used; including quantitative data by means of an online survey (n = 282) collected throughout South Africa and qualitative data by means of two focus group discussions (n = 12) collected in KwaZulu-Natal. Study participants were dietitians registered with the Health Professions Council of South Africa (HPCSA).

Results: Dietitians' average knowledge score was 64.8% ± 12.5. Those working in infant and young child feeding (IYCF) had a 5% higher knowledge score. Perceptions on the Regulations were generally positive and supportive. Representatives of designated products were mostly supportive and positive towards the Regulations. The majority of dietitians' practices were compliant with the Regulations. The major barriers to the implementation of the Regulations identified were a lack of awareness among HCPs and the general public and a lack of training for HCPs. The major enablers identified were other breastfeeding promotion initiatives, greater awareness and compliance from industry and awareness creation by the Department of Health (DoH). Knowledge scores were linked to certain perception and practice questions, generally respondents with higher knowledge scores selected more decisive answers. Perceptions and practices seemed to correlate in certain areas; commonly, with more positive perceptions correlating with more compliant practices. The major themes that arose from the focus group discussions included: less knowledge among dietitians and mothers about products controlled under the Regulations, non-compliance of other HCPs, the dietitians' role in supporting and enforcing the Regulations, the discrepancy between practice in private and public sectors and a lack of enforcement.

Conclusion: Dietitians revealed an average knowledge score of 64.8% relating to the Regulations. Perceptions and practices were generally positive and compliant. Higher knowledge scores seemed to be linked to a better ability to practice in accordance with the Regulations and more compliant practices. Many enablers and barriers arose which provided interesting insights into how the Regulations were being

established within the country. There are still gaps that need to be addressed in the regulation of IYCF, South Africa has taken the first step in legislating the WHO Code and should upscale programmes to ensure consistent monitoring and enforcing of the Regulations. Research that evaluates the implementation and determines the impact of legislating the WHO Code is important to strengthen weaknesses and provide insights to policy makers going forwards.

OPSOMMING:

Perspektiewe van Suid-Afrikaanse dieetkundiges aangaande die Regulasies op Voedingstowwe vir Babas en Jong Kinders.

Inleiding: Die onvanpaste bemarking van borsmelk plaasvervangers het ’n negatiewe impak op optimale borsvoedingspraktyke. Die WHO Kode vir die bemarking van borsmelk plaasvervangers is in werking gestel deur die samewerking van verskeie lande om hierdie negatiewe impak te bekamp en borsvoeding te beskerm. Die Wêreld Gesondheids Alliansie (WGA) het die WHO Kode wettig gemaak in 1981 en Suid-Afrika het die wet aangeneem in Desember 2012 naamlik - ‘Die Regulasies op Voedingstowwe vir Babas en Jong Kinders’. Die perspektiewe van gesondheidswerkers aangaande die Regulasies is ’n belangrike faktor om te oorweeg aangesien hulle ’n sleutelrol in die implementasie van die Regulasies speel.

Doelstelling: Die doelwit van hierdie studie was om die kennis, persepsies, gedrag en praktyke van dieetkundiges in Suid-Afrika met betrekking tot die Regulasies op Voedingstowwe vir Babas en Jong Kinders te bepaal.

Metodologie: ’n Gemengde metode, dwars deursnit ontwerp was gebruik. Kwantitatiewe data was ingesamel dwarsdeur Suid-Afrika deur middel van ’n aanlyn opname (n = 282). Kwalitatiewe data is ingesamel in Kwa-Zulu Natal deur middel van twee fokusgroepbesprekings (n = 12). Alle deelnemers was dieetkundiges wat geregistreer is by die ‘Gesondheids Beroepe Raad van Suid-Afrika’ (HPCSA).

Resultate: Dieetkundiges se gemiddelde kennis met betrekking tot die Regulasies was 64.8% ±12.5. Die wat met jong kinder en baba voedingspraktyke werk het ’n 5% hoër kennis gehad. Die algemene gevoel teenoor die Regulasies was positief van aard. Dieetkundiges wat verteenwoordigers was van borsmelk plaasvervanger maatskappye was ook meestal ondersteunend en positief gesind teenoor die Regulasies. Die meerderheid van dieetkundiges se praktyke voldoen aan die Regulasies. Die grootste struikelblokke vir die implementering van die Regulasies is geïdentifiseer as ’n gebrek aan bewustheid onder gesondheidswerkers en die publiek sowel as ’n tekort aan opleidingsgeleenthede. Die belangrikste instaatstellers van die Regulasies was bewusmaking deur die Department van Gesondheid (DoG), borsvoedingsinisiatiewe en groter bewusmaking en aanvaarding van die Regulasies deur alle nywerheidsrolspelers. Daar was ’n positiewe korrelasie tussen positiewe persepsies en praktyke gevind en individue met beter kennis het meer beslissend geantwoord. Die hooftemas wat geïdentifiseer was uit die fokusgroepbesprekings was onderandere – ’n gebrek aan kennis oor die produkte wat deur die Regulasies beskerm word, gesondheidswerkers wat nie die Regulasies toepas in die praktyk nie, die dieetkundige se rol in die ondersteuning en handhawing van die Regulasies, die verskil in praktyke tussen die privaat- en openbare sektore en die handhawing van die Regulasies.

Gevolgtrekking: Dieetkundiges se gemiddelde kennis met betrekking tot die Regulasies was 64.8% ± 12.5 en hul persepsies en praktyke was oor die algemeen positief en voldoende. Dit blyk of beter kennis aangaande die Regulasies lei na beter toepassing van die Regulasies. Daar is verskeie faktore geïdentifiseer wat die suksesvolle implemetering van die WHO Kode in Suid-Afrika verhinder of vergemaklik. Leemtes in

die Regulasies moet oorbrug word deur programme aan te bied wat monitoring en handhawing van die WHO Kode versterk. Navorsing wat die suksesvolle implementering en impak van die Kode evalueer is belangrik om sodoende swakpunte te identifiseer en versterk en insig te verskaf aan beleidmakers.

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CONTRIBUTIONS BY PRINCIPAL RESEARCHER AND FELLOW RESEARCHERS

The principal researcher, Megan Clarke developed the idea and the protocol. The principal researcher planned the study, undertook data collection without a research assistant, captured the data for analyses, analysed the data with the assistance of statistician Dr Carl Lombard, interpreted the data and drafted the thesis. Dr Nelene Koen and Prof Lisanne du Plessis (Supervisors) assisted with protocol idea development, provided input at all stages of the research and revised the protocol and thesis.

LIST OF DEFINITIONS

Bacterial translocation: The passage of viable bacteria from the gastrointestinal tract to extra-intestinal sites; such as, the mesenteric lymph node complex, liver, spleen, kidney and bloodstream.[1]

Breastfeeding: The suckling of the infant or the young child on the mother's breast.[2]

Breast milk: Human milk. Can be obtained by suckling of the infant or young child on the mother's breast or by the expression of milk from the breast.[2]

Breast milk substitute: Also called 'formula' or 'replacement'. Any food marketed or otherwise represented as a partial or total replacement of breast milk, whether or not suitable for that purpose.[3]

Complementary food: Any foodstuff, whether in liquid, solid or semi-solid form, given to an infant from the age of six months as part of the transitional process during which an infant learns to eat food appropriate for their developmental stage while continuing to breastfeed or be fed with an appropriate formula.[2]

Department of Health (DoH): The executive department of the South African government which is assigned to health matters.[4]

Designated product: An infant formula, a follow-up formula, an infant or follow-up formula for special dietary management for infants with specific medical conditions, complementary foods, liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants or young children, feeding bottles, teats and feeding cups with spouts, straws or teats and any other products marketed or represented as suitable for feeding infants and young children that the Minister of Health may so designate by notice published in the Government Gazette.[2]

Distributor: A person, corporation or other entity in the public or private sector engaged in the business (whether directly or indirectly), marketing and/or distributing of any designated product – at a wholesale or retail level.[2]

Double burden of malnutrition: Characterised by the co-existence of under-nutrition along with over-nutrition (that is, overweight, obesity or diet-related non-communicable diseases [NCDs]) of individuals, households and populations across the life-course.[5]

Educational material: Any written or audio-visual material intended for the general public; such as, flyers, brochures, books, newspaper articles, video tapes, information from the Internet or other forms, that purport to give guidance on the appropriate use of products for infants and young children.[2]

Exclusive breastfeeding (EBF): The infant receives only breast milk without any other liquids or solids, not even water, except for oral rehydration solution, drops or syrups of vitamins, minerals or medicines.[6]

Feeding bottle: A device with an artificial teat, which is used to feed infants or young children.[2]

Feeding cup: A cup with an artificial teat, spout or straws which is used to feed infants or young children.[2]

Follow-up formula: A product formulated industrially according to the composition of which is based on the applicable Codex Alimentarius standard and marketed or otherwise represented as suitable for an infant from six months on or a young child.[2]

Gift: Something given free of charge. In this context includes, but is not limited to, free samples of designated products, meals and refreshments, diaries, stationary, calendars, cot tags, stickers, growth charts, prescription pads, tongue depressors, or any item of whatever value by manufacturers, distributors, retailers and their representatives of the designated products.[2]

Graphic representation: 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 or animals and/or flowers, among others.[2]

Gut permeability: Also called 'intestinal permeability'. The capacity of the mucosal surface of the intestine to be penetrated by specific substances through unmediated diffusion.[7]

Health care providers (HCPs): Any person providing health services and/or social services in terms of any law, including in terms of the Allied Health Professions Act, 1982 (Act No.63 of 1982), Health Professions Act, 1974 (Act No.56 of 1974), Nursing Act, 1978 (Act No.53 of 1974), Pharmacy Act, 1974 (Act No.53 of 1974), and Dental Technicians Act, 1978 (Act No.19 of 1979).[2]

Infant formula: A formulated product specially manufactured in accordance with the applicable Codex Alimentarius standard to satisfy (by itself) the nutritional requirements of infants during the first months of life up to the introduction of appropriate complementary feeding.[2]

Infant: A person not more than 12 months of age.[2]

Infant and young child feeding (IYCF): The act of giving food[8] to a person from birth to 12 months of age or older than 12 months but younger than five years.[9] The term refers to feeding practices which directly affect the nutritional status of children and, ultimately, impact child survival.[10]

Infant and young child nutrition (IYCN): The nutrition of infants (0 to 12 months) and young children (12 months to five years.)[9] Nutrition is the intake of food, considered in relation to the body's dietary needs. Good nutrition (that is, an adequate, well balanced diet combined with regular physical activity) is a cornerstone of good health. Poor nutrition can lead to reduced immunity, increased susceptibility to disease, impaired physical and mental development as well as reduced productivity.[11]

Label: Any tag, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed, impressed on or attached to a container of any designated product within the scope of the Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).[2]

LinkedIn: A social networking site designed specifically for the business community.[12]

Manufacturer: A person, corporation or other entity engaged in the business of manufacturing; such as, production, preparation, processing, preservation or any other manufacturing process of a designated product, whether directly, through an agent or through a person controlled by or under an agreement with such a person, corporation or other entity.[2]

Marketing: Promoting, distributing, selling or advertising of a designated product; includes, product public relations and information services, including the use of professional service representatives, or any person acting on behalf of a manufacturer or distributor.[2]

Medicinal claim: A claim which states or implies that a product has the property of treating, preventing or curing human disease. In order to be permitted to make a medicinal claim, a product must be classed as a 'medicine' in accordance with the definition in Section 1 of the Medicines and Related Substances Act, 1965 (Act No.101 of 1965).[2]

Mixed feeding: An infant younger than six months of age is given other liquids and/or foods together with breast milk. This could be water, other types of milk or any type of solid food.[6] In the literature, the term 'mixed feeding' is also sometimes referred to as 'partial breastfeeding'.[13]

Non-communicable diseases (NCDs): A medical condition or disease that is by definition non-infectious and non-transmissible among people. Currently, these are the leading causes of death and disease worldwide. The four main types of NCDs include: (1) cardiovascular disease, (2) cancer, (3) chronic lung disease and (4) diabetes.[14]

Nutrient content claim: A claim that describes the level of a nutrient or energy contained in a foodstuff.[2]

Nutrition claim: Any representation that refers to a specific nutrient or food constituent content of a particular foodstuff; such as, but not limited to, nutrient content or comparative claim. The following do not constitute nutrition claims: the mention of substances in the list of ingredients, the mention of nutrients as a mandatory part of nutrition labelling, quantitative or qualitative declaration of certain nutrients or ingredients on the label if required by national legislation.[2]

Nutrition labelling: The section of information on the food label that declares nutrient content is termed 'nutrition labelling'. This may also be referred to as 'nutrition panel', 'nutrition facts' or 'nutrition facts panel.'[15]

Private sector: The part of the national economy that is not under direct state control and is run by individuals and companies for profit. The private sector encompasses all for-profit businesses that are not owned or operated by the government.[16] In this context, referring to dietitians who are not working for the state.

Public sector: The part of a country's economy which is controlled or supported financially by the government[17] and provides various government services. The composition of the public sector varies by country, but in most countries the public sector includes health care.[18] In this context, referring to dietitians who are working for the government and employed by the DoH.

Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations): Published regulations under the Foodstuffs, Cosmetics and Disinfectants Act of 1972. In terms of these regulations, a number of restrictions are placed on the labelling, advertising and promoting of infant and follow-up formulae, liquid or powdered milk marketed as being suitable for infants or young children, complementary foods, feeding bottles, teats and feeding cups with spouts, straws or teats.[2]

Sample: Any quantity of a designated product provided at no cost.[2]

Sponsorship: Any financial or in-kind assistance to a person, group or activity, alone or with others, and 'sponsor' has a corresponding meaning.[2]

SurveyMonkey®: An online survey software facilitating the creation and distribution of online surveys.[19]

Teat: A device for an infant or young child to suck on which is used to feed from a bottle, feeding cup or other feeding device.[2]

Technical scientific material: Any material containing technical and/or proven scientific data about designated products or related to knowledge of nutrition, intended for health care personnel.[2]

The Baby Friendly Hospital Initiative: A worldwide programme launched by the WHO and the United Nations International Children's Fund (UNICEF) in 1991, following the Innocenti Declaration of 1990. The initiative is a global effort to implement practices that protect, promote and support breastfeeding.[20]

The Innocenti Declaration: The Innocenti Declaration was produced and adopted by participants at the WHO and UNICEF policymakers' meeting on "Breastfeeding in the 1990s: A global initiative", co-sponsored by the United States Agency for International Development (USAID) and the Swedish International Development Cooperation [*sic*] Agency (Sida) held at the Ospedale degli Innocenti, Florence, Italy, on 30 July to 1 August 1990. The Declaration reflects the content of the original background document for the meeting and the views expressed in group and plenary sessions.[21]

The International Code of Marketing of Breast-milk Substitutes: Also known as the 'WHO Code'. An international health policy framework for breastfeeding promotion adopted by the WHA of the WHO in 1981.[22] The Code was developed as a global public health strategy and recommends restrictions on the marketing of BMS, such as infant formula, to ensure that mothers are not discouraged from breastfeeding and that substitutes are used safely if needed. The Code also covers ethical considerations and regulations for the marketing of feeding bottles and teats. A number of subsequent WHA resolutions have further clarified or extended certain provisions of the Code.[23,24]

The Tshwane Declaration: A declaration in support of breastfeeding, made by the members of the national breastfeeding consultative meeting at the St George Hotel in Gauteng on 22 to 23 August 2011.[25]

Tie-in-sales: The sale of any designated product that is linked to the purchase of any other product including any designated product.[2]

TRUSTe: A privacy certification standard that provides consumer protections and establishes privacy standards.[26]

Young child: In this context, a child older than 12 months but younger than the age of 36 months (that is, three years).[2]

LIST OF ABBREVIATIONS

ADSA: Association for Dietetics in South Africa

BHF: Board of Healthcare Funders

BMS: Breast milk substitutes

DoH: Department of Health

EBF: Exclusive breastfeeding

FOP: Front of pack

HIV: Human immunodeficiency virus

HPCSA: Health Professions Council of South Africa

IYCF: Infant and Young Child Feeding

IYCN: Infant and Young Child Nutrition

MBFI: Mother Baby Friendly Initiative

SANHANES: South African National Health and Nutrition Examination Survey

UNICEF: United Nations International Children's Fund

WHA: World Health Assembly

WHO: World Health Organization

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Chapter 1: Introduction

On the 6th of December 2012, the South African DoH adopted 'The Regulations relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).' These Regulations legislate the WHO's 'International Code of Marketing of BMS' adopted in 1981. Such regulations aim to protect caregivers from the harmful marketing of BMS as well as follow on or growing up milks and complementary foods intended for young children. Currently, it is unclear what impact the passing of the Regulations had in South Africa and how the Regulations have been integrated within health care systems and the country since adoption. HCPs' perspectives on the Regulations are valuable as they have an essential role in the implementation of such legislation. Research that evaluates HCPs' perspectives can make a valuable contribution to enhance strategies to promote implementation of the Regulations.

1.1 Study aim and objectives

1.1.1 Research question

What are South African dietitians' perspectives on the South African Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)?

1.1.2 Main aim

To determine the knowledge, perceptions*, behaviours and practices of dietitians in South Africa regarding the South African Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).

* At the outset of the research, it was believed that attitude, rather than perception, was being measured. However, recent insight has found that attitude is a complex construct composed of many variables and usually measured quantitatively with an attitude scale. Attitudes have traditionally been measured with the use of Likert Scales, but the weaknesses of this method are being increasingly realised.[27] Beck and Rose[28] looked at the introduction of a Best-Worst Measurement Scale to replace the Likert Scale, which is less reliable for testing people's attitudes. 'Attitude' is defined as the way a person views something or tends to behave towards it, often in an evaluative way.[29] 'Perception' is defined as insight or intuition gained by perceiving.[30] Thus, it was decided that the term 'perceptions' was more appropriate to describe what was actually measured and this term is used consistently throughout the remainder of the thesis (excluding the materials that were developed prior to this realisation, which mostly relate to the addenda).

1.1.3 Main objectives

- To determine the **knowledge** and understanding of dietitians relating to products covered under the Regulations, general labelling requirements of designated products, required nutritional information on labels and promotional material directed at HCPs.
- To determine the **perceptions** of dietitians on the acceptance of the Regulations, the importance, relevance, practicality and responsibilities of HCPs as related to the Regulations.

- To determine the **behaviours** and **practices** of dietitians in terms of implementation and use of the Regulations in the workplace, educating clients on labels, relationship with company representatives and responses to violations of the Regulations.
- To determine the **barriers** faced by dietitians relating to challenges experienced with the Regulations; for example, violations, lodging of complaints, enforcement, support and promotion-related matters (such as, research grants, financial contributions, sponsorship and restrictions placed on product representatives.)
- To determine the **enablers** experienced by dietitians relating to communication from the DoH, support, co-operation from product manufacturers and representatives as well as positive outcomes experienced.

1.1.4 Secondary objectives

- To determine the differences in level of knowledge according to various sub-groups. The sub-groups included: level of awareness of the Regulations, gender, age, residing province, category of practice, type of work performed and work experience.
- To investigate associations between knowledge, perceptions, behaviours and practices. Knowledge scores were compared to each individual answer in the perceptions and practice sections to determine any difference in knowledge level according to specific perceptions or practice variables. Knowledge scores were compared to the total number of barriers and enablers listed to determine if the amount of barriers or enablers selected were related to knowledge. Knowledge scores were also compared to each individual barrier or enabler to determine if the selection of certain choices were related to knowledge.

  In order to investigate associations between perceptions, practices, barriers and enablers it was decided to choose three key perception questions and three key practice questions to make this feasible. The reasoning behind the choice of questions is outlined under the Methods section. The key perceptions and practices questions were then compared to each other and each individual enabler and barrier to determine any associations.

1.2 Thesis outline

The thesis is composed of five main chapters and is structured according to the article format. References are included in Chapter six and the addenda in Chapter seven.

Chapter 1: Introduction

This chapter introduces the study topic, outlines the study aims and objectives and provides an overview of the thesis structure.

Chapter 2: Literature review

The literature review outlines the current breastfeeding climate in South Africa and globally. It explores the need for regulations to restrict the marketing of BMS and divulges the role that HCPs have to play in the success of such regulations. The review also touches on consumer perceptions of labelling and how this relates to the regulation of foodstuffs.

Chapter 3: Methods

This chapter defines the study type and sample population, and details the process followed throughout the research study. The Methods chapter includes the data collection process and analyses, statistical analysis and ethical considerations. It was decided to include a Methods chapter even though this is summarised in the article to elaborate on the process in more detail and explain each step of the research fully.

Chapter 4: Article

Title: Perspectives from South African dietitians on IYCF Regulations

Author contributions:

- Megan Clarke: Principle researcher
- Dr Nelene Koen: Supervisor
- Prof Lisanne du Plessis: Co-supervisor
- Dr Carl Lombard: Statistician

The article format was chosen to facilitate submission of the research for publication purposes. The article is written according to the submission format for the *Maternal & Child Nutrition* journal as it is intended that the article will be submitted to this journal for publishing. It was decided to write only one article to increase the impact of the findings and to tie the results of the survey and focus group discussions together.

Chapter 5: Conclusion

This chapter highlights the main findings of the research and draws the results from the survey and focus groups together. The chapter includes a summary of findings, limitations, recommendations and final concluding remarks. The recommendations include those that arose from participants' suggestions and the researcher's recommendations based on the findings.

Chapter 2: Literature review

2.1 Introduction

The literature review aims to provide a motivation for the research study as well as outline important background information relative to the topic and acclimatise the reader to the situation in which this research has relevance. IYCF is an important topic on the health and development agenda worldwide.[31] Specifically, breastfeeding has received a lot of attention in recent decades as a vital practice to support and achieve better health outcomes in infants and young children.[9,13,21,22,25] Many countries have started to adopt policies and legislation to improve IYCF practices and support breastfeeding. In line with this, it has been recognised for many decades that the inappropriate marketing of BMS is a stumbling block to achieve satisfactory breastfeeding rates[22] and countries have begun to adopt legislation to control the marketing of these products – South Africa included.[2,32,33] The literature review that follows explores the current situation both worldwide and in South Africa that has specifically led to the publishing of legislation to curb the inappropriate promotion of BMS and the significance of this event. Since HCPs have an important role to play when supporting and implementing the new policies[13,34,35] their role is also explored with the view to clarify the reasons behind the chosen research topic.

2.2 IYCF: Globally and in South Africa

2.2.1 Global recommendations for IYCF

Breastfeeding has long been recognised as a strategy to improve IYCN and a vital element to achieve decreased morbidity and mortality in infants and young children.[21,31] The recommendation by the WHO is for all mothers to breastfeed exclusively for the first six months and up to two years and beyond, with the addition of appropriate complementary foods from six months. In the past, Human Immunodeficiency Virus (HIV) positive mothers were first advised to avoid breastfeeding completely, then the recommendation changed to breastfeed exclusively only until 6 months and later to continue breastfeeding for up to one year. Since the revised HIV and infant feeding guidelines were released by the WHO in 2016, there is now one unified message (regardless of HIV status) to breastfeed for up to two years, which may help to reduce confusion regarding the ideal duration of breastfeeding.[6] Breastfeeding provides optimal nutrition for infants and young children and supports ideal growth and development.[36] In countries with high levels of malnutrition, the link between breastfeeding and improved nutritional status is significant.

2.2.2 The nutritional status of infants and young children

Undernutrition is a concern both worldwide and in South Africa. Globally, undernutrition is a contributing factor in over a third of deaths in children under five years.[37] In 2016, it was found that 155 million children worldwide were chronically malnourished.[38] According to the South Africa Demographic and Health Survey (SADHS) published in 2016, in children under five years old the prevalence of stunting and severe stunting is at 27.4% and 9.8%, wasting and severe wasting at 2.5% and 0.6% and underweight and severe underweight

at 5.9% and 1.1%.[39] In comparison with the South African National Health and Nutrition Examination Survey (SANHANES)[40] published in 2013, indices for wasting and underweight have remained more or less the same whereas indices for stunting and severe stunting have increased dramatically from 15.4% and 3.8% respectively. Although this difference may be partially explained by the different age groups included in the SADHS (0 to five years) and SANHANES (0 to 14 years) and bearing in mind the limitation in comparing data from cross-sectional studies, it is clear that chronic malnutrition reflected as stunting is a major public health nutrition problem.[41] Stunting has been linked to poor brain development, less productivity, poorer school achievements, lower wages, altered physical development and a higher risk of poor health in general; notably, the development of cardio-metabolic disease.[42]

There has been a decline in the rates of exclusive breastfeeding (EBF) in many regions of the world since 1974.[22] According to a fact sheet on IYCF by the WHO[43], worldwide about 40% of infants under six months are exclusively breastfed. It is estimated that more than 820 000 lives in children under five years could be saved every year if all children from 0 to 23 months were breastfed optimally.[43] It is expected that factors related to nutrition contribute to about 45% of deaths in children younger than five years, and most deaths are due to poor nutrition.[44]

The current EBF rate in South Africa is at 32% for infants under six months[39]; this is lower than the target of 50%.[45] However, it is an improvement from the former rate of 7% reported in the SADHS in 1998[46] and the 8% measured in 2012 in the SANHANES study.[40] The number of children who are exclusively breastfed decreases with increasing age. Forty four percent (that is, 44%) of infants from 0 to one month versus 24% of infants from four to five months are exclusively breastfed. South Africa's infant mortality rate is at 35 per 1 000 live births (or 3.5%).[39] This indicator is an improvement on the 2010 statistic of 41 per 1 000 live births (or 4.1%).[47] While it is encouraging to see a decrease in infant mortality alongside an increase in breastfeeding rates there is still much work to be done to achieve the WHA global target of 50% of infants from 0 to six months exclusively breastfeeding.[45] The lower than ideal breastfeeding rates in South Africa are still a cause for concern due to the high prevalence of malnutrition and infant and child mortality in the country.[36]

Despite the relatively high levels of undernourished children[44], countries of middle and low incomes are experiencing an increase in children that are overweight and obese.[5] Globally, approximately 41 million children under five years are overweight or obese.[38] In South Africa, 13.3% of children under five are overweight, which is more than double the global average of 6.1%.[39] The number of adults that are overweight and obese is similarly a growing concern in the country, according to the SADHS of 2016, 67.7% of adult women and 31.3% of men are overweight or obese.[48] Together with the rise in obesity, there has been a concurrent rise in chronic diseases. Diabetes was the second most prominent underlying cause of death in South Africa in 2015, based on statistics collected by Statistics South Africa (Stats SA).[49] Nine and a

half percent (that is, 9.5%) of adults over the age of 15 are affected by diabetes in South Africa.[40] Hypertension prevalence is also high in South Africa with 46% of women and 44% of men over 15 years being affected.[48] Dyslipidaemia is a further chronic disease on the rise. A high total cholesterol is present in one in four adults (23.9%), 28.8% of adults have high low-density lipoprotein cholesterol (LDL-C) (also known as 'bad' cholesterol), and one in two (47.9%) have low high-density lipoprotein cholesterol (HDL-C) (also known as 'good' cholesterol).[40] Considering the high levels of both under- and over-nutrition it is important to identify strategies and interventions that may be able to address both simultaneously.

2.2.3 The impact of breastfeeding in addressing the double burden of malnutrition

The double burden of malnutrition is a growing concern in many countries, including South Africa. This double burden is characterised by the simultaneous occurrence of undernutrition with overweight and obesity or chronic disease of lifestyle within individual people, households as well as populations throughout the life cycle. The nutrition transition has been identified as the main causal factor for the double burden of malnutrition. According to the WHO[5]:

> The nutrition transition describes the shift in dietary patterns, consumption and energy expenditure associated with economic development over time, often in the context of globalization [*sic*] and urbanization [*sic*]. This change is associated with a shift from a predominance of undernutrition in populations to higher rates of overweight, obesity and NCDs.

Environmental factors that influence the double burden of malnutrition include the urban and built environment, trade and trade policy and food supply and systems.[5]

Breastfeeding is an important practice to assist in addressing the double burden of malnutrition as it provides protection against undernutrition, overweight, obesity and chronic diseases of lifestyle. Breastfeeding holds benefits for both mother and baby. The nutrition received during the early stages of life has been found to impact the immune system, brain development and the balance between energy use and expenditure, as well as the storage of fat in the body.[50] Breast milk protects infants against both infectious and chronic diseases.[51–54] Breastfeeding decreases infant mortality as a result of its protective role against frequently occurring childhood illnesses (such as gastrointestinal infections)[55–57] infectious diseases,[58] respiratory infections and pneumonia.[50, 54] Breastmilk also enhances recovery from illness in infants.[60–63]

The benefits of breastfeeding (for both mother and baby) increase the longer the duration of breastfeeding. When breastfeeding is practiced exclusively for the first six months, the benefits are enhanced for the infant.[64] In addition, breastfeeding has also been linked to a reduced risk of chronic diseases for the baby later in life; including obesity[60–62], hypertension, dyslipidaemia and type 2 diabetes.[62, 63] For mothers, breastfeeding has been linked to a lower risk of retaining the weight gained during pregnancy, the metabolic syndrome, type 2 diabetes and heart attack.[69] In South Africa, where the

burden of chronic disease risk factors is high[70], breastfeeding is an important strategy to prevent these NCDs.[36]

In countries experiencing the double burden of malnutrition it is imperative to support initiatives that address both under- and over-nutrition; such as, the protection, promotion and support of breastfeeding, while at the same time discouraging practices which may contribute to under- and over-nutrition, such as the inappropriate use of BMS or complementary foods.

2.2.4 The potential impact of incorrect use of BMS and complementary foods

While replacement feeding is necessary is some cases, the potential dangers and disadvantages of its use are often overlooked. Formula feeding has been linked to an increased risk of diarrhoea[71] due to contamination of foods with microbes as well as the use of unhygienic feeding apparatus[72] and unsafe water sources. A meta-analysis including 18 developing countries found that in the first five months of life, the relative risk of dying from diarrhoea was 10.52 higher (95% CI 2.79 to 39.6*)* in infants given BMS compared with those who were exclusively or mainly breastfed.[71] Some urban areas do not have sufficient water and sanitation structures in place which creates a higher risk of diseases originating from unclean water and subsequent malnutrition.[73] During a hearing on the promotion and use of infant formula in developing countries held in 1978 in the USA, concerns were raised that formula feeding would not be feasible in areas without access to clean water, sanitation, adequate finances and literacy – most of which are not present in many areas of developing countries.[71]

Mixed feeding; that is, providing infants with breast milk as well as other fluids (including formula, water, tea or juice) or solids before six months, has also been highlighted as a concern in the African and South African context.[13,74,75] Semi-solid foods are commonly introduced before the age of four months.[74] These practices are of concern because mixed feeding is related to early cessation of breastfeeding as it interferes with the hormonal response between stimulation of the breast and supply of breast milk. When solids and liquids other than breast milk are introduced too early to an infant; that is, before six months when the gut of the infant is still immature, this increases the risk of persistent gut permeability, bacterial translocation and illnesses such as diarrhoea.[76] The first solids introduced are often of low nutrient density which compromises the nutritional status of infants.[74]

Further concerns brought about by poor complementary feeding practices are overweight, obesity and stunting. Likewise, energy dense nutrient poor snack foods are a concern for both overweight and underweight children. Overconsumption of these products can exacerbate overweight in children and the replacement of more nutrient dense foods for these products may worsen undernutrition in children. The promotion of commercially-produced snack foods for young children needs to be restricted so that the intake of more wholesome and nutritious food is encouraged.[77] Inappropriate complementary feeding practices can largely be attributed to cultural practices, inadequate knowledge of caregivers and confusing

health messages.[74] It is also notable, that the use of traditional or family foods alone to meet the micro-nutrient needs of young children from six to 24 months is difficult without the inclusion of animal-source foods, which are often not available or affordable.[78]

The increase in the use of BMS and less than optimal foods for complementary feeding can be partially attributed to the marketing of these products for IYCF. It was recognised at the 27th WHA in 1974 that one of the reasons for the decrease in breastfeeding was due to inappropriate practices of advertising formula feeds.[22] There has been slow progress in many developing countries in the past 20 years in improving the overall rates of EBF. However, those countries that have demonstrated a commitment to improving IYCF have made notable improvement in EBF rates.[79] One such commitment, being the implementation of legislation on the WHO Code.

2.3 A brief history leading up to Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)

The WHA has acknowledged the need to evaluate promotional activities of BMS and related products since 1974.[80] Subsequent global efforts have included: the Geneva Conference in 1979 where delegates from various sectors convened to address IYCF; the adoption of the International Code of Marketing of Breast-milk Substitutes (WHO Code) in May 1981 to guide the appropriate marketing and distribution of these products[22]; the Innocenti Declaration in 1990 calling for world action to support, protect and promote breastfeeding[21] and the launch of the Baby Friendly Hospital initiative (now the Mother Baby Friendly Initiative [MBFI]) in 1991 based on the WHO's 'Ten steps to successful breastfeeding.'[20]

The WHO Code was the founding document in the plight to control the marketing of BMS and products for infants and young children that undermine the support and protection of breastfeeding. It consists of an introduction to the current situation and an explanation for why such a code is necessary, a brief explanation of the procedure by which the WHO Code was drawn up, key points that member states recognise as necessary in achieving optimal nutrition for all infants and young children and 11 articles that recommend a basis for action to control marketing practices of IYCF products. The articles include the aim and scope of the WHO Code, definitions, information and education, the general public and mothers, health care systems and health workers, people employed by companies that manufacture and distribute BMS, labelling and quality of products and implementation and monitoring. WHA member states were encouraged to adopt the contents of the WHO Code into national legislation.[22] One hundred and ninety seven (that is, 197) countries adopted the WHO Code in 1981, but few have legalised the content.[33] Without legislation the WHO Code is not binding, which presents challenges with implementation.

Taylor[81] examined four countries (including South Africa) and found that 16 years after the WHO Code was adopted, violations continued to take place. It was found that mothers were still receiving free samples of

BMS and healthcare workers were receiving gifts and information that violated the WHO Code. Without commitment to implementation and monitoring of the WHO Code on a national level, there was not much chance of protecting breastfeeding mothers from the aggressive marketing of BMS. Sobel et al.[82] (using a qualitative study in the Philippines) found that mothers who had been subjected to advertising messages by formula companies and those who had been recommended to use formula by a HCP or family member were more likely to formula feed their children. It was found that in 2013 in Cambodia, 86% of mothers had seen commercial promotions for BMS even though a sub-decree had been passed to regulate the promotion of commercial infant and young child products in 2005. Nineteen percent (that is, 19%) reported that they had seen IYCF branding or logos on health care facility equipment and 18.4% of mothers had received a recommendation from a HCP to use a BMS. Mothers who were given BMS as pre-lacteal feeds were 3.9 times more likely to be formula feeding at the time of the study.[83]

Multiple reports of violations have been made in various countries.[84,85] Studies conducted in Turkey[86] and West Africa[87] reported violations of the WHO Code and at the time Turkey had legislated some of the provisions of the WHO Code.[33] In West Africa, it was found that the levels of violations taking place were similar in a country with legislation and a country without.[87] Research conducted in stores in Cambodia, Nepal, Senegal and Tanzania found that point of sale promotion of BMS occurred less in countries that had made this aspect of the WHO Code into law. However, there was still a small amount of point of sale promotion taking place in countries where this is prohibited.[88] This suggests that legislation alone is not effective in ensuring the WHO Code is implemented. In places that have less BMS available, such as Kathmandu in Nepal and Dar es Salam in Tanzania, there is a lower usage of these products.[88] This suggests that control of the amount and type of products on the market may also have an influence on caregivers' feeding choices for infants and young children.

HCPs need to be aware of and support legislation surrounding IYCF if it is to be effective. In Pakistan, Salasibew et al.[89] looked at the awareness among HCPs after the WHO Code was adopted into national legislation. It was found that the majority of those interviewed did not know about the breastfeeding law or the WHO Code. Those with more experience were found to have greater awareness of the legislation. It was also found that gifts, sponsorships and free samples were still being given – clear violations of the WHO Code more than five years after it was adopted into law. It is recommended that HCPs should have a good understanding of the WHO Code and take on the role of recognising inappropriate promotional practices and reporting violations to the relevant authorities. In doing so, they can contribute to eliminating these undesirable practices in their environments in order to improve child survival in the long-term.[71,82,85,90]

In the South African context, Sweet et al.[72] looked at field-testing a set of draft guidelines to guide appropriate labelling of complementary foods for infants and young children in South Africa. Many of the components in the Regulations, when they were gazetted, were similar to the contents of the draft

guidance; for example, the inclusion of appropriate local languages on the product labels. Analysis of complementary product labels in South Africa illustrated that none of the labels complied with all checklist criteria. It was recommended that making such draft guidelines official would help governments to develop laws to guide the appropriate labelling of food products for infants and young children.[72]

Prior to the legislation of the WHO Code, the South African Code of Ethics for the Marketing of BMS was developed in 1986 by the DoH and representatives from industry. The South African Code was based on the WHO Code and was voluntary. It did not include article 11 of the WHO Code, which provides guidelines for implementation and monitoring, and thus could not be enforced. The Regulations relating to Foodstuffs for Infants and Young Children (R991) (The Regulations) evolved over a number of years; the first draft was published in 2003 and extensive amendments were recommended which resulted in the document being published for comment a second time. By 2007, many comments had been received but the process was put on hold as a result of the upcoming publication of the South African Regulations Relating to Labelling and Advertising of Foodstuffs (R146) in 2010.[91] In 2011, the Tshwane declaration was announced; indicating the country's support for breastfeeding.[25] It was an important turning point for the country including decisions, among others, to: adopt the WHO 2010 HIV and infant feeding guideline[92] encouraging EBF in HIV positive mothers; to stop uniformly issuing free formula milk at public health institutions as part of the 'Prevention of Mother to Child Transmission' programme; and that the WHO Code be finalised and adopted into legislation within 12 months.[25,34] The declaration recognised that the protection, support and promotion of breastfeeding required collaboration of many role players, including government and legislators, healthcare workers and managers. The formulation of policies and guidelines, such as the WHO Code[22] to support breastfeeding was also identified as a crucial aspect in the process.[43] In 2012, the third draft of the Regulations was published, 63 sets of comments were received and the final draft was gazetted on 6 December 2012.[91]

2.4 The South African Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)

South Africa passed its own legislation in response to the call for action to upscale programmes to support and promote breastfeeding. On 6 December 2012, the DoH published the Regulations[2] under the Foodstuffs, Cosmetics and Disinfectants Act of 1972.[93] The publishing of the Regulations adds South Africa to the list of 39 countries who have adopted most or all of the WHO Code stipulations into law.[94] The Regulations place a number of limitations on the labelling and advertising of infant and follow-up formulae and products intended for use by young children that may be a complete or partial replacement for breastmilk, as well as bottles, cups with spouts and teats. These products are termed 'designated products'.[2] The Regulations support breastfeeding as the best feeding option for infants and safeguards

caregivers and HCPs from unsuitable marketing of BMS and products intended for young children. The Regulations are in line with the WHO Code and WHA resolutions.[75]

The Regulations stipulate the wording to be used on food labels and dictate what information must be included in the labelling of designated products. Definitions of all products and terms covered under the Regulations are provided in the document. Promotional practices of designated products such as gifts, discounts and tie-in sales are prohibited. It sets specifications and restrictions on the general labelling and packaging of designated products, disallows graphic representations on products other than those necessary for correct preparation, and sets out the minimum nutritional information that should appear on the labels. Many of the aspects of nutrition labelling that are perceived as challenges by consumers are addressed in the Regulations; for example, small font size. The Regulations stipulate the ingredients that may or may not be added to foodstuffs for infants and young children, it sets the minimum font sizes and compulsory health messages to be displayed regarding the superiority of breastmilk and the dangers of formula feeding, restrictions are also placed on nutritional and medicinal claims on labels. The Regulations clarify that a minimum number of languages and age ranges must be included in the labelling. Contact between product representatives and HCPs, distribution of educational material, financial contributions or sponsorship by product companies, and restriction of the promotion of designated products in health care establishments are also controlled under the Regulations.[2]

The Regulations cover all of the provisions of the WHO Code, which is a commendable achievement since other countries that have enacted legislation surrounding the WHO Code have neglected to include many key provisions. According to the National Implementation of the International Code Status Report 2016[94] which included analysis of 194 countries – 39 countries have laws that incorporate all or most of the WHO Code stipulations and a further 135 countries have some form of legislation in place related to the WHO Code. This is an improvement on the 103 countries in 2011 when the previous analysis was carried out. The type of legislation enacted varies widely throughout the world. Only 38% of countries specifically cover products for children over one year, 58% of countries prohibit advertising of products covered under the WHO Code, and nutrition and health claims on product labels are only prohibited in 40% of countries.[94]

Since the Regulations were passed, only one amendment has been made, Amendment (R591)[95] was gazetted in July 2015 which clarified some of the R991 Regulations' definitions, amended certain compulsory messages on the product labels, added sub-regulations to the section on ready-to-use liquid formulae, specified that all designated products need to have a date marking which guarantees a product's safety and nutritional content, provided clarity on areas that may have been wrongly interpreted, added a section on distribution of free or low cost supplies of complementary foods, deleted Regulation 12 and 13 which related to the lodging of complaints and inspection, extended the deadlines by which to comply with the R991 Regulations and updated the annexure on nutrient reference values for infants and young

children. The deletion of Regulation 12 is concerning as currently there is no means of enforcing the Regulations. The main areas of the Regulations that require strengthening are the establishment of a strong and maintainable monitoring system to ensure enforcement and increased collaboration from other relevant sectors.[94]

The Regulations are aimed at protecting the consumer from harmful marketing of IYCF products and ensuring that food labels are adequate and provide sufficient information to enable the consumer to use the product safely. As such, it is useful to investigate consumer's perceptions of labels.

2.5 Consumers' perceptions and use of food labels

Consumers obtain information about foods from many sources. Nutrition labelling of foods is one of the main sources of nutritional information for consumers. There is growing evidence on how useful food and nutrition labelling can be as an educational tool for buyers.[96] Van der Merwe et al.[97] define 'food labels' as including information on ingredients, nutritional content, nutrition and health claims, expiry date, manufacturer, country of origin, safe preparation and storage instructions, product weight and the brand name or logo of the manufacturer. Nutrition labelling specifically refers to the section of information on the food label that declares nutrient content.[15] In some countries, this might be referred to as 'the nutrition information panel'[98] or nutrition facts label.[99] In South Africa, it is more commonly known as the 'nutrition information table'. The Regulations relating to the labelling and advertising of foodstuffs (R146)[100] define a 'label' as "any tag, brand, mark, pictorial, graphic or other descriptive matter, which is written, printed, stencilled, marked, embossed, impressed upon, or permanently attached to a container of a foodstuff, and includes labelling for the purpose of promoting its sale or disposal". Many countries are starting to adopt compulsory nutrition labelling with developed countries leading the way.[101] South Africa has food labelling legislation in place and various regulations on nutrition labelling that have been adapted over time. South Africa strives to adopt regulations that are consistent with the Codex Alimentarius which was established in 1963; that is a set of international food standards, guidelines and codes of practice that assist in regulating the international food trade in terms of safety, quality and fairness.[102]

The first important food-labelling related legislation for South Africa was the Foodstuffs, Cosmetics and Disinfectants Act of 1972[93]; since then, various food labelling regulations have been published under the Act. The South African Regulations Relating to Labelling and Advertising of Foodstuffs (R146) were passed in 2010. The main objective of these regulations is to regulate misleading labelling of foodstuffs and advertising and to encourage healthier food choices among consumers through better labelling.[103] These regulations only came into effect in March 2012 and were intended to act as interim legislation until a more complete and permanent regulation was formed.[104] Two amendments have since been made to R146 in November 2010 and January 2012.[105,106] The R991 Regulations were passed in December 2012 as mentioned in the section above.[2] Thereafter, the Regulations Relating to the Labelling and Advertising of

Foods: Amendment (R 429) was published in May 2014 for comments, which included suggested changes to R146 such as compulsory nutrition information labels on foods and guidelines for the marketing of foods to children.[107] Currently, this amendment has not yet come into effect.

A fairly large amount of international studies on consumer's perceptions of labels are available. It has been found that specific groups of consumers are more or less likely to use labels. A systematic review by Campos et al.[108] including studies from seven different countries shows that certain groups of people are associated with an increased use of nutrition labels, these include: females, Caucasians, those with healthier eating habits (or those who are more health aware), have more time to shop, have positive attitudes and motivation to use labels, use food labels often, living in larger households and homes with children, higher income, higher education level, nutrition-related health conditions and special dietary needs. In contrast, the groups of people who use labels less often include: people with limited time to shop, those who are children or adolescents, and older adults who are obese.[108]

Consumer's thoughts on labels provide interesting insights. Where self-reported label use was high, consumers perceive nutrition labels to be a reliable source of information and a link has been illustrated between the use of nutrition labels and healthier eating practices, although this is not a consistent finding. When nutritional information is displayed on the front of pack (FOP), this was found to be more effective.[108] Lupton et al.[101] indicate that consumers are less confused by a distinct, consistent and trustworthy FOP labelling system and this approach is more effective.[101]

Legislation on labelling plays a role in improving consumer's understanding thereof. Interventions have shown positive results in improving the knowledge and understanding of nutrition labels[109,110], but nutrition information on labels needs to be presented more clearly, in a consumer-friendly way for better understanding and use.[108] Legislation on labelling is an effective policy tool that can be used by governments for promoting healthy eating and improving the health of the general population.[111] Several countries have already implemented compulsory nutrition labelling legislation. It is recommended that those implementing labelling regulations consider the packaging of products as a whole to gain the most benefit from consumers. The review by Campos et al.[108] concludes that nutrition labels are a low cost implementation that have the ability to reach a large number of consumers, but governments need to monitor details of nutrition labels so that they can be used to make healthier and more knowledgeable food choices.

The labelling of foods intended for children is an especially complex area. An Australian study[98] on IYCF products in particular found that there are many non-essential foods being marketed to children, which are often high in sugar or fat. Health claims on these products cause confusion and may mislead both adult and child buyers. Many different marketing tools are employed to make products seem more appealing to children; such as, bright packaging, pictures of cartoons or images of children, discounts, tie-ins and so on.

Parents have voiced concerns about the use of cartoons or famous characters to advertise products[112,113] and the use of premiums.[112,114] Parents feel that shopping with their children can be stressful due to the children demanding certain food items.[115] Inlight of the above, the WHO have advised member states to implement actions to control the marketing of IYCF products to children.[116] South Africa has made progress in this regard with the R429 amendment to the Regulations relating to the labelling and advertising of foods that proposes guidelines for the marketing of foods to children. This guideline includes (for example) guidelines on: nutrition and health claims on food labels, reference values and standards for nutrient content, claims and endorsements, ingredients and additives.[107]

Cross branding of products has been used as a tool to market to children. In some instances, BMS are promoted discreetly through the promotion of commercially-produced complementary foods with the same branding or produced by the same manufacturer.[88] Branding of products and the use of numbered stages for BMS and complementary foods can lead to confusion and the use of non-age appropriate products for infants and young children.[117] In addition, the wide variety of BMS available in stores may also be a source of confusion among consumers.[88] A study conducted in Illinois, USA by Abrams et al.[99] focused on how consumers perceive FOP labels of products intended for children. It is noted that FOP are an important element to capture the attention of consumers and are often relied upon to make decisions on purchases. Initial impressions of a product often stick.[99] In light of this, it is interesting to note that the Regulations have banned health claims and largely limited FOP visuals on IYCF products.[2] The study found that parents linked aspects on products that would most entice young children as being generally unhealthy choices, such as the association of characters on a package with a high sugar or artificial ingredients content.[99] Children are most drawn to products with characters, bright colours, fun-looking elements and pictures of the food.[118] This is important to note because it has been found that harassment from children and their preferences can influence parents' decisions on what products to buy for them.[119,120]

Parents were easily led to believe that a product was healthier based on healthy FOP images (such as real fruit) or health claims. However, health claims were sometimes found to be confusing or contradictory and a source of scepticism.[99] Health claims and FOP visuals may be misleading to consumers by representing a product in a false way.[121] Harris et al.[122] focused on the packaging of children's cereals and they share a similar view. Parents find symbols, such as The Heart Foundation (USA) tick, is helpful when scrutinising products. Other common themes found were that brand trust is an important aspect when buying. Sometimes, parents adopt an attitude of 'ignorance of bliss' and self-consciousness and social stigma comes into play when buying IYCF products for events where other parents would be present. It is concluded that the food industry needs to have better guidance through regulating how manufacturers should display flavours and ingredients on FOPs so that this is done in a way that helps consumers to make

healthier choices.[99] Harris et al.[122] agree that further regulations on product labels are needed to protect consumers. However, having regulations or legislation in place does not necessarily translate into compliance. A study on commercially-produced complementary foods in four countries in Africa and Asia found that not all products contained an appropriate age range on the label, some products were recommended for use before six months and not many products provided a daily serving. This draws attention to the need to monitor practices of manufacturers to ensure compliance with national regulations.[123]

Studies conducted in South Africa show some similarity to those done internationally. A study undertaken in Potchefstroom by Venter et al.[124] found that consumers base their perceptions on food packaging mainly on functional and physical aspects. Thus, the physical appearance of a product is an important element to gain the consumer's attention when shopping for food products. In the North West in an urban-rural hybrid area, it was found that among those who read labels, consumers mostly have positive attitudes regarding food labels and report the use of labels before purchasing a product.[97]

Another study in Potchefstroom[125] investigated the reasons consumers use food labels. It found that the assessment of nutritional value, personal beliefs, health characteristics and product quality were the main influences. It suggested that while some consumers were motivated to purchase a product by the food label, others do not consider the label of high importance.[125] Jacobs et al.[126] find that the information most commonly used on food labels is the expiry date, list of ingredients and the nutritional content. Labels are most often utilised by educated women of a high socio-economic class. A large study conducted among South African consumers investigated their opinions and use of food labels. The main findings indicate that most respondents agreed that there is a link between food and health and consumers believe health messages on food labels are supported by scientific evidence.[127]

In Cape Town, Koen et al.[128] investigated consumer knowledge and use of food and nutrition labelling and found that only 36% of people read labels frequently, an interesting contrast to Campos et al's[108] finding that nutrition label use was generally high. Although similarly, it was revealed that older people, those of white race, and those with higher education and income levels were more likely to read labels.[108] It was found that knowledge on nutrition labels is fair to below average at 44.4%. The reasons given for not reading labels include always purchasing the same product and a lack of interest in the nutritional information. The authors found that price, expiry date and specials or promotions are the major influences on purchasing behaviour. Consumers want simpler labels that contain more pictures and colour, and a single health endorsement logo would be preferred.[128]

There are certain challenges with the use of food labels. Those that international consumers experienced with the use of nutrition labels relate to a lack of understanding and lack of ability to correctly use them.

Aspects of nutrition labelling that are perceived as challenges include: quantitative information (for example, recommended daily allowance), different formats, small and illegible writing, complex or unfamiliar terms, and a lack of trust in claims and serving sizes. It has been found that consumers prefer simpler labels, graphic information, symbols or images and colour. Many consumers depend on symbols indicating healthier options and health claims when purchasing products, but these are not always standardised, consistent or well regulated.[108]

In South Africa, problems associated with reading food labels include: font size, confusion due to too much information on the label, other attributes of products; such as, price being considered more important, lack of education and knowledge of nutrition content of foods, and time constraints. Habitual purchasing was another reason identified for lack of use of nutrition labels.[127] Consumers do not always understand how to use the information on food labels to make an informed choice on which products to purchase and often view label information as a marketing strategy to sell a product rather than a means to provide nutritional information. External influences, such as food labelling regulation and the manufacturer's role also play a part in the understanding and use of the information on food labels. Currently, FOP labelling is not compulsory or consistent in South Africa.[96] Jacobs et al.[126] state that improvements need to be made to the current food labels in South Africa and highlight a need for consumer education on food labels. It is conceivable that South African consumers may be more vulnerable than consumers in high income Western countries to marketing tactics such as health claims and deceiving FOP visuals due to the high levels of poorly educated persons in the country. South Africa has a high dropout rate after the nine years of compulsory schooling. Of the learners who started school in 2003 and those who matriculated in 2015, only about 45% completed high school. Furthermore, the education standards in South Africa are very poor in general with rural pupils being at a greater disadvantage.[129]

Despite the relatively large amount of international studies available, there are still gaps in certain areas. Limitations of current literature are that many studies are conducted in high income Western countries; thus, the results cannot necessarily be generalised to different cultures, regions or income groups and much of the information is self-reported, so may be subject to overrepporting the use of nutrition labels.[108]

South African studies are also limited in certain areas. Studies on consumers' perceptions of nutrition labels are limited to small samples and geographical areas. No consumer research to date could be identified that has looked at products for infants and young children in South Africa in particular. While it is likely that South African consumers may share some similar perspectives to those of international consumers, more research is needed on consumers' attitudes and understanding of nutrition labels; especially, since South Africa has a diverse population and results from international studies or small studies undertaken in South Africa cannot be generalised to reflect the South African population as a whole. With these limitations in mind, it is worthwhile acknowledging the potential shortcomings with the R991 Regulations in particular.

2.6 Problems experienced with regulation and legislation of foodstuffs for infants and young children

There are often barriers when it comes to acceptance of new guidelines, as can be expected. The main problems that seem to arise from the WHO Code (and as in the case of South Africa, the Regulations legislating the WHO Code) are those of understanding and compliance with the stipulations.[85]

The Regulations have been criticized by some as being unnecessarily restrictive.[130,131] It is inevitable that some mothers will choose to formula feed and when they do, they need to be given counselling on how to correctly prepare and give formula safely.[13] There has been some confusion among HCPs on how they should communicate and maintain an appropriate relationship with formula milk companies and their representatives.[85] This is relevant as HCPs need to receive information from product representatives on designated products in order to stay up to date with current products on the market and be able to inform caregivers appropriately. HCPs may be limited by the amount of information they can offer if they adhere to the Regulations; for example, they will not be able to give advice or indicate preference on different brands or products. HCPs may also have less knowledge on the various products available if the product companies are limited in terms of providing information to HCPs. Manufacturers and distributors of products have the right to give information about their products to consumers and consumers have the right to receive that information. There needs to be a balance between these rights and the importance of supporting, protecting and promoting breastfeeding.[130]

The DoH should be commended for their efforts to make progress on the breastfeeding protection, promotion and support front; however, questions arise about the effectiveness of these Regulations in supporting that aim.[130] Although the passing of the Regulations is a positive step forward, sources have stated that many other factors need to be considered to improve the breastfeeding climate[35,130,132]; such as, supporting breastfeeding mothers in the work environment[35] and improving the knowledge and counselling skills of HCPs.[132] Health professionals should be encouraged not to advise caregivers to give BMS and the use of pre-lacteal feeds in health care facilities is another factor that needs to be curbed.[77] It is suggested by Mills[130] that more efforts need to be directed toward addressing such factors. Some sources have questioned how well authorities will be able to ensure enforcement of the Regulations.[130,131] The resources and budget of the food industry that markets IYCF products far outweighs that of governmental bodies who are burdened with the task of enforcing the Regulations, restricting marketing and promoting healthy behaviours.[132] Globally, the sales of formula milk for 2015 was about 47 billion US dollars.[133] With that in mind, it is clear that the monitoring and enforcement of the Regulations may be a potential stumbling block.

In order to address the issues of monitoring and supporting the WHO Code and related WHA Resolutions that came thereafter, the WHO created the 'Network for Global Monitoring and Support for Implementation of the International Code of Marketing of Breast-milk substitutes' known as 'NetCode'. The aim of this network is to ensure that there is no unsuitable or unethical marketing of BMS. The system strives to improve implementation of the WHO Code through empowering member states and civil society to support and reinforce national WHO Code legislation, monitor compliance with the WHO Code on an on-going basis and intervene where violations are taking place.[43] The World Alliance for Breastfeeding Action (WABA) has a similar initiative known as 'Code Watch'; which aims to encourage implementation of the WHO Code by training and education, creation of educational materials, monitoring compliance with the WHO Code and the development of legislation.[134]

As mentioned previously, the monitoring of Regulations is essential to ensure adequate implementation. It is useful to investigate how other countries are monitoring WHO Code legislation. Internationally, regulations to enforce legislation surrounding the WHO Code are lacking.[132] In 2016, only 32 countries who had enacted WHO Code legislation reported to have monitoring mechanisms established (of the 174 who have some form of legislation in place) and, of the 32, there are only a few that are functioning optimally. Less than 25% of countries who have proper monitoring practices in place publish the results of that monitoring. Budget allocations are apparently also a problem area, as only six countries report having a budget or some type of funding that is dedicated to monitoring and enforcing the WHO Code legislation. The WHO indicates the following challenges to monitoring and enforcing the WHO Code: A lack of co-ordination among key stakeholders; a lack of co-operation from manufacturers and distributors; a lack of political action to legalise and enforce the WHO Code; a lack of adequate statistics and expertise regarding matters related to the WHO Code, and a lack of resources both nationally and internationally.[94]

In South Africa it appears as though such monitoring needs strengthening and a task force needs to be identified to claim responsibility for this role. Apparently, the intention was for the Office of Standards Compliance at the DoH to be responsible for the monitoring and implementing of the Regulations. At the time of the passing of the Regulations, this office was only recently established, and the focus was on other priority programmes. As it stands, the monitoring of the Regulations falls under the Nutrition Directorate of the DoH and is largely directed to the provincial offices. All violations are to be reported to the Director General of the DoH through the Nutrition Directorate. Currently, it appears as though all amendments to the Regulations have been put on hold since 2015/2016.[135]

In view of the literature discussed up to this point, this research study aimed to determine dietitians' perspectives on the Regulations to gain insight into how the Regulations are being implemented and the strengths and weaknesses observed. The following paragraphs detail the research tools that were used to achieve the study's aims.

2.7 Research tools to determine dietitians' perspectives on the Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations): Electronic surveys and focus group discussions

It was decided to use an online survey as the research tool to enable the inclusion of dietitians throughout South Africa.

2.7.1 Using surveys to measure knowledge, perceptions and practices

Surveys are a common method used in the literature to evaluate knowledge, perceptions and practices – they allow for targeting of participants on a national level. Using an online survey platform facilitates easier distribution and data collection. There has been an increase in online surveys used since Internet use has become more popular. Online research can be very effective and productive. Some advantages of using online surveys include the ability to reach individuals in distant settings and participants who may be difficult to contact, access to a variety of populations, access to a large number of participants and people who share specific characteristics and the convenience of having automated data collection, which can save considerable time and energy for the researcher. Online research also allows the opportunity to include participants who may be more reluctant to meet face to face.[136] Many of the costs of data collection are lowered with online research, and it allows researchers to be less obtrusive. There is a reduced pressure on participants and they have greater freedom to withdraw at any time during the online process. Online surveys are flexible and less susceptible to errors, as the need for manual transcription is reduced. Online survey creation packages can provide the option to export the data onto statistical software packages and many services provide assistance with the design of surveys and analysis of data.[137] Free versions of packages are often available and can be used to test-run the survey creation tool.[138]

However, the use of online research is not without its disadvantages, and these need to be considered and accounted for. Shortcomings with the use of an online survey include a lack of confidence in data validity, sampling issues, and issues regarding the design, application and evaluation of an online survey. Obtaining information (such as email addresses) to disseminate the survey link may be a challenge as it is difficult to establish a sampling frame, it is not possible to obtain a truly random sample which makes it difficult to generalise.[136] Response rates can be low and participants can easily withdraw, which makes it necessary to offer some form of monetary incentive but this itself may decrease credibility of the survey as there are many scams on the Internet.[136,137] Disadvantages include systematic bias in the sample and invasion of privacy of potential participants who do not wish to receive emails.[136] Online research presents concerns about data quality and the treatment of research subjects. The major risk that faces participants relates to their privacy. Good data management practices are essential to ensure that the privacy of participants is respected. Obtaining informed consent, conveying instructions and debriefing participants are more difficult to achieve online; thus, it is important that these instructions and tools be pretested more thoroughly and a rigorous pilot study is recommended. In some cases, the documentation of informed

consent can be waivered for online research or the use of a 'click to assent' option in research that only involves minimal risk to participants. Researchers need to be diligent and put provisions in place to prevent multiple submissions by the same individual, to protect privacy of research subjects and maintain data confidentiality.[137]

Deciding which package to use for the creation of an online survey will depend on the budget and personal preference of the researcher, as well as the specific features desired in the survey design. Online survey tools range from basic to more advanced versions. Generally, the more advanced survey tools come at a higher price and offer features such as a flexible survey look, skip logic[a], piping[b], randomisation[c], website integration and assistance with data analysis.[138]

Basic tools offer simple survey-building software and the ability to view the results online. The basic packages are provided at a lower cost and are appropriate for smaller surveys where advanced features will not be needed. Examples are SurveyMonkey®, Typeform, Google Forms and SurveyGizmo.[138]

Lower cost integrated tools are also available, which offer a cheaper solution that will include some additional features excluding the survey functions; such as, the ability to send emails. The survey building tools are more basic with these packages and might not be appropriate for those needing advanced survey features, such as data analysis. Examples of these integrated packages are ConstantContact, Formsite and Moodle.[138]

Advanced survey software is useful to conduct research on a larger scale. These packages usually offer innovative question setup, skip logic and data analysis features. However, the advanced packages may prove challenging for those who are inexperienced in survey design. For example, Question Pro, LimeSurvey and Key Survey.[138]

In order to strengthen the survey findings, it was decided to add a qualitative component in the form of focus group discussions.

2.7.2 Using focus groups to measure behaviour, experiences and perceptions

Qualitative methods are gaining popularity in health research and the inclusion of a qualitative component complements the quantitative data, collected via the survey, by adding more in-depth perspectives on participants' behaviours, experiences and perceptions towards the topic. The addition of focus group discussions will help to overcome data being limited to pre-set responses in the survey, allowing other potential answers, or opinions to be explored and further explanation of findings. Focus groups are unique

[a] Skip logic: Create a custom path through the survey that varies based on a respondent's answers.
[b] Piping: Used to insert a respondent's answer from a previous question, to a question and answer choice that comes later in the same survey.
[c] Randomisation: Reduce answer bias by randomising the order of the pages in the survey or the order of questions within a page.

from other research methods as the group interaction often allows for the collection of more in-depth and rewarding data with a wider scope.[139]

There are various aspects of focus group discussions that can be advantageous. Participation is encouraged from those who may be reluctant to be interviewed on their own and focus groups can be especially useful for investigating peoples' knowledge, perceptions, experiences and needs as well as the reasons behind people's thinking. The research has the potential to go in new or unexpected directions and the interactions between group members form part of the data. A group discussion can make participants perspectives clear through the debate that goes on within the group and is ideal for exploring processes and understanding.[140] Participants can explore shared perceptions, disagreements and a greater variety of communication is possible.[141] Practically, focus groups can provide a reasonably large amount of information in a short span of time.[139]

Possible disadvantages with the use of focus group discussions include: the influence of peer pressure, the tendency for individuals who do not agree with the majority group opinion to be silenced and compromised confidentiality due to the presence of other research participants.[140] Focus group discussions depend on co-operation within the group; as such, it is important for participants to be briefed on confidentiality issues beforehand. Many of these disadvantages can be overcome or mitigated by a competent facilitator.

In contrast to one-on-one interviews, group processes can help people explore and explain their opinions more easily. Different forms of communication (such as, jokes) can be analysed, allowing focus groups to reach parts of communication that other research methods cannot. Some researchers have found that focus groups have a tendency to produce more critical comments than interviews, which is beneficial when the aim of research is to improve services. Differences in perspectives are easier to explore in the focus group environment as these can be explained and discussed during the group as opposed to doing it afterwards as in individual interviews. Participants can relate to each other's experiences and voice ideas or opinions that might not be exposed in individual interviews. While interviews may be more suited for gathering information such as individual biographies, focus groups are more appropriate to explore how knowledge, opinions and ideas are developed and function within a given context.[140] Another option for collecting qualitative research, participant observation, is possibly better suited to researching social roles and formal organisations.[141] Thus, when the aim of the research is to investigate knowledge and perceptions, focus groups are an unequalled method, and are especially useful to complement survey data by exposing the gaps.[141] As surveys are a more one-on-one method of data collection, it may prove useful to add a group dynamic to the research rather than another method (that is, interviews) also conducted individually.

Since this research study aimed to determine HCPs' (dietitians') perspectives on the Regulations, it is useful to explore the potential role of HCPs in this context.

2.7.3 The role of HCPs in the implementation of new infant feeding-related policies

Co-operation of HCPs is an important element to consider in the context of implementing any policy in the health care environment and furthering the breastfeeding agenda. Article 6 and 7 of the WHO Code[22] specifically outline the important role that health care systems and HCPs have in the protection, promotion and support of breastfeeding.

It has been found that South Africans respect HCPs' opinions when it comes to eating problems in their children.[78] HCPs are an important source of information on infant feeding for mothers and families and are in an ideal position to help mothers determine infant feeding decisions.[13,34,35] Tshikovhi et al.[142] investigated factors that influence mothers and caregivers to purchase infant formula in Tshwane, South Africa. They found that nurses and paediatricians are the main sources of information on infant feeding, and paediatricians' recommendations are one of the main influential factors. A review of IYCF practices in hospitals and at home in KwaZulu-Natal confirmed the important role of HCPs when it comes to IYCF information and found that the main sources of information for caregivers on feeding their child(ren) were health facilities, both clinic and hospital institutions, and HCPs.[143]

In addition, HCPs play an essential role in the bridge between policy and practice.[34] On-going training and education of HCPs are essential to assist them in fulfilling this role.[13,34] Seonandan and McKerrow[143] recommend the strengthening of on-going training to HCPs to ensure that information given to the public is correct. It is imperative that HCPs provide information and counselling on IYCF that is grounded in the best current evidence-based principles in accordance with the country's relevant policies and regulations in order to convey clear and consistent messages to caregivers. In doing so they will assist in increasing knowledge on IYCN and preventing misperceptions among caregivers.[74]

HCPs can provide valuable input in terms of barriers or enablers experienced when implementing new guidelines or policies. An investigation of barriers in relation to the implementation of a new policy guideline in the Netherlands found that barriers arise relating to the knowledge and attitude of HCPs, lack of agreement and a lack of strong leadership. It was found that commitment from hospital management is essential to achieve co-operation in other departments. Characteristics of the guidelines, specifically content that is misleading or missing information, was also identified as a barrier. Important elements to consider are too much jargon and the phrasing of a guideline. Various factors play a role in the implementation of a policy; including, contextual, social, financial, belief, infrastructure, practical support, and national views on such policies.[144]

Adherence to the implementation of the new guidelines has also been identified as a problem. Cabana et al.[145] identify seven major barriers to adherence of clinical practice guidelines; these are "lack of awareness, lack of agreement, lack of familiarity, lack of outcome expectancy, inertia of previous practice, lack of self-efficacy and environmental factors." Other aspects that may influence guideline adherence include the style of leadership in a facility, the efficiency of communication and the ability to carry out teamwork.[146] It is recommended that a guideline should include advice on what to do in the case of non-compliant HCPs and the roles of different professionals in relation to the guidelines to ensure that each group of HCPs is aware of their responsibilities.[144]

This study evaluated HCPs' (that is, dietitians') perspectives to determine the impact of the relatively new Regulations. As a result, the study considers the pivotal role that HCPs have to play in ensuring the success of implementing the Regulations in the workplace, their unique experience and influence with caregivers, and their ability to identify barriers and enablers to the Regulations on various levels. With the research tools and the role of HCPs in mind, the final section to follow provides a motivation for this research study.

2.8 Motivation for the proposed study

Salasibew et al.[89] reason that because there are no rules in place to implement the legislation on the WHO Code, violations are still taking place. This highlighted a need for future studies to explore the standing on implementation of the WHO Code and relevant legislations. Legislation needs to be accompanied by imparting information, training and systems to monitor implementation to ensure that both HCPs and product companies are compliant with the WHO Code.[87] There is a lack of available research investigating the impact of the Regulations to restrict the marketing of IYCF products.[147]

While there are many studies investigating HCPs attitudes, perceptions, knowledge and challenges related to infant feeding and their influence on infant feeding practices[13,35], none appear to address the Regulations in particular. Some of the perspectives from the legal side and manufacturers, retailers and distributors have been viewed, as is evident from the guidelines to industry and health care personnel document[148] and the article by Mills[130], but little is known regarding the perspectives of HCPs on the Regulations. There also appears to be much confusion as to how the Regulations should be interpreted.[148] It is clear that more research is needed to understand HCP's perceptions on the current conditions surrounding the implementation of the Regulations. This could provide valuable information to policy makers to improve on areas seen as barriers to successful implementation of the Regulations.

The improvement in rates of EBF requires interventions that increase knowledge and awareness of the current situation and its causes, promote perceptions and social norms that are conducive to healthy infant feeding practices and increase the intention to employ such practices. The Regulations is one such

intervention, and as such efforts are needed to determine how the Regulations have been accepted among HCPs and what challenges they are experiencing. The proposed study aims to explore these issues by determining knowledge, perceptions, behaviours and practices of dietitians with regard to the Regulations.

South African dietitians were chosen as the study population since this group could offer a unique perspective on the topic, as many of them perform work with mothers, infants and caregivers; precisely, the groups the Regulations aim to protect. Dietitians have wide-ranging knowledge about the foods commonly used by patients or clients as well as the practical, therapeutic, financial and preferential factors involved in obtaining and preparing food. Furthermore, dietitians have been found to be at ease with studies concerning research aspects such as practice guidelines, implementation and evaluation of effect.[149] In addition, dietitians were chosen to establish a useful baseline survey as no other studies to date have investigated the opinions of HCPs on the Regulations.

IYCF is a priority area in South Africa, considering the less than optimal breastfeeding rates and high levels of malnutrition. In recognition of the fact that unrestricted marketing of products intended for infants and young children may be harmful to the public, South Africa passed the Regulations in 2012 to legislate the contents of the WHO Code. This was a proud moment for the country, in taking a bold stance to improve the IYCF climate. HCPs have an important role in ensuring that these Regulations are successful. Dietitian's, who are seen as the experts in all things nutrition-related, have a particularly important role and thus this study aims to evaluate the impact of the Regulations by determining dietitians' perspectives thereof.

Chapter 3: Methods

3.1. Overview of research

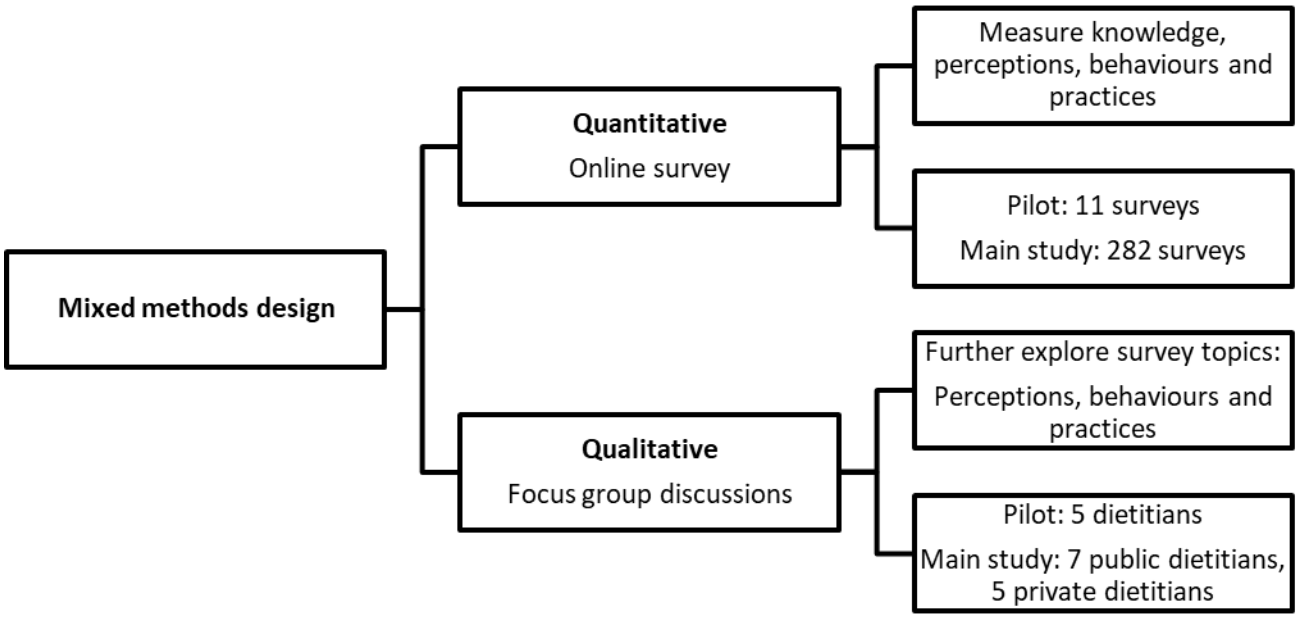
3.1.1 Research question

What are South African dietitians' perspectives on The Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)?

3.1.2 Main aim

To determine the knowledge, perceptions, behaviours and practices of dietitians in South Africa regarding The Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).

3.2 Conceptual framework of research methods



3.3 Study type

A cross-sectional descriptive study with an analytical component was conducted. A mixed methods design was used, including quantitative and qualitative methods. Quantitative data was collected by means of a self-administered electronic survey, while qualitative data was collected by means of focus group discussions.

3.4 Study population

The study population consisted of dietitians registered with the HPCSA from both the public and private sectors.

3.5 Sample selection

3.5.1 Self-administered electronic survey

Snowball Sampling was used for the online survey component. Participants were recruited through various channels to obtain as large a sample of feasible responses to increase the strength of the findings. Channels to recruit participants included ADSA, BHF, the DoH and social media. Dietitians were encouraged to inform their colleagues and contacts of the study to help increase the response rate.

3.5.2 Focus group discussions

Purposive sampling was utilised for the focus group discussions. The sample for the discussions consisted of registered dietitians working within KwaZulu-Natal. It was decided to conduct focus group discussions among KwaZulu-Natal dietitians for reasons of convenience as the researcher resides in KwaZulu-Natal and focus group samples do not necessarily need to be representative (in this case) of a specific geographic area. Rabiee[139] encourages similarity among focus group participants to encourage participants to engage fully and generate richer data. In addition, KwaZulu-Natal has taken on the task of training and refresher courses of HCPs in the area of IYCF.[34] Thus, it could be anticipated that the HCPs in KwaZulu-Natal would more likely be aware of the Regulations and focus groups in this province might provide more fruitful insights. The focus groups were conducted with both public (employed by the Government and working for the DoH) and private (self-employed or working for a private company or institution) dietitians.

3.6 Sample size

3.6.1 Self-administered electronic survey

At the time of data collection there were 4 452 dietitians registered with the HPCSA in South Africa.[150] This number was used as the sampling frame. A sample size of 341 participants was calculated in order to estimate a proportion of 60% of participants who were expected to be knowledgeable about the Regulations – assuming 5% precision and 95% level of significance. This calculation is based on the assumption that 60% would be knowledgeable.[151] This sample size was adequate to generalise results to the population of dietitians in South Africa. However, the desired sample size was not obtained due to a poor response rate and the final sample consisted of 282 participants. The smaller sample resulted in a precision of 5.7% and a confidence level of 95%. All registered dietitians in South Africa, who consented to participate and had access to the Internet were eligible to participate. Pilot study participants and student dietitians were excluded.

3.6.2 Focus group discussions

Two focus group discussions of five to 12 participants each were conducted. One focus group was conducted with dietitians working in the public sector and the other with dietitians working in the private sector. This method was used to ensure that dietitians from all spheres were included since it is likely that the work environment will have an influence on perspectives of the Regulations. The aim of the focus

groups was to add an additional element to the research rather than achieve data saturation; thus, it was decided that two groups would be sufficient. All registered dietitians working in KwaZulu-Natal who responded to the invitation and gave their consent to participate and to have the focus group discussion audio recorded were included.

3.7 Data collection

3.7.1 Procedure

3.7.1.1 Self-administered electronic survey

The online survey was sent out between March 2017 and July 2017. The survey was kept open for longer than anticipated due to a poor response rate. A link to the survey was sent out through various channels to reach as many registered dietitians in South Africa as possible. The survey was in the form of a self-administered electronic, online survey. It was developed using the SurveyMonkey® online survey software. A cover letter (Addendum A) was included with the invitation to participate in the survey. The SurveyMonkey® survey was designed in such a way that it ensured each participant could only complete the survey once; this would avoid duplicate entries by the same participant and it allowed the participants to go back and complete the survey at a later stage if they so wished.

An informed consent declaration was included with the cover letter to the survey. An incentive to complete the survey was included to encourage potential participants to respond. The time taken to complete the survey was kept to approximately 15 to 20 minutes; this assisted in encouraging respondents to participate since lengthy surveys are less likely to be well received.

After the survey was sent out, the link was active for a period of five months. This was much longer than the planned period of six weeks due to the poor response rate. This allowed respondents more than enough time to complete the survey. Eventually, it was decided that a longer period would not necessarily improve the response rate. Reminders to complete the survey were sent out twice to each group of potential respondents after the initial communication, to encourage dietitians who had not done so to take part. The ability to send out reminders to ADSA-registered dietitians was subject to their policy on communication with members; an initial communication and one reminder were sent out to ADSA members.

3.7.1.2 Focus group discussions

Focus group discussions were conducted during December 2016 and June 2017 in KwaZulu-Natal. The reason for the focus group discussions being performed several months apart was that the first group was the pilot study, and thus could be conducted prior to completion of the online survey. The second group was for the main study, and as the aim of the focus group discussions was to elaborate on the survey findings, the data collection for the online survey needed to be completed prior to conducting the second focus group discussion. Since the survey was kept active for longer than anticipated, this resulted in the

extended time period between focus group discussions. An invitation to participate in focus group discussions was sent out to dietitians via organisers of dietetics-related meetings or events. Oversampling was done for the focus groups to compensate for individuals who may not have shown up on the day. The purpose of the addition of the focus groups was to elaborate on and add to the survey findings, with the focus on perceptions, behaviours and practices (including enablers and barriers) as these objectives are better achieved with qualitative methods. The focus group discussions were conducted in private venues booked for the purpose of the discussion. The venues were appropriate and conducive to conduct the discussion in a relaxed and comfortable setting, with no loud noises or interruptions. Refreshments were provided and participants were seated in a circle to facilitate discussion. The principle investigator facilitated the discussions and an observer was present to record handwritten observations during the discussions; such as, which participant made which statement and non-verbal ques. Contact details were requested from those who responded to the invitation so that a reminder could be sent out before the event and on the day of the focus groups.

All participants were asked to sign a consent form (Addendum B) prior to participating in the discussion. The discussions were recorded using an audio recorder. In addition, the facilitator kept a reflection diary to record the observations made directly after each focus group discussion took place. Each participant was given a gift voucher after the groups were conducted. The planned duration of each focus group was between 60 to 90 minutes in length. This was done to limit the inconvenience to participants and to encourage individuals to accept the invitation to participate as a lengthy discussion is less likely to be well attended. The two focus groups were 53 minutes and 66 minutes respectively in length.

3.7.2 Recruitment of participants

3.7.2.1 Self-administered electronic survey

It was decided to use as many channels as possible to recruit survey participants to achieve a desirable response rate. The networks that were used are listed below.

- *Advertisements with ADSA*

An explanation of the study and a link to the survey was posted in the ADSA newsletter. The number of dietitians registered with ADSA at the time of the survey was 1 250. An invitation was sent out during March 2017 and a reminder sent out during April 2017.

- *BHF*

Emails were sent out to all the private dietitians registered with the BHF of Southern Africa, including an explanation of the study and a link to complete the survey.

The number of dietitians registered with the BHF at the time of the survey was 1 189. Two reminders were sent out after the initial invitation.

- *DoH*

Management working within the various provincial nutrition directorates were contacted and asked to assist with providing email addresses for dietitians, or to help disseminate information regarding the study's details and the link to the online survey to dietitians within each province. Certain provinces requested ethics approval from the National Health Research Database (NHRD) prior to dissemination of the survey (KwaZulu-Natal, Limpopo, North West and Gauteng provinces) and this was obtained before the survey was distributed. In the other provinces (Western Cape, Northern Cape, the Free State, Eastern Cape and Mpumalanga) prior NHRD approval was not requested. For provinces where the email addresses were shared with the researcher, two reminders were sent out after the initial communication. Colleagues working within the DoH were contacted and asked to assist with the distribution of the link to the study.

An invitation was sent out to DoH dietitians in all provinces; excluding, Gauteng as no response was received from the NHRD by the end of the data collection period. It was decided that this would not bias the results to a large extent as Gauteng had the largest percentage of participants (29.1%) in comparison to the other provinces and it was felt that the province was adequately represented.

A link to complete the survey was added to the nutrition page of the KwaZulu-Natal DoH's Intranet site.

- *Social media*

Messages were sent out to all the researcher's Linked In and Facebook contacts who are registered dietitians working in South Africa as well as Facebook pages with dietitian members (for example, "Dietetics- Nutrition is a Profession" and "Association for Dietetics South Africa"). The number of LinkedIn contacts was approximately 644.

A message was included in the survey to encourage dietitians to inform their colleagues and contacts of the study to help increase the response rate.

3.7.2.2 Focus group discussions

The focus group discussions were organised at accessible locations, around events that dietitians were already attending: one was conducted after an ADSA meeting and the other after an eThekwini district Integrated Nutrition Programme (INP) meeting. The organisers of the events were contacted by the researcher and their permission was requested to conduct a focus group discussion around the event. Since the organisers were willing to accommodate these discussions, it was requested that an invitation to participate in the focus groups be sent out to the dietitians together with the invitation to the event. Participants were informed on the content of the focus group in the invitation.

Furthermore, a section in the survey asked participants whether they would be interested in participating in a focus group discussion if they selected KwaZulu-Natal as their residential province. An email address was requested from the respondents that indicated that they would be interested so that these participants could be invited to attend the focus group discussions. The email addresses obtained were only

used for this purpose and for contacting the winners of the lucky draw. Unfortunately, a poor response was received from those that indicated they would be interested and it was not feasible to organise a focus group in this manner.

3.7.3 Data collection tools

3.7.3.1 Self-administered electronic survey

SurveyMonkey® was chosen as the tool to execute the survey. SurveyMonkey® is an online survey platform facilitating the creation and distribution of online surveys. The 'Select' package was used, which allowed for unlimited questions (up to 1 000 responses) and priority email support 24 hours a day from experts who could have offered assistance with the design and implementation of the survey. The platform allowed the download of survey data onto a Microsoft ® Excel® spreadsheet, which assisted with the data capturing and analysis; thus, a considerable amount of time was saved during the data capturing process. The package included analytics and allowed for the manipulation of data as well as the creation of charts and reports. The package also included access to survey templates certified by experts and a library of guidelines and tutorials to assist throughout all the stages of the survey design, implementation and analysis.

SurveyMonkey® is a trusted platform that uses the latest technology to protect sensitive information. Data is password protected and TRUSTe, BBB Accredited Business and McAfee SECURE provide further protection and validation.[152] Disadvantages of using SurveyMonkey® are that the survey will be kept on the company server for a specified amount of time, which may present a risk to the participants in terms of confidentiality or privacy, and responses are limited to 1 000 per month when using the 'Select' package.[136] However, the SurveyMonkey® enterprise has a privacy policy stating that they will not use researchers' data for their own purposes. The researcher is the owner of all data collected or uploaded into the survey.[153] It was anticipated that the number of responses would not exceed 1 000 based on the target population size of 4 452 and the usual response rate to surveys of approximately 10% to 20%.[154] The data collection extended over a period of five months, which would have allowed for more than 1 000 responses if the need arose.

The survey questions were developed by the researcher with the assistance of the study leaders. The survey content was created by careful examination of the R991 Regulations document and selection of a variety of sections of the document that addressed the study objectives. The knowledge questions were developed by selecting various parts of the R991 document to ensure that different areas were included; knowledge questions comprised varying levels of difficulty. Survey writing tips from SurveyMonkey® tutorials were used to improve the quality of the survey. Content validity was assessed by five experts in the fields of IYCN, nutrition policy, legislation and labelling. All input and comments received were discussed with the study leaders and adaptations were made accordingly. These experts also examined relevance of survey questions, potentially biased questions and offered additional suggestions to include

components the researcher may have overlooked. The survey (Addendum C) consisted of six sections: (1) demographic information, (2) knowledge, (3) perceptions, (4) practices (that is, behaviours) and (5) enablers and (6) barriers (to the implementation of the Regulations). Pre-set responses and Likert Scales were used to assess perception and practice related questions. The survey included four point Likert scales (strongly agree, agree, disagree and strongly disagree) and five point Likert scales (always, often, sometimes, seldom, never). It was decided not to include a neutral option in the four point scale to encourage participants to answer decisively. A not applicable option was provided for all Likert scale questions. A limited number of open-ended questions were included, but completion of these questions was kept optional to keep the time used to a minimum. Pictures were used to illustrate scenarios or practices and to help participants maintain interest in the questions. The order of the sections in the survey flowed as follows: 'Perceptions', 'Knowledge', 'Practices', 'Enablers' and 'Barriers'. A progress bar was displayed to show the participant how far they had progressed through the survey. For questions that were only applicable to certain participants, the SurveyMonkey® 'skip logic' function was employed to direct participants to the next applicable question.

3.7.3.2 Focus group discussions

A focus group discussion guide was developed to guide the discussion and probe responses (Addendum D). The discussion guide was developed by the researcher with the assistance of study leaders. The discussion guide was developed to address the research objectives and created using examples from the literature and the R991 Regulations document to establish the content. Probing questions were developed with the survey questions in mind and the intention of elaborating on those findings. The focus group discussion guide was drafted before commencement of the study and was refined based on the survey responses to explore additional factors related to perceptions, behaviours and practices (including enablers and barriers).

3.8 Pilot studies

3.8.1 Self-administered electronic survey

Content validity was assessed prior to conducting the pilot study, as mentioned in section 3.7.3.1. The pilot study was conducted to determine face validity. The pilot study was conducted from the same population; that is, registered dietitians in South Africa, on a different set of participants than those who were included in the main study.

The pilot study of the survey was conducted between October 2016 and January 2017. The pilot study took longer than expected due to a poor response rate. The researcher was also reluctant to send it out too widely to prevent reducing the sample population for the main survey. The pilot study was conducted on a convenient selection of 11 registered dietitians in South Africa. The pilot study allowed for the exploration of practical issues; such as, time taken to complete, types of responses and assisted with coding and

refining of the data capturing form. Participants were asked to give feedback after completing the survey by completing a short evaluation survey (Addendum E). They were asked to comment on the format and layout, appropriateness of questions posed, time taken to complete and any other aspects that they felt could be improved upon. Links were sent out to the participants via email to complete the survey and the evaluation survey; once completed, the researcher accessed the data using the SurveyMonkey® program. The data collected from the pilot study was not used in the study results, but to refine the data capturing tool and make final changes before commencement of the actual data collection phase. The main changes that were made to the survey after the pilot study included; correction of spelling mistakes, refinement of the skip logic function for questions pertaining only to certain groups, re-arranging of certain questions, removal of repetitive questions and non-essential questions in an attempt to shorten the time taken to complete, clarification of misunderstood questions and removal or adaptation of knowledge questions that were perceived as too difficult.

3.8.2 Focus group discussions

The pilot study of the focus group discussion was conducted on a convenient sample of five participants. The pilot was conducted during December 2016 after an ADSA meeting in KwaZulu-Natal. The pilot was done to test the process, the type of responses to expect and to assist the facilitator to prepare for any practical issues that may arise in the main study. After conducting the pilot study, time was allowed for participants to comment on the questions posed, the flow and process of the discussion. This assisted with refining the discussion guide to ensure the clarity of the questions and avoiding any leading questions. The main changes that were made to the discussion guide after the pilot study included; adding a more detailed explanation of the study objectives, removing or rephrasing of questions that were not well received by participants, the addition of visual aids to stimulate discussion and to maintain participants' interest and the repeating of questions during facilitation of the group to allow all participants the opportunity to respond.

It was decided that the data obtained from the pilot focus group would be used in the main study. This was outlined in the protocol and the participants were made aware of this at the time. The pilot focus group data was used because it offered different insights to the main focus group, the focus group discussion guide was kept much the same after the pilot study and there was a poor response rate to participate in focus group discussions.

3.9 Quality assurance

3.9.1 Data storage

Data obtained during the study and email addresses of participants were kept safely by the researcher on the researcher's personal laptop after data entry. Identifying information of participants (that is, email addresses) was kept separate from the study data. Back-up copies of the data were made for insurance

purposes, and are also safeguarded by the researcher and kept in a locked cabinet in the researcher's office. Data and contact information obtained will not be used for any other purpose than stated in the study proposal. Email addresses obtained from the BHF were only used to disseminate the survey to potential participants. Email addresses obtained from participants were only used to contact the winners of the lucky draw and to send out an invitation to those who indicated an interest in the focus group discussions. Access to the data was restricted to those involved in the study and access to contact information was restricted to the principle researcher. The email addresses of the participants were deleted after the completion of the study. The recordings of the focus group discussions were securely stored until they were transcribed and then they were destroyed. Data will be kept for a period of five years by the researcher, after which it will be permanently deleted or discarded. The SurveyMonkey® enterprise has a privacy policy concerning data as stated in Section 3.7.3.1 and data collected is kept private and confidential.

3.9.2 Training of facilitator

The researcher facilitated both focus group discussions and the training of additional facilitators was not considered necessary. The researcher studied the available literature on facilitating focus group discussions and received guidance from study leaders on conducting focus groups. Both study leaders involved in this study have experience in qualitative methods. The observers were colleagues of the researcher with Matriculation exemption who agreed to assist with the focus group discussions. The observers were briefed on the research topic and objectives beforehand and instructed on their responsibilities during the focus groups.

3.10 Data analysis

3.10.1 Data capturing

3.10.1.1 Self-administered electronic survey

Data from the survey was captured using Microsoft® Excel®. The SurveyMonkey® package includes a function of converting the data into Microsoft® Excel® format. The principle investigator was responsible for cleaning, re-arranging and coding the data after it was transported into Microsoft® Excel®.

3.10.1.2 Focus group discussions

Recordings of the focus group discussions were made on an audio recorder and handwritten observations were taken by the observer during discussions. After the focus groups were conducted, the principle investigator was responsible for transcribing all information gathered into Microsoft® Word®.

3.10.2 Quantitative data

The SurveyMonkey® results were exported into Microsoft® Excel® spreadsheets, as mentioned before. The researcher was responsible for organising and cleaning data, and basic summary statistics (for example, graphs, tables, frequencies, means and medians) of the raw data received from the online survey.

The assistance of a statistician was sought for advanced statistical analysis; for example, to assess the differences between groups of participants, and to make comparisons and associations between various parameters measured.

The Stata Version 14 software package was used for statistical analysis. Continuous variables were summarised using means or medians and associated variability (standard deviation or range.) Categorical data was analysed using the Pearson's Chi Square Test and logistical regression methods. Quantile regression was used to compare median knowledge scores across demographic, perceptions and practice variables. Scatter and Box Plots were created to visualise associations. The 95% confidence intervals and 'p' values[d] were calculated. Since the perception and practice variables can be considered ordinal variables, Spearman Correlation Coefficients between knowledge score and perceptions and practices variables were calculated and tested. The 95% confidence intervals and p values were calculated. To compare perceptions variables with practice variables and the former two variables with barriers and enablers, Pearson's Chi Square Test was used and 'p' values calculated.

The percentage of knowledge that was expected for the knowledge section of the survey was approximately 60%. This percentage was chosen based on a study conducted by Steyn et al.[151] on South African dietitians, which found their mean knowledge on a dietetics-related topic to be between 56.5% and 62.5%.

To investigate further associations between perceptions, practices and/or barriers and enablers it was decided to identify three key questions under both the perceptions and practices sections. The following questions (in grey) were used (a brief explanation has been included after each question to motivate why the specific question was chosen).

Perceptions

1. **It is important for HCPs to be aware of the Regulations (R991).**

This question gives a basic idea whether dietitians feel the Regulations are relevant and something HCPs need to know about.

2. **It is my responsibility as a HCP to report violations of the Regulations (R991) when I become aware of a violation.**

This indicates whether dietitians actively support enforcement of the Regulations and claim some form of responsibility.

[d] The p-value is the level of marginal significance within a statistical hypothesis test representing the probability of the occurrence of a given event. The p-value is used as an alternative to rejection points to provide the smallest level of significance at which the null hypothesis would be rejected. A smaller p-value means that there is stronger evidence in favour of the alternative hypothesis.[163]

3. **Before the Regulations (R991), clients were being influenced to purchase designated products based on advertising in the media.**

This gives an indication whether dietitians feel that the Regulations have been effective at reducing advertising.

Practices

1. **I confidently employ the principles of the Regulations (R991) in my work environment.**

This question denotes whether dietitians feel competent in complying with and enforcing the Regulations in their day to day work.

2. **How often do you make an effort to ensure that designated products are not visible to patients and/or clients in your work environment?**

This question indicates whether dietitians actively practice implementing the Regulations.

3. **If you receive a free gift from a company manufacturing, importing or distributing designated products under the Regulations (R991) (for example, a pen with the company's logo), how often would you accept it?**

This suggests how compliant dietitians are when it comes to product representatives.

3.10.3 Qualitative data

The researcher transcribed focus group discussion recordings, reflective notes and notes made by the observer. The data was systematically examined and manually coded using three major stages as described by Strauss and Corbin.[155] Firstly, it was open-coded by breaking up the transcription into small pieces and assigning codes; secondly, it was axial-coded where the codes were grouped into categories; thirdly, it was selective-coded where themes were developed to express the content of the groups. The themes were summarised into cohesive descriptions in a way that addressed the objectives of the study and enabled the discussion of the data. It was decided to analyse the data without the use of a computer software programme as only two discussions were conducted.

3.11 Ethics and legal aspects

3.11.1 Ethics and research approval

Ethics approval was obtained from the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University (Ref no.: S16/02/024). Public sector nutrition managers in Kwa-Zulu Natal, Limpopo, North West and Gauteng provinces requested NHRD approval to conduct research among dietitians working in the public sector prior to disseminating the survey. The research protocol was submitted to the NHRD for these provinces and obtained prior to dissemination. NHRD approval was submitted for Gauteng via the NHRD, but no response had been received by the time data collection was completed, despite multiple attempts to contact the administrators. Public sector nutrition managers in the Western Cape, Northern Cape, the Free State, Eastern Cape and Mpumalanga were satisfied with the ethics

approval from the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University and did not request additional NHRD approval.

3.11.2 Participant confidentiality

Study participants remained anonymous and no personal information was recorded without permission. Any contact details obtained by the researcher for the purposes of the study were kept confidential and not used for any other purpose than those stated in the study. Contact details were deleted or discarded after completion of the study. Participation in the study was voluntary and participants were free to withdraw at any time. The anonymity of focus group participants was protected by assigning codes to each participant. Participants were informed that all content discussed during the group must remain confidential and a section in the consent form was dedicated to confidentiality so that participants were fully aware of the responsibilities inherent in participation.

Data was kept safely and securely by the researcher under password protection. Access to the data was restricted to those involved in the study: that is, the researcher, study leaders, focus group discussion observers and statistician.

3.11.3 Informed consent

3.11.3.1 Survey

Survey participants gave consent by means of a 'click to assent' box included on the first page of the survey; this was a pre-requisite to completing the survey. The cover letter introduced the study, explained the aim, addressed issues of confidentiality and consent, and provided standardised instructions on how to complete the survey. It was emphasised that by clicking the assent to participate, respondents were giving their informed consent.

3.11.3.2 Focus group discussions

Informed consent forms were signed by all the participants on the day of the focus group discussions after the facilitator explained the purpose of the discussion and responsibilities of the participants. The consent form was explained by the facilitator to the participants and any questions were addressed. Two copies were completed: one for the participants' personal records and one for the study. Consent forms were made available only in English, as participants recruited were fluent in English. It was anticipated that most dietitians would be fluent in English as English is the language of communication used by the HPCSA, ADSA and the government of South Africa. Dietetics degrees in South Africa are also predominantly taught in English. Of the nine universities in South Africa offering a degree in Dietetics, six of them use English as the only language of instruction and the other three teach in a combination of English and Afrikaans.[156] Thus, it was reasonably expected that South African dietitians would be fluent in English and the translation of the consent forms was unnecessary. The consent forms included the giving of consent to participate and the giving of consent for the focus group discussion to be recorded (via audio equipment). Participants signed twice to give consent for both of the above.

3.11.4 Incentives

3.11.4.1 Survey

An incentive was included in the survey to ensure that a reasonable response rate was achieved. This was in the form of a lucky draw to win one of four vouchers (that is, Yuppiechef, Woolworths, Spree or Takealot) to the value of R1 000 each. Participants were given the option to enter this lucky draw and email addresses were recorded for the purpose of contacting the winners. The email addresses that were obtained were kept separate from the study data and the winners were randomly selected from a list and sent their electronic vouchers via email.

3.11.4.2. Focus group discussions

Focus group participants were compensated for their time and travel with a R200 voucher (from Woolworths). This amount was chosen as it was thought sufficient to compensate participants but not to unduly entice them into participation. Vouchers were distributed to study participants on the day of the focus groups.

Chapter 4: Article

It is planned that the article will be submitted to the *Maternal & Child Nutrition* journal; thus, the article has been written according to the journal's guidelines for authors.

Perspectives from South African Dietitians on IYCF Regulations

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Contributor statement:

The first author (MC) drafted the research protocol, undertook data collection, captured the data for analyses, analysed the data with the assistance of statistician (CL), interpreted the data and drafted the manuscript. NK and LdP assisted with protocol development, provided input at all stages of the project and provided extensive input to the manuscript.

Abstract

This study aimed to determine the knowledge, perceptions and practices of dietitians in South Africa regarding the Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations).

A mixed method, cross-sectional design was used. Quantitative data was collected using an online survey (n = 282) and qualitative data by means of two focus group discussions (n = 12). Participants were dietitians registered with the HPCSA.

Dietitians' average knowledge score was 64.8% ±12.5. Those working in IYCF had a 5% higher knowledge score (95% CI: 1.4% – 8.6%, p = 0.01). Perceptions towards the Regulations were generally positive and the majority of practices were compliant. The most frequently selected enabler to the implementation of the Regulations was 'Increase in other initiatives which support, protect and promote breastfeeding' and barrier was 'Lack of awareness of the Regulation among HCPs'. Those with higher knowledge selected more extreme answers on the Likert Scale questions. Positive perceptions seemed to correlate with compliant practices. The major themes from the focus group discussions included: less knowledge among dietitians and mothers about products controlled under the Regulations, non-compliance of other HCPs, the dietitians' role in support and enforcement, the discrepancy between practice in private and public sectors and a lack of enforcement. There are gaps that still need to be addressed for successful implementation and adherence to the Regulations. South Africa has taken a bold step in legislating the International Code of Marketing of Breast-milk Substitutes (WHO Code) and should upscale programmes to ensure consistent monitoring and enforcing of the Regulations.

Key words

Infant, young child, feeding, regulations, dietitians, marketing

4.1 Introduction

IYCF is an important topic on the health agenda worldwide.[31] Breastfeeding specifically has received much attention in recent decades as a vital practice to support and achieve better health outcomes in infants and young children.[9,13,21,22,25] Despite this, there has been a decline in the rates of EBF in many regions of the world since 1974. It was recognised at the 27th WHA in 1974 that one of the reasons for the decrease in breastfeeding was due to inappropriate practices of advertising BMS.[22] South Africa passed legislation in response to the call for action to upscale programmes to support and promote breastfeeding. On 6 December 2012, the DoH published the Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)[2] under the Foodstuffs Cosmetics and Disinfectants Act of 1972.[93] The Regulations placed restrictions on the marketing and advertising of BMS and foodstuffs intended for young children.[2]

The study aimed to determine South African dietitians' perspectives on the Regulations with a view to clarify how the Regulations are being accepted and implemented in the country and to identify areas that need strengthening. Dietitians' knowledge, perceptions and practices (including barriers and enablers) around the Regulations were explored and are described here.

Key messages

Dietitians have an overall positive perception about the Regulations; they support the legislation and assist with the implementation thereof to an extent; however, this perception does not seem to extend to other HCPs.

Dietitians believe that the restrictions placed on product representatives have led to dietitians, other HCPs and mothers having less knowledge about BMS and IYCF products.

The monitoring and enforcing of the Regulations requires strengthening and a task team needs to be established to carry out this task.

4.2 Methods

Study type and population

A mixed method, cross-sectional design was used. Quantitative data was collected by means of an online survey and qualitative data collected by means of focus group discussions. The quantitative component was included to extend the reach of the research, as an online survey could be sent out nationwide. The addition of the qualitative component aimed to complement the survey data by further exploring perceptions, practices and behaviours.

The study population consisted of dietitians registered with the HPCSA.

Selection of sample and sample size

Snowball Sampling was used for the online survey component. Participants were recruited through various channels; including, ADSA, BHF, the DoH in South Africa and social media. At the time of the data's

collection there were 4 452 dietitians registered with the HPCSA[150], which formed the sampling frame for the survey. A sample size of 341 participants was calculated in order to estimate a proportion of 60% of participants who were expected to be knowledgeable[151] about the Regulations, assuming 5% precision and 95% level of significance. However, a sample size of only 282 participants was realised due to a poor response rate and this resulted in a 5.7% precision and 95% level of confidence.

Sampling for the focus group discussions was done purposively and consisted of registered dietitians working within KwaZulu-Natal. The focus group discussions were organised at accessible locations, around events where dietitians were already attending; one was conducted after an ADSA meeting and the other after a district Integrated Nutrition Programme (INP) meeting. Two focus group discussions were conducted: one with seven public sector dietitians and one with five private sector dietitians.

Data collection

Procedure

A link to the self-administered electronic survey was sent out through the various networks between March and July 2017. A cover letter, which included general information about the study, an invitation to participate in the survey and an informed consent declaration, was contained within the invitation to participate in the survey. It was compulsory to indicate agreement to informed consent prior to completing the survey. A lucky draw prize was used as an incentive. The time taken to complete the survey was kept to approximately 15 to 20 minutes. Reminders to complete the survey were sent out twice after the initial communication.

Focus group discussions were conducted during December 2016 and June 2017 in KwaZulu-Natal. The focus group discussions were conducted in private venues booked for the purpose of the discussion. The principle investigator facilitated the discussions and an observer was present to record handwritten observations. The anonymity of participants was protected by assigning codes to each participant. All participants were asked to sign a consent form prior to participating in the discussion. The consent form was explained to the participants by the facilitator and included giving consent to have the discussion recorded. The discussions were recorded using an audio recorder. Each participant was given a gift voucher as compensation for their time and travel expenses.

Data collection tools

The survey was developed using the SurveyMonkey® online survey software: a platform that facilitates the creation and distribution of online surveys. The survey questions were developed by the research team with assistance from experts in the field. The survey consisted of approximately 75 questions with six sections: (1) demographic information, (2) knowledge, (3) perceptions, (4) practices, (5) barriers and (6) enablers (to the implementation of the Regulations). Pre-set responses and Likert Scales were used to assess perception-related questions. Five open-ended questions were included. Images were used to illustrate scenarios or practices to help participants maintain interest in the questions.

Content validity of the survey was assessed by five experts in the fields of IYCN, nutrition policy, legislation and labelling. All input and comments received were considered and adaptations were made accordingly.

In addition, a pilot study was conducted prior to data collection to assess the face validity of the survey, to identify and correct any technical problems with the online survey and to assist with coding and refinement of the data capturing form. The pilot study was conducted with a convenient sample of 11 registered dietitians in South Africa (who were excluded from the main study). A link to complete the survey was sent via email to the pilot participants. Participants were asked to give feedback after completion of the survey by completing another short survey. The data collected from the survey pilot study was not used in the study results.

For the focus group discussion component, a discussion guide was developed to direct the discussion and probe responses. The discussion guide concentrated on perceptions, behaviours and practices; as these objectives were better achieved with qualitative methods. This was drafted before commencement of the study and was refined based on survey responses to explore additional factors related to perceptions, behaviours and practices.

A pilot study, to assist with the refinement of the focus group discussion guide and the procedures followed, was conducted after an ADSA meeting in KwaZulu-Natal on a purposive sample of five participants. All dietitians who attended the ADSA meeting were invited to participate and five dietitians working in the private sector responded. It was decided that the data obtained from the pilot focus group would be used in the main study because it offered different insights, the discussion guide was kept much the same after the pilot and there was a poor response rate to participate in discussions. Participants were made aware of this possibility at the time.

Data capturing and analysis

Quantitative data

Data from the survey was captured using Microsoft® Excel®. The SurveyMonkey® package included a function of converting the data into Microsoft® Excel® format.

The Stata Version 14 software package was used for statistical analysis. Continuous variables were summarised using means or medians and associated variability (standard deviation or range). Categorical data was analysed using the Pearson's Chi Square Test and logistic regression methods. Quantile regression was used to compare median knowledge scores across demographic, perceptions and practice variables. Ninety five per cent (that is, 95%) confidence intervals and 'p' values were calculated. Spearman Correlation Coefficients between knowledge score, perceptions and practice variables were calculated and tested. Ninety five per cent (that is, 95%) confidence intervals and 'p' values were calculated. To compare perception variables with practice variables and the former two variables with barriers and enablers, Pearson's Chi Square Test was used and 'p' values calculated. A response of 'Not Applicable' was set to

'missing'. Missing values were excluded during data analysis and statistics were adjusted for non-response. A 'p' value of < .05 was considered statistically significant.

Qualitative data

Recordings of the focus group discussions were made on an audio recorder and handwritten observations were taken by the observer during discussions. Thereafter, the first author transcribed all the information gathered into Microsoft® Word®.

After transcription of the focus group recordings, the data was manually and systematically examined, open-coded, organised, categorised and grouped into themes to determine meaning. These were summarised into cohesive descriptions in a way that addressed the objectives of the study and enabled the discussion of the data.

Ethics approval

Ethics approval was obtained from the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University (Ref no.: S16/02/024). Approval was also obtained from the NHRD to conduct research among dietitians working in the public sector.

4.3 Results

The results from the survey and focus group discussions were combined and are presented as per the objectives of the study.

Demographic characteristics

A total of 282 complete survey responses were collected. This was less than the anticipated target of 341 participants and the precision was altered from 5% to 5.7%. The participants consisted of 94% females, with a mean age of 33 ± 7.95 years and the most participants resided in Gauteng (29.1%). Demographic information collected from survey participants is summarised in Table 1.

The focus group discussions comprised of females only in both groups, all participants were living and working in KwaZulu-Natal. One group consisted of five private sector dietitians and the other of seven public sector dietitians.

TABLE 1: DEMOGRAPHIC PROFILE OF SURVEY PARTICIPANTS

Age (mean ±SD)	33 (±7.95)	**Gender**	
Years of experience (mean ±SD)	8.9 (±7.2)	Male	17 (6.0%)
Visited by product rep(s)	204 (72.3%)	Female	265 (94%)
Employed as product rep	7 (2.5%)		
Aware of the Regulations	270 (95.7%)	**Read the Regulations**	218 (77.7%)
Years working in IYCF (mean ±SD)	6.4 (±5.6)	**Working with IYCF**	189 (67%)
Province			
Eastern Cape	16 (5.7%)	Mpumalanga	15 (5.3%)
Free state	13 (4.6%)	Northern Cape	25 (8.9%)
Gauteng	82 (29.1%)	North West	9 (3.2%)
KwaZulu-Natal	51 (18.1%)	Western Cape	54 (19.1%)
Limpopo	17 (6%)		
Category of practice*			
Public service	149 (52.8%)	FSM	7 (2.5%)
Training institution	15 (5.3%)	Food industry	13 (4.6%)
Private practice	106 (37.6%)	NGO	10 (3.5%)
Research	11 (3.9%)	CSO	2 (0.7%)
Education	5 (1.8%)	Corporate	21 (7.4%)
Academia	5 (1.8%)	Other	15 (5.3%)

Abbreviations: civil society organisation (CSO), food service management (FSM), infant and young child feeding (IYCF), non-governmental organisation (NGO) representatives (reps).

*Category of practice percentages does not add up to 100% as participants could select more than one category.

Knowledge

Knowledge scores for the knowledge section of the survey were determined by calculating average percentages for each of the 20 questions and for each participant. The average knowledge score for all participants was 13/20 (64.8% ±12.5). Table 2 gives a summary of the knowledge questions and the percentage correct answers for each question. Participants scored the highest averages on questions relating to the prohibition of free gifts with designated products (96.5%); the requirement for nutritional information for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks to include nutritional information per single serving (92.9%), and the prohibition of discounting designated products in stores (89.4%). Participants scored the lowest averages on questions relating to additives that are not permitted in foods for IYCF (17%) and products that are covered under the Regulations (30.1%).

For the statistical analysis of the knowledge section, quantile regression was used to compare the median knowledge score to demographic variables with resultant Scatter and Box Plots. The median knowledge score of the older age groups (> 25 years) was 5% higher than the younger age groups, but this effect was not significant ($p = 0.67$). Less experienced dietitians seemingly had less knowledge, although this effect

was only evident for the first five years of practice. Participants who worked with IYCF compared to those who did not, had a 5% higher median knowledge score (95% CI: 1.4% – 8.6%, p = 0.01).

From the focus group discussions it emerged that participants felt they had less knowledge about products controlled under the Regulations. Participants were dissatisfied that the Regulations inadvertently led to them receiving less product information from the representatives: "Now we don't get our information from anyone". It was described as a "catch-22" situation and they "almost don't feel equipped enough to discuss product". It was mentioned that "it is important to know what's on the market" so that HCPs are knowledgeable and could advise appropriately if the need arose.

TABLE 2: SUMMARY OF KNOWLEDGE QUESTIONS AND SCORES

Question	Score (%)
This picture is part of a newspaper advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the Regulations. *Advertisement of a growing up milk with a tie-in sale and a free toy.*	96.5
According to the Regulations nutritional information for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks must include nutritional information per single serving. True or false?	92.9
The following picture indicates a cost saving on the products displayed. This practice is not permitted. True or false? *Picture of Stage 2 and 3 formulae on sale*.	89.4
Please select the most appropriate answer. Based on the Regulations a health claim, such as "This milk can help to ensure baby has a healthy tummy": *Allowed on designated products/ Allowed to be on complementary foods but not infant or follow-up formulae/Not allowed on any designated product*.	86.2
The following illustration may not be shown on the category of formula within the designated products. True or false? *Illustration of the steps to prepare a feed and sterilise equipment*.	83.0
The following picture as part of a dinner invitation sent out to HCPs would not be permitted. True or false? *Picture of an invitation with images of the company's product range for infant formulae.*	83.0
The picture provides an example of appropriate educational material for HCPs. True or false? *Formula advertisement including a toddler using a laptop and the caption "Giving toddlers a head start in life".*	82.3
The following picture is allowed to be displayed on an infant formula, follow-up formula, or infant or follow-up formula for special dietary management for infants with specific medical conditions. True or false? *Picture of a teddy bear.*	77.0
The educational material displayed in the picture would be appropriate for HCPs to hand out to mothers in a unit taking care of infants and young children, pregnant mothers or mothers of infants and young children. True or false? *Picture of an educational material on breastfeeding with the brand name of a formula producing company*.	75.2
This picture is part of a product catalogue, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the Regulations. *Picture of a jar of Purity with the price.*	72.0
The product displayed in the picture below is covered under the Regulations as a designated product. True or false? *Picture of a growing up milk for over one year*.	63.5
Please select the most appropriate answer. In the Regulations, a 'young child' refers to: *0–6 months/ 12–36 months/ 12–59 months.*	59.9
Based on the Regulations, which of the following are false regarding the labelling of infant formula, follow-up formula, or infant or follow-up formula for special dietary management for infants with specific medical conditions? *Appropriate age range must be present on the label/ The statement "Breast milk is the best food for babies" must be on the label/ The claim "Gluten-free" must be on the label if a product does not contain gluten/ The statement "This product is not always sterile and may contain harmful micro-organisms. It must be prepared and used appropriately." must be on the label*	59.6
This picture is part of a magazine advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the Regulations. *Picture of a bottle with the price.*	56.4

Question	Score (%)
Please select the most appropriate answer. According to the Regulations (R991), which of the following health messages must be present on containers and/or labels of infant formula and infant formula for special dietary management for infants with specific medical conditions? *Infant formula increases an infant's risk of allergy/ Infant formula increases an infant's risk of ear infections/ Infant formula increases an infant's risk of acute respiratory disease/ Infant formula increases an infant's risk of gastrointestinal infections/ All of the above/ At least one of the above*	46.1
Health, medicinal or nutrition claims are permitted in materials directed at HCPs. True or false?	45.7
The distribution of free or low cost sales of designated products is permitted if the designated products are given to hospices, orphanages or places of safety. True or false?	42.9
This picture is part of an online shopping advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the Regulations. *Image of a growing up milk for over three years with a discounted price.*	37.6
Please select which of the following products are not covered under the Regulations. *Feedings bottles and teats/ Infant formula/ Sterilising equipment for bottles and teats/ Follow-up formula/ Feeding cups for older children/ Complementary foods*	30.1
Which of the following are not permitted to be used in foods for IYCF? *Trans-fatty acids/ Pesticide residues/ Honey or maple syrup/ Herbs and spices/ Sweeteners*	17.0

Abbreviations: health care provider (HCP), infant and young child feeding (IYCF)

Perceptions

Overall, survey participants seemed to have supportive perceptions towards the restriction of marketing of designated products. It came across that participants were passionate about breastfeeding and supported the regulation's aim; on average 88% of participants selected strongly agree/ agree to questions relating to support of the Regulations or positivity towards the Regulations. According to the survey participants, product representatives were mostly supportive and complaint with the regulations; 61% of participants selected strongly disagree/ disagree that representatives are still promoting designated products and 100% of representatives selected that they support the Regulations and try to adhere to them. Participants felt that the Regulations were important for HCPs and companies to be aware of and accept some responsibility with regard to reporting violations. Table 3 provides a summary of the participant's answers to the perceptions section of the survey.

TABLE 3: SUMMARY OF PERCEPTION QUESTIONS RESPONSES

Question	Strongly agree n (%)	Agree n (%)	Disagree n (%)	Strongly disagree n (%)
It is important for HCPs to be aware of the Regulations.	236 (83.7)	45 (16)	0	0
It is important for manufacturers, importers and distributors of designated products to be aware of the Regulations.	267 (94.6)	14 (5)	0	0
The sections of the Regulations that apply to HCPs are adequately enforced by the relevant authorities.	37 (13.1)	109 (38.7)	102 (36.2)	21 (7.5)
The Regulations will decrease the inappropriate use (for example, incorrect mixing or storage) of designated products by mothers and/or caregivers.	45 (16)	123 (43.6)	84 (29.8)	24 (8.5)

Question	Strongly agree n (%)	Agree n (%)	Disagree n (%)	Strongly disagree n (%)
It is my responsibility as a HCP to report violations of the Regulations when I become aware of a violation.	158 (56)	115 (40.8)	7 (2.5)	1 (0.4)
The Regulations are a positive step forward for South Africa to protect, promote and support breastfeeding.	171 (60.6)	92 (32.6)	17 (6.0)	0
I support the reasons behind the passing of the Regulations (for example, to support and protect breastfeeding) and would like to do what I can to ensure that they are adhered to and enforced.	183 (64.9)	88 (31.2)	8 (2.8)	0
The Regulations have relevance in the everyday work of HCPs working in IYCN.	169 (59.9)	106 (37.6)	5 (1.8)	1 (0.4)
I feel pressurised to back-up or refute claims when clients are influenced by claims and information in advertisements of designated products.	67 (23.8)	117 (41.5)	68 (24.1)	9 (3.2)
I think it is about time South Africa made the WHO Code into law through the Regulations, as the WHO Code was set in place 35 years ago.	142 (50.4)	102 (36.2)	21 (7.5)	4 (1.4)
The Regulations infringe on a mother's right to choose how she wants to feed her baby.	16 (5.7)	46 (16.3)	112 (39.7)	86 (30.5)
Before the Regulations, clients were being influenced to purchase designated products based on advertising in the media; for example, newspapers, magazines and TV.	111 (39.4)	139 (49.3)	22 (7.8)	6 (2.1)
For healthcare professionals visited by product representatives (n = 204)				
Product representatives are still promoting products designated in the Regulations as being prohibited to be promoted.	11 (5.4)	60 (29.4)	93 (45.6)	32 (15.7)
Representatives of designated products are mainly focused on serving their clients.	20 (9.8)	107 (52.5)	68 (33.3)	5 (2.5)
Representatives of designated products are mainly focused on promoting their products.	28 (13.7)	97 (47.6)	63 (30.9)	7 (3.4)
For representatives of designated products (n = 7)				
I support the Regulations and make an effort to adhere to them while doing my work.	5 (71.4)	1 (14.3)	0	0
I do not feel pressurised to adhere to the Regulations as there are no negative consequences if they are not adhered to.	0	0	1 (14.3)	5 (71.4)
I feel that there is a conflict between my duties as a product representative to promote the products I represent and my legal and ethical duties as a HCP to adhere to the Regulations.	1 (14.3)	1 (14.3)	1 (14.3)	3 (42.9)

Not applicable answers were excluded. **Abbreviations:** health care provider (HCP), infant and young child nutrition (IYCN), The International Code of Marketing of Breast-milk Substitutes (WHO Code)

For the statistical analysis of the survey data, quantile regression was used to compare the median knowledge score across perception levels. Spearman Correlation Coefficients were calculated to confirm associations. Only significant associations are reported here. Participants with higher knowledge scores had a tendency to have more realistic perceptions towards the Regulations. Those who strongly disagreed that the sections of the Regulations that apply to HCPs are being adequately enforced by relevant authorities had a median knowledge score of 10% higher than those who strongly agreed (95% CI: 1.1 – 18.9, p = 0.03). Those who strongly disagreed that the Regulations would decrease the inappropriate use of designated products by mothers and/or caregivers had a median knowledge score of 10% higher than those who strongly agreed (95% CI: 0.6 – 19.4, p = 0.04). Participants who disagreed that representatives of designated products were mainly focused on promoting their products had a 10% higher knowledge score than those who strongly agreed (95% CI: 2.6 – 17.4, p = 0.01). Those who strongly disagreed that clients were being influenced to purchase designated products based on advertising in the media before the Regulations, had a median knowledge score of 20% higher than those who indicated that they agreed or strongly agreed (95% CI: 6.3 – 33.7, p = 0.00) (Figure 1). Participants who disagreed that representatives of designated products were mainly focused on promoting their products had a 10% higher knowledge score than those who strongly agreed (95% CI: 2.6 – 17.4, p = 0.01). The Spearman Correlation Coefficients test confirmed a positive correlation between the first three associations mentioned in the paragraph above.

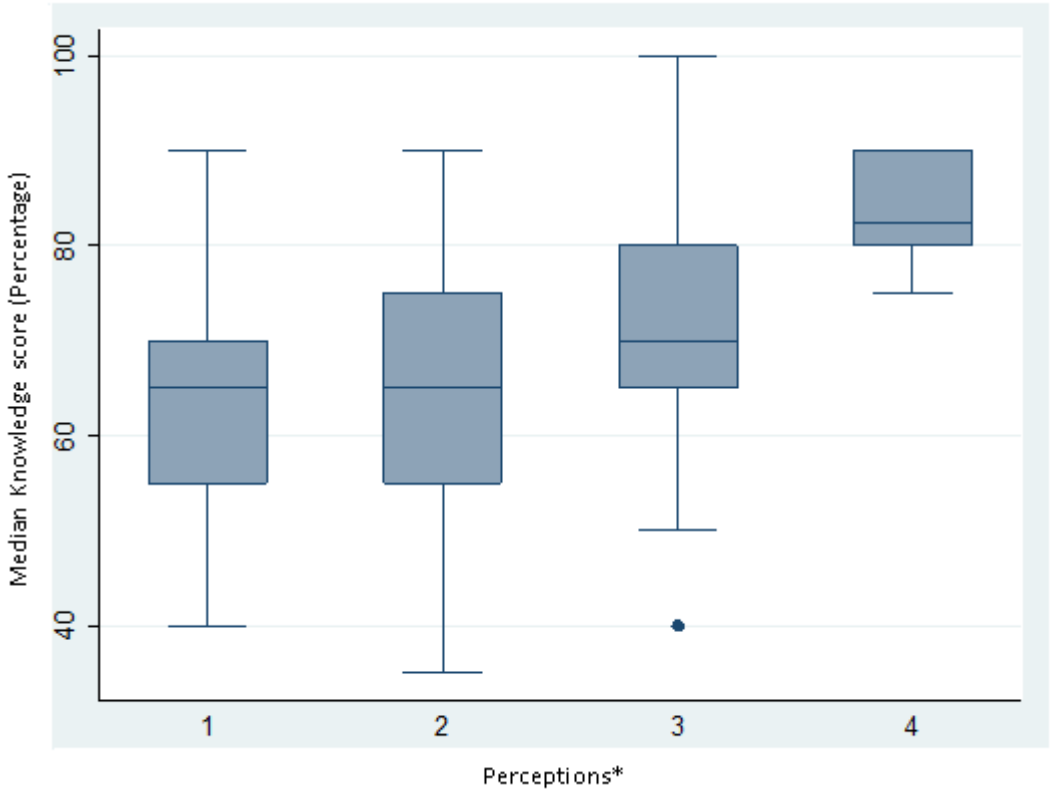

FIGURE 1: BOXPLOT OF PERCEPTIONS QUESTION VERSUS KNOWLEDGE SCORE

***Perceptions**: 1: Strongly agree, 2: Agree, 3: Disagree, 4: Strongly disagree

The participants from the focus group discussions felt that enforcement is lacking in the sections pertaining to HCPs. It was also apparent that participants did not feel fully confident in interpreting the Regulations and felt that "it is quite complex" and "there's a lot of grey areas".

Focus group participants believed that mothers have less knowledge about products controlled under the Regulations. It was perceived that mothers were receiving more general advice on replacement feeding and less information because dietitians were afraid to name brands or could not favour a specific product over another, which presumably resulted in confusion among the public: "I'm sure it's difficult for the moms out there … where to start, it's word of mouth at the end of the day" [stated slightly gloomily]. It was stated that mothers "do want an answer of what brand to use and if the client wants the information they're gonna get it anyway, they're just not gonna get it from a credible source". This was an interesting finding as the Regulations do not state that an HCP cannot recommend a particular product to a client if they believe a certain product is suitable. It was added (with frustration) that in some cases, medication is replacing feeds indicated for certain conditions due to a lack of knowledge: "you get all these thickened formulas but then the doctors will prescribe… PPIs [proton pump inhibitors]… A lot of the time medication is actually replacing… a specific formula because the moms don't know". Participants who were mothers and chose to use BMS admitted to finding it difficult to select a product. It was perceived that conflicting information was sometimes given by doctors or nurses and dietitians, which added to the confusion experienced by mothers. The large variety of designated products available on the market also made it overwhelming for mothers to choose.

Practices

Participants' practices appeared to be mostly compliant with the Regulations. Sixty nine and a half percent of participants (69.5%) indicated that they had a hard or electronic copy of the Regulations, and 37.9% of participants were aware of the supporting document created by the DoH providing guidelines on how to interpret the Regulations. Fifty four point six percent (54.6%) of participants indicated that they had attended training relating to the Regulations and 41.1% knew to whom violations of the Regulations should be reported. See Table 4 for a summary of answers to individual practice questions.

TABLE 4: SUMMARY OF PRACTICE QUESTIONS RESPONSES

Question	Always	Often	Sometimes	Seldom	Never
	n (%)	n (%)	n (%)	n (%)	n (%)
How often do you consult the Regulations to clarify an issue or due to uncertainty regarding its content?	4 (1.4)	24 (8.5)	63 (22.3)	114 (40.4)	59 (20.9)

Question	Always	Often	Sometimes	Seldom	Never
	n (%)	n (%)	n (%)	n (%)	n (%)
How often are you in a situation or consultation where you can make use of the Regulations (For example, a mother asking for advice on what type of formula to feed her baby)?	16 (5.7)	57 (20.2)	87 (30.9)	68 (24.1)	33 (11.7)
How often does your place of work accept donations of designated products?	0	2 (0.7)	3 (1.1)	13 (4.6)	232 (82.3)
I confidently employ the principles of the Regulations in my work environment.	108 (38.3)	93 (33)	35 (12.4)	13 (4.6)	1 (0.4)
How often in your experience are HCPs being held accountable for practices that are not compliant with the Regulations? (For example, the use of pens with logos of companies of designated products.)	4 (1.4)	38 (13.5)	40 (14.2)	83 (29.4)	84 (29.8)
How often do you make an effort to ensure that designated products are not visible to patients or clients in your work environment?	129 (45.7)	67 (23.8)	28 (9.9)	11 (3.9)	7 (2.5)
If you saw a violation of the Regulations, how often would you report it?	64 (22.7)	70 (24.8)	55 (19.5)	40 (14.2)	32 (11.4)
If you received a free gift from a company manufacturing, importing or distributing designated products under the Regulations; for example, a pen with the company logo, how often would you accept it?	30 (10.6)	24 (8.5)	59 (20.9)	51 (18.1)	93 (33)
How frequently have you accepted the following from a company manufacturing, importing or distributing a designated product under the Regulations in the last year?					
Promotional gifts (For example, stationery, calendars and diaries).	15 (5.3)	18 (6.4)	42 (14.9)	41 (14.5)	138 (48.9)
Sponsorship for research or to attend conferences	10 (3.6)	5 (1.8)	12 (4.3)	19 (6.7)	202 (71.6)
Free samples of designated products	7 (2.5)	4 (1.4)	15 (5.3)	20 (7.1)	207 (73.4)
Donations of designated products	3 (1.1)	0	5 (1.8)	13 (4.6)	228 (80.9)

Question	Strongly agree n (%)	Agree n (%)	Disagree n (%)	Strongly disagree n (%)
When educating patients or clients on the use of the information on the labels of designated products, the following aspects are important:				
Serving size	186 (66)	75 (26.6)	2 (0.7)	1 (0.4)
NRV (Only for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks.)	64 (22.7)	132 (46.8)	67 (23.8)	10 (3.6)
Total sugar content (Only for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks.)	85 (30.1)	137 (48.6)	46 (16.3)	6 (2.1)
Sodium content	75 (26.6)	135 (47.9)	59 (20.9)	4 (1.4)
Preparation instructions	247 (87.6)	28 (9.9)	0	1 (1.4)
Storage instructions	230 (81.6)	46 (16.3)	0	1 (0.4)
For healthcare professionals visited by product representatives (n = 204)				
I critically assess the appropriateness and scientific accuracy of the information provided by representatives of companies manufacturing, distributing or importing designated products.	83 (40.7)	104 (51)	13 (6.4)	1 (0.5)
It is the HCPs' right to decide whether or not they want to meet with representatives of companies manufacturing, distributing or importing designated products.	112 (54.9)	82 (40.2)	6 (2.9)	2 (1)
I have put boundaries in place with regard to meetings with representatives of companies manufacturing, distributing or importing designated products; for example, I only agree to a meeting if there is information that I need.	52 (25.5)	85 (41.7)	48 (23.5)	6 (2.9)
If a representative of a company manufacturing, distributing or importing designated products contravened the Regulations during a meeting with me I would report them to the relevant authorities at the DoH.	51 (25)	93 (45.6)	44 (21.6)	3 (1.5)
For representatives of designated products (n = 7)				
Since the implementation of the Regulations, I only provide HCPs with peer-reviewed scientific information.	3 (42.9)	2 (28.6)	1 (14.3)	0
Since the implementation of the Regulations, I no longer take gifts, such as pens or diaries to HCPs.	6 (85.7)	0	1 (14.3)	0
I check the educational material that I distribute to HCPs beforehand to ensure that they adhere to the Regulations.	6 (85.7)	0	1 (14.3)	0

Not applicable answers were excluded. **Abbreviations:** Department of Health (DoH), health care provider (HCP), nutrient reference values (NRV)

For the statistical analysis of the practices section, quantile regression was used to compare the median knowledge score across practice variables. Spearman Correlation Coefficients between knowledge score and practice variables were calculated and tested. Only significant associations are reported here. Participants who had a copy of the Regulations achieved a median knowledge score of 5% higher than those who did not (95% CI: 2.2 – 7.8, p = 0.00). Participants who knew to whom violations should be reported achieved a median knowledge score of 5% higher than those who did not (95% CI: 2.2 – 7.8, p = 0.00). Those who indicated that they never consulted the Regulations had a median knowledge score of 10% lower than those who always or often consulted the document (95% CI: -17.9 – -2.1, p = 0.01). This was confirmed by Spearman Correlation Coefficients (p = 0.02). Participants who report violations less frequently had significantly lower knowledge scores overall (p = 0.02). Disagreeing that Nutrient Reference Values (NRVs) were important when educating clients was associated with a 5% higher knowledge score than strongly agreeing (95% CI: 4.2 – 15.7, p = 0.00).

Pearson's Chi Squared Test was used to compare certain perception and practice variables. It was found that strongly positive perceptions towards the Regulations were related to more compliant or confident practices. For example, 100/215 (46.5 %) of participants who strongly agreed versus 8/35 (22.9%) of those who only agreed that it was important for HCPs to be aware of the Regulations always employed the principles of the Regulations with confidence (p = 0.00).

The focus group participants revealed that some dietitians report violations but those that do seem to be in the minority. Participants cited the following main reasons for not reporting violations: uncertainty regarding the procedure, too much effort and time consuming, a lack of action taken and the lack of feedback after reporting a violation. Dietitians recognise that they have a role to play in supporting and enforcing the Regulations; including implementing it in their own work environments, reporting violations, setting an example, training and "passing on information to other health care workers or police(ing of) other health care workers". Maintaining a professional relationship with product representatives and setting the tone for appointments with them is something that the participants felt dietitians needed to establish. One participant passionately stated: "We as dietitians need to enforce it (the Regulations)". The relationship between dietitians and product representatives has changed; fear of overstepping the Regulations, less information disseminated and not receiving gifts are possible reasons for this shift.

The focus group discussions revealed that a large discrepancy existed between the private and public sector practices. In the private sector, mothers might not be offered breastfeeding support routinely, this was an extra service and "they have to pay extra!" In government institutions, this was generally offered to all mothers at no extra cost. The following pensive comment, "I think we in government maybe are put more under the microscope" infers that public institutions seem to enforce the principles of these Regulations more strictly. The MBFI is currently not in place in many private facilities in South Africa, which one

participant identified as a "huge problem." New regulations are communicated better to public sector dietitians as they fall under the DoH's direct lines of communication. An interesting finding was that the participants working in the private sector felt that restriction of sponsorships was unnecessary; however, the participants in the public sector felt that this restriction was necessary and justified.

Enablers

Under the enablers section of the survey, participants were given a suggested list of 12 enablers and asked to choose the most relevant ones. Table 5 below provides a list of the enablers and the frequency with which each was selected by the participants.

TABLE 5: SUMMARY OF ENABLER QUESTIONS RESPONSES

Enabler	n (%)
Increase in other initiatives which support, protect and promote breastfeeding (for example, MBFI).	232 (82.3)
Greater awareness, compliance and positive changes by manufacturers, distributors and importers of designated products to be in line with the Regulations.	216 (76.6)
Awareness creation by the DoH among HCPs (working with infants or young children or in maternity care) of the Regulations.	207 (73.4)
A more scientific and less promotional approach by the representatives of companies that manufacture, distribute or import designated products.	199 (70.6)
Increased training of HCPs relating to the Regulations has taken place.	191 (67.7)
Greater awareness and support of the Regulations by dietitians assist in achieving their implementation.	187 (66.3)
Other measures taken by the DoH to support, protect and promote breastfeeding (for example, making breaks during the working day for lactating mothers to express breastmilk compulsory).	185 (65.6)
An increase in the number of mothers who are choosing to breastfeed has helped to confirm the importance of the Regulations.	176 (62.4)
Improved understanding of the Regulations as a result of the supporting document created by the DoH called, *Guidelines to industry and health care personnel: the Regulations Relating to Foodstuffs for Infants and Young Children, R. 991 of 6 December 2012 ("Regulations")*.	164 (58.1)
Effective communication from the DoH regarding the Regulations.	163 (57.8)
Improved enforcement of the Regulations.	160 (56.7)
Less focus on specific brands and their offering (brand loyalty) by mothers when selecting designated products encourages HCPs to support the Regulations.	110 (39.0)

Abbreviations: Department of Health (DoH), health care provider (HCP), Mother Baby Friendly Initiative (MBFI), Regulations Relating to Foodstuffs for Infants and Young Children (R991) (The Regulations)

Additional suggested enablers that emerged from the open-ended question in the survey included: a more effective procedure for reporting violations, awareness creation among mothers, improved enforcement of the Regulations, collaboration with the private sector and breastfeeding organisations, and strengthening and enforcing the Regulations in private health care facilities.

Of note is that the public sector focus group participants feel the INP in KwaZulu-Natal enforces these Regulations very strictly – to the extent that all product representatives visiting public health institutions need to go through the INP manager first. Participants reported that dietitians have found this to be a helpful approach.

Barriers

Under the barriers section of the survey, participants were given a suggested list of 15 barriers and asked to choose the most relevant ones. Table 6 provides a list of the barriers and the frequency with which each was selected by participants.

TABLE 6: SUMMARY OF BARRIER QUESTIONS RESPONSES

Barrier	n (%)
Lack of awareness of the Regulations among the general public.	232 (82.3)
Lack of awareness of the Regulations among HCPs.	231 (81.9)
Lack of training of HCPs on the Regulations.	213 (75.5)
There are other factors that prevent mothers from breastfeeding which undermine the goal that the Regulations aim to achieve; that is, improved breastfeeding rates. For example, lack of paid maternity leave.	198 (70.2)
Lack of training of enforcement officials on the Regulations.	188 (66.7)
Lack of confidence in the interpretation of the Regulations by HCPs.	177 (62.8)
Lack of monitoring and enforcing the Regulations by inspectors appointed by the Director-General.	168 (59.6)
HCPs who could assist with enforcement of the Regulations by reporting violations, are not doing so.	150 (53.2)
Lack of awareness of the Regulations among manufacturers, distributors and importers of designated products.	133 (47.2)
Complexity of the Regulations.	123 (43.6)
Penalties for contravening the Regulations are too lenient.	111 (39.4)
Some HCPs do not support the Regulations.	107 (37.9)

Barrier	n (%)
Lack of support from the DoH.	101 (35.8)
Marketing departments of companies who manufacturer, distribute and import designated products do not fully understand the purpose of the Regulations.	97 (34.4)
Manufacturers, distributors and importers of designated products are not complying with the Regulations as they are too restrictive.	69 (24.5)

Abbreviations: Department of Health (DoH), health care provider (HCP)

Additional barriers suggested by the survey participants included: poor communication from the DoH about the Regulations, non- or partial compliance from product representatives, the social stigma around breastfeeding, lack of knowledge regarding the procedure to report violations among the public and HCPs, conflicting information in the *Guidelines to Industry* document and the Regulations, as well as promotion of BMS on television shows.

The survey participants felt that doctors, midwives, nurses, speech therapists, some dietitians, hospital managers and pharmacists in particular were not always supportive of the Regulations; particularly, in the private sector. Many reasons were given for this lack of support; including, a lack of passion for breastfeeding, a lack of time and willingness to adequately support mothers breastfeeding in healthcare facilities, a lack of knowledge of the dangers and/or disadvantages associated with BMS, the ease of switching to BMS versus assisting a mother with breastfeeding problems, and a lack of awareness, knowledge and understanding of the Regulations among certain HCPs. Participants mentioned that there was also often a perception among mothers that breastmilk was not filling enough or that infants have insufficient weight gain when on breastmilk.

Participants listed many other factors that prevent mothers from breastfeeding in an open-ended question in the survey; some of the most frequently occurring were: insufficient maternity leave; mothers going back to work, and the difficulty of expressing breastmilk (including a lack of facilities in the workplace to express and store breastmilk); a lack of knowledge and implementation of the law allowing mothers to take breastfeeding or expressing breaks at work; inadequate paternity leave and involvement by fathers; and a lack of quality breastfeeding support in healthcare facilities.

The statistical analysis of the barriers section of the survey revealed a moderate positive correlation between number of barriers selected and the number of enablers selected using Spearman Correlation Coefficients ($r = 0.49$). Scatter Plots and Pearson's Chi Square Test indicate that those who strongly agreed that it was important for HCPs to be aware of the Regulations listed more barriers ($p = 0.03$) and more enablers ($p < 0.001$).

Numerous associations were found between specific enablers and barriers as well as perceptions and practices. While these findings were interesting, they were not the main focus of the study; thus, only a few notable examples are reported here. Those who strongly agreed that it was important for HCPs to be aware of the Regulations were more likely to choose the following barriers: 'Lack of awareness of the Regulations among manufacturers, distributors and importers of designated products' ($p = 0.02$) and 'HCPs who could assist with enforcement of the Regulations by reporting violations are not doing so' ($p = 0.02$). Participants who strongly agreed that clients were being influenced by the media prior to the Regulations were more likely to select the option 'Lack of awareness of the Regulations among the general public as a barrier' ($p=0.01$).

The focus group discussions brought up the influence of the media and the difficulty of regulating the area. Mediums such as "international TV shows" and "magazines from abroad" were not restricted by these Regulations and mothers and/or caregivers could be exposed to inappropriate marketing in this way. In a world where social media is widespread, violations can also "go under the radar"; an enthusiastic example was given of a celebrity's post on social media about a specific BMS and it being promoted in that way.

The focus group participants in both groups were of the opinion that other HCPs were not always compliant with the Regulations. The participants felt that other HCPs are generally not supportive of the Regulations either due to lack of awareness, a belief that it is not in their scope of practice or simply a lack of concern. Statements such as: "I don't think they [that is, other HCPs] care about this law" and "Doctors and nurses are saying: 'I'm not meant to be saying this... but this is what I recommend'" illustrates the perceived lack of support and compliance. It appears that other HCPs are not very willing to take responsibility for or ownership of the Regulations. This is an unfortunate finding as one of the participants stated that: "people are more likely to listen to a paediatrician or midwife than the dietitian".

According to the focus group participants, enforcement of the Regulations needed strengthening. Currently, it is trusted that those in the know will report violations and no task team has been appointed to take responsibility for enforcement. The procedure for reporting a violation was hastily described as "too much of an effort" and another participant agreed it was "a bit of a process". The following question was raised: "Is that complaint going to be heard?" This illustrates the perceived lack of transparency and feedback with regard to complaints that were reported. Refer to the text in the box below.

Box 1: Suggestions made during the focus group discussions

- The Regulations should include dummies and prohibition of the use of bottles in health care institutions.
- The types of bottles and feeding cups available on the market should be controlled, in accordance with what HCPs are advised to recommend to mothers and country appropriate. One respondent indicated that, "We're trying to not push people to buy bottles but there are so many bottles on the shelves."
- A standard scoop size for all BMS would be beneficial to prevent caregivers from reconstituting powdered milk incorrectly.
- A summary of the Regulations should be made for easier reading and understanding.
- The marketing of adult nutritional feeds and medications should be regulated as well to make the market fair.
- BMS should be made a prescription-only item to control its use, and to ensure that it is used safely and appropriately, and to control the accessibility of BMS as it is currently very readily available.
- The process for lodging a complaint needs to be made easier; for example, identifying a task team responsible for enforcing the Regulations, and creating an online portal or a call centre to report violations.

*Additional information from the focus group discussions is available as a separate addendum (Addendum F).

4.4 Discussion

This study can be considered a baseline study since it is the first in South Africa to investigate knowledge, perceptions and practices on the Regulations. The study was conducted nationwide and included dietitians from all provinces and sectors.

In the context of studies that assess dietitians' knowledge on certain topics, the findings of this study show some similarities. The mean knowledge score of 64.8% found in this study was similar to that of Steyn et al.[151] evaluating dietitians' knowledge of dietary supplements, which found a mean knowledge score ranging from 56.5 to 62.5%. Likewise, the older and (by default) more experienced participants had higher knowledge scores. Comparable to a study conducted in the USA among dietitians, investigating knowledge and perceptions of intuitive eating which found that greater knowledge of the topic was linked to greater use[157], this study found that those with greater knowledge of the Regulations were more likely to report integration of the Regulations into practice (for example, make an effort to adhere to the guidelines for health care establishments.) It could be argued that a knowledge score of 64.8% is less than impressive considering the topic involves legislative aspects of nutritional products and dietitians should be aware of this. It is plausible that the complexity and meticulous nature of the document is a partial explanation. The dietitians viewed it as a complicated and detailed legislation with the potential to be misinterpreted. However, the dietitians that participated in the survey would (by default) be those who were more interested in the Regulations; thus, it is possible that the knowledge of dietitians in general could be lower.

The study found a link between knowledge, positivity towards the Regulations and compliance and confidence in implementing the Regulations. This was a significant as it implies that if more efforts were directed at creating awareness of the Regulation and training HCPs it may translate into better implementation. It was interesting to find that those who strongly agreed that it was important for HCPs to be aware of the Regulations listed more barriers and more enablers; this suggests that more awareness gives rise to a better understanding of barriers and enablers surrounding the Regulations. Another interesting finding was that a lack of awareness by the public and HCPs were viewed as the two most prominent barriers and yet awareness creation by the DoH was viewed as a prominent enabler. A possible explanation for this is that awareness creation has been effected but has not been far-reaching enough to achieve satisfactory results beyond the DoH's immediate reach. It is also worth noting that MBFI came up as a prominent enabler to implementation of the Regulations and if this initiative were implemented in all facilities (as opposed to predominantly government facilities) the management and care of mothers would be more consistent and in line with the Regulations. This also emphasizes the discrepancy in practice between the private and the public sector that was identified in the study.

The dietitians who participated in this study felt that they had less knowledge on designated products since the passing of the Regulations. This may be a perception, since the intention of the Regulations was not to

place restrictions on factual information, but rather to prohibit enticing information and marketing ploys by manufacturers of designated products. The Regulations also do not restrict interaction between HCPs and the representatives, but dictate that the information shared must be scientific and factual. Nevertheless, there seems to be reluctance among dietitians to meet with representatives of companies that manufacture BMS and designated products and vice versa. This finding is not entirely negative; since, HCPs and representatives should be cautious and ensure that they follow the law.

There are various areas in which the current Regulations could be improved. Although not identified in this study, cross-branding seems to be a grey area that needs attention in the current Regulations. In some instances, BMS are promoted discreetly through the promotion of commercially-produced complementary foods with the same branding or produced by the same manufacturer.[88] Since complementary foods are currently exempt from any marketing restrictions under the Regulations, this may be the necessary follow-up step for national legislation in South Africa. The development of national quality standards for nutritional content, not only for BMS but also for complementary foods is necessary. In Kathmandu Valley in Nepal it was found that the consumption of commercially-produced snack foods by young children was high. These snack foods are often high in salt or sugar and may replace a more nutritious food item.[158] In South Africa (where optimal IYCN has risen on the Government's agenda) restricting the availability of less nutritious and commercially-produced snack foods may be a future option for improving feeding practices.

This study revealed that the enforcement of the Regulations is a barrier than requires attention. Champeny et al.[88] suggest that the manufacturers, distributors, importers, retailers and wholesalers of designated products need to accept the bulk of the responsibility for complying with food regulations that have been nationally legalised. This would be a more realistic expectation than the Government appointing a task team to monitor and enforce the legislation, since funding will likely be an obstacle. It was encouraging to find that for the most part industry seems to be compliant with the Regulations and product representatives seem to have supportive perceptions towards the Regulations and are making an effort to comply with them. The health sector should be willing to co-operate with industry to an extent in order to win their full cooperation with regards to the Regulations. Perhaps some form of corporate responsibility recognition or a system of resource sharing could be implemented for those companies that do comply with the legislation. The 2nd World Breastfeeding Conference 2016,[159] held in Johannesburg in December 2016, highlighted the importance of raising awareness and involving communities in the monitoring of the WHO Code. Community or social mobilisation to support the Regulations in South Africa would be beneficial to increase its reach. However, it is vitally important that all HCPs and not only dietitians should comply with this legislation and take responsibility for its enforcement. Further training of HCPs would certainly assist in achieving this, but in addition some form of monitoring needs to be in place to evaluate HCPs practices in relation to the Regulations and a system for enforcing accountability among HCPs would be very beneficial.

Dietitians briefly discussed the increase in digitalisation and the role that social media and online sites may play in advertising or promoting certain products. Control of this domain is a challenge, but is one that should not be ignored as it has the potential to influence many consumers and caregivers. Online reporting of contraventions of the Regulations could be a counter mechanism to this marketing platform. The procedure for reporting violations of the Regulations was found to be a noticeable barrier; only 41.1% of participants knew where to report a violation. It is useful to explore ways in which this area could be strengthened. The NetCode, which is a body created by the WHO to assist with the monitoring and enforcement of the International Code of Marketing of Breast-milk Substitutes (WHO Code), has created a means of recording government monitoring activities online by filling in a universal reporting form and uploading the file.[160] In Myanmar, a cell phone application was developed for WHO Code monitoring by the non-governmental organisation (NGO), Save the Children. The application was adopted by Myanmar's Department of Health and is apparently widely used throughout the country.[160] Adopting a similar user-friendly application in South Africa, and creating awareness among HCPs and the public of such a system could be one way to improve the challenges around reporting of violations.

Further, restricting the availability of products on the market may be a possibility to prevent inappropriate marketing from taking place and decreasing exposure to these products. In Senegal, the sale of BMS is restricted to pharmacies alone. Although the research did not demonstrate a definite link between the number of different products available in stores and the use of those products, there were possible correlations. For example, in Phnom Penn the increase in variety of BMS on the market coincided with declining breastfeeding rates.[88] One of the focus group participants suggested a similar idea of BMS becoming a prescription-only item to curb the ease with which it can be obtained and to decrease mothers' and/or caregivers' exposure to such products as well as prevent the incorrect use of these products. A system such as this would ensure that BMS are available to those who need them but that they are used safely and correctly under the supervision of a HCP.

The majority of BMS are imported to countries such as Cambodia, Nepal, Senegal and Tanzania.[88] This appears to be the case in South Africa as well. The importation of IYCF products may be problematic due to the availability of products on the shelf that are not always appropriate for South African consumers. For example, the measurement markings on bottles sold in South African stores display both millilitres and ounces, although only the metric system (millilitres) is in use in the country. One participant suggested restricting sales of bottles in general as feeding cups are preferred for hygiene reasons.

Despite resistance from certain countries, companies and even HCPs, legislating the WHO Code is without a doubt a vital step forward with a noble goal. Brazil is one of the leading countries in the regulation of BMS marketing, with action taking place as early as 1980 and the WHO Code being legislated in 2006.[134] Since then, breastfeeding rates in Brazil have shown continuous improvement.[161] In this study, some dietitians

felt that the restriction of BMS marketing and promotion of breastfeeding are two separate entities. While this may be true, it is clear that the restriction of harmful marketing practices is one of the key elements necessary to build an enabling environment to improve breastfeeding practices.

The restriction of marketing of IYCF products needs to happen alongside various other programmes and initiatives that have a vested interest in improving IYCN in order to realise the goal of providing every infant and young child with optimal nutrition. Such platforms might include breastfeeding awareness programmes among the public, organisations such as the International Baby Food Action Network (IBFAN), the WHO and La Leche League International (LLLI), Breastfeeding Week, laws surrounding breastfeeding (maternity leave and expression breaks), Human Milk Banking and child malnutrition programmes.

In conclusion, this study was the first of its kind to investigate South African dietitians' perspectives on the Regulations. The mean knowledge score of 64.8% could be considered acceptable. It was apparent that most dietitians have accepted the Regulations and were integrating them into their practices. The enablers and barriers identified helped to determine the strengths and weaknesses surrounding the implementation of the Regulations and could offer valuable insight to policy makers and governments in strive for universal legislation and implementation of the WHO Code.

The study's limitations include the non-random sampling strategy used to recruit participants, the inability to reach the initial sample size calculated and the difficulty in interpreting the findings in context. Sampling for the survey participants was opportunistic and convenient; thus, no inferences or generalisations could be made based on the data collected and all statistical analyses conducted only pertained to the 282 respondents of the study. The desired response rate was not achieved and approximately 83% of the targeted sample was obtained, which negatively influenced the strength of the findings. Interpreting the results was somewhat challenging, since there was not an abundance of similar research available for comparison purposes.

Chapter 5: Conclusion

5.1. Introduction

This chapter aims to summarise the findings of the study and draw logical conclusions from the results. The chapter includes a summary of findings, limitations, recommendations and final concluding remarks. The summary includes the main results of the study and a brief discussion of them. The limitations of the study throughout the process are also acknowledged. The recommendations consist of those from the study's findings and the researcher's deductions. The concluding remarks capture the essence of the study and highlight the value of the results to academic literature.

5.2. Summary of findings

South Africa passed a new legislation in 2012, the Regulations. The Regulations legislated the contents of the WHO Code drawn up by the WHA in 1981. This study aimed to determine the impact of the Regulations by evaluating dietitians' knowledge, perceptions and practices (including barriers and enablers) towards these Regulations and to get an indication of how the Regulations were being implemented within the country. The secondary objectives of the study were to determine the differences in knowledge level among sub-groups of participants and to investigate associations between knowledge, perceptions, practices, enablers and barriers. The perspectives of dietitians were determined by addressing each objective set out.

It was determined that dietitians have an average knowledge of 64.8% and those who work in IYCN had a 5% higher knowledge score. The participants felt that both dietitians and mothers have less knowledge on the products that are controlled under the Regulations. The mean knowledge score found in this study was similar to the study by Steyn et al.[151] evaluating dietitians' knowledge of dietary supplements, which found a mean knowledge score ranging from 56.5 to 62.5%; similarly, the older and (by default) more experienced participants had higher knowledge scores. The level of knowledge among this group of dietitians may be higher than that of dietitians in general as it was likely that those who participated in the study had a particular interest in the Regulations. It is interesting that the participants of this study perceived that they had less knowledge of products controlled under the Regulation; as interactions with representatives of designated products are not disallowed, but imparting information which is not scientific and factual is. This suggested that previously much of the information given to HCPs contained marketing and promotive aspects and now that this is restricted it appeared that there was less information available.

A positive response was received by the dietitians and the study found that the majority of dietitians supported the Regulations and were compliant with the conditions set out. Similarly, among those who work as representatives for designated products, the majority were also supportive of the Regulations. Unfortunately, the general feeling was that other HCPs were not as supportive and compliant as dietitians.

Dietitians recognise that they have a role to play in supporting and assisting the enforcement of the Regulations. Higher knowledge scores were often linked to more positive perceptions and more compliant practices. This was encouraging in the sense that if knowledge improved it might lead to more favourable perceptions towards the Regulations and more compliant practices.

The most common barriers to the implementation of the Regulations were a lack of awareness and training. An interesting finding was that a lack of awareness in the public and HCPs were selected as the two most prominent barriers and yet awareness creation by the DoH was selected as a prominent enabler. It might be that awareness creation has been effected but has not been as far-reaching as it should to achieve satisfactory results beyond the reach of the DoH. It was felt that a large discrepancy existed between what was practiced in the public sector and what was practiced in the private sector. It was felt that enforcement of the Regulations by authorities was also lacking.

Champeny et al.[88] suggest that the manufacturers, distributors, importers, retailers and wholesalers of designated products need to accept the bulk of the responsibility by complying with food regulations that have been nationally legalised. This would be a more realistic expectation in South Africa than for the Government to appoint a task force to monitor and enforce the legislation as funding will likely be an obstacle. It is apparent that the study participants would agree with this, as 99.6% agreed that it is important for manufacturers, importers and distributors of designated products to be aware of the Regulations. Seventy seven percent (that is, 77%) of participants selected the option: 'Greater awareness and compliance and positive changes to be in line with the regulations (R991) by manufacturers, distributors and importers of designated products' as an enabler, which was an encouraging finding.

The most common enablers to the Regulations identified in this study were other breastfeeding promotion initiatives, positive changes from industry and awareness creation by DoH. Countries that have restricted marketing of BMS, such as Brazil, have been able to improve breastfeeding practices.[161] Legislating the WHO Code is a vital step forward with a noble goal. It was mentioned in this study that the restriction of BMS marketing and promotion of breastfeeding are two separate entities. While this may be true, it is clear that the restriction of harmful marketing practices is one of the key elements necessary to provide the right environment to improve breastfeeding practices. Brazil is one of the leading countries in the regulation of BMS marketing, with action taking place as early as 1980 and the WHO Code being legalised in 2006. The breastfeeding rates in Brazil have shown continuous improvement[134] and South Africa strives for the same outcome.

This study is the first to investigate knowledge, perceptions and practices on the Regulations. One of the strengths of this study was that although random sampling was not feasible, the study was conducted nationwide and included dietitians from all provinces and sectors; thus, the results were anticipated to be representative to some degree. This study offers new knowledge to the academic community that helps to

determine and understand how the Regulations are being implemented in South Africa, it also helps to identify where the successes and shortcomings lie and develop recommendations for improvement.

5.3 Limitations

The limitations of this study need to be acknowledged. A random sampling method was not appropriate for the online survey. In order to achieve an acceptable response rate, sampling was opportunistic and convenient; thus, no inferences or generalisations could be made based on the data collected, and all statistical analyses conducted only pertained to the 282 respondents of the survey.

The response rate for the survey was less than optimal and approximately 83% of the target sample size was obtained. This resulted in a slightly lower precision of 5.7%.

The number of dietitians working as product representatives for designated products who participated in the survey was very small (n = 7) and no real statistical analysis could be done on this data. It would be interesting to gain further insight into the perspectives of product representatives on the Regulations.

Since this is a baseline study it is difficult to interpret the findings in relation to other studies and place the research into context. It is also challenging to determine an acceptable level of knowledge in this context as little information is available in the literature investigating the knowledge of South African dietitians in particular. The topic is also relatively new.

5.4 Recommendations

As is often the case, education is needed when development takes place. The education of HCPs (dietitians and others) is vital to create better awareness and understanding of the Regulations and assist in creating a positive perception toward the Regulations. The Regulations document is perceived as cumbersome and some dietitians find it difficult to interpret. A summarised or simplified version of the Regulations may assist in alleviating some of this confusion. The inclusion of breastfeeding training, including on the Regulations in the curriculum for other HCPs (for example, nurses, doctors, speech therapists, etc.) would assist in improving their knowledge and support for breastfeeding. In addition to awareness creation among HCPs, the public should be more aware of these Regulations and encouraged to support the implementation. Better communication of new regulations and other new legislation or programmes is needed; and this should reach all HCPs, not only those employed by the DoH. Perhaps the use of a national board, such as the HPCSA, for communication and continuous professional development (CPD) opportunities on the Regulations would be more effective.

The Regulations should be linked with other breastfeeding support initiatives and campaigns for maximum exposure; such as MBFI, National Breastfeeding Week and local malnutrition programmes. Greater collaboration between the private and public sectors will help ensure a strong and unified message with

regard to breastfeeding promotion. Alongside the education of HCPs; Feeley et al.[77] suggest that we continue to educate mothers on safe and nutritious feeding of infants and young children, the health benefits of breast milk, the disadvantages of using commercially-produced snack foods and the implications of poor nutrition in children. Educating mothers on the disadvantages of elective caesarean section delivery will assist in earlier initiation of breastfeeding and prevention of pre-lacteal feeds.

It may be beneficial to control which products are allowed into the market. National quality standards for nutritional content of complementary foods would be a further step in the right direction. Restricting the access to BMS may assist in shifting the mind-set of the public to one that values and respects breastfeeding; either by making BMS a prescription-only item or by restricting sales to only pharmacies. Making it a prescription-only item would assist in eliminating some of the confusion due to the large variety on the market. Further restriction of the marketing of complementary foods may help to prevent branding associations between BMS and complementary foods produced by the same company and to ensure that unhealthy complementary foods are not marketed unfairly to children.[88] Tightly controlling the importation of designated products could help ensure that the products available on the shelves are appropriate for South African consumers. For example, bottle manufacturers should place only millilitre markings on bottles imported to South Africa.

It appears as though monitoring and enforcement of the Regulations requires urgent attention. If a specific team were selected or employed to take the responsibility for the monitoring and enforcement then this would address many of the barriers currently experienced. Community involvement in the monitoring process would help increase the reach. More people would be willing to report violations if the procedure was made user-friendly, and awareness being created surrounding the steps to report a violation would be beneficial. The reporting of complaints or violations would also likely improve if the reporter received adequate and timely feedback in relation to the complaint. The monitoring of HCPs, specifically in the private sector, can improve, and a system for establishing accountability for transgressions may be beneficial.

It is advisable that dietitians and other HCPs visited by representatives adapt their relationships so that the maximum amount of product knowledge is transferred without overstepping the Regulations. The Regulations allow for factual scientific information to be given out by representatives and HCPs can request factual information about any product. HCPs have a duty to communicate replacement feeding options to mothers or caregivers and to provide them with all the information needed to make an informed decision about infant feeding, without showing undue preference to any particular product.

Suggestions for future research would be to include other HCPs such as nutritionists, nutrition advisors, nurses and doctors in a study. The results of this study suggest that improved knowledge is linked to more favourable practices; it would be interesting to investigate whether an educational intervention in HCPs

leads to improved perceptions and practices with regard to the Regulations. Since manufacturers, distributors and importers of designated products bear the majority of responsibility under the Regulations, it would be useful to investigate the contrast in perspectives between the industry and the health sector.

Regulations that protect the interests of the majority of the population are a necessity; especially those that target the vulnerable groups such as mothers and infants. It is the most vulnerable who suffer when commercial interests are contrary to public health priorities.[162] It is the responsibility of HCPs to always act in the best interests of their patients and to provide the best possible care within their available resources; if we are not implementing the Regulations then we are not doing this. The dietitian, as a professional that values optimal nutrition and development and understands the importance of early life nutrition, should have a particular interest in fostering the successful implementation of these Regulations. Prioritising breastfeeding is no longer a choice, it is a responsibility.

5.5 Conclusion

It is important to consider the perspectives of HCPs when evaluating the impact of regulations to restrict the marketing of products for IYCF as they have an indispensable role in assisting with successful implementation of such regulations. This study aimed to determine dietitians' perspectives on the Regulations passed in South Africa by investigating knowledge, perceptions and practices.

The Regulations have for the most part been well received by dietitians and the survey indicated an acceptable knowledge thereof (64.8% ± 12.5). If one uses the standard academic ratings to assess the level of knowledge, ≥ 50% would be considered acceptable (a pass) and ≥ 75% would be considered a *cum laude.* Thus, the knowledge level in this group of dietitians can be considered acceptable. It was perceived by the participants that the knowledge and awareness of the Regulations in other HCPs is lacking. The results of this study indicate that better knowledge results in a better ability to practice in accordance with the Regulations; a better knowledge of how to report violations and more willingness to do so, avoidance of any unintentional promotion of designated products in the workplace and greater awareness of enablers and barriers. Perceptions and practices were generally positive and compliant. Positive perceptions towards the Regulations were linked with more compliant and supportive practices. It is encouraging to find that improved knowledge seems to correlate to more supportive practices; this infers that training and education on the Regulations can lead to positive outcomes in implementation. Many enablers and barriers arose which provide interesting insights into how the Regulations are being integrated within the domain of IYCF.

The focus group discussions provided intuitive and often unexpected results, which helped to explore the issues that dietitians experience in their day-to-day practice with the Regulations, their opinions on the strengths and weaknesses of the implementation, and their suggestions for areas of improvement.

According to the literature, legislation that restricts the marketing of designated products mainly requires improvements in the strength of the legislation and the monitoring and enforcement thereof.[88] This study identified the lack of monitoring and enforcement as major concerns. Sixty per cent (that is, 60%) of study participants selected the option: 'Lack of monitoring and enforcement of the regulation (R991) by inspectors appointed by the Director-General' as a barrier.

This study was the first to investigate South African dietitians' perspectives on the Regulations. The mean knowledge score of 64.8% can be considered acceptable. It is apparent that dietitians have accepted the Regulations and are integrating them into their practices for the most part. The enablers and barriers identified, help to determine the strengths and weaknesses surrounding the implementation of the Regulations. There are gaps that remain and that still need to be addressed pertaining to the regulation of infant and young child foodstuffs. South Africa has made the first step in legislating the WHO Code and should upscale programmes to ensure consistent monitoring and enforcement. Research that evaluates the implementation and determines the impact of legislating the WHO Code is important to strengthen weaknesses and offers valuable insight to policy makers and governments in the strive to achieve universal legislation and implementation of the WHO Code.

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Chapter 7: Addenda

7.1 Addendum A: survey cover letter and consent form

SURVEY COVER LETTER AND CONSENT FORM

UNIVERSITEIT STELLENBOSCH UNIVERSITY

To whom it may concern,

Re: Regulations Relating to Foodstuffs for Infants and Young Children (R991): perspectives from South African dietitians.

You are invited to take part in a research study, conducted as part of a master's degree through Stellenbosch University. You have been invited to participate because as a registered dietitian working in South Africa your input is valued. Please note that your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

The principle investigator is Megan Clarke, a registered dietician at Mahatma Gandhi Memorial Hospital, with N. Koen and L. du Plessis as study leader and co-study leader. This study has been approved by the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

The aim of the study is to determine the knowledge, attitudes, practices, barriers and enablers of dietitians in South Africa regarding the Regulations Relating to Foodstuffs for Infants and Young Children. Secondary study objectives will be to investigate differences and associations between various subgroups and parameters measured.

Data on the perspectives of dietitians will be collected using an online questionnaire that will be distributed to registered dietitians in South Africa through several professional organisations and social media. The questionnaire will be completed using SurveyMonkey and no information will be linked to any participant directly. No personal information will be recorded without permission. Email addresses may be given if the individual chooses to take part in a lucky draw/ to be contacted to take part in a focus group discussion on a future date. Any contact details obtained by the researcher will be kept confidential and not used for any other purpose than contacting the winners of the draw/ communicating details of the focus group discussion. Contact details will be deleted/ discarded after completion of the study. Study findings will be submitted for publication in peer reviewed journals.

What will your responsibilities be?

- Participation in the study will involve clicking on the link to the online survey and completing the questions. There are six sections in total and should take approximately twenty to thirty minutes to complete.
- Your responsibilities will include completion of the online survey and ensuring that your answers are as honest and accurate as possible.

Will you benefit from taking part in this research?

- The benefit of participating in this research is that it provides the opportunity to make your perspectives known on the Regulations relating to Foodstuffs for Infants and Young children.
- The study has the potential to provide benefit to government and policy makers to improve matters related to the R991 regulations.

Are there any risks involved in your taking part in this research?

The only potential risk you take in participating is if you decide to disclose your contact details to be entered into a lucky draw. This is optional and contact details will not be used for any other purpose but to contact winners of the draw, the researcher will safeguard all contact information and it will be deleted after completion of the study. Only the principle investigator will have access to contact information.

Who will have access to your questionnaire answers and contact information?

- All information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participant will remain anonymous. Only individuals directly involved in the study will have access to this information; the researcher, study leaders and statistician.
- Study monitors or auditors or research ethics committee members may need to inspect research records. If this is deemed necessary, the confidentiality of information will be protected at all times.

Will you be paid to take part in this study and are there any costs involved?

No you will not be paid to take part in the study. There will be no costs involved for you, if you do take part. As compensation for your time and effort in participating in the study you will be entered into a lucky draw to win one of four R1000 vouchers (if you choose to leave your contact information.)

Is there anything else that you should know or do?

- You can contact the researcher, Megan Clarke at 0825572257 or meganclarke05@gmail.com if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the researcher.

Before completing the survey please make sure you have read through the participant information leaflet and consent form above. By clicking the "I agree" box on the first page of the survey **you are giving your consent to take part in the study.** The survey will be available until 15 July 2017. If you agree to participate, please click on the link to take the survey.
https://www.surveymonkey.com/r/R991

Thank you for choosing to participate, your input is highly valuable to achieve the aims of this study and through gaining a better understanding of dietitians' perspectives on the regulations it is possible to improve implementation and ultimately infant and young child feeding practices in the country.

Kind regards,
Megan Clarke RD (SA)

Declaration by participant

By giving my assent to participate (by clicking the "I agree" box on the first page of the survey) I agree to take part in the research study entitled Regulations Relating to Foodstuffs for Infants and Young Children: perspectives from South African dietitians.

I declare that:

- I have read this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.

7.2 Addendum B: consent form for focus group discussions

PARTICIPANT INFORMATION LEAFLET AND CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Regulations Relating to Foodstuffs for Infants and Young Children: perspectives from South African dietitians.

REFERENCE NUMBER: S16/02/024

PRINCIPAL INVESTIGATOR:

Megan Clarke

ADDRESS:

14 Beulah Hill

Pinehurst Village

Mount Edgecombe Country Club Estate 2

4302

CONTACT NUMBER:

0825572257

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study staff any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee of the Faculty of Medicine and Health Sciences at Stellenbosch University** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practice and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- *Participating in the study will involve partaking in a focus group discussion among registered dietitians in South Africa. The focus group will last for approximately one hour and you will be encouraged to give your perspectives on the Regulations Relating to Foodstuffs for Infants and Young Children (R991).*
- *The Focus group discussion will be conducted in _____ KwaZulu-Natal. There will be one other focus group conducted at a venue to be confirmed. In total the groups will consist of 6-12 participants at each venue.*
- *The project aims to determine dietitians' attitudes, behaviours and practices (including barriers and enablers) regarding the Regulations Relating to Foodstuffs for Infants and Young children (R991/2012). It is hoped that the research will provide useful insights for government and policy makers going forward.*

Why have you been invited to participate?

- *You have been invited to participate because as a registered dietitian working in South Africa your input is valued.*

What will your responsibilities be?

- *To be present on the day of the focus group discussion, at the venue and time communicated to you by the researcher and to actively participate in the discussion, this will be approximately one hour duration.*
- *To keep all content discussed during the focus group confidential.*

Will you benefit from taking part in this research?

- *The benefits of participating in this research is that it provides the opportunity to make your perspectives known on the Regulations Relating to Foodstuffs for Infants and Young children and to engage with colleagues on topics relating to the regulations.*
- *The study has the potential to provide benefit to government and policy makers to improve matters related to the R991 regulations.*

Are there any risks involved in your taking part in this research?

- *There are no risks to you by taking part in this research.*

Who will have access to the information collected during the focus groups?

- *All information collected will be treated as confidential and protected. If it is used in a publication or thesis, the identity of the participants will remain anonymous. The identity of participants will remain anonymous by using codes instead of names. Only individuals directly involved in the study will have access to this information; the researcher, observer, study leaders and statistician.*
- *Study monitors, auditors or research ethics committee members may need to inspect research records. If this is deemed necessary, the confidentiality of information will be protected at all times.*

Will you be paid to take part in this study and are there any costs involved?

No, you will not be paid to take part in the study but you will be compensated for your time and travel expenses with a voucher to the value of R200. There will be no costs involved for you, if you do take part.

Is there anything else that you should know or do?

- The focus group discussion will be recorded using an audio recorder, by signing this consent form you give your permission for the discussion to be recorded.
- You can contact the researcher, Megan Clarke at 0825572257 or meganclarke05@gmail.com if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee of the Faculty of Medicine and Health Sciences, Stellenbosch University at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the researcher.
- You will receive a copy of this information and consent form for your own records.

Declaration by participant

By signing below, I …… agree to take part in a research study entitled Regulations Relating to Foodstuffs for Infants and Young Children: perspectives from South African dietitians.

I declare that:

- I have read or had read to me this information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.
- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.

- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) ..... on (*date*) ..... 2017.

....

Signature of participant **Signature of witness**

By signing below, I ..... **agree to have the focus group discussion audiotaped.**

Signed at (*place*) ..... on (*date*) ..... 2017.

....

Signature of participant Signature of witness

Declaration by investigator

I *(name)* ..... declare that:

- I explained the information in this document to .....
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter. (*If an interpreter is used then the interpreter must sign the declaration below.*

Signed at (*place*) ..... on (*date*) ..... 2017.

....

Signature of investigator **Signature of witness**

Declaration by interpreter

I *(name)* …… declare that:

- I assisted the investigator (*name*) …… to explain the information in this document to (*name of participant*) …….. using the language medium of Afrikaans/Zulu.
- We encouraged him/her to ask questions and took adequate time to answer them.
- I conveyed a factually correct version of what was related to me.
- I am satisfied that the participant fully understands the content of this informed consent document and has had all his/her question satisfactorily answered.

Signed at (*place*) ..... on (*date*) ……..

....

Signature of interpreter **Signature of witness**

7.3 Addendum C: online survey

PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

INTRODUCTION

Hi and welcome to the survey on ASSESSING PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991). Thank you for taking the time to complete it, your contribution will be most valuable. The survey should take approximately 30 minutes to complete.

The Regulations relating to Foodstuffs for infants and Young Children (R991)are published regulations under the Foodstuffs, Cosmetics and Disinfectants Act. In terms of these regulations a number of restrictions are placed on the labelling, advertisement and promotion of infant and follow-up formulae, liquid or powdered milk marketed as being suitable for infants or young children, complementary foods, feeding bottles, teats and feeding cups with spouts, straws or teats.

Please make sure you take time to read the participant information leaflet and consent form before starting.

The survey consists of six sections. Please answer all applicable questions. As the survey is aimed at assessing understanding and interpretation of the R991 regulations, you may refer to the regulations if you wish to while completing the questions. Copy and paste the following link into your browser to access the R991 document: http://faolex.fao.org/docs/pdf/saf122685.pdf.

We would appreciate it if you would answer the survey questions as honestly as possible.

If you have read through the survey cover letter and consent form and agree to take part in the study by completing the questionnaire, please indicate so by clicking 'I agree' below.

◯ I agree

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

1. DEMOGRAPHIC INFORMATION

To start, please share some background information on yourself.

1.1. Are you aware of the Regulations Relating to Foodstuffs for Infants and Young Children (R991)?

- ◯ Yes
- ◯ No

1.2. Have you read the regulations (R991)?

- ◯ Yes
- ◯ No

1.3. What is your gender?

- ◯ Male
- ◯ Female

1.4. What is your date of birth?

Date DD / MM / YYYY

1.5. Which province do you reside in?

If you live in KwaZulu-Natal and would like to participate in a focus group discussion on the same topic as this survey in the next few months, please leave your email address so you can be contacted with the details of the focus group. (Emails will only be used to send details out to those interested.)

1.6. How many years have you been practicing as a dietitian?

(Please round off to the nearest whole number.)

1.7. What category of practice are you currently working in? (You may check more than one if appropriate.)
*If not currently working, please select last place of work.

- [ ] Public service
- [ ] Training institution
- [ ] Private practice
- [ ] Research
- [ ] Education
- [ ] Academia
- [ ] Food service management
- [ ] Food industry
- [ ] Non-governmental organisation
- [ ] Civil society organisation
- [ ] Corporate
- [ ] Other (please specify)

1.8. Do you currently work with infants and young children (children under 5 years), or in maternity care?

- ( ) Yes
- ( ) No

1.9. How many years of experience do you have working with infants and young children, pregnant women or breastfeeding mothers? (Even if you are not currently working in these areas you may indicate your previous experience.)

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

2. ATTITUDES

This section contains a number of short questions to find out what you think and how you feel about the Regulations Relating to Foodstuffs for Infants and Young Children (R991).

Definition of designated products:
Products that fall within the scope of the R991 regulations (i.e. infant formula; follow-up formula; infant or follow up formula for special dietary management for infants with specific medical conditions; complementary foods; liquid milks, powdered milks, modified powdered milks, or powdered drinks marketed or otherwise represented as suitable for infants and young children; feeding bottles, teats, and feeding cups with spouts, straws or teats; and 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.)

Please use a 5 point scale when answering these questions to indicate your extent of agreement to each statement. Check the 'not applicable' option if a question does not apply to you.

1: Strongly Agree
2: Agree
3: Disagree
4: Strongly Disagree
5: Not applicable

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
2.1. It is important for health care providers to be aware of the regulations (R991).	○	○	○	○	○
2.2. It is important for manufacturers, importers and distributors of designated products to be aware of the regulations (R991).	○	○	○	○	○
2.3. The sections of the regulations (R991) that apply to health care providers are adequately enforced by the relevant authorities.	○	○	○	○	○
2.4. The regulations (R991) will decrease the inappropriate use (e.g. incorrect mixing/ storage) of designated products by mothers/ caregivers.	○	○	○	○	○
2.5. It is my responsibility as a health care provider to report violations of the regulations (R991) when I become aware of a violation.	○	○	○	○	○
2.6. The regulations (R991) are a positive step forwards for South Africa to protect, promote and support breastfeeding.	○	○	○	○	○
2.7. I support the reasons behind the passing of the R991 regulations (e.g. to support and protect breastfeeding) and would like to do what I can to ensure that they are adhered to and enforced.	○	○	○	○	○
2.8. The regulations (R991) have relevance in the everyday work of health care providers working in infant and young child nutrition.	○	○	○	○	○
2.9. I feel pressurised to back-up or refute claims when clients are influenced by claims and information in advertisements of designated products.	○	○	○	○	○
2.10. I think it is about time South Africa made the Code into law through the regulations (R991), as the Code was set up 35 years ago.	○	○	○	○	○
2.11. The regulations (R911) infringe on a mother's right to choose how she wants to feed her baby.	○	○	○	○	○
2.12. Before the regulations (R991), clients were being influenced to purchase designated products based on advertising in the media. E.g. Newspapers, magazines, tv.	○	○	○	○	○

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2.13. In your workplace are you visited by representatives of companies importing, manufacturing, and distributing designated products?

(Please refer to the definition of designated products above.)

- ◯ Yes
- ◯ No

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

2. ATTITUDES

Please answer the following questions about visits by representatives of companies importing, manufacturing, and distributing designated products using the same 5 point scale as the previous question.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
2.14. Product representatives are still promoting products designated in the regulations (R991) as being prohibited to be promoted.	○	○	○	○	○
2.15. Representatives of designated products are mainly focused on serving their clients.	○	○	○	○	○
2.16. Representatives of designated products are mainly focused on promoting their products.	○	○	○	○	○

Please answer the next few questions on your practices in relation to visits by representatives of companies producing, manufacturing and distributing designated products.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
2.17. I critically assess the appropriateness and scientific accuracy of the information provided by representatives of companies manufacturing, distributing or importing designated products.	○	○	○	○	○
2.18. It is the health care providers' right to decide whether or not they want to meet with representatives of companies manufacturing, distributing or importing designated products.	○	○	○	○	○
2.19. I have put boundaries into place with regards to meetings with representatives of companies manufacturing, distributing or importing designated products. E.g. I only agree to a meeting if there is information I need.	○	○	○	○	○
2.20. If a representative of a company manufacturing, distributing or importing designated products contravened the regulations (R911) during a meeting with me I would report it to the relevant authorities at the Department of Health.	○	○	○	○	○

PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

2. ATTITUDES

2.21. Are you a product representative for a company manufacturing, transporting or distributing designated products as defined in the regulations (R991)?

- ◯ Yes
- ◯ No

PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

2. ATTITUDES

Please answer the following questions for representatives of companies importing, manufacturing, and distributing designated products using the same 5 point scale as the previous question.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
2.22. I support the regulations (R991) and make an effort to adhere to them while doing my work.	○	○	○	○	○
2.23. I do not feel pressure to adhere to the regulations (R991) as there are no negative consequences if they are not adhered to.	○	○	○	○	○
2.24. I feel that there is a conflict between my duties as a product representative to promote the products I represent and my legal and ethical duties as a health care provider to adhere to the regulations (R991).	○	○	○	○	○

Please answer the next few questions on your practices as a representative of a company importing, manufacturing, and distributing designated products.

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
2.25. Since the regulations (R991) I only provide health care providers with peer reviewed scientific information.	○	○	○	○	○
2.26. Since the regulations (R991) I no longer take gifts, such as pens or diaries, to health care providers.	○	○	○	○	○
2.27. I check the educational material I distribute to health care providers beforehand to ensure that they adhere to the regulations (R991).	○	○	○	○	○

PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

3. KNOWLEDGE

Thank you for your answers to this point. This section aims to determine current knowledge relating to the regulations (R991). Please answer each question to the best of your ability and if uncertain of an answer please select which you think is most appropriate. You may refer to the regulations (R991) while answering the questions.

3.1. Please select which of the following products are<u>not</u> covered under the regulations (R991). (More than one answer may be selected.)

- ☐ Feedings bottles and teats.
- ☐ Infant formula.
- ☐ Sterilising equipment for bottles and teats.
- ☐ Follow-up formula.
- ☐ Feeding cups for older children.
- ☐ Complementary foods.

3.2. This picture is part of a newspaper advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the regulations (R991).

- ○ Permitted
- ○ Not permitted

3.3. This picture is part of an online shopping advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the regulations (R991).

- ◯ Permitted
- ◯ Not permitted

3.4. This picture is part of a magazine advertisement, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the regulations (R991).

- ◯ Permitted
- ◯ Not permitted

3.5. This picture is part of a product catalogue, please indicate if the practice depicted in the picture is permitted or not permitted in terms of the regulations (R991).

- ◯ Permitted
- ◯ Not permitted

3.6. Please select the most appropriate answer.
In the regulations (R991), a 'young child' refers to:

- ◯ A person from 0-6 months old.
- ◯ A person between 12 and 36 months.
- ◯ A person from 12-59 months old.

3.7. Please answer true/ false to the following statement. The distribution of free or at low cost sales of designated products is permitted if the designated products are given to hospices, orphanages or places of safety.

- ☐ True
- ☐ False

3.8. Please answer true/ false to the following statement.
The following illustration may <u>not</u> be shown on the category of formula within the designated products.

- ◯ True
- ◯ False

3.9. Please select the most appropriate answer.
Based on the regulations (R991) a health claim, such as "This milk can help to ensure baby has a healthy tummy":

- ○ Is allowed to be displayed on designated products.
- ○ Is allowed to be displayed on complementary foods but not for infant or follow-up formula.
- ○ Is not allowed to be displayed on any designated product.

3.10. Please answer true/ false to the following statement. According to the regulations (R991) nutritional information for complementary foods and liquid milks, powdered milks, modified powdered milks and powdered drinks must include nutritional information per single serving.

- ☐ True
- ☐ False

3.11. Please answer true/ false to the following statement.
The product displayed in the picture below is covered under the regulations (R991) as a designated product.

- ○ True
- ○ False

3.12. Please select the most appropriate answer.
According to the regulations (R991) which of the following health messages must be present on containers/ labels of infant formula and infant formula for special dietary management for infants with specific medical conditions?

- ○ Infant formula increases an infant's risk of allergy.
- ○ Infant formula increases an infant's risk of ear infections.
- ○ Infant formula increases an infant's risk of acute respiratory disease.
- ○ Infant formula increases an infant's risk of gastrointestinal infections.
- ○ All of the above.
- ○ At least one of the above.

3.13. Based on the regulations (R991) which of the following are false regarding the labelling of infant formula, follow-up formula, or infant or follow-up formula for special dietary management for infants with specific medical conditions? (Select all that apply.)

- [ ] Appropriate age range must be present on the label.
- [ ] The statement 'Breast milk is the best food for babies' must be on the label.
- [ ] The claim 'Gluten free' must be on the label if a product does not contain gluten.
- [ ] The statement 'This product is not always sterile and may contain harmful micro-organisms. It must be prepared and used appropriately' must be on the label.

3.14. Please answer true or false to the following statement.
The following picture is allowed to be displayed on an infant formula, follow-up formula, or infant of follow-up formula for special dietary management for infants with specific medical conditions.

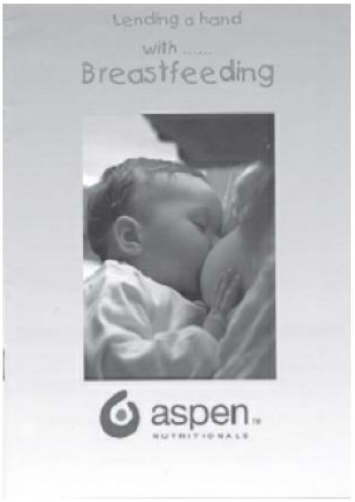
- ( ) True
- ( ) False

3.15. Please answer true or false to the following statement.
The following picture indicates a cost saving on the products displayed. This practice is not permitted.

- ( ) True
- ( ) False

3.16. Please answer true or false to the following statement.
The educational material displayed in the picture would be appropriate for health care providers to hand out to **mothers** in a unit taking care of infants and young children, pregnant mothers or mothers of infants and young children.

- ◯ True
- ◯ False



3.17. Please answer true or false to the following statement.
The following picture as part of a dinner invitation sent out to health care providers would<u>not</u> be permitted.

- ◯ True
- ◯ False

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3.18. Please answer true or false to the following statement.
Health, medicinal or nutrition claims are permitted in materials directed at health care providers.

- ◯ True
- ◯ False

3.19. Which of the following are<u>not</u> permitted to be used in foods for infant and young child feeding? (Please select all that apply.)

- ☐ Trans-fatty acids
- ☐ Pesticide residues
- ☐ Honey/ maple syrup
- ☐ Herbs and spices
- ☐ Sweeteners

3.20. Please answer true or false to the following statement.
The picture provides an example of appropriate educational material for**health care providers**.

- ◯ True
- ◯ False

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

4. PRACTICE

Thank you for your answers to this point, we appreciate your taking the time. The next section aims to find out how the regulations (R991) are being used in practice.

4.1. Do you have a hard or electronic copy of the regulations (R991)?

- ◯ Yes
- ◯ No

4.2. Are you aware of the supporting document created by the Department of Health providing guidelines on how to interpret the regulations (R991) entitled "*Guidelines to industry and health care personnel: the regulations relating to foodstuffs for infants and young children*"?

- ◯ Yes
- ◯ No

4.3. Have you ever attended a training session/ presentation/ orientation/ lecture on the regulations (R991)?

- ◯ Yes
- ◯ No

4.4. Do you know to whom violations of the regulations (R991) should be reported?

- ◯ Yes
- ◯ No

Please use a 6 point scale when answering the following questions and indicate how often you experience each scenario. Check the 'not applicable' option if a question does not apply to you.

1: Always
2: Often
3: Sometimes
4: Seldom
5: Never
6: Not applicable

	Always	Often	Sometimes	Seldom	Never	N/A
4.5. How often do you consult the regulations (R991) to clarify an issue/ due to uncertainty regarding its' content?	○	○	○	○	○	○
4.6. How often are you in a situation/ consultation where you can make use of the regulations (R991) (e.g. a mother asking for advice on what type of formula to feed her baby)?	○	○	○	○	○	○
4.7. How often does your place of work accept donations of designated products?	○	○	○	○	○	○
4.8. I confidently employ the principles of the regulations (R991) in my work environment.	○	○	○	○	○	○
4.9. How often in your experience are health care providers being held accountable for practices that are not compliant with the R991 regulations? (E.g. use of pens with logos of companies of designated products.)	○	○	○	○	○	○
4.10. How often do you make an effort to ensure that designated products are not visible to patients/ clients in your work environment?	○	○	○	○	○	○

4.11. If you saw a violation of the regulations (R991), how often would you report it?

Always	Often	Sometimes	Seldom	Never	N/A
○	○	○	○	○	○

If you have indicated that you would seldom/ never report it, please elaborate on why.

4.12. If you receive a free gift from a company manufacturing, importing or distributing designated products under the regulations (R991), e.g. a pen with the company logo, how often would you accept it?

Always	Often	Sometimes	Seldom	Never	N/A
○	○	○	○	○	○

4.13. How frequently have you accepted the following from a company manufacturing, importing or distributing a designated product under the regulations (R991) in the last year?

	Always	Often	Sometimes	Seldom	Never	N/A
4.13.1 Promotional gifts (e.g. stationery, calendars, diaries).	○	○	○	○	○	○
4.13.2 Sponsorship for research/ to attend conferences.	○	○	○	○	○	○
4.13.3 Free samples of designated products.	○	○	○	○	○	○
4.13.4 Donations of designated products.	○	○	○	○	○	○

For the next set of questions please use the 5 point scale and indicate your extent of agreement to each statement.

4.14. When educating patients/ clients on the use of the information on the labels of designated products, the following aspects are important:

	Strongly agree	Agree	Disagree	Strongly disagree	N/A
4.14.1 Serving size.	○	○	○	○	○
4.14.2 Nutrient Reference Values (NRV). (Only for complementary foods and liquid milks, powdered milks, modified powdered milks, and powdered drinks.)	○	○	○	○	○
4.14.3 Total sugar content. (Only for complementary foods and liquid milks, powdered milks, modified powdered milks, and powdered drinks.)	○	○	○	○	○
4.14.4 Sodium content.	○	○	○	○	○
4.14.5 Preparation instructions.	○	○	○	○	○
4.14.6 Storage instructions.	○	○	○	○	○

PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

5. ENABLERS

We are almost there and there are just two more quick sections left to help us understand your thoughts on the regulations (R991).

Please check the appropriate blocks that you believe are enablers (anything that facilitates/ promotes/ helps/ supports) to the successful implementation of the regulations (R991).
(More than one answer can be selected.)
(If you don't work with infants and young children regulary, please select which you think might be enablers. Answers to this question are not compulsory.)

- [ ] 5.1. An increase in the number of mothers who are choosing to breastfeed has helped to confirm the importance of the regulations (R991).
- [ ] 5.2. Greater awareness and compliance and positive changes to be in line with the regulations (R991) by manufacturers, distributors and importers of designated products.
- [ ] 5.3. A more scientific and less promotional approach by the representatives of companies that manufacture, distribute or import designated products.
- [ ] 5.4. Awareness creation by the Department of Health among health care providers (working with infants or young children or in maternity care) of the regulations (R991) relating to foodstuffs for infants and young children.
- [ ] 5.5. Increased training of health care providers relating to the regulations (R991) has taken place.
- [ ] 5.6. Effective communication from the Department of Health regarding the regulations (R991).
- [ ] 5.7. Less focus on specific brands and their offering (brand loyalty) by mothers when selecting designated products encourages health care providers to support the regulations (R991).
- [ ] 5.8. Increase in other initiatives which support, protect and promote breastfeeding (e.g. Mother Baby Friendly Hospital Initiative).
- [ ] 5.9. Other measures taken by the Department of Health to support, protect and promote breastfeeding (e.g. making breaks during the working day for lactating mothers to express breastmilk mandatory).
- [ ] 5.10. Greater awareness and support of the regulations (R991) by dietitians assists in achieving their implementation.
- [ ] 5.11. Improved enforcement of the regulations (R991).
- [ ] 5.12. Improved understanding of the regulations (R991) as a result of the supporting document created by the Department of Health 'Guidelines to industry and health care personnel: the Regulations Relating to Foodstuffs for Infants and Young Children, R. 991 of 6 December 2012 ("Regulations")'
- [ ] 5.13. Other (please specify).

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

6. BARRIERS

Please check the appropriate blocks that you believe are barriers to the successful implementation of the regulations (R991).
(More than one answer can be selected.)
(If you don't work with infants and young children regulary, please select which you think might be barriers. Answers to this question are not compulsory.)

- [ ] 6.1. Lack of awareness of the regulation (R991) among health care providers.
- [ ] 6.2. Lack of awareness of the regulation (R991) among manufacturers, distributors and importers of designated products.
- [ ] 6.3. Lack of awareness of the regulation (R991) among the general public.
- [ ] 6.4. Lack of confidence in the interpretation of the regulations (R991) by health care providers.
- [ ] 6.5. Complexity of the regulation (R991).
- [ ] 6.6. Lack of training of health care providers on the regulations (R991).
- [ ] 6.7. Lack of training of enforcement officials on the regulations (R991).
- [ ] 6.8. There are other factors that prevent mothers from breastfeeding which undermine the goal that the regulations (R991) aim to achieve, i.e. improved breastfeeding rates. For example lack of paid maternity leave.
- [ ] 6.9. Manufacturers, distributors, and importers of designated products are not complying with the regulations (R991) as they are too restrictive.
- [ ] 6.10. Penalties for contravening the regulation (R991) are too lenient.
- [ ] 6.11. Health care providers who could assist with enforcement of the regulation (R991) by reporting violations are not.
- [ ] 6.12. Lack of monitoring and enforcement of the regulation (R991) by inspectors appointed by the Director-General.
- [ ] 6.13. Marketing departments of companies who manufacturer, distribute and import designated products do not fully understand the purpose of the regulations (R991).
- [ ] 6.14. Lack of support from the Department of Health.
- [ ] 6.15. Some health care providers do not support the regulation (R991).
- [ ] 6.16. Other (please specify).

6.17. If you have selected *"There are other factors that prevent mothers from breastfeeding which undermine the goal that the regulations (R991) aim to achieve, i.e. improved breastfeeding rates. For example lack of paid maternity leave"* please specify what factors you believe are preventing mothers from breastfeeding.

6.18. If you have selected *"Some health care providers do not support the regulation (R991)"*please specify which health care providers do not support the regulations and suggestions as to why.

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PERSPECTIVES OF DIETITIANS ON THE REGULATIONS RELATING TO FOODSTUFFS FOR INFANTS AND YOUNG CHILDREN (R991 OF 2012)

THANK YOU

We would greatly appreciate your help in getting as many dietitians as possible to participate in this research so please send the link out widely.

If you would like to be entered into the lucky draw and stand a chance to win one of four vouchers each valued at R1000.00 (Takealot.com/ Yuppiechef/ Woolworths/ Spree), please enter your email address below. (This information will only be used to contact the winners).

7.4 Addendum D: focus group discussion guide

TOPIC	MINUTES (min/max)
Introduction	6-10
Practices	12-20
Attitudes	12-20
Enablers	12-20
Barriers	12-20
Close	6
Total	60-96

Place:

Date:

Time:

Number of participants:

INTRODUCTION (6-10 minutes)

Welcome

Welcome and thank you for volunteering to take part in this focus group. You have been asked to participate as your point of view is important. I realize you are busy and I appreciate your time.

My name is Megan. I am a dietitian working at Mahatma Gandhi Memorial Hospital and will be the facilitator for the focus group today.

With me is my colleague, _____, who is here to observe our discussion today and take some notes.

Introduction

The general purpose of today's focus group is to gain an understanding of dietitians' perspectives on the Regulations relating to Foodstuffs for Infants and Young children. The focus group should take between one to one and a half hours. We will be focusing on 4 main areas: (1) attitudes, (2) practices, (3) barriers and (4) enablers as they relate to the R991 regulations. I will pose a topic or question for discussion and I would like you all to feel free to discuss any issue or opinions under the topic or question suggested and to raise other issues that are not brought up that you feel may be relevant.

Each of you will receive a R200 gift voucher to compensate you for the time you have taken out of your day and your travel expenses to participate in the group.

At this point I would like to ask your permission to record the focus group. If you agree to participate and to have the discussion recorded, please sign the informed consent form provided in duplicate. One copy will be yours to keep for your own records.

(Facilitator will go through consent form and participants will be asked to sign.)

Anonymity

Although the focus group discussion will be tape recorded, the discussion will be anonymous. Your answers and responses will only be used for the research project I am conducting and all information obtained will remain confidential and names of all participants will remain anonymous. The audio recording will be kept safely in a locked facility and after it has been transcribed the recording will be destroyed. The transcribed notes of the focus group will not contain any information that would link individuals to specific statements. When I am transcribing the recordings of today's group I will assign each person a number and no names will be transcribed. Please try to keep your answers and comments as honest and accurate as possible. There are no correct or incorrect answers; it is your opinion that is valuable. It would be appreciated if the contents of what is discussed today are not spoken of outside of the focus group so that any information discussed remains confidential. If there are any questions or discussions that you would rather not comment on, you do not have to do so, but please try to be as actively involved as possible.

When expressing your opinions please try to speak one at a time so that the recording is clear and to show respect to your fellow group members as all contributions are important.

1. Introductory questions:

*(*Prompting questions are in italics)*

Before we start I'd like everyone to briefly introduce themselves and say where you work. This will not be used for the research but just to get everyone acquainted and for ease of discussion.

I would like to go through the main objectives of the research to give you a better idea of the aim of today's group:

- To determine the attitudes of dietitians on the acceptance of the regulations, the importance, relevance and practicality, and responsibilities of HCPs as related to the regulations.
- To determine the practices of dietitians in terms of implementation and use of the regulations in workplace, educating clients on labels, relationship with company representatives and responses to violations of the regulations.
- To determine the barriers faced by dietitians relating to challenges experienced with the regulations, violations, lodging of complaints, enforcement and support and promotion-related matters (such as research grants, financial contributions and sponsorship, restrictions placed on product representatives.)
- To determine the enablers experienced by dietitians relating to communication from the Department of Health (DoH), support, co-operation from product manufacturers and representatives and positive outcomes experienced.

1.1. When you hear the phrase 'Regulations for Foodstuffs relating to Infants and Young Children' what are the first thoughts or ideas that come to mind?

1.2. Do you remember when you first became aware of the regulations?

1.3. Is this online advertisement permitted in terms of the regulations? Why do you say so?

(Facilitator shows visual 1: Nido advertisement)

GUIDING QUESTIONS (48-80 minutes)

2. Practices (12-20 minutes)

2.1. In what ways do you think your own practices and those of other HCPs have changed since the regulations came into being?

2.2. What changes have you made in your work environment to implement the regulations?

2.3. If a mother asks you for advice on which specific formula brand to use, how would you deal with the question?

2.4. When meeting with company representatives, how have these visits changed from the past, before the regulations were published?

2.5. What aspects of the dietitian do you think influence their practices in relation to the regulations? (For example: age, years of experience, province they reside in.)

2.6. What would you do if you encountered a violation to the regulations?

3. Attitudes (12-20 minutes)

3.1. Would you say you have a positive or negative attitude overall toward the R991 regulations? Please explain why you feel that way.

3.2. What do you like about the R991 regulations?

3.3. What do you dislike about the R991 regulations?

3.4. Why do you feel that passing of regulations to control the marketing and labelling of infant feeds and products for young children is important in the South African context?

3.5. What do you feel your responsibilities are as a HCP in relation to the regulations? (For example: advocate breastfeeding, report violations)

3.6. This brochure was given out to HCPs prior to R991, please say whether or not you feel is it still appropriate and briefly explain why?

(Facilitator shows visual 2: 'Giving toddlers a head start in life' brochure.)

3.7. What differences have you noticed in the attitudes of HCPs to the regulations between the public and the private sector?

3.8. Which HCPs need to know about the regulation?

3.9. Are there any aspects of the regulations that you feel are unnecessary?

3.10. Is there anything you feel has not been included in the regulations that should have been? (For example: other milks like goat's milk or almond milk or foods for older children?)

3.11. Do you feel that the regulations are practical? (Can they be adhered to? Are they possibly too restrictive or not restrictive enough? Do the labels of products influence feeding choices to a large extent?)

4. Enablers (12-20 minutes)

4.1. Which factors, aspects, actions, laws, or other policies and programs do you feel facilitate successful implementation of the regulations?

4.2. Have you received communication from the DoH regarding the regulations? (For example: notices, updates, discussions at symposiums)

4.3. Have you received any form of support in relation to understanding and implementation of the regulations? If not, is there any support you would like to receive? (For example: invitations to training, support visits at your facility to ensure compliance with the regulations)

4.4. Do you feel that company representatives have changed their approach to dealing with HCPs? (For example: more factual scientific material presented, less promotional minded)

4.5. Can you recall any other situations or experiences relating to the R991 regulations that have left a positive impression on you?

4.6. Do you think there are other initiatives or laws that support the legislation? (For example: MBFI or laws around breastfeeding for working mothers.)

4.7. In what ways do you believe dietitians can help to enable successful implementation of the regulations?

4.8. Can you think of an occasion where you noticed that a product label had made changes in order to comply with the regulations?

5. Barriers (12-20 minutes)

5.1. What do you perceive as challenges relating to the regulations?

5.2. Do you think that those who are aware of the regulations understand them fully?

5.3. Have you encountered many violations?

5.4. Do you think HCPs and dietitians in particular are aware of how to report violations? (If yes, how do you suggest this should be done?)

5.5. Do you feel that the process for lodging complaints is effective?

5.6. Do you think that violations are adequately addressed and the regulations are enforced effectively?

5.7. Do you believe that it is justified to restrict product manufacturing companies from providing financial support? For example research grants to HCPs.

5.8. Do you think that dietitians need to be more aware of the regulations?

5.10. Can you recall any other situations or experiences relating to the R991 regulations that have left a negative impression on you?

5.11. How do you think these barriers can be addressed or improved upon?

CLOSE (6 minutes)

6.1. Is there anything we didn't cover that you would like to talk about?

6.2. Do you think it would be useful for further studies to evaluate the impact of the R991 legislation? If so, what areas do you feel are important to look at?

We are done. Thank you for your time. Your opinions will be a valuable addition to the study. We hope you have found the discussion interesting. If there is anything you are unhappy about or want to complain about please feel free to contact me to discuss further. I would like to remind you that all comments featuring in the study report will be kept anonymous. Before you leave, please ensure you have completed two copies of the informed consent form and please collect your gift voucher.

Visual 1: Nido advertisement

FORMULA 3+

NESTLE

NIDO 3+ 1.8KG K

Item Code: 098212000EA

~~WAS R209.00~~

NOW R179.00

OR PAY WITH

Benefit Points 20900

Discovery Miles 1 790

Visual 2: 'Giving toddlers a head start in life' brochure

7.5. Addendum E: pilot survey evaluation survey

PILOT STUDY EVALUATION QUESTIONNAIRE

Please complete a few short questions to give your feedback on the questionnaire.

1. How long did the questionnaire take to complete? (Please answer in minutes.)

2. Do you think that the time taken to complete this questionnaire was reasonable?

- ○ Yes
- ○ No

If you have answered no would you like to elaborate or comment?

3. Do you feel that the questions testing knowledge of the R991 Regulations were appropriate for dietitians?

- ○ Yes
- ○ No

If you have answered no, would you like to elaborate or comment?

4. Do you think that the questions were phrased clearly?

- ○ Yes
- ○ No

If you have answered no, would you like to elaborate or comment?

5. Do you think that the layout of the questionnaire was suitable?

- ○ Yes
- ○ No

If you have answered no, would you like to elaborate or comment?

6. Please indicate if there were any specific questions which you felt were unclear, too difficult to answer or not appropriate. Please indicate the section, the question number and your comment. (You may click on the link to the questionnaire again to go back and check question numbers.)

7. Are there any other areas of the questionnaire that you feel could be improved upon?

PILOT STUDY EVALUATION QUESTIONNAIRE

THANK YOU

Thank you so much for completing the questionnaire and for taking the time to give your feedback. Your contribution is very valuable to the research.

7.6. Addendum F: Additional information from focus group discussions

As the article format was used for the thesis, reporting of qualitative data was fairly selective. In order to elaborate on the findings of the focus group discussions, this addendum has been added to provide more detail on the themes that were discussed in the results and to provide insight into some of the lesser themes that were found but not reported in the results. The table below presents the themes in the left hand column with relevant quotes from the discussions connected to each theme in the right hand column. The major themes found are in bold and the lesser themes in plain text. The quotes from the private sector participants are in plain text and those from the public sector participants are in italics for purposes of comparison.

THEME	QUOTES
Dietitians have less knowledge about the products controlled under the Regulations	• "I don't feel dietitians are going to push someone to formula feed." (Expressing that dietitians should still receive information and use their discretion when counselling to ensure they comply with the Regulations.) • *"They only speak about the products on tender, not other products." (Public sector dietitians are only told information from representatives about products on the government tender.)*
Mothers have less knowledge about products controlled under the regulations	• "Moms actually are not as well informed about.. different infant feeding foodstuffs." • "It won't say if it's for constipation, or…, it will just say the name of the formula and it's up to the mom to interpret what it is." (Referring to labelling changes.) • *"Like you choosing to formula feed you just don't have support because it's all so regulated and whatever."* • *"Are they mixing correctly the number of scoops?"* On educating mothers who choose to formula feed: • "I'd try and talk more about the research." • "Based on a talk I went to… I've sort of steered towards (names an infant formula)..that kind of thing sticks in your mind and then you tend to promote stuff without even trying to." • *"Just give them categories to choose from."* • *"I'm just like, all of the ones on the South African market do meet the required standards."*
Other HCPs are not always compliant with the regulations	• *"Some are aware that they are not supposed to allow any company representatives to come and promote whatever product… But some they aren't, they don't know."* • *"There's no evidence to support that, but because they've had experience with that, then that influences what they tell the mom."(Referring to other HCPs giving mothers advice on which formulae to use.)* • *"Baby's refluxing or for any other reason and their doctor immediately switches over from, even breastmilk to a soya formula."* • *"It's our baby." (Meaning dietitians are expected to take the bulk of the responsibility for the Regulations.)*
Dietitians have a role to play in supporting and enforcing the regulations -Not accept gifts -Training -Reporting violations	• "If you are formula feeding as a dietitian, what are you also doing." "Are you practising what you preaching?" • *"Back in the day if (Company X or Y) came and gave us a pen we would take the pen."* • *"When we train it's good now cuz we tell them it's actually a law" (Referring to training of other HCPs on the Regulations- which forms part of MBFI training.)* • *"A study we were doing…monitoring the Code of compliances…facilities…the violation*

-Being an example -Maintaining a professional relationship with representatives	*wasn't that much"* • *"I've complained so many times!" (Reporting violations)* • *"I would say 'you can't give us that!'" (Refusing gifts from product representatives.)*
A large discrepancy exists between practice in the private and the public sector	• "In private… they don't want to use a dietitian." (Referring to the cost involved if a dietitian is consulted in the private sector.) • *"They have resources that we don't have and funds…" (Referring to the private sector and industry.)*
Enforcement of the regulations needs strengthening (Including a better procedure for reporting violations) -Lack of knowledge on how to report -lengthy and tedious task -Inconsistent -No response to violation reports -Insufficient consequences for violations/ not transparent -Responsible individuals	• "Is that complaint going to be heard?" (Referring to the reporting of violations.) • "I think they're trying… There are only…so many watchdogs…they're implementing it slowly." • *"I never got any feedback about that there was any consequences." (After reporting a violation.)* • *"You know…they want these details (if you do report a violation) so it does involve… if you in the shop for five minutes to pick up something and you saw a violation, it's not like you can be like 'ok I'm going to take this picture and I'll deal with it later', it's…at the time you have to make a decision… you must speak to the manager…it's a bit of a process."* • *"I think KZN is the strictest. That's what all the reps tell us."* • *"Would it be worth them actually breaking the violation just to save that money on the stock that might have gone to waste if they didn't sell it?" (Referring to violations in stores/ promoting designated products.)*
Increased sensitivity to branding of designated products among dietitians	• "I'm always very cautious about naming a product by brand." • *"I don't even mention any names." (When counselling clients on infant feeding.)*
A shift in the relationship between dietitians and product representatives	• "They just come now and leave something on your desk, they don't even bother to talk to you because they don't really have anything that they want to say.. they're so worried." • "Often times you'll go to… the pharmacies…but they'll be like 'well what are you going to give me?'" (A dietitian who works as a product representative for designated products talks about the HCP's expectation of gifts.) • "They used to spend more time, going through all the nutritional aspects of each of their products… Now if you even see them you're lucky." • *"They don't really tell us anything."* • *"Reps won't come in and then just give talks and (gifts)."*
Mixed feelings towards the restriction of sponsorships	• "You stop the sponsorship from happening so then the education of the health care professionals stops." • "There is lots of under the table stuff that goes on." • *"It's actually helpful in a way, to be…regulated in such a way. It makes it easy for us to say no." (Referring to restrictions on sponsorship.)* • *"It's almost like the Code is actually doing an injustice."* • *"How is information gonna go out there? There's no money out there, so it's the companies that help relay messages…" "A lot of evidence that we are exposed to that we wouldn't have been exposed to otherwise." (Referring to allowing product company employees to speak at conferences etc.)* • *"For example like now the symposiums and stuff, we're really limited with regards to your speakers." "It also limits the kind of information that we are exposed to."*
Stigma around	• "You formula fed… if you wanted to appear affluent."

breastfeeding	• *"It's just seen as food now and not… the therapy behind it." (Referring to breastmilk.)*
Communication/ training around the regulations -to HCPs -To the public -To the companies that manufacture, import or distribute designated products	• "I didn't receive anything" • "After comm. serv. it then doesn't actually translate, it doesn't come in." • "I think if you're in private practice that is the only way that you get any information like that." (Referring to ADSA.) • "It actually should come from Department of Health." • "And not just to government employees." • "(There was) certainly not like training or no workshops or anything." • *"A notice was sent out." "One of our district meetings."* • *"I don't think people understand why there are these regulations."* • *"There's obviously been good communication though with um the companies that provide the formula…it's not often that you are seeing violations."* • *"It was part of the meetings."* • *"I think there was a formal training."*
Change in the infant formula market	• "Before the regs… it was dominated by the big boys." "It's diversified the feeds a little bit I think." "People…not feeling bullied into…using a certain brand." • "With no advertising it kind of leaves an even playing field." • *"It's something that's not as much in your face as it was before."*
Other challenges for breastfeeding mothers (besides marketing)	• "You have to be so dedicated to doing it." (Expressing breastmilk) "Moms give up because it's difficult and then it's straight on to formula after three months." • "Expressing's time consuming as well." • "At your place of work they'd have to provide you with some kind of nice place to do so (express breastmilk), you don't want to go sit in the toilet and do that." • *"You still get the moms who say 'in four months I have to go back to work so I have to stop breastfeeding.'"* • *"It's so easy, like anyone can go into the shop and buy it." (Referring to formula milk.)*
Integration with other initiatives -MBFI -Code of good practice (part of Basic conditions of employment act/ labour law) to allow expressing breaks at work	• *"It was part of MBFI." (When asked if facilities had received support visits about R991 compliance.)* • *"You don't know how many people are enforcing it though." (Referring to the expressing law.)*
Influence of the media	• *"A magazine I saw someone being um pointed out for breastfeeding in public and that was great. Not to see someone using a bottle…A positive light on breastfeeding."* • *"But then you get public figures…(who) can sometimes be promoting….how wonderful this bottle was or this formula was or something like that…and then you know this person will have 700 followers."*

Abbreviations: Association for Dietetics in South Africa (ADSA), community service (comm. serv.), health care provider (HCP), Mother Baby Friendly Initiative (MBFI), representatives (reps).