

Effectiveness, Implementation and Monitoring of the International Code of Breast-Milk Substitutes in New Zealand: A Literature and Interview-Based Review

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for the

Ministry of Health

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Ethics approval

The study was approved by the Victoria University of Wellington's Ethics Committee. Interview respondents were provided with written information about the study, the interview questionnaire and signed informed consent in advance of their interview.

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Acronyms, Abbreviations and Terms

Table 1: Acronyms, abbreviations and terms used in this report

ASA	Advertising Standards Authority
CCCF Act	Credit Contracts and Consumer Finance Act
complaints process	Refers to all three parts of the Ministry of Health’s process including initial complaint and response, Compliance Panel, and Adjudication
CP	Compliance Panel
DSRL	Dispute Resolution Services Limited
HDC	Health and Disability Commissioner
Health Workers’ Code	Code of Practice for Health Workers
IFANZ	Infant Feeding Association of New Zealand
INC	Infant Nutrition Council, until early 2009 INC was the New Zealand Infant Formula Manufacturers Association (NZIFMA)
INC Code	Infant Nutrition Council Code of Practice for the Marketing of Infant Formula, the New Zealand interpretation of the International Code
International Code	International Code of Marketing of Breast-milk Substitutes
MAF	Ministry of Agriculture and Forestry (NZFSA now part of MAF)
NGO	Non-Government Organisation
NZFSA	New Zealand Food Safety Authority (now part of MAF)
NZIFMA	New Zealand Infant Formula Manufacturers Association, now named the Infant Nutrition Council (INC)
OECD	Organisation for Economic Co-operation and Development
SRA	Self Regulating Authority
SRO	Self Regulatory Organisation
UN	United Nations
WHA	World Health Assembly
WHO	World Health Organization

1. Executive Summary

Introduction

New Zealand adopted the International Code of Marketing of Breast-milk Substitutes ("the Code") in 1983, and gives effect to this commitment through three voluntary Codes and legislated food standards regulation (WHO 1981). This is set out in a 2007 publication *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand* ("The Code in New Zealand")(Ministry of Health 2007) .

The Ministry of Health ("the Ministry") administers a process to handle complaints under two of the voluntary Codes, firstly the Infant Nutrition Council ("INC") *Code of Practice for the Marketing of Infant Formula*, which is a voluntary agreement between major infant formula manufacturers not to market formula for infants younger than six months of age in New Zealand. The second is the Ministry's *Code of Practice for Health Workers* ("Health Workers' Code"), which recommends best practice for health workers, including protecting and promoting breastfeeding, and ensuring the proper use of breast-milk substitutes when these are necessary. Both these Codes are contained in The Code in New Zealand.

In 2008, a complaints process that had been in place since the late 1990s was updated by the Ministry following recommendations from a formal review in 2004. The Government has approved a new review of The Code in New Zealand which will commence in 2011. As such, the Ministry has sought independent background evidence around the complaints process and literature review, to provide a basis for planning towards the 2011 review. That is the purpose of this report.

The complaints processes for both the INC and the health workers' Codes are substantially the same. The processes operate in three parts. First, when a complaint about a manufacturer or health worker is received, it is forwarded to the subject of the complaint. The subject's response is returned to the Ministry and forwarded to the complainant. If the complainant is satisfied by the response, the complaint is closed; if they are not then the complaint is considered by a five-member Compliance Panel (CP). The CP may determine there has been a breach and issue recommendations, but has no power under the law. A CP decision may be appealed to an independent Adjudicator. Only upheld decisions are made public, and the identity of the complainant is generally not revealed to the subject except with the complainant's permission. Since 2008, 13 complaints have been filed, 11 under the INC Code, and two under the Health Workers' Code.

Methods

Research for this report primarily followed two approaches. First, we reviewed the academic literature for information on the economics of self-regulation, research on implementation of the Code in other countries, and reviews of the Code in New Zealand. Second, 31 stakeholders, including complainants, formula manufacturers, health workers, officials, and non-government organisations (NGOs), participated in the information gathering exercise undertaken late in 2010. We also researched six other complaints processes operating in New Zealand to identify features in common with, and different from, the Code complaints process operated by the Ministry.

Literature Review

The review of the economic literature suggests marketing of infant formula is a strong candidate for self-regulation. Advertising is suited to decentralised monitoring,¹ there are relatively few large suppliers, and companies are encouraged to conform because “breast is best” is an industry and social norm. There is organised monitoring of company activities by NGOs and by manufacturers who report monitoring their rivals. Infant formula is a credence good (meaning its quality is difficult or impossible to assess even after consumption), and suppliers are large multi-product and multi-national firms. These factors make formula manufacturers relatively vulnerable to reputation damage for misbehaviour: reputation is an important driver of sales and consumers are able to punish non-compliance across all their products, not just infant formula, and in all countries they operate. This may explain why companies report undertaking major internal efforts to achieve compliance. A benefit of self-regulation is its low costs: its alternative is public regulation which is more costly. A disadvantage of self-regulation is that industry will tend to undersupply monitoring and enforcement, particularly if the industry is dominated by a single large supplier (which makes regulatory capture more likely), but that is not the case in infant formula.

The Code limits marketing but not sales, and as such it resembles collusive agreements of the type sometimes produced by professional organisations which profitably effect limits on marketing by member firms: it is possible the INC Code is profitable for manufacturers. Companies cite Commerce Act concerns as preventing them agreeing to an expansion of the INC Code to 12 months, a policy change sought by many complainants and NGOs. We suggest a means by which Commerce Act concerns might be settled; this may clear the way to agreement on 12 months.

A review of the available literature on the Code since 2000 provided information on activities in other countries, but few other insights. Much of the literature on the Code reads as advocacy. Complaints processes in Australia and United Kingdom are transparent, decisions being publicly released (and in Australia, tabled in Parliament). Data from Australia show 83 percent of complaints are out of scope, i.e. they raise no question of compliance (no equivalent figure for the United Kingdom can be derived). Between 2002 and 2009, three breaches in the Australian implementation of the Code have been found from 1688 complaints. In the United Kingdom between 2005 and 2010 complaints made against companies in relation to infant formula were upheld in two cases and partly upheld in three cases.

Other New Zealand Complaints and Disputes Processes

A review of other self-regulatory complaints and disputes processes in New Zealand was instructive, highlighting two notable differences between the Ministry process and those used in other regimes. First, all other processes conduct a jurisdiction test, or vetting, as a first step, i.e. a check that the complaint may be considered by the adjudicating body under its rules and raises a question of compliance with the regulation/self-regulation for which the body has oversight. Although this step is documented in a flow chart of the Ministry’s complaints process, this check is not documented in the CP terms of reference.² A jurisdiction test is essential: comments

¹ Elsewhere we argue the complaints process is difficult for complainants, but this is due to problems with the complaints process itself and not the difficulty of monitoring *per se*.

² In correspondence, the Ministry maintains the role of the CP is to consider complaints referred to it, and that a jurisdiction test is conducted by the Ministry. We have not seen documentation of this test. In the interview process, formula manufacturers repeatedly expressed concerns that complaints that are out of jurisdiction were being heard by the CP.

made in the qualitative review, and evidence noted above from Australia, suggest some complainants will use a complaints process as a vehicle for expressions of concern that fall outside agreed conducts. These may be legitimate concerns, but a compliance process is not the place to handle them. The second difference is that other processes (but not the Advertising Standards Authority process) generally assist complainants in the preparation and processing of complaints. We understand that in the Code complaints process, the Ministry does not support complainants in an effort to be seen to remain independent.

Qualitative Review

In the qualitative review we interviewed 29 respondents by telephone (one of which provided further written comment) and received written responses from an additional two participants to the current complaint process. This was a non-representative sample of what the Ministry identified as 'key informants' to the current complaint process. Across all categories of interview respondents, there is agreement on the superiority of breastfeeding over formula, and dissatisfaction with the current complaints process. Complainants report finding the process difficult: they must assemble evidence of behaviour, and identify the provisions in the four Codes they believe the company or health worker has breached. The complaints process then requires complainants to essentially prosecute the case, receiving and responding to information usually prepared by lawyers acting for the subject. Complainants describe the process as intimidating and frustrating. Complainants also believe the scope of the Code in New Zealand is too narrow, and should apply to formula for infants to 12 months of age.

INC representatives (formula manufacturers) are primarily concerned about the operation of the complaints process, alleging repeated infringements of due process by the CP, a failure to test jurisdiction, and accuse the CP of bias. INC representatives are adamant that health workers should be informed of new developments in infant formula, and complain that they have difficulty obtaining sufficient access to health workers. Health workers interviewed reported wide variation in knowledge of the Code among their health worker peers; some expressed concern that promotion of breastfeeding has gone too far, and that in some cases mothers who cannot or choose not to breastfeed are unable to access timely information on formula feeding from health workers. We received unverified reports of infant malnourishment, misreporting of official statistics,³ feelings of guilt among mothers who cannot breastfeed, and difficulty in obtaining information on formula feeding. Other health workers interviewed, however, did not report these issues but felt formula manufacturers continue to have too much influence in feeding decisions.

NGOs believe the current scope of the Code in New Zealand is too narrow and should be increased to include formula for infants up to 12 months of age. A repeated concern expressed by NGOs is the alleged influence of the agriculture industry on the compliance process.

Discussion

Based on the evidence collected and provided, we have come to the following views. The complaints process facilitates a dialogue, treating the complainant as if they were a wronged person to be made whole, when they are more appropriately thought of as a "whistle-blower," that is, a person with information that an agreement may have been breached. Because of this, the process is unnecessarily onerous on complainants. Both complainants and those who are the subjects of complaints

³ We provide a health worker's description of this phenomenon on page 48.

report feeling the process is weighted against them, and we think this is process-related: a product of the (perceived or actual) incomplete documentation of the complaints process, and because of infringements of due process by the CP alleged by some complainants, health workers, and manufacturers. These allegations include amongst other things an un-notified change in CP personnel mid-process, failure to pass on all information from the complainant to the subject, a finding of breach on a matter not in the original complaint, and consideration of complaints that are out of scope. Due process problems likely confer advantage to those with access to legal representation, usually the complaint subject (industry) and not the complainant.

Complaints against health workers are distinct from those against manufacturers because obligations arise and are discharged differently. Whereas INC members have understood and agreed to a Code of Practice, health workers have not, and it was reported to us that many health workers are not aware of the Code (others reported strong understanding among health workers, which may indicate a patchy distribution of knowledge among workers). Where workers do not know about the Code, industry practices offer protection against inadvertent breach. It is reported that many workers use a rule of thumb which is to not discuss infant formula at all. Even where health workers understand their obligations under the Code, by providing advice on formula feeding workers risk reprisal from the charge nurse or midwife who, we understand, are encouraged to increase breastfeeding rates to improve the health of the mother and infant. Health workers who discuss infant formula also risk being the subject of a complaint; one health worker in the qualitative review was the subject of a 21 month complaint process (in which a finding of breach was quashed on appeal). These costs are not necessarily avoided by providing advice on infant formula that is Code-compliant; however, they are avoided by refusing to provide advice on infant formula at all, and it appears many health workers have adopted this strategy.

As a result there are strong indications that mothers frequently have difficulty obtaining timely information on, and access to, infant formula when they cannot or choose not to breastfeed. The Health Workers' Code requires health workers to provide information on infant formula where necessary. We think the main concern with Code compliance is not in the failure of health workers to promote breastfeeding, but a failure to provide advice on formula feeding when it is required. These findings with respect to health workers must be treated with caution because they mainly rely on second-hand reports from the qualitative review: we flag this as an area for further research in the Ministry review to be conducted later this year. Reluctance among some health workers to provide information on infant formula is, we think, almost certainly a product of a mix of policy and institutional settings, and not a reflection on workers themselves. Other knowledge gaps include what is the market share of small and organic infant formula producers (who are currently not part of the INC Code), the effect of excluding retailers and pharmacists from the scope of voluntary agreements, and the experience of mothers in obtaining access to advice on infant formula.

Findings

In regards to health worker compliance, we suggest a first step in any complaint against a health worker, after application of a jurisdiction test, is to bring the Code of practice to the attention of the health worker, since it is possible and perhaps likely that any breach was inadvertent (many health workers may not be aware of the Code). Only in the event of a second complaint against a particular health worker, also found to be in-scope, should a complaints procedure be initiated.

We suggest the Ministry outsource the complaints process, and that it ask industry to fund the third party operation of the process, as is standard practice in other

industries, including five of the six alternative New Zealand complaints processes we reviewed.

If the Ministry does not outsource the complaints process, we suggest that it seek to appoint a retired High Court judge to chair the CP, in an effort to remedy (perceived or actual) failures to adhere to due process. We think the process should be fully and publicly documented. The full text of all decisions (excluding individuals' names) should be made public regardless of the outcome. The satisfaction test should be eliminated from the process; a jurisdiction test should be added.

2. Introduction

Breastfeeding is widely recognised as a way to improve the health and nutrition of infants and young children.⁴ Following a global decline in breastfeeding rates, New Zealand adopted the International Code of Marketing of Breast-milk Substitutes ("the Code") in 1983, and gives effect to this commitment through three voluntary Codes and through food standards regulation:

- The Infant Nutrition Council ("INC") Code of Practice, a voluntary agreement between the major infant formula manufacturers and the Ministry of Health ("the Ministry") to encourage breastfeeding rates, prevent the marketing of formula for infants younger than six months, and not to give gifts or inducements to health practitioners;
- The Code of Practice for Health Workers ("Health Workers' Code"), which recommends best practice for health workers, including protecting and promoting breastfeeding, and ensuring the proper use of breast-milk substitutes when these are necessary;
- The advertising of follow-on formula or food for infants aged over six months is overseen by the Advertising Standards Complaints Board under the voluntary Code for Advertising of Food; and
- The labelling, composition or quality of formula or other food is regulated by the Australia New Zealand Food Standards Code, administered by the New Zealand Food Safety Authority ("NZFSA") now part of Ministry of Agriculture and Forestry ("MAF")

The Ministry operates a complaints process under two of the voluntary Codes, the INC Code of Practice and the Health Workers' Code. In 2008, following the 2004 formal review, the complaints process that had been in place since the late 1990s was changed by the Ministry, and a new larger compliance panel and an independent adjudicator were appointed.

The Ministry seeks to improve the process, and the Government has approved a review which will commence in 2011. In advance of that review, the Ministry is seeking independent background evidence to provide a basis for planning; that is the purpose of this report. The Ministry's objective for this report is to measure in qualitative and quantitative terms the performance of the existing arrangement in New Zealand and overseas, and identify ways to improve monitoring and implementation of the Code in New Zealand.

This report proceeds as follows:

- In the remainder of this section, we provide background on the development of the Code and New Zealand's implementation of that process; we provide a description of the current complaints process;
- In section 3 we describe the research methods used in this report;
- In section 4, we summarise our findings from a review of the academic and grey literature, including a summary of practices in other countries and of other complaints processes in New Zealand;

⁴ For example see National Breastfeeding Advisory Committee (2009).

- In section 5 we provide our findings from a series of interviews and submissions from 31 participants;
- In section 6 we provide analysis and discuss the major findings of the research;
- In section 7 we list knowledge gaps which may be of use as a pointer to areas for future research; and
- Section 8 concludes with our key findings.

2.1. The International Code

Infant formula, a substitute for breast milk, was invented in the early twentieth century, and by the 1970s the World Health Organization (“WHO”) had become concerned at the decline in breastfeeding rates.⁵ In 1974 the World Health Assembly (“WHA”) adopted the following resolution:⁶

noting that the general decline in breast-feeding, related to socio-cultural and environmental factors, including the mistaken idea caused by misleading sales promotion that breast-feeding is inferior to feeding with manufactured breast-milk substitutes.

At the 31st session in 1978, the WHA considered infant nutrition and resolved that Member States should give priority to supporting and promoting breastfeeding, and facilitating breastfeeding through legislation and social action.

Later that year, WHO and UNICEF announced they were planning a joint meeting about infant and young child feeding to convene in Geneva in October 1979. The meeting was attended by 150 government representatives, inter-governmental bodies including the United Nations (“UN”), the infant formula industry representatives, and experts in related disciplines. The meeting produced a statement and recommendation that an international code of marketing infant formula be adopted, and is the basis for the modern Code. In May 1980, the 33rd WHA endorsed the statement and recommendation in its entirety, and requested that the Director-General of the WHO prepare a Code in consultation with Member States.

What followed was a period of intense consultation with four draft Codes undergoing rounds of feedback from experts and Member States. In January 1981 the Executive Board of the WHO endorsed the fourth draft of the Code and unanimously recommended the text to the 34th WHA. In May 1981 the Assembly debated and then adopted the Code, resolution WHA34.22, 118 votes in favour, one against, with three abstentions. Because the International Code was adopted in the form of a recommendation, the Code does not have treaty or convention status.⁷ The Code is an over-arching document whose principles and aims are intended to be applied by individual countries as consistent with their social and legislative frameworks.⁸

The International Code of the Marketing of Breast-Milk Substitutes (“the International Code”) recommends various requirements and restrictions in relation to the marketing and distribution of breast-milk substitutes (formula), bottles and teats, and

⁵ This section is based on Shubber (1998). These documents provide a detailed review of the development of the International Code.

⁶ The WHA is the forum through which the World Health Organization (WHO) is governed by its 193 member states. The WHA is the WHO’s supreme decision-making body.

⁷ Public Health Commission (1995).

⁸ Ministry of Health, personal communication.

contains obligations for manufacturers and distributors of infant formula, health workers, health facilities, and labelling requirements.

The International Code comprises a Preamble and 11 Articles (WHO 1981). Article 1 states the Code's aim:

The aim of this Code is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breast-feeding, and by ensuring the proper use of breast-milk substitutes, when these are necessary, on the basis of adequate information and through appropriate marketing and distribution.

Article 2 of the International Code defines its scope:

The Code applies to the marketing, and practices related thereto, of the following products: breast-milk substitutes, including infant formula; other milk products, foods and beverages, including bottlefed complementary foods, when marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk; feeding bottles and teats. It also applies to their quality and availability, and to information concerning their use.

Article 3 defines, among other things, infant formula as “a breast-milk substitute formulated industrially in accordance with applicable Codex Alimentarius standards, to satisfy the normal nutritional requirements of infants up to between four and six months of age”.

For products within the scope of the Code, product advertising and promotion is prohibited: mothers and pregnant women are not to be given free product samples; discounts and special displays at the retail level are prohibited; representatives of formula manufacturers may not initiate contact with mothers.

The International Code requires health workers to encourage and protect breastfeeding. Product information given to health professionals by manufacturers and distributors should be ‘scientific and factual’ and not promote the products. Product samples may be given only when necessary for professional evaluation or institutional research, and not in any circumstances be passed to mothers. Manufacturers and distributors should not give material or financial inducements to health workers.

The WHA has issued Resolutions approximately every two years since 1982 aimed at clarifying or revising part of the International Code. The subsequent Resolutions have equal status to the International Code and have closed loopholes in the Code. The WHA has adopted the following resolutions:⁹

- WHA Resolution 39.28 (1986): Any food or drink given before complementary feeding is nutritionally required may interfere with the initiation or maintenance of breastfeeding and therefore should neither be promoted nor encouraged for use by infants during this period; The practice being introduced in some countries of providing infants with specially formulated milks (so called follow up milks) is not necessary.
- WHA Resolution 47.5 (1994): Member States are urged to foster appropriate complementary feeding from the age of about six months.
- WHA Resolution 49.15 (1996): Member States are urged to ensure that complementary foods are not marketed for or used in ways that undermine exclusive and sustained breastfeeding; Member States are urged to ensure

⁹ Full WHA resolutions related to the International Code are available from: http://www.who.int/nutrition/topics/wha_nutrition_1jcn/en Accessed 10 March 2011.

that financial support for professionals working in infant and young child health does not create conflicts of interest.

- WHA Resolution 54.2 (2001): Member States are urged to strengthen activities and develop new approaches to protect, promote and support exclusive breastfeeding for six months...and to provide safe and appropriate complementary foods with continued breastfeeding for up to two years of age or beyond...
- WHA Resolution 55.25 (2002): Member States adopt and implement the global strategy; to strengthen existing, or establish new, structures for implementing the global strategy, to define for this purpose, national goals and objectives, a realistic timeline for their achievement, and output indicators; and ensure that marketing of nutritional supplements does not replace, or undermine support for the sustainable practice of, exclusive breastfeeding and optimal complementary feeding; that the Codex Alimentarius Commission continue to give full consideration to improve the quality standards of processed foods for infants and young children and to promote their safe and proper use at an appropriate age, with adequate labelling consistent with the International Code of Marketing of Breast-Milk Substitutes, Resolution 54.2, and other relevant resolutions of the WHA.
- WHA Resolution 58.32 (2005): to ensure that nutrition and health claims are not permitted for breast-milk substitutes, except where specifically provided for in national legislation; to ensure that financial support and other incentives for programmes and health professionals do not create conflicts of interest.

The position of the WHO as of 2008 was:¹⁰

To achieve optimal growth, development and health, WHO recommends that infants should be exclusively breastfed for the first six months of life. Thereafter, to meet their nutritional requirements, infants should receive adequate and safe complementary foods while breastfeeding continues up to two years of age and beyond.

2.2. New Zealand Code Implementation

Implementation of the International Code at country level occurs using a range of measures including legislation and voluntary agreement. New Zealand was among the 118 signatories of the International Code in May 1981. This committed New Zealand to progressing the Code's aims.¹¹ The Ministry is the agency responsible for implementing the WHO Code and monitoring compliance.¹²

The International Code was adopted on a voluntary basis in New Zealand on 13 April 1983.¹³ The Minister of Health was given responsibility for the Code, and established a Monitoring Committee. In 1991, after a review of all ministerial advisory committees under the Department of Health, the Monitoring Committee was disbanded. An independent consultant was intended to be appointed to monitor the Code, but the 1992 health reforms overtook this and responsibility for management of the Code was transferred to the Public Health Commission in January 1993.¹⁴ The Commission provided oversight and reported alleged breaches to the Minister of Health.

¹⁰ WHO (2008b).

¹¹ Ministry of Health (2004).

¹² Ministry of Health (2004).

¹³ Public Health Commission (1995).

¹⁴ Public Health Commission (1995).

The Public Health Commission reviewed the New Zealand interpretation in 1994, which produced a recommendation that the interpretation and monitoring of the International Code be through two voluntary, self-regulatory Codes of practice. The Codes of practice were the Infant Feeding Guidelines for New Zealand Health Workers (Ministry of Health 1997), recently updated to the Code of Practice for Health Workers¹⁵ and the Code of Practice for the Marketing of Infant Formula (NZIFMA 2007), updated in 2007, by manufacturers which is now known as the Infant Nutrition Council Code (“INC Code”).¹⁶

A Compliance Panel (“CP”) was established in the mid-1990s to oversee monitoring and implementation of the two Codes of practice.¹⁷ As of 2004, the Ministry (Ministry of Health 2004) reported:

Over eight years the Compliance Panel has met five times to deal with 14 formal complaints, which related to 0800 numbers, capsules to add to formula, price displays and advertisements. All complaints have been about the industry, not health workers.

The Ministry (Ministry of Health 2007) reviewed the complaints process and provides a summary of complaints process reviews to 2007:

A review of the voluntary, self-regulatory implementation and monitoring process for the New Zealand interpretation of the International Code began in 2001. The consultation phase consisted of a public submission process and meetings... Fifty-nine questionnaires and 14 written submissions were received during the submission process... The Ministry became aware that the International Code was not well known in New Zealand and that some misinterpretations existed. For example, the International Code was being misinterpreted to mean health practitioners were not allowed to provide information about formula feeding and this was creating difficulties for families and caregivers who were not breastfeeding... [T]he Ministry set up a consensus process where two meetings were held in 2003 and 2004 with representatives from stakeholder groups to assist in the completion of the review... The Ministry decided to continue with a voluntary, self-regulatory approach to implementing and monitoring the International Code in New Zealand (Ministry of Health 2004)... The review was completed and the review report published in 2004 (Ministry of Health 2004). The review resulted in 11 actions to refine and strengthen the implementation and monitoring in New Zealand. The Ministry held a third meeting in 2006 with the stakeholder group to begin the process for implementing the actions in the review.

Among the concerns with the Ministry’s complaints process identified in the 2004 review were (Ministry of Health 2004):

complaints were not being upheld; individuals and groups were not complaining because they felt there would be little follow up especially given the voluntary nature of the process and New Zealand’s weak interpretation of the WHO Code; the complaints process was not simple or timely; the industry is part of the Compliance Panel, specifically that it has a role in funding the panel

As we discuss in section 5, similar concerns are raised in the qualitative review in this report of the Ministry’s complaints process.

¹⁵ Available from <http://www.moh.govt.nz/moh.nsf/indexmh/breastmilksubstitutemarketingcode-healthworkers-online> Accessed 21 December 2010.

¹⁶ Available from <http://infantnutritioncouncil.com/wp-content/uploads/2009/03/infant-nutrition-council-code-of-practice-in-nz.pdf> Accessed 21 December 2010.

¹⁷ We understand the full name of the Compliance Panel is: The Ministry of Health WHO Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-Milk Substitutes in New Zealand: The Code In New Zealand.

2.3. The Complaints Process

Figure 1 shows the current process for complaints under the INC Code and the Health Workers' Code. The process represents the New Zealand implementation and monitoring of its obligations under the Code. It is administered by the Ministry. The process is in three parts:

Table 2: INC Code and Health Workers' Code Complaints Process¹⁸

Part	Description
Part 1: The complainant and respondent correspond	<p>A written complaint is lodged with the Ministry of Health. If there is a possible breach of either Code, the infant formula company, and/or health worker, and/or other affected party, where indicated, is asked by the Ministry of Health to respond to the complaint.¹⁹</p> <p>The respondent has 20 working days to respond to the written complaint.</p> <p>The response is then sent to the complainant. If the complainant is dissatisfied with the response their complaint is referred to the Compliance Panel.</p>
Part 2: The complaint is referred to the Compliance Panel	<p>The Compliance Panel considers the complaint. Additional information may be sought before the Compliance Panel makes their decision. Once the Compliance Panel makes their decision, all affected parties are notified in writing, and any affected party has 20 working days to lodge a written appeal with the Ministry of Health.</p>
Part 3: The appeal	<p>If a written appeal is lodged with the Ministry of Health about a Compliance Panel decision, all affected parties are notified, and all relevant documentation received by the Compliance Panel is sent to the Adjudicator. The Adjudicator decides whether grounds for appeal are met and makes their decision in writing, within 30 working days of receipt of the complaint documentation. All affected parties are notified of the Adjudicator's decision and recommended action. The Adjudicator's decision is final. The Adjudicator may refer the decision back to the Compliance Panel.</p>

When a complaint is submitted, the Secretariat confirms receipt of the complaint and then forwards the provided information to the subject of the complaint. The identity of the complainant is not revealed to the subject. The subject's response is forwarded back to the complainant. Generally, the response will have been prepared with legal advice and may be of a technical nature. The complainant is then asked whether they are satisfied with the subject's response. If the complainant indicates they are

¹⁸ In this report we refer to this three part process as "the complaints process". Source: <http://tinyurl.com/34m9x6v> Accessed 9 December 2010 (Ministry of Health web site).

¹⁹ Complaints regarding the advertising of follow-on formula (targeting infants aged six months or older) are considered by the Advertising Standards Authority. Complaints regarding the labelling, composition or quality of formula is considered by the NFSA (now part of MAF). See <http://tinyurl.com/4wyb2dd> Accessed 10 March 2011.

satisfied, then the process as it is documented ends at this point, regardless and without knowing whether a breach in the INC Code has occurred. If the complainant indicates they are not satisfied, then the complaint and response is forwarded to the Compliance Panel (“CP”) for consideration. If the complainant does not respond, then the complaint is closed.

The CP comprises five persons and there is an independent Adjudicator. The CP is composed of (Ministry of Health 2008):

- an independent Chair;
- one community/consumer representative;
- the INC CEO;
- one health practitioner; and
- one academic in a field related to infant and maternal nutrition.

The CP is currently funded to meet up to four times a year. The role of the CP is to evaluate the evidence put forward by the complainant and subject, and to decide whether a breach has occurred in relation to either the Health Worker or INC Codes of practice. The CP may seek additional information from either or both parties, but generally no correspondence is entered into.²⁰ Decisions by the CP and the Adjudicator are confidential unless a breach is upheld.

The CP’s terms of reference state:²¹

Objective: “The overall objective of the CP, which was established by the Ministry of Health, is to contribute to the wider policy environment which supports the provision of safe and adequate nutrition for New Zealand infants.”

Role: “make decisions on unresolved complaints relating to either the Code of Practice for Health Workers (Ministry of Health 2007) or the Infant Nutrition Council (INC) Code of Practice for the Marketing of Infant Formula (2007) (the Codes)... provide advice on appropriate action to remedy a breach of either Code in New Zealand.”

Performance: “The CP will be performing effectively when it provides relevant and timely decisions on unresolved complaints to the complainant and to the respondent and stays within its allocated budget.”

The Terms of Reference include natural justice as a guiding principle of the CP, and that the CP is expected to “ensure that all decisions reflect an appropriate balance between protecting the rights and well-being of consumers, of health practitioners, and INC members”.

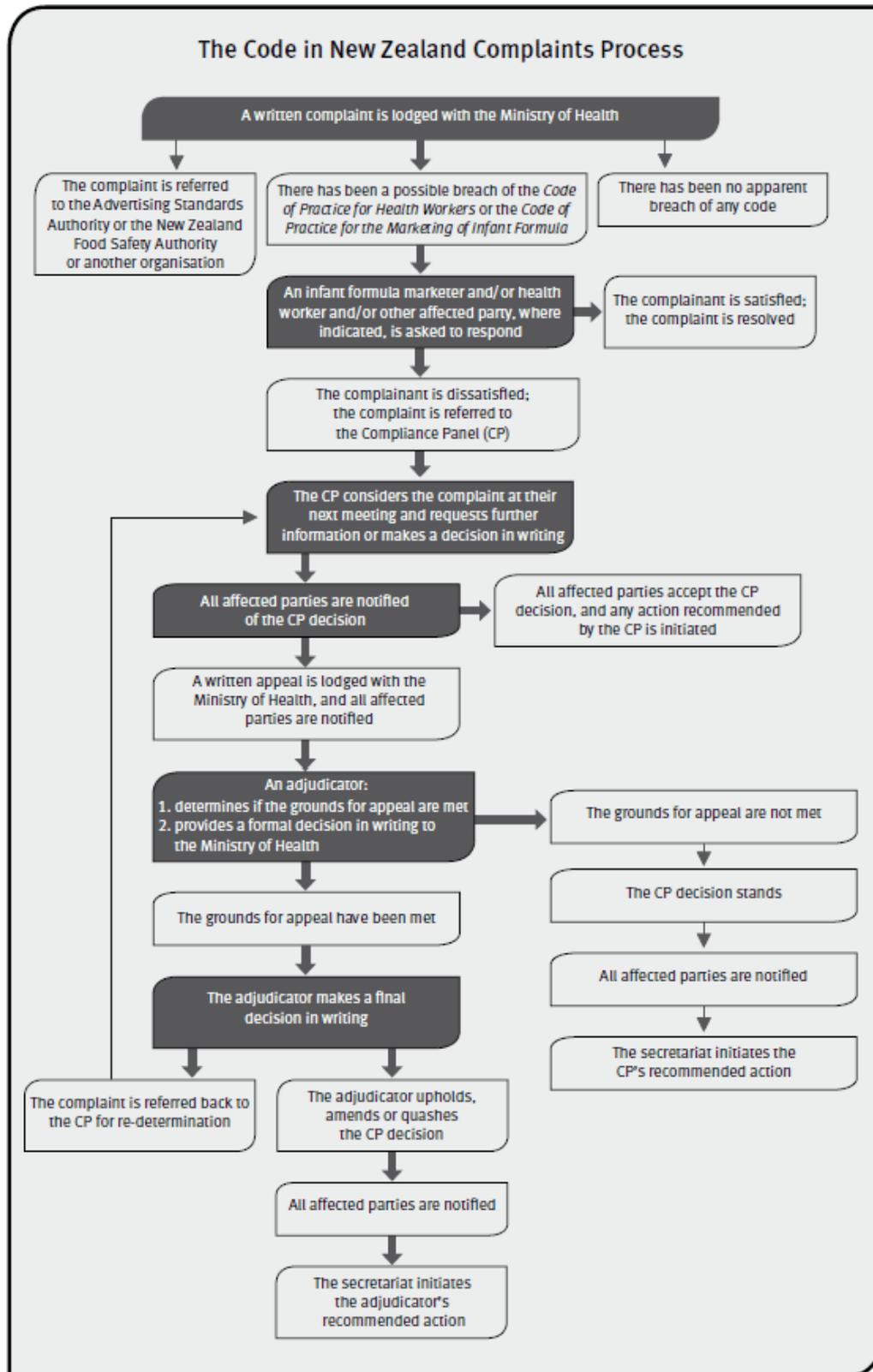
The CP has no power to compel sanctions on subjects: it is overseeing two voluntary Codes of practice, and so compliance under self-regulation is achieved not through force but incentives.²² The CP can declare a complaint upheld or not upheld. In the event it is upheld, the CP may issue a recommendation to remedy the breach.

²⁰ Personal communication as part of qualitative review.

²¹ The Terms of Reference for the Compliance Panel and the Adjudicator Process is available in the Appendix H.

²² We discuss self-regulation in more detail in section 4.1.

Figure 1: The Complaints Procedure Flowchart for the Health Workers' Code and/or INC Code of Practice²³



²³ Source: <http://tinyurl.com/34m9x6v> Accessed 9 December 2010 (Ministry of Health web site).

Either the complainant or the subject may appeal a decision to the Adjudicator, whose decision is final. The Adjudicator's procedure is contained in Appendix 1 of the Terms of Reference document. The Adjudicator may only hear an appeal if it appears that the CP, in making its decision:

1. did not follow a fair process based on the principles of natural justice;
2. failed to take a relevant fact into consideration or took an irrelevant fact into account, or gave a relevant fact insufficient weight; or
3. did not properly apply the relevant Codes in its decision.

Provided one or more of these grounds for appeal are met, the Adjudicator has four options in response: to uphold the complaint, amend the CP decision, quash the CP decision, or refer the complaint back to the CP for re-determination.

CP panellists and the independent Adjudicator are appointed by the Director of Public Health for a term of at least three years. The only reserved position on the panel is for the Executive Director of the INC (Ministry of Health 2008).

2.3.1. Analysis of Decisions since 2008

Since 2008, 13 complaints have been filed with the Ministry: five in 2008, four in 2009 and four in 2010.²⁴ Eleven have been complaints under the INC Code, and two have been under the Health Workers' Code. Of these 13 complaints, 11 complainants have received responses from INC or health workers and complainants have been asked if they are satisfied: four have been satisfied by the response, and seven have been dissatisfied, thus referring the complaint to the CP. The remaining two complaints are recent and at the time of writing this report were in part 1 of the process, as described in Table 2.

Table 3: Complaint Processing Steps and Times, April 2008-November 2010

	Days per Step	Total Days (cumulative)
Complaint received	- (sample=13)	-
Message to INC/Health Practitioner	8.7 days (sample=12)	8.7 days
Response sent to complainant	38.7 days (sample=11)	47.4 days
Complaint first considered by CP	68.0 days (sample=7)	115.4 days
CP decision	80.8 days (sample=7)	196.2 days
Appeal sent to Adjudicator	151.6 days (sample=4)	347.8 days
Adjudicator decision	81.5 days (sample=4)	429.3 days
Parties notified	13.0 days (sample=4)	442.3 days

²⁴ This section uses data provided to us by the Ministry of Health.

3. Methods

3.1. Literature Review Methods

We utilised a meta-search engine provided by Victoria University of Wellington called “Multi Search” to search for:²⁵

- Academic literature on regulation and self-regulation from an economics perspective; and
- Academic literature on the International Code from the following indexes: JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect, PubMed (including MedLine) and Google Scholar.

We list the search terms in the literature search in the Appendix, section Appendix C on page 83.

3.2. Qualitative Review Methods

A total of 31 stakeholders provided responses for the qualitative review. We interviewed by telephone 29 stakeholders, comprised of complainants, INC members and the CEO of the INC, health workers, enquirers to the Ministry’s complaints page but who did not go on to complain, breastfeeding NGOs, health workers, and complaint responders including the INC CEO, INC members, CP chair, CP Adjudicator, NZFSA (now part of MAF) and Advertising Standards Authority (“ASA”) officials.²⁶ Three participants submitted written questionnaire responses, two in place of their interviews, and one in addition to their interview. We considered these written responses.

Interview participants were invited to participate by the Ministry. The Ministry made initial contact with participants and, on their consent to be included in the interview process, their contact details were forwarded to the Research Trust. Research Trust then contacted participants to arrange a time for the interview. Questions were provided to each participant in advance of the interview. Interviews were recorded and transcribed, and the summary of findings from the interview process contained in section 5 is based on those transcripts. Two invitations to participate were declined, one of these due to being the subject of a new complaint.

Interview participants were given the option to withdraw their comments up to 10 days after the interview took place; none took this option. Interviews were conducted between 26 October and 25 November 2010. The consent letter to interview participants is included in Appendix E. The questionnaire is included in Appendix F. Interviews were recorded and transcribed, and analysis was conducted from the categorised responses to questions in the transcripts. Responses to each question in each interview was noted, each response was collected and placed into a common area for that question. Responses were then grouped according to respondent category, re-read and summarised for inclusion in the text of this report.

The interview process operated under ethical consent from the University of Victoria’s Human Ethics Committee. Under our agreement with the Ministry, the

²⁵ This search engine is available to staff and students of Victoria University of Wellington, but is not available to the general public.

²⁶ Details on the number of participants in each of these categories is in Table 8 on page 31.

Research Trust is required to destroy all recordings and transcriptions no later than 25 March 2011, on completion of the production of the final version of this report.

4. Literature Review

4.1. Economics of Regulation

In this section we provide a brief overview of the economic literature on regulation and self-regulation and set out the conditions in which theory and available evidence indicate that self-regulation may provide advantages over alternatives of government regulation and strict liability enforced through courts. The literature review provides background for the qualitative analysis of the complaints process in section 5, and it informs our recommendations.

Self-regulation refers to industry monitoring and enforcement of rules agreed by industry participants with the aim of inducing compliance by all participants. Usually these objectives are achieved through one or more industry-funded bodies. Frequently these bodies operate in competition with one another, allowing firms and their consumers to select among a menu of standards and compliance. Self-regulation generally covers the setting of minimum standards, a monitoring function, a complaints procedure, and procedures for enforcing rules on members. Self-regulation may be backed by government in various ways, from providing an oversight role, to requiring all industry participants to maintain membership. Self-regulation is not always or even generally efficient; the literature indicates self-regulation is comparatively efficient in industries where innovation is important, where an industry is not dominated by one large operator, where industry-specific human capital is important, and where qualitative aspects of a product or service is hard to codify in formal regulation (such as ethical behaviour or quality) (Priest 1997).

Standard explanations for regulation include mitigating social valuation and coordination failures involving such issues as public goods, externalities and information gaps which cause markets to fail.²⁷ Regulation may also be used to ensure processes meet social norms, such as the right to privacy in media (Barker and Evans 2007). Special-interest groups use regulation to further their particular interests, generally at the expense of the wider population.²⁸ The economic theory of regulation views an economy's regulatory structures as representing the balance of competing special interest group pressures that leave each group optimally disgruntled with their share of the activity in which they have most interest (see Stigler 1971).

4.1.1. Self-Regulation

Self-regulation is a subset of regulation, and is defined as “the delegation of regulatory authority... the formalised promulgation and enforcement of legal rules by the regulated” (Grajzl and Baniak 2009). Nunez (2007) defines self-regulation as “a scheme whereby the enforcement of quality is delegated to the suppliers”. Ogus (1999) notes the “self-” in self-regulation does not literally mean “self”. Rather, self-regulation refers to a “collective restraint” derived from some body other than government, to “achieve desirable outcomes that individual behaviour alone would not achieve” (Black 1996 via Ogus 1999).

²⁷ Markets frequently deal well with market failure. For example, the market's failure to provide lighthouses was a textbook case for market failure and government intervention until Coase (1974) discovered that lighthouses were privately provided.

²⁸ An interest group is defined as a coalition of persons or entities with a common goal or philosophy.

Self-regulation can be thought of as operating on a continuum in two dimensions (Ogus 1999). In the first dimension, self-regulation varies according to degrees of autonomy from government. At one extreme of autonomy, rules may be set within firms and privately, with enforcement subject only to internal processes. At the other extreme, there is no autonomy: rules may be subject to approval by a minister or public authority. These extremes are connected by a continuum along which interest groups may participate in decision-making, through they may not conclusively determine the outcome. In the second dimension, legal force varies from voluntary standards through to formally binding, public or private law sanctions for non-compliance. Between these extremes exist Codes of practice, and non-legal sanctions for breach of norms, such as expulsion from industry groups (Ogus 1999).²⁹ Stefanadis (2003) notes:

[S]elf-regulation does not imply a totally passive government. Although the government refrains from formal regulation, it has to use ex ante warnings and ex post monitoring to induce SROs [Self Regulatory Organisations] to comply with its objectives.

Self-regulation can be the result of a co-ordinated industry-wide action designed to pre-empt government regulation (Maxwell et al 2000; Stefanadis, 2003 cited in Grajzl and Baniak, 2009), sometimes as a direct result of the industry's bargain with the government to avoid stiffer regulatory provisions (Glachant, 2003; Segerson and Miceli 1998 cited in Grajzl and Baniak, 2009). Threat of public regulation can be efficient in that it induces higher compliance without the full cost of rules development, oversight and enforcement by public authorities. Compliance can be achieved without the full cost of government intervention. DeMarzo et al (2005) explains:

[G]overnment oversight of self-regulation can benefit customers by leading the SRO to engage in more aggressive enforcement. The SRO would choose an enforcement policy that is just aggressive enough to pre-empt the government doing its own enforcement.

Ogus (1999:593) notes self-regulatory organisations (SROs) are more aggressive where industry believes a public agency may intervene (also see Maxwell et al 2000).

Innovation also increases the comparative value of self-regulation, because information asymmetries between government and industry are exaggerated by changing technology (Stefanadis 2003). Where innovation is important, government can limit itself to providing warnings *ex ante* (before the fact) and undertake monitoring *ex post* (after the fact) to induce self-regulated firms to operate efficiently. This form of regulation relies on threat of intervention by government for non-conformance, and is relatively cost efficient.

4.1.2. Benefits and Disadvantages of Self-Regulation

Self-regulation is an alternative to government regulation and strict liability, and has several benefits: it is relatively low-cost and conserves government resources, it is less adversarial and more flexible (Baggott and Harrison 1986), more timely (Stefanadis 2003), and monitoring and enforcement costs are typically reduced (Ogus 1999). Under self-regulation, administrative regulatory costs are usually internalised to the industry and thus there is a stronger incentive for cost efficiency (Grajzl and Baniak, 2009).³⁰ The lower costs of self-regulation permit a greater scope

²⁹ For collective action problems in industry self-regulation, see King and Lenox (2000, 2006) and Lenox and Nash (2003). See Nunez (2001, 2007) and DeMarzo et al (2005) for analysis of agency problems between a self-regulatory organization and its members (via Grajzl, and Baniak, 2009).

³⁰ However, Priest (1997) warns cost savings may in part be illusory: self-regulation may create market power for members resulting in above-competitive prices.

for regulation than would otherwise be possible for given financial constraints (Priest 1997). Self-regulation is frequently broader in scope than government regulation, and can be more effective where qualitative factors and matters of morality and taste, which are hard to codify in legislation, are important, as is the case in advertising (Baggott and Harrison 1986). Cost and timing advantages of self-regulation may increase international competitiveness (Priest 1997).

However, self-regulation also has disadvantages. Self-regulation contains an inherent bias toward the regulated. When setting standards, the purpose of the industry level self-regulatory organisation is to minimise its members' costs: this is the source of pro-industry bias (Grajzl and Baniak 2009). As Kay (1988), cited in Ogus (1999), notes "with self-regulation, regulatory capture is there from the outset."

Self-regulation dulls competition among members, who undertake less-frequent investigations of members than customers would prefer (DeMarzo et al 2005). Nunez (2007) considers the conditions in which a self-regulation authority becomes vulnerable to corruption, finding that fraud is increasing in the relative imbalance of the regulated industry: the level of fraud depends on the bargaining power of the self-regulatory authority and the corrupting member. Sharma et al (2010) argue for moderate, manageable initial requirements for self-regulation in the food industry, ahead of future strengthening. This ratcheting of provisions is a general pattern in self-regulation:

Governments are motivated to maintain or extend the use of self-regulation because, while they may derive political benefits from measures which appear to benefit consumers and others, the costs are not revealed in any public accounts. And it is difficult for the cost-bearers both to determine the amount of wealth transfers and to coordinate their activities in opposing them. (Ogus 1999)

How does self-regulation produce compliance without the power to coerce? Under self-regulation, the power to enforce rules is capped by the maximum sanction the regulating authority can impose on members, usually expulsion from the industry body. Where human capital is industry-specific, as in most professions, these costs are high, and self-regulation is relatively effective (Donabedian 1995). Secondly, self-regulation makes use of reputation for its authority. In a voluntary legal system, loss of business and reputation is the ultimate threat and repeated interactions raise the cost of non-cooperation (O'Driscoll and Hoskins 2006). Brand names transform what would be many one-shot dealings in repeated dealings, raising the cost of non-compliance (Klein 1997b, cited in O'Driscoll and Hoskins 2006).

Incentives for compliance under self-regulation are enhanced when industry perceives a threat of government enforcement, leading the self-regulating authority to pre-empt the government by increasing enforcement by just enough (DeMarzo et al 2005). Under this system, compliance that may be comparable to that under full public regulation is achieved by voluntary self-regulation at lower cost.

4.1.3. Where Self-Regulation is most likely to be effective

We list the elements of industry which increase the comparative advantage of self-regulation over alternative regulatory or legal arrangements.

Table 4: Industry features conducive to self-regulation

Industry characteristic	Explanation	References
Relatively few industry players	Lower monitoring costs, larger reputation/brand costs for non-compliance	Priest (1997)
Firms are multi-product	Cheating can be more effectively punished when a firm operates across multiple markets: it is possible to punish the deviating firm in all markets when it deviates in just one	Stefanadis (2003)
Firms can observe rivals' behaviour	Firms in competition have incentives to monitor rivals' activities for breach	Gehrig and Jost (1995)
High industry exit costs/industry-specific human capital	Exit costs cap the punishment self-regulating organisations can impose on industry members: higher exit costs increase maximum effective punishment of self-regulation	Donabedian (1995)
Industry marked by innovation or technology	Information asymmetries between industry and government become severe in innovative industries, resulting in costly delay if regulation is via government	Stefanadis (2003), Gehrig and Jost (1995)
Industry is not dominated by a single large firm	Self-regulating authority may be too lenient to a single large firm which other fringe firms are unable to counter	Nunez (2007)
The industry is not hazardous	In hazardous industries, self-regulation may under-supply compliance on health and safety matters relative to public regulation	Grajzl and Baniak (2009)

Industry characteristic	Explanation	References
Appropriate behaviour hard to codify in legislation	Greater tolerance for imprecision in rules in a non-adversarial regulating environment	Baggott and Harrison (1986), Ogus (1999)
Self-regulation compatible with ethical behaviour	Lowers monitoring costs: if regulated behaviour is consistent with social norms, deviation from regulation is more easily identified	Priest (1997)

The literature reviewed does not provide evidence on the value of self-regulation from an individual workers' perspective, such value being particularly dependent on the structure of the self-regulation, and its application. We offer our thoughts on the value of self-regulation under the Health Workers' Code in section 6.7.

4.1.4. Self-Regulation and Advertising

Baggott and Harrison (1986) study self-regulation and advertising. The basis for most demand for greater control of the advertising industry has been the protection of consumer interests. This is problematic: consumers are a large and diffuse group with wide interests, and so organised political representation of their interests tends to be undermined by free rider problems, as the benefits of membership are dominated by costs at the margin (see Stigler 1971). This is why consumer groups have trouble attracting membership.

Baggott and Harrison (1986) state the early drivers of self-regulation in the advertising industry in Britain included a desire for credibility through an “image of professional responsibility”, without which advertising could not persuade. Self-regulation also provided a means for dispute resolution out of the public view, allowing an image of industry unity and stability to be developed (Baggott and Harrison 1986). Self-regulation has other advantages in advertising. Because it may be difficult to codify the desired behaviour from advertiser in law, particularly in an adversarial relationship with the regulator, formal regulation may be counterproductive (Ogus 1999).

Ogus (1999) continues:

Since [Self-Regulating Authorities] SRAs typically command a greater degree of expertise and technical knowledge of practices and innovatory possibilities within the relevant area than the principal, information costs for the formulation and interpretation of standards are lower. Secondly, for the same reasons, monitoring and enforcement costs are also reduced, as are the costs to the regulatees of dealing with regulators, given that such interaction is likely to be fostered by mutual trust.

Ogus warns that self-regulation may also produce anti-competitive harms:

[M]ost professional associations have, at some time or another, prohibited their members from advertising, ostensibly on the ground that ‘touting’ for business is incompatible with the ethical nature of professional practice (OECD, 1985). As we have seen, such bans can eliminate wasteful consumer searches on elusive quality characteristics (Barzel, 1982), but they can also inhibit comparative price shopping, thus generating monopoly rents for practitioners (Trebilcock 1982).

This insight from Ogus is potentially relevant to understanding the willingness of industry to comply with voluntary restraints on advertising infant formula.

4.1.5. Conclusion on Economics Literature

The literature in economics is helpful in establishing both the conditions under which self-regulation is likely to be effective, and the costs and benefits of this form of regulation. Self-regulation has the potential to provide lower cost monitoring, enforcement and compliance with requirements on industry participants, but for lower cost and effectiveness to be achieved a variety of conditions must be met. Those conditions include the existence of an effective mechanism for processing and adjudicating complaints received, and costs for those who breach the requirements that are sufficient to strongly incentivise compliance.

4.2. International Code Compliance

In this section we provide a review of the academic literature on the International Code. We offer two caveats on this review. First, the literature is largely qualitative in nature, with a limited amount of empirical work to draw on to gauge understanding, enforcement or compliance with the Code across countries. Much of the compliance monitoring appears to be undertaken by non-governmental organisations. Second,

our impression gained from the literature is that the Code is considered by many researchers to be an ethical matter, rather than a scientific one. The tone of articles is frequently strident, raising questions about objectivity and reliability. There are frequent references to manufacturer size, resources and profitability, usually without explaining the link to health outcomes, possibly indicating ideological objections. The literature review assisted in identifying knowledge gaps, listed in section 7. We have placed greater weight on studies providing robust quantitative information and reports published in peer-reviewed journals.

There appear to be few studies of International Code compliance in the academic literature. Much of the available compliance information is sourced from an informal literature, the reliability and subjectivity of which is difficult to assess. Nevertheless, a number of studies report widespread non-compliance with the Code. The literature tends to indicate greater compliance in developed countries than in developing countries. In a survey of labelling practices in Puerto Rico, Parrilla-Rodríguez and Gorrín-Peralta (2008) find all 34 labels surveyed failed to meet standards in Article 9 of the International Code: 74 percent did not have a statement that “breastfeeding is best” or words to that effect; 97 percent had text idealising the use of infant formula. Mendoza (2010) cites research showing “rampant violations...reported in both industrialized and developing countries”. In a telephone sample of 3209 US maternity sites between 2006 and 2007, Merewood et al (2010) report 91 percent of hospitals distribute formula sample packs. Cattaneo and Quintero-Romero (2006) state, “the International Code is systematically infringed,” and cite two studies showing this:³¹

A study carried out in 1996 in four countries (Bangladesh, Poland, South Africa and Thailand) showed that 8-50% of health facilities received and accepted free samples of milk formula; 2-18% of health workers received and accepted gifts from companies; in 15-56% of health facilities information that violated the International Code had been provided by companies and was available to staff.

The study cited by Cattaneo and Quintero-Romero (2006) is Taylor (1998). The definitions in the Taylor paper include:

All products marketed for infants younger than 6 months and all follow on formulas were considered to be breast milk substitutes... These definitions were based on World Health Assembly resolution 47.5 (1994)

Using country surveys in 2002 and 2007, Cattaneo et al (2010) shows increasing compliance in Europe. Of the 30 countries surveyed³² Cattaneo et al (2010) found that by 2007 six countries lacked a national policy to comply with WHO recommendations, three lacked a national plan, and four lacked a national breastfeeding coordinator and committee. In an earlier version of Cattaneo, et al (2010), Cattaneo et al (2005) report that in Europe the Code is not fully applied, and is not fully subject to independent monitoring; less than 15 percent of births occur in baby-friendly hospitals; some countries do not comply with the Innocenti Declaration. McInnes et al (2007) study the Code compliance in primary care organisations in Glasgow, an area of relatively low breastfeeding rates. They report one-third of facilities displaying non-compliant marketing materials, but also find samples were rare, and contact between health workers and formula manufacturers was minimal and usually unsolicited. Over a third of health workers in a survey by McInnes et al (2007) reported concerns about obtaining access to product information.

³¹ Cited studies are Taylor (1998) and Aguayo et al. (2003). UNICEF (2010) also provides information on Bangladesh, as well as Benin, Philippines, Sri Lanka, Uganda and Uzbekistan.

³² Cattaneo et al (2010) report 29 countries returned surveys in 2002 and 24 in 2007.

Aguayo et al (2003) checks compliance with the Code in two west African nations, Togo and Burkina Faso, with a survey of health facilities, sales outlets, health providers, and mothers. Aguayo et al found:

- 14 percent of health facilities had received donations of breast milk substitutes;
- 12 percent of health facilities had received free samples of breast milk substitutes for purposes other than professional research or evaluation;
- Health professionals in 12 percent of health facilities had received promotional gifts from manufacturers;
- Promotional materials of commercial breast milk substitutes were found in 16 percent of health facilities;
- Displays promoting commercial breast milk substitutes were found in 44 percent of sales and distribution points; and
- Aguayo also alleged violations of labelling standards of the Code, reported low Code awareness among health providers (90 percent had never heard of the Code) and 63 percent of mothers had not received any counselling on breast feeding by their health providers.

Cattaneo and Quintero-Romero (2006) also report on grey literature which links weaker legislation in Kenya, Bolivia and Mexico with lower compliance rates.³³ Taylor (1998) draws a similar conclusion by noting that Bangladesh, which has laws governing Code compliance, the lowest number of Code violations were found in her sample of four countries. Mendoza (2010) reports the Philippines, which legislated the Code in 1986 from the original text of the Code nearly verbatim but *excluding* a prohibition on marketing of milk formula and substitutes, exclusive breastfeeding rates were among the lowest in the world in 2003, at 16 percent in the first six months. Cattaneo and Quintero-Romero (2006) point out that no population-based controlled studies have been done to measure the relationship between enforcement of the International Code, and compliance.

It must be noted that studies using data sourced in these countries may be of limited use: levels of corruption is an important difference between New Zealand and some of these countries, and this interferes with comparability. If breach of the Code is a product of this or other local factors, rather than representative of company-wide practices, this may limit the lessons one can draw from these studies.

On compliance, Kaplan and Graff (2008) report:

The Code entrusts governments to regulate what information, education, and equipment women, health care providers, and others in their countries receive on breastfeeding and formula, and there is no mechanism for international enforcement. A 1998 report from the International Baby Food Action Network (IBFAN) surveyed 31 countries and found that most were not compliant with the Code; a 2004 IBFAN report noted that most of the marketing practices employed by international baby food manufacturers and 14 bottle and nipple companies violated the Code. The USA has never enforced the Code with any legislation or regulatory action.

Section 11.6 of the Code specifies:

11.6 In accordance with Article 62 of the Constitution of the World Health Organization, Member States shall communicate annually to the Director-General information on action taken to give effect to the principles and aim of this Code.

³³ Cited study: IBFAN (2003).

By the end of 1999, WHO reported that 160 Member States, comprising 84 percent of members, had reported to WHO on action taken to give effect, in whole or in part, to the International Code (Armstrong and Sokol 2001). The International Baby Food Action Network (IBFAN) is a non-governmental organisation (NGO) which established the International Code Documentation Centre (ICDC) in 1986 to research and keep track of Code implementation at the national level.³⁴

In Europe, nearly all of the members of the European Union have enacted laws to implement the European Community Directive on Infant Formulae and Followup Formulae (1991). Yet about one-half of those countries' laws allow advertising in baby care magazines and samples of follow up formulae (Armstrong and Sokol 2001). Armstrong and Sokol (2001) report Australia, South Africa, Sweden, Malaysia and New Zealand have complied with the Code by developing voluntary Codes in cooperation with the infant food industry.

The WHO provides bi-annual reporting on progress in child nutrition.³⁵ WHO (2002) reported a substantial improvement in the prevalence and duration of exclusive breast feeding in the previous 10 years, however rates of exclusive breastfeeding at that time remained low.³⁶ Of WHO's 191 members, 162 members had reported on actions to give effect to the Code. The WHO (2008b) Code implementation status update focuses on new standards and guidelines development but did not provide compliance data.

Walker (2001) documents and criticises marketing strategies used by formula companies, based on a compliance survey undertaken by the National Alliance for Breastfeeding Advocates (NABA). According to Gossler (2003), Walker (2001) documents the following strategies:

- Code avoidance, through targeting health care workers by, for example, sales representatives encouraging health professionals to wear a name badge holder bearing a formula maker's logo;
- Providing health professionals with financial incentives;
- Sales representatives encourage health workers to promote their product;
- Misleading or deceptive information in advertising materials; and
- Exaggeration or half-truths in advertising, publishing own research.

Reddy (2008) cites other studies which found health workers received gifts from infant formula manufacturers including t-shirts or jackets.

UNICEF (2010) summarises compliance:

Most countries have experienced difficulties in mounting sustained and effective Code monitoring programmes. Training has been held for Code monitors both regionally and in country at various levels in all five countries with Codes. In the 1980s and sometimes in the 1990s NGOs such as IBFAN and various national breastfeeding advocacy groups were active in Code monitoring. Recently Code monitoring activity has declined in most countries. Enforcement has posed even greater challenges, with no or very weak penalties in place for companies that persist in violating regulations.

³⁴ See <http://www.ibfan.org/>

³⁵ For example see WHO. (2002) and WHO. (2008a).

³⁶ WHO (2002) reports on a literature survey of 3000 articles on the optimum duration of breastfeeding. The survey recommended states promote exclusive breastfeeding for six months, with continued breastfeeding along with complementary foods for up to two years or beyond.

4.2.1. Recommendations on Code Implementation

For Australia, Donath and Amir (2005) recommend:

- *“appointing a national breastfeeding coordinator with appropriate authority, and establishing a multisectoral national breastfeeding committee composed of representatives from relevant government departments, nongovernmental organizations, and health professional associations”.*
- *“ensuring that every facility providing maternity services fully practices all the ‘Ten steps to successful breastfeeding’ set out in the WHO/UNICEF statement on breastfeeding and maternity services”.*
- *“giving effect to the principles and aim of the International Code of Marketing of Breast-milk Substitutes and subsequent relevant Health Assembly resolutions in their entirety”.*
- *“enacting imaginative legislation protecting the breastfeeding rights of working women and establishing means for its enforcement”*

Kaplan and Graff (2008) recommend:

Public health agencies, however, can and should work to counter this corporate influence by creative and aggressive breastfeeding promotion, utilizing the same channels that have been leveraged by formula manufacturers...

Public health agencies and government partners should institute policies and interventions that support breastfeeding, especially in light of undermining corporate influences. These include “advertising” breastfeeding through the channels that the formula companies have used to promote their products, and helping women to access services and other support that will help them initiate and continue breastfeeding

In a paper on the promotion of breastfeeding in low-income countries, Cattaneo and Quintero-Romero (2006) recommend:

the full implementation of: (1) the International Code of Marketing of Breastmilk Substitutes and subsequent relevant Resolutions of the World Health Assembly, and (2) the ILO Maternity Protection Convention.³⁷

Countries should revise their current legislation to ensure that it is fully in line with all the provisions of the International Code; they should obviously enforce it, with adequate information to the public and to health professionals.

Walker (2001), in a review of compliance with the Code focusing on the United States, recommends.³⁸

adopt, implement, and monitor the Code; engage in a Code education program for the health care system; support a national breastfeeding promotion campaign; reimburse health care providers for lactation care and services; encourage adherence to the 10 steps to successful breastfeeding; and channel formula rebates from the WIC program into strengthening breastfeeding programs that increase initiation and duration rates of breastfeeding.

UNICEF (2010), in concluding their review of breastfeeding programs in six countries, notes, “[e]ffective national Code legislation with sustained advocacy, ongoing monitoring, publicity of violations, and enforcement helps keep negative marketing practices in check.” UNICEF (2010) recommend:

³⁷ Full reference is ILO (2000).

³⁸ As reported by Gossler (2003).

Strengthen Code legislation and training, as needed, and ensure that strong monitoring and enforcement systems are in place, with adequate sanctions for violations that will deter Code infractions.

4.3. Country Status

Implementation of the International Code varies by country. In this section we review implementation in selected countries. Table 5 below provides an overview of implementation of Code by country, as interpreted by IBFAN, a NGO which conducts research and provides regular reporting on Code-related issues.³⁹

Table 5: Countries Status re Implementation of the Code (2006): Selected Countries⁴⁰

	Law	Many provisions law	Policy or voluntary measure	Few provisions law	Some provisions or voluntary guidelines	Measure drafted, awaiting final approval	Being studied	No action
New Zealand			✓					
Australia			✓					
United Kingdom		✓						
United States (Federal govt)								✓
Canada				✓				
Hong Kong					✓			
Singapore					✓			
France		✓						
Germany		✓						
Total Count, All Countries (2006)	32	44	18	25	21	22	17	9

Donath and Amir (2005) reports breastfeeding rates around the world: Australia has fewer than 50 percent of infants receiving breast milk at six months. Norway, from a 1998 survey quoted by Donath and Amir, has reportedly achieved 80 percent of infants continuing to breastfeed at six months. In the United States, 38 percent of infants are exclusively breastfeeding at three months (Kaplan and Graff 2008) and 30 percent of infants are breastfed at six months; in the United Kingdom, 21 percent of infants breastfeed at six months (Donath and Amir 2005). One estimate, cited by Cattaneo and Quintero-Romera (2006), is that 1.3 million deaths of children under five years, representing 13 percent of total age-specific mortality, could be prevented each year if 90 percent of infants were exclusively breastfed to six months.⁴¹

³⁹ Assigning a single descriptor to a country's set of policies may produce over-simplification, and Ministry of Health has commented that it disagrees with the New Zealand classification by IBFAN. The Ministry noted: "The Ministry disagrees with their categorisation of New Zealand as we have a mix of voluntary codes and legislation. Specifically as per The Code in New Zealand (Ministry of Health 2007) the International Code is implemented through four New Zealand codes. Three codes (Ministry's Code of Practice for Health Workers (2007), INC's Code of Practice for the Marketing of Infant Formula (2007) and the ASA Code for Advertising of Food 2010 are voluntary, and the Australia New Zealand Food Standards Code (2002) is legislated." (personal communication)

⁴⁰ Source: IBFAN (2006).

⁴¹ Taylor (1998) cites a WHO study that says 1.5 million babies could be prevented from dying each year if breastfeeding was undertaken exclusively to 6 months and up to 2 years.

4.3.1. Australia

The Australian interpretation of the International Code is the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (“MAIF”). The MAIF is overseen by the Advisory Panel on the Marketing in Australia of Infant Formula (“APMAIF”), a non-statutory advisory panel appointed by the Australian Commonwealth government in 1992.⁴² That year MAIF was authorised under the *Trade Practices Act 1974*.⁴³ The panel advises the Australian government on the MAIF agreement, and monitors compliance through a complaints process.⁴⁴ The MAIF is a voluntary agreement, and covers manufacturers and importers of formula in Australia. Industry members of MAIF are Abbott Australasia, Bayer Australia, H J Heinz Company Australia, Nestlé Australia Limited, Nutricia Australia Pty Ltd and Wyeth Australia.⁴⁵

APMAIF has no formal regulatory power either to compel industry participants to provide information or to force compliance with the MAIF agreement, nor are there financial or legal sanctions for breach.⁴⁶ Instead APMAIF relies on co-operation of industry participants to implement APMAIF’s recommendations on marketing. Breach is described in the annual report of the APMAIF, and this report is tabled in Parliament.

Australia has no equivalent to the Ministry’s New Zealand’s Health Workers’ Code. Health worker guidelines on infant feeding were produced in 1996. However, no complaints process regarding health worker has been established at the Commonwealth level.⁴⁷ Policy for health workers regarding the Code may be implemented at the state level, although we have not been able to find evidence of this.

The APMAIF comprises six panel members including a Chair, a consumer representative, two infant nutrition and public health experts, an industry representative, and a legal expert. The Chair is appointed to a four year term.

Complaints Process⁴⁸

On receiving a complaint, the Secretariat of the APMAIF is charged with determining whether the complaint is within the scope of the MAIF agreement. APMAIF reports (APMAIF 2009):

Out-of-scope complaints are recorded in the complaints register and statistics which the secretariat provides at each APMAIF meeting, but are not otherwise considered by the APMAIF. The secretariat advises complainants in writing if their complaints are outside the scope of the MAIF Agreement.

For complaints within scope, the Secretariat advises the manufacturer or importer of the complaint; they are invited to respond with evidence or other information. The APMAIF considers the complaint and response at the next meeting, and a summary is prepared by the Secretariat. APMAIF may find that a breach has not occurred. It

⁴² The text of the agreement is available at: <http://tinyurl.com/2dt4bs4> Accessed 15 December 2010.

⁴³ Australian House of Representatives (2007).

⁴⁴ Annual reports are available from <http://tinyurl.com/23uny5r> Accessed 15 December 2010.

⁴⁵ See APMAIF brochure, available from <http://tinyurl.com/27xhl48> Accessed 15 December 2010.

⁴⁶ APMAIF (2010:1). Details on the complaints handling process is available at <http://tinyurl.com/68f23bf> Accessed 23 March 2011.

⁴⁷ Source: APMAIF Secretariat, personal communication.

⁴⁸ This section is based on Chapter Two of APMAIF (2009). See footnote 46.

may find that further consideration is required, in which case the industry and the complainant may be invited to provide more information for the next meeting of APMAIF.

The complainant and the subject of the complaint are advised of a decision, with the reasons for it. A finding of breach is reported to the Parliamentary Secretary for Health, and recorded in the APMAIF annual report.

In response to concerns about a complaint handled in 2007-8, in particular relating to quality of evidence, a formal Complaints Handling Process has been recently produced (contained in Appendix C of APMAIF 2009). The APMAIF report makes no mention of an appeals process.

Complaints Process Statistics

The APMAIF provides summaries of complaints received in its annual reports, which we compile here. APMAIF records a total of 1377 complaints received in Australia.⁴⁹

Table 6: Summary of complaints under MAIF, 2002-2009, Australia⁵⁰

	2002-03	2003-04	2004-05	2005-06	2006-07	2007-08	2008-09
Complaints for the period	189	80	69	163	982	159	46
In scope	20	31	17	10	123	27	9
Out of scope	149	34	14	71	709	130	32
Breaches	1	1	0	0	0	0	1
Carried over to following year	20	15	38	82	150	2	4

Of the complaints received by APMAIF, 1139 (83 percent) were decided to be out of the scope of the MAIF.

Knowles Report 2001

In 2001, the Australian government commissioned an independent report on the APMAIF, called the Knowles Report (Knowles 2001). Knowles reported a fundamental disagreement at the time between industry and advocates' views of the APMAIF. Knowles (2001) states:

Industry views the agreement as providing a framework for the provision of comprehensive information to all mothers i.e. both mothers who breast feed and those who infant formula feed their infants. On the other hand, breast-feeding advocates see the agreement solely as a mechanism to curb industry marketing activity, which may undermine efforts to increase breast-feeding rates... one of the few areas of consensus was the view that an effective voluntary agreement between government and industry was the more preferred model for ensuring implementation of the Code.

The Knowles (2001) report also notes or recommends:

- Much of the criticism of the current arrangements relates to activity outside of the scope of the current MAIF Agreement;
- Concerns over time to resolve complaints

⁴⁹ Complaints for the Period includes carried over complaints from the previous year. The total number of complaints received is the sum of Complaints for the Period (1688) minus Carried Over to Following Year (311).

⁵⁰ Source: APMAIF (2010). Field "Complaints for the period" includes complaints carried over. For 2007-08 and 2008-09 it is not clear from the tables provided what number of complaints were carried over, and for these years we have used "Number of complaints" as reported.

- An industry proposal to distribute samples to health professionals for evaluation is against the spirit of the MAIF agreement;
- There is a need for pharmacies and retailers to be included in a Code of practice;
- There is a need for a clear separation of investigation and deliberation responsibilities, and the APMAIF secretariat; wherever it is located ought to have responsibility for receipt and investigation of complaints or breaches under the MAIF Agreement. The Panel will then be able to focus its energy on whether a breach has occurred or not;
- An appeals process should be introduced on technical matters to protect against breaches of natural justice;
- Increase panel size from three to five to avoid stalemates; and
- Consider selecting a Chair with legal experience, preferably in the health sector.

4.3.2. United Kingdom

In the United Kingdom, the International Code's interpretation and implementation is through law rather than self-regulation. The Code was first given legal effect in the United Kingdom in 1995 through the Infant Formula and Follow-on Formula Regulations 1995. These implemented the 1991 Directive 91/321/EEC⁵¹ on infant and follow-on formula, which included rules on composition and labelling for infant and follow-on formulae and gave effect to the International Code. The United Kingdom Regulations prohibited advertising of infant formula for the first time, with an exception: the 1995 Regulations only permitted advertisements "in a publication specialising in baby care and distributed only through the health care system; in a scientific publication; or for the purposes of trade prior to the retail stage".

In early 2008, regulations were tightened when the Infant Formula and Follow-on Formula (England) Regulations (2007) came in to force. Equivalent parallel Regulations were also made in Scotland, Wales and Northern Ireland.

Complaints Process

The handling of complaints about advertising of infant and follow-on formula is the responsibility of the Advertising Standards Authority (ASA) in the United Kingdom. The ASA receives complaints on breaches in its United Kingdom Code of Broadcast Advertising (BCAP), which came into force on 1 September 2010.⁵² The BCAP (BCAP 2010) requires:

These rules must be read in conjunction with the relevant legislation including the Infant Formula and Follow-on Formula Regulations 2007 (as amended) and the Regulation 1924/2006.

13.8 Advertisements for infant formula are prohibited.

13.8.1 Advertisements must not confuse between infant formula and follow-on formula.

⁵¹ Available from faolex.fao.org/docs/texts/eur18745.doc Accessed 15 December 2010.

⁵² See Adjudications on ASA website: <http://www.cap.org.uk/The-Codes/BCAP-Code/BCAP-Code-pdf-versions.aspx> Accessed 15 December 2010.

Complaints Statistics

The United Kingdom ASA provides a searchable database for all adjudicated decisions back to December 2005. We searched the database for all INC Members, all except Fonterra appear in the ASA database. Since these are multi-product firms and the United Kingdom ASA receives complaints not related to the marketing of infant formula, we examined each complaint to check whether it was Code-related, and the result of any Code-related complaints. Table 7 summarises our findings.

Table 7: Summary of United Kingdom ASA Adjudication December 2005-December 2010⁵³

	All Adjudicated decisions	Adjudicated decisions related to formula				Notes
		Number	Upheld	Partly Upheld	Not Upheld	
Nestle	8	1	0	0	1	
Bayer	1	0	0	0	0	
Heinz	3	1	0	1	0	
Nutricia	8	8	2	1	5	
Wyeth	2	2	0	1	1	109 complaints for one advertisement (not upheld)
Total	22	12	2	3	7	

In 2009, the United Kingdom ASA received 29,000 complaints. The United Kingdom ASA reports it took on average 13 working days to adjudicate a decision (ASA UK 2010b).

4.3.3. Canada

Canada has taken a largely non-legislative approach to implementation of the International Code, with laws covering only quality, labelling and consumer protection (OPHA 2008). Nathoo and Ostry (2009) provide a general overview of Code implementation in Canada, reporting increasing and then declining levels of effort at the federal level in Canada since 1981.

Code implementation in Canada has primarily occurred through a series of public initiatives to encourage breastfeeding. Nathoo and Ostry report that in the 1980s the Canadian federal government was involved in multi-pronged efforts with womens' groups, La Leche League, professional associations, industry and hospitals. However, in the 1990s Nathoo and Ostry report efforts waned somewhat, and became fragmented.

Provincial governments have developed breastfeeding policies, beginning with Quebec in 2001, Nova Scotia in 2005 and New Brunswick in 2006. Other provinces, though not having breastfeeding policy, have rolled out breastfeeding initiatives including British Columbia, Alberta, Manitoba, and Saskatchewan.

A federal Baby-Friendly campaign was launched in 1998, and by 2006 four Canadian hospitals had achieved baby-friendly status. In 2010, an Infant Feeding Expert Advisory Group was formed to provide Health Canada with advice on the revision of nutrition and feeding recommendations for the healthy term infant. Health Canada is a major producer of information and statistics on breastfeeding.⁵⁴

⁵³ Source: ASA UK web site, <http://www.asa.org.uk/ASA-action/Adjudications.aspx> Accessed 13 December 2010. The UK ASA provides adjudication data since December 2005.

⁵⁴ See for example <http://tinyurl.com/62nmvnh> and <http://tinyurl.com/4s8tsed> for links to statistics Accessed 25 March 2011.

We were unable to find any evidence of a formal infant formula complaints procedure in operation in Canada. However, it is clear that Canadian authorities receive complaints from the general public about infant formula and respond from time to time with an investigation. For example, in 2007 complaints led to a joint investigation between Health Canada and the Canadian Food Inspection Agency over three years in which authorities monitored marketing practices of formula companies, leading companies to agree to changes in their labelling and possible prosecution.⁵⁵

Canada was among the 118 signatories to the International Code in 1981.

4.3.4. Singapore

Singapore supported the 1981 WHA vote in establishing the International Code. At the time, Singapore had already adopted a Code of Ethics, in 1979, which was designed to promote breastfeeding. The Singapore Code was formulated by the Sale of Infant Foods Ethics Committee, Singapore (SIFECs). The Code of Ethics was revised in 1995. (SIFECs 1995)

The Code in Singapore covers the promotion, marketing and distribution of breast milk substitutes, including infant formula (to six months) and any other foods recommended for use as a partial or total replacement for breast milk. The Code also covers bottles and teats.

The Code is voluntary in Singapore. All firms distributing infant foods have agreed to comply with the Code. SIFECs operates a vetting process: firms provide their promotional, educational and product use instructional materials for approval by the Vetting Committee of SIFECs before distribution occurs.⁵⁶

In addition, the Health Promotion Board in Singapore supports a committee called the Sale of Infant Foods Ethics Committee. The committee provides guidelines on appropriate marketing and distribution of breast milk substitutes among infant milk industries and health professionals.

A 2001 survey in Singapore, which sampled nearly 2100 mothers, found approximately 95 percent of the mothers surveyed attempted breastfeeding. This is compared to 65 percent in 1980. 84 percent of the mothers surveyed reported the most important reason for initiating breastfeeding was that breast milk was healthier for their babies (HPB Singapore 2005).

4.3.5. Hong Kong

Hong Kong currently operates under a voluntary system, and the Hong Kong Department of Health reports “the marketing of formula milk is wide-spread and aggressive”. Ip PL (2006) similarly describes conformance with the Code in Hong Kong

Unfortunately violations are rampant in Hong Kong. The Department of Health has produced comprehensive information on infant feeding for the public yet commercial materials with many subtle messages undermining breastfeeding are seen in many clinics and hospitals. Most distributors of infant formula have mother-and-baby clubs enabling company personnel to distribute samples and messages to mothers that impede breastfeeding... All hospitals in Hong Kong receive free supplies although the Hospital Authority is working towards discontinuing this practice

The Hong Kong Department of Health says “the marketing of formula milk is wide-spread and aggressive” and has recently signalled its intention to develop a Code of

⁵⁵ See for example <http://www2.dose.ca/news/story.html?id=2433393> Accessed 27 April 2011.

⁵⁶ See for example <http://tinyurl.com/2fbwyuw> Accessed 14 December 2010.

Marketing of Breastmilk Substitutes for Hong Kong. (Hong Kong Department of Health 2010)

4.3.6. Philippines

Mendoza (2010) provides an overview of the Philippines experience in regards to Code enforcement. According to Mendoza, the Philippines has had a particularly varied experience in Code enforcement. The Philippines adopted the Code by executive order into law in 1986. However, the Code was not fully implemented: it did not include an absolute prohibition on advertising and marketing of breast-milk substitutes. According to Mendoza, formula companies undertook aggressive promotion of formula. There appeared to be a decline in breastfeeding: Mendoza cites a 2003 survey reported 16 percent of babies born in the Philippines were exclusively breastfed after four to five months, the lowest rate among 56 countries in a 10 year period.

In the mid-2000s, the government responded with a range of measures including a tightening of the 1986 regulation to include both infants and young children, prohibited any form of marketing of breast-milk substitutes and supplements, created additional labelling requirements, and allowed departments to levy sanction on offenders.

UNICEF (2010) also provides a summary of compliance activity in the Philippines:

The Philippines drafted a Code in 1981, but it took 5 years of forceful advocacy, including street marches and public discussions, before it was signed into law. During the next 20 years, the Department of Health, in collaboration with NGOs and international agencies, fought for passage of effective implementing rules and regulations (IRRs), while the formula companies continued to find ways to more aggressively advertise and promote their products.

In 2000 the IRR was revised in favor of the formula companies. In 2004 the struggle to close the loopholes began again, with 12 drafts of IRRs prepared. Finally in 2006 a revised IRR was signed which included guidance on enforcement. It was temporarily delayed by a restraining order requested by an industry association representing the formula industry. Finally, after intense and creative advocacy, including eye-catching demonstrations at public hearings, record-breaking simultaneous breastfeedings, and a massive media campaign, with UNICEF and NGOs playing key leadership roles, the Revised IRR was re-instated, with most of its provisions intact.

UNICEF (2010) reports the Philippines public response included a Department of Health and WHO-sponsored multimedia campaign via the web, posters, radio, television, and the production of a video called "Formula for Disaster".

4.4. Other Complaints and Disputes Processes in New Zealand

We have reviewed a range of alternative complaints and disputes regimes currently operating in New Zealand and provide a summary of their key characteristics and the mechanisms used for rule enforcement in Appendix A, Table 11 on page 72. This Table includes a summary of the relevant characteristics of Fair Trading Act enforcement given some synergies of the concepts embodied in the Fair Trading Act to the codes of practice being considered in this paper.

The alternative processes are quite diverse. Among them, the Advertising Standards Authority ("ASA") (self-regulatory) and the Fair Trading Act (regulatory) complaints processes, we think, are closest to the monitoring role that oversight of the Code fulfils. In these processes, the complainant is a "whistleblower," that is, a person with information that an agreement between third parties or a law may have been

breached. A whistleblower may also be one of many victims of an alleged breach. Other processes are designed to resolve disputes, in which the complainant alleges they have been wronged and is seeking redress.

Each of the alternative processes is complaints driven, and each provides some mechanism to assist complainants where the preparation of a formal complaint is a material component of the investigation and decision-making on enforcement. The exception is the Fair Trading enforcement regime, where complaints are treated strictly as whistle-blowing and the staff of the Commission determine whether the public detriment is material, and if so, investigate and prepare a case against the offender(s).

All agencies responsible for enforcing these alternative regimes (including the Commerce Commission, de facto) have a jurisdiction test, that is, a mechanism that provides an initial assessment of whether the complaint is within the scope of the complaints regime. In each instance, a single person conducts the jurisdiction test, and in most cases it is the most senior person in the process (the chair or chief executive in most cases). Several of these mechanisms also provide the staff of the agency responsible for enforcing the regime with the option to resolve the dispute through mediation.

Table 11 also suggests that each of the alternative processes reviewed places a great deal of emphasis on the independence of the chair of the panel that considers the initial complaint. In particular, in the choice of the chair of the panel there appears to be an emphasis on skills in dispute resolution and legal process rather than on industry / stakeholder knowledge, since the latter can easily be construed as creating bias in the views of the panel. The ASA is particularly noteworthy in this respect: none of the panel has advertising or media backgrounds.

All alternative processes considered, other than the Fair Trading Act, are industry funded.

Table 11 includes information on the number of complaints received by each alternative process, and actual and target times to resolve complaints.

4.5. Summary

The literature on compliance in other countries is limited, and a high proportion of it is in the form of reports and advocacy documents, the robustness and independence of which are questionable. We have focussed on those studies providing robust quantitative information and reports published in peer-reviewed journals.

The compliance record in Australia and New Zealand appears to be similar, though Australia's processes for enforcement of self-regulation appear to have some advantages over those in New Zealand, such as a process for determining whether complaints are in or out of scope, and greater transparency through the public reporting of all decisions and annual tabling of all decisions in Parliament.

In the UK enforcement of the Code is through law rather than self-regulation. The number of complaints received under this regime appears to be larger than in New Zealand, but the number of complaints actually considered is similarly small (given the relative size of the populations).

Compliance with the Code appears more limited in developing countries, but it is not clear what lessons New Zealand can learn from this. Low compliance in these countries is consistent with more general problems in imposing the rule of law.

Other complaints and disputes regimes in New Zealand vary from the Code in respect of both institutions and processes. These differences suggest opportunities

to improve the way in which compliance with the Code is assessed and enforced. In particular, they suggest a need to more clearly distinguish between the complaints process where “whistle-blowing” results in public officials investigating and bringing a formal complaint against a company (as in Fair Trading Act enforcement) or a process where the complainant must pursue the complaint through the dispute process and a formal consideration of the complaint, but has assistance from a public agency in preparing and focussing the complaint within the terms of reference for the regulatory regime.

5. Qualitative Review

In this section we summarise findings from 31 stakeholders on Code compliance. Twenty-nine of these stakeholders were interviewed by telephone (one of which provided further written comment) during October and November 2010 with the remaining two participants submitting written responses. Table 8 summarises the composition of the participants in the qualitative review. Interview questions for each category are included in Appendix F. The qualitative review should not be thought of as representative of the wider population, in particular consumers of infant formula were not represented in the interview process. Comments in this section are based on interviewee comments and do not necessarily represent the views of the authors of this report, the Research Trust, or the Ministry. The views presented may not be factually correct.

In considering the presentation of the information gained from the interviews, we considered a more formal and detailed quantitative presentation of the views expressed by the interviewees. We rejected this approach for two reasons. First, a quantitative presentation might lead readers of this report to believe that the interviewees provided a random sample of opinion, but since they were chosen for their known interest in the issue this would be misleading. Second, knowing that the interviews were scheduled, we have come to the view that interviewees with common interests are likely to have discussed what they would say in the interviews. While this was effective in conveying their views, it means that the views of individuals in the sample are not independent of each other, so the number of interviewees who raised each issue does not provide any statistically robust information to add to consideration of the issues.

Table 8: Qualitative Review Participants⁵⁷

Category	Category Description	Count
Complainant	Person who has complained to the Ministry of Health under the INC Code or the Health Workers' Code	10
INC Representative	Member companies of the Infant Nutrition Council (INC), and the INC CEO	6
Complaint recipient	Receive and consider complaints: the Compliance Panel Chair and independent Adjudicator, ASA and NZFSA (now part of MAF)	4
Health worker	A current health worker, including one who was the subject of a formal complaint in the Health Workers' Code	5
Enquirer	A person who made an enquiry on the Ministry of Health complaints page but did not proceed to lodge a formal complaint. Enquirers are all active in the area of breastfeeding.	4
NGOs	From New Zealand breastfeeding advocate groups	2
Total Participants		31

⁵⁷ Thirty-one stakeholders participated in the qualitative review, Twenty-nine stakeholders were interviewed by telephone (one of which provided further written comment). Another two stakeholders submitted written responses.

5.1. Overview by Respondent Category

Across all categories of interview respondents, there is agreement on two matters: the superiority of breastfeeding over formula, and dissatisfaction with the current complaints process, the latter for reasons that vary by group.

5.1.1. Complainants

The view held by all or nearly all complainants is that the scope of the New Zealand implementation of the International Code is too limited. Complainants feel the New Zealand Code should extend to formula for infants up to 12 months, and it should include teats and breast pumps.⁵⁸ Some complainants were willing to concede formula manufacturers are compliant with the New Zealand Code, but believe companies are not compliant with the International Code. Other complainants believe companies are flagrant in their breaches of both the New Zealand and International Code.

Complainants consider the complaint process is very difficult, for two main reasons. First, it requires the complainant to not only assemble relevant evidence, but also to have awareness of the various Codes and regulations in New Zealand so as to specify the parts of these Codes that they wish to allege the company or health worker has breached. The Ministry does not provide assistance in this part of the process to complainants. Complainants report the second main source of difficulty is that the process requires that complainants read and respond to arguments and evidence from companies and health workers. These are frequently complex documents prepared by legal counsel, and may be aggressive in tone. Complainants report feelings of intimidation, frustration and of being “steamrolled” by the difficulty and time requirements of reading, understanding and responding to these documents.

We asked complainants whether they would lodge another complaint based on their experience: six said they would, three said they would not. Responses ranged from “absolutely...definitely,” to, “No... never.” Among complainants who said they would not lodge another complaint, the main reasons cited were a sense of futility that the process produced, and the time and effort required. A majority of complainants said that they would complain again, but in a process that is reliant on complaints from interested parties we consider that attention should be focussed on the fact that experience of the process has deterred one-third of complainants from considering further complaints.

Many complainants expressed concern at the voluntary nature of the INC Code and suggested the current system lacks “teeth”; others expressed concern at the influence they see industry has on oversight. Many complainants reported discomfort with the lack of organised monitoring by government, though most recognised that monitoring is occurring.

All complainants reported learning about the Code either through participation in NGOs, or because they are health workers. There were no members of the general public (i.e. unconnected with either NGOs or the health sector) among complainants.

5.1.2. INC Representatives

INC representatives, comprising the CEO of the Infant Nutrition Council, and representatives of five member companies in the INC, have as their primary concern

⁵⁸ A respondent explained that they wished to see breast pumps included as being out of a desire to protect mothers from what they termed ‘marketing ploys’ and commercialism that is, they said, unrelated to real problems. As the respondent put it, “in a way, breast pumps are almost becoming the new formula”.

the quality of the process in handling complaints. INC representatives allege repeated infringements of due process by the Compliance Panel. The decision to uphold a complaint against one INC member on appeal is a source of particular concern for INC representatives: they considered the decision to be the product of a failure in due process. They hold the view that they can learn little from the breach because no guidelines were issued following the decision.⁵⁹ INC representatives believe the CP is comprised of people who are not objective, and cite repeated failure of CP decisions to be upheld before the Adjudicator as evidence of this. INC representatives believe complaints should be vetted to exclude those which are not within the scope of the INC Code.

All or nearly all INC representatives expressed strong concern at their lack of access to health workers in order to provide them with information about formula. While accepting that it was not appropriate that INC members have direct communications with mothers, INC Representatives were adamant that health workers be informed about developments in formula so that mothers can, when necessary, obtain information.

5.1.3. Complaint Recipients

Complaint recipients receive and process complaints from their positions on the Compliance Panel, the NZFSA (now part of MAF) and the ASA. Recipients emphasised the importance of process in complaint handling, and all recognised deficiencies in the current Compliance Panel process. Complaint recipients hold the Health and Disability Commissioner (“HDC”) and the ASA in high regard for the quality of their complaints processes.

5.1.4. Health workers

The health workers group is diverse and includes one health worker who was the subject of a complaint. This group provides insight on the day to day experience of the effect of the Code in health care delivery. The group broadly, but not universally, felt health care workers are either aware of the Code directly, or responded to it indirectly by not speaking to mothers about formula for fear of sanction from the charge nurse. Some health workers expressed concern that implementation of the Code had gone too far, that insufficient advice is being provided to mothers who cannot or choose not to breastfeed. Furthermore, these health workers consider there is too much reluctance to provide formula when temporary issues arise in breastfeeding, leading to instances of dehydration and weight loss among babies.

5.1.5. Enquirers and NGOs

Enquirers were included in the interview process because they had made an enquiry on the Ministry’s complaints page, without submitting a complaint. This group appears to be composed of breastfeeding advocate NGOs.

These NGOs strongly believe the New Zealand interpretation of the Code is too narrow, that it leaves out provisions of the International Code including WHA resolutions subsequent to the original 1981 declaration. In particular, they believe that the New Zealand Code should cover formula made for infants to 12 months of age. NGOs are concerned that companies are able to exploit the power imbalance with complainants to avoid or at least delay compliance with the INC Code. NGOs are concerned at the industry’s presence on the CP, and suspect the agriculture industry has influence over the compliance process in New Zealand. Even though

⁵⁹ We discuss the decision further in section 5.2.2 on page 38.

there is no direct evidence that this position results in a bias to the findings of the CP, their concern stems from the potential for conflict that this position provides. The appearance of conflict of interest can be important in influencing the willingness of parties to use a complaints process.

5.2. Overview by Issue

In this section we consider issues identified in the qualitative review and report responses to each issue separated by group. Quoted text is from recorded telephone interviews.

5.2.1. Scope of the INC Code

Complainants' most-frequently cited concern is the comparatively limited scope of the New Zealand interpretation of the International Code. Complainants refer to the New Zealand Code as "watered down," "fake," and "toothless". The specific concern is that the New Zealand Code allows advertising of follow-on formula for infants aged six months and older: many complainants felt this should be from 12 months.

Some complainants acknowledged compliance by manufacturers with the letter of the New Zealand Code, but not with the International Code: for these complainants, their use of the complaints process seemed to be directed at signalling discontent with current rules, rather than breach.

The following comment is broadly representative of complainants wishes on scope changes:

[T]he Code should apply to all companies, not just ones that are signed up to the Code of practice of Marketing Association. It should include all foods that are replacing breast feeding and that means food under 6 months, it means any type of formula milk for any child because breast feeding can continue for three or four years of age and follow-on formulas are marketed as what you do when you're finished breastfeeding at a year or whatever it is. No donations at all to health care systems. No samples for the health workers, even if they're not formula samples, no samples or gifts or anything. And no marketing at all to mothers by the companies. And no sponsorship of any child care or child institution. And no free products, even in emergency - Complainant

Two INC representatives noted what they consider is the one-sided nature of the New Zealand interpretation of the International Code. One said:

[T]he bigger issue we have around is this Code of practice. Particularly as it, at least in our view, seems to contravene the purpose of the WHO Code which is around mothers should be able to get access to information about infant formula where this Code specifically you know bans basically samples and the role of health care workers in the process. You know we're vehemently opposed to that position that seems to have gotten into Code and policy which we find very unfortunate because we don't believe that that is the right thing, nor in the spirit of the WHO Code – INC Representative

Health workers shared similar concerns as complainants. One suggested many midwives would like to see the International Code reflected in New Zealand.

A NGO representative shared similar views to complainants, and pointed out the National Breastfeeding Advisory Committee takes the view that New Zealand's implementation fails to meet the minimum standards of the International Code. An

enquirer referred to the gap between the International Code and the INC Code as a “yawning chasm”.⁶⁰

5.2.2. Performance of the complaints process

Complainants

There is near-universal dissatisfaction with the current complaints process. Complainants reported a sense of power imbalance, and that they were disadvantaged by the lack of access to technical expertise. The process is perceived to be corrupted by the power of the manufacturers and the agriculture industry in New Zealand, and to reward power. One complainant suggested legal representation not be allowed. For some complainants, there was confusion about how many appeals are permitted and under what circumstances. Another complainant reported the subject of her complaint appealed several times, but was left confused when her request for appeal was declined because she reports she was told, “the process doesn’t allow for that.”⁶¹

Lack of punitive power prevents self-regulation being effective, with one complainant suggesting it was a “slap on the wrist.” Complainants repeatedly expressed concerns at the presence of an industry representative on the CP, and believe self-regulation is inherently incapable of disciplining the regulated. Two complainants indicated their view that the Ministry sees compliance as a process to keep everyone happy, and that this view is too generous to industry.

Some complainants reported the process requires the complainant to deal with complex technical documents sent in response by subjects of the complaint, and described the experience using terms such as intimidating, overwhelming, exhausting, and frustrating. One complainant described receiving a subject’s response as an indignity. Another complainant felt she was under legal risk when notified that the subject of their complaint had retained a lawyer:

It was difficult, horrendous, alarming in terms that the health worker immediately got [] lawyered up and so I got a somewhat anxious call from a person at the Ministry of Health when they received the letter from the health worker’s lawyer. And I remember asking [], did I need to get a lawyer? – Complainant

A number of complainants point to the requirement to identify the parts of the Codes which they wish to complain has been breached is difficult without assistance. One complainant interpreted the unwillingness of Ministry to provide guidance on the parts of the Code to report being breached as not understanding it.

Many complainants were concerned at the time required to complete the complaints process. One complainant was concerned that behaviour she had alleged was in breach continued throughout the two year duration of her complaint process.

One complainant reported being satisfied for lack of energy to continue:

[B]y the time I got the response from the formula company, which was just denying the whole thing ever had happened, I didn’t have the energy to continue on and refer it on... It was very forthright, and I wouldn’t say abusive but it wasn’t a pleasant thing to read or receive... And so it didn’t go to the panel. I would have expected my complaint to go to the compliance panel and then they would deal with the company.

⁶⁰ The Ministry has advised that the National Breastfeeding Advisory Committee was replaced by the National Breastfeeding Committee, which is currently in abeyance. Source: National Breastfeeding Advisory Committee of New Zealand (2009),

⁶¹ The Ministry has rejected this complainant’s recollection or interpretation of events in this case, noting that only a single round of appeal is permitted in the complaints process (personal communication, 1 March 2011).

Six complainants indicated they would submit another complaint, three indicated they would not. Complainants were complimentary of the Ministry's performance in administering the complaint, and its communications. Some complainants noted the Ministry is supportive of their complaint, but takes care to retain objectivity. Said one, "The acknowledgement of the receipt of the complaint was prompt. An explanation of the process I felt was well done."

INC Representatives

INC representatives tended to focus on process rather than the experience, but concerns in common with complainants also emerged, in particular time frame and procedural fairness.

Several INC representatives expressed concern about the complexity of the New Zealand process; some felt it was convoluted. Some felt the process was costly, that the CP is large for the number of complaints it receives, and the CP on occasion meets when there are no complaints to consider. The process, in their opinion, does not protect against complaints that are "clearly outside the scope of the agreement" and which "seem to be inconsistent with the authority of the Compliance Panel".

Nearly all INC representatives expressed concern about a lack of adherence to a process in investigations. Several INC representatives felt companies are considered guilty unless they can prove their innocence under the process. One INC representative gave an example of a complaint against a manufacturer in which the Ministry sought information from a retailer⁶²:

[T]here needs to be some understanding of how you investigate the complaints and if the company doesn't respond or if you want some proof from the retailer that they haven't been involved then the company needs to supply that too from the retailer. Not going directly outside the company. I think that's a fairer process – INC Representative

One INC representative alleged the CP does not limit itself to the complaint before it but searches for a violation. Another expressed concern that the process includes third parties without the knowledge of the complaint's subject, and that companies were sometimes not made aware that a complaint was being investigated.

Several INC representatives felt both the Ministry and the CP included people with a bias against formula manufacturers in their views that results in a lack of objectivity, that decisions are made on emotion not reason, and these could affect natural justice. The overturning of CP decisions on appeal is repeatedly cited by INC representatives as evidence of process problems with the CP. INC representatives see the Code enforced selectively, with provisions relating to manufacturer obligations to educate health care professionals on formula being de-emphasised. One INC representative indicated the ministry did not appear to understand its complaints process, the process as documented is unclear, and investigations appear to proceed in an *ad hoc* way. Another INC representative indicated the CP does not appear to understand the importance of due process or the legal risk that a failure to follow due process can create. Another indicated the panel appeals to be unpredictable and that improved guidelines could assist in resolving this uncertainty.

The first step in the complaints process is the "satisfaction test".⁶³ One INC representative said continuing the process when the complainant is not satisfied is a

⁶² The Ministry notes that the retailer and company provided contradictory information.

⁶³ The complaints process including the satisfaction test is documented on page 8.

“crazy notion”. Another INC representative explained their concern with the satisfaction test:

So the complainant gets... an invitation, if you're not happy with this then you can take it to the compliance panel. Now that is considered natural justice. I consider it convoluted because human nature, if you get a response directly from [company] without any guidance from anybody else who understands the Code, then you are suspicious of that company in the first place, you're not going to accept what they say. And you're naturally going to take it to the compliance panel... you need to make sure that, that the complainant has the opportunity to be understood in what they're complaining about. And I think it's the role of the Ministry of Health Secretariat to assist the complainant to identify the articles of the Code that they're complaining about. You can't necessarily expect a complainant to know what articles of the Code fit into what they're complaining about – INC Representative

One INC representative did indicate satisfaction with the complaints process overall. There is broad satisfaction among INC representatives with the wording of the INC Code, which most INC representatives felt was clear enough.

Health Workers

A health worker, the subject of a complaint, had many comments on the complaints process. They noted the voluntary nature of the Code and compared this to “receiving a letter from the Riccarton Tennis Club”. The worker was concerned that the Ministry did not explain the voluntary nature of the Code in their communications. According to the worker, the consequence of electing not to participate in the process was unclear: could the panel declare the worker in breach in the worker’s absence? The worker ultimately decided to participate in the complaint.

The worker had concerns about due process. The worker felt that making the complainant anonymous was ‘extraordinary’ and made the process look biased and untenable. The worker alleged not all information from the complainant was passed to them, the subject of the complaint: information not previously revealed to the subject was alluded to in an appeal decision. The worker also raised a concern that the composition of the CP changed midway through their complaint, the worker alleges they were not notified but discovered this by noting changing names on CP written decisions.⁶⁴ The worker felt the process is loaded in favour of the complainant.

Another health worker, not the subject of a complaint, commented that the lack of enforcement power means the complaints process does not protect children, and suggested greater publicity could encourage compliance.

Other Groups

Respondents in other categories (complaint recipients, health workers, enquirers, and NGOs) made the following comments on the complaints process. A complaint recipient said the process did not provide certainty, due in part also to the wording of the Code:

I don't think it gives certainty to industry and it's partly because of the way the Code is worded and partly because of the external process. I don't think it gives any satisfaction to the complainant because they, I think, perceive it as a very laborious legalistic process. I also think it leaves health professionals exposed to being held in breach of the Code but it's actually quite ill-defined. I think it's failed everybody – Complaint Recipient

⁶⁴ We have confirmed with the Ministry that the composition of the CP did change midway through this complaint, and that complaints are made anonymous to subjects. The CP terms of reference state that resigning members of the CP should see out a complaint.

A complaints recipient defended the performance of the process on grounds that it is new and settling, indicated a particular process concern regarding new information being provided to the Adjudicator on appeal and that this was unusual and “needs to be tidied up”, and noted concerns with the length of time it was taking to close complaints which, it is intended, will be addressed on completion of this review.

Enquirers made several comments: they believe having the Code implemented across multiple documents adds complexity and confusion; the difficulty in having complaints upheld on appeal creates a sense of futility; the initial complaint is easy to make but they perceive the process after that requires considerable effort; the parsing of various Codes of practice to work out where to complain to is time-consuming; one expressed the view there is no value in the government operating as a go-between and that it should “take charge” rather than placate complainants and companies.

A NGO representative commented on the power imbalance between companies, which can protect themselves through lawyers, and complainants who cannot. This power is used, according to the NGO, to prolong the complaints process so that by the time it is resolved the advertising has already run its course. This contributes to a sense of frustration for people in the complaints process. Another NGO expressed the view that there is industry influence over the complaints process, and this is a product of the consensus approach taken by the Ministry.

Time and cost estimates from participants

Complainants reported spending between two hours and a day to prepare the initial complaint. A complainant who went through the appeals process reported spending between 30 and 40 hours in total on the process.

INC representatives and a health worker who was the subject of a complaint reported various amounts: one INC representative quoted a figure of NZ\$10,000 per complaint. Another indicated a complaint could take 200 hours of time to manage. Another indicated ten hours of time is required. A health worker indicated 30 hours was spent on their complaint. A complaint recipient reported the value of time spent per complaint at NZ\$5,000.

The Bayer Decision⁶⁵

One CP decision has been upheld on appeal, and this was against Bayer on 11 September 2009 for a presentation on feeding options for women who are not fully breastfeeding, held on 23 and 25 June 2008 in Auckland. The decision caused serious concern among INC representatives. One INC representative noted that it wasn't clear why the company had been breached, or what needed to change as a result because, said the representative, no guidelines were issued following the decision. Guidelines, they said, would not only assist industry to understand boundaries better, it would assist new members of the CP when they come on board and help prevent arbitrary decisions. The representative noted that when new people come onto the compliance panels in Australia and New Zealand, they may have very different interpretations. The representative concluded:

...that makes it very difficult when you're trying to be compliant and it feels like the goal posts are shifting somewhat – INC Representative

Other representatives cited due process concerns. One felt that the company was presumed guilty unless they could prove their innocence, and that there was no

⁶⁵ The Ministry notes that the decisions/rationale of both the CP and independent Adjudicator were documented and provided to all parties (personal communication, 1 March 2011).

evidence either way on the particular matter for which they were found in breach. Another alleged the company was breached on a matter that was not complained about, and the company was not given the opportunity to respond to that matter.

An INC representative also commented on the parallel complaint against a health worker that was ultimately not upheld. The representative labelled the process 'brutal' and commented:

[T]he cost to the doctor to defend himself for doing what I'd have to say we would perceive to be nothing inappropriate. He was in fact providing information to health workers which was entirely appropriate – INC Representative

5.2.3. Performance compared to previous Panel

The complaints process changed in 2008, and we asked interviewees about their impressions comparing before and after. Four interviewees offered a view on this. Overall, the view was that little had changed. Complainants noted an increase in complexity, because "now you have to know health worker or industry standard". One complainant noted the experience before 2008 seemed faster. An INC representative was surprised to learn anything had changed:

To be honest when you said the panel's changed in April I was surprised because I didn't know that. To me it hasn't changed at all – INC Representative

However, a health worker noted the new compliance panel is seen to be more independent. Previously, the health worker said, there was a sense that the industry had too much input.

5.2.4. Code compliance in New Zealand

We asked interviewees whether the current self-regulation and complaints process was producing compliance in New Zealand. Complainants' responses ranged from a sense that there is compliance but with room to improve, through to there being essentially no compliance by formula manufacturers in New Zealand. Some complainants observed manufacturers were achieving compliance with the letter of the New Zealand Code, but no complainants felt compliance was being achieved with the International Code and most considered this the appropriate standard. Compliance was being achieved, they said, through "clever tactics" that push the boundaries of the Code, the most frequently-cited example of this being the similar labelling of formula for infants under six months and infants over six months. Complainants expressed the view that the self-regulation "doesn't work". One complainant noted:

Attempts are often made to market artificial milk in hospitals through loopholes in the New Zealand Code and that's in paediatric units and also by the ignorance of staff. There are continual attempts to advertise incorrectly and then if caught, stop the advertising but the damage has been done already - Complainant

One complainant suggested the Code needed to be extended to cover supermarkets, and that financial disincentives were required to increase compliance.

INC representatives indicated there is strong compliance in New Zealand, and explained the various internal systems and processes for achieving compliance. Systems include local and global internal policy documents, remuneration for some employees is tied to meeting Code requirements and is a part of annual performance reviews and "you can get in a lot of trouble if you don't comply," said one representative. Additional measures include the use of external materials and process auditing for compliance, and a requirement in some companies that when a complaint is received head office is notified. Driving this, said a representative, is reputation:

...it's really quite a rigorous thing and half the world gets to know about it if you've done something wrong – INC Representative

Representatives cited the low number of complaints and upheld breaches under the complaints process as evidence of compliance, which indicated an industry view that there is respect for the Code. Representatives indicated that where problems arise it is because of some uncertainty in the rules.

On the low number of complaints, an enquirer explained this as the product of three factors: a) lack of general awareness about the complaints process; b) lack of general awareness of the Code; and c) dissatisfaction with the complaints process itself.

One health worker felt the process is producing compliance. The worker reported a strong understanding of the Code among their colleagues regarding marketing in their business, and in regards to what staff can discuss with patients about formula, and restrictions on distribution of samples. The business does work with formula manufacturers in information distribution, but have an established internal process for this as a compliance step. Industry marketing representatives are not permitted to speak directly with staff.

However, another health worker, while acknowledging marketing is not occurring for infants under six months, noted marketing from six months on that is quite aggressive: “practice nurses and general practices... are giving out infant formula widely to every baby who turns up at six months.” The worker also suggested a dishonesty in the marketing, in which companies:

...spend a lot of time working out how they can get to mothers under 6 months without actually advertising infant formula... I get the sense they don't advertise the formula but by golly they get their branding out there – Health Worker

A NGO expressed a similar view:

[I]ndustry adherence to the Code in New Zealand, their level of adherence although it's a voluntary Code and they've undertaken to, without legislation, to provide this level of voluntary compliance, but it's actually quite cynical the way they adhere. They're clever, like cigarette marketers, that they'll find ways to get around adherence while looking as if they are adhering. An example is that all of their range of formula all look the same. So the one they're not allowed to advertise is number one, which is naught to six months, but they have a huge amount of advertising for numbers two and three, number two being follow-on formula for six to twelve months and three being toddler milk for babies over one. And the packages will look exactly the same. - NGO

5.2.5. Monitoring

We sought views on who is monitoring compliance with the Code in New Zealand, and summarise our findings in Table 9, which counts the mentions recorded from interview participants. IFANZ is most-frequently cited, with eight mentions.

Table 9: References to Institutions Monitoring the Code in New Zealand

	Complainants	INC Reps	Complaint Recipient	Health Workers	NGOs	Enquirer ⁶⁶
Consumers		1			1	
Infant Feeding Association of New Zealand	2			1	3	2
Infant Nutrition Council		1				
Ministry of Health		1		1		
NZBA					1	
Other Companies ⁶⁷		4				
Women's Health Action					3	

Monitoring and compliance is also occurring outside formal channels. One health worker noted their response on seeing a possible breach in the Code was to contact the manager of the shop and alert them to the problem.

Some complainants expressed doubt that any monitoring is occurring. One was of the view that the only monitoring was through the Baby Friendly Hospital Initiative. Another expressed the view that industry “isn’t monitoring themselves.”

INC representatives mentioned several times that they monitor each other to ensure everyone “is on a level playing field” and that no one gains an unfair advantage. The INC has an internal compliance mechanism that allows companies to report breaches, and one representative described this INC process as “100 times more effective than the [complaints process] simply because of the speed,” and added:

[I]f there is a damaging marketing practice taking place, damaging from the point of view of threatening breastfeeding and that's why we have these things, then surely it's better to have that addressed and removed rather than have it sit there, have the damage done whilst the convoluted complex process takes a number of months to resolve it – INC Representative

One representative noted companies must specialise in understanding provisions of the Code to a much greater degree than members of the public. Reputation protection was repeatedly emphasised by representatives as a driver of compliance:

It is not in the interest of these big companies to breach the Code of practice. I mean it would be madness to do so knowing that, because they, they, while there's no apparent sanction such as fining or reporting to their House of Parliament in New Zealand, they are published and any breaches are distributed globally within seconds of them being published and that is, and the companies are report to their global offices. They sit in a global environment, they have global policies around the WHO Code and it's, it's not looked upon well if they breach the Code – INC Representative

Representatives say they monitor retailer advertising of their products, and contact retailers in the event they see a promotion that raises concerns.

Two complaints recipients expressed views on monitoring. One said they were not aware of any monitoring activity in New Zealand other than people making

⁶⁶ An Enquirer is a person who made an enquiry on the Code complaints page operated by the Ministry, but who did not go on to make a complaint.

⁶⁷ This refers to mutual monitoring of competing formula manufacturers.

complaints. Another complaints recipient noted that a major source of complaints is companies reporting rivals alleging a breach in labelling standards:

Competitors might diligently label their products and formulate their products in accordance with the rules and they might note that their competitors apparently are not doing so, so they may complain to us – Complaint Recipient

Another source of complaints for this recipient is other regulatory agencies, who pass complaints out of their jurisdiction to the overseeing organisation.

One health worker said alleged breaches reported by “overzealous” advocates needed to be treated with some scepticism, as “they have not been validated”.

NGOs noted IFANZ monitors compliance with the International Code, while the Ministry was responsible for compliance with the New Zealand interpretation only. An enquirer felt that without the government formally implementing a monitoring program the current system is inadequate.

5.2.6. Regulator oversight

Respondents were asked who should oversee compliance with the Code in New Zealand. We show results in Table 10. Some respondents offered more than one option: each of their responses is counted in this summary.

Table 10: Summary of Comments on Who Should Oversee Compliance in New Zealand

	Complainant	INC member	Complaint recipient	Health worker	NGOs	Enquirer
Ministry of Health/ Compliance Panel	5	2		1	2	1
Ministry of Health and Industry				1		
HDC			1			
Advertising Standards Authority	1	3	1		2	
IFANZ	3					1
INC			1			
The Government	1	1			1	
New Organisation	1					

The ASA is the second most-frequently mentioned option, behind the Ministry. The INC Code covers more than advertising, which is outside the current purview of the ASA, nevertheless these opinions suggest the ASA could be the referral agency for complaints about the INC Code.

Shift to HDC

We asked interviewees their opinion on a shift in oversight of the Health Workers’ Code to the Health and Disability Commissioner (“HDC”). Among complainants, four expressed warm support, and five were negative. One expressed no opinion. Those in favour expressed admiration for the competence and experience of the HDC in the area; one felt that the legal expertise of the HDC would add balance the process when dealing with manufacturers. Those against were concerned about further fragmentation of responsibilities for the Code, and with the increasingly cumbersome nature of the HDC.

Among INC representatives, three expressed no opinion and three were comfortable with the move. Those in favour said it was inappropriate for industry to sit on a panel adjudicating on health workers, and that under the current arrangement, “health workers have pressure put on them to go well beyond what the Code actually

requires,” and a shift to the HDC might restore requirements on health workers back to what the Code says.

Among complaint recipients, one was against the move to HDC citing fragmentation. Three were in favour, noting the HDC’s strength in systems and process. Another suggested it would add “a bit more teeth” to the process. One complaint recipient said in regards to the current complaints process there are “questions around what capability or capacity do they have to investigate those complaints.”

Health workers had no strong opinions on the matter. One was weakly in favour, saying the benefit of HDC was in their stronger process, but investigating health workers complaints might be outside their normal experience. Another was in favour provided the HDC develops an understanding of the Code. A third had no opinion.

NGOs were also lukewarm, two raising concerns about fragmentation, one was in favour saying “the HDC has a fair and transparent process for handling complaints,” and a fourth expressed no opinion.

An enquirer was against the idea, saying a professional association would provide stronger oversight of health workers, and that the Code is about industry marketing practices, the implication being that the HDC has no particular expertise with this.

5.2.7. Interview respondent suggestions on improvement

We asked interviewees for their views on how improvements could be made to the Code and to the complaints process.

The most common views expressed by complainants were extending the Code to include infants up to 12 months, and enforce the Code through law. Some complainants also suggested formula should only be available on prescription; that the INC should be removed from the oversight process; the complaints process should be moved to an independent body; two complainants suggested the Infant Feeding Association of New Zealand (IFANZ); and send all complaints immediately to the CP, skipping the “complainant satisfaction” test.

INC representatives voiced the following opinions on changes: suggested adding a vetting process to prevent out of scope complaints proceeding; require greater adherence to due process; increase process transparency and fully document the complaints process; shift responsibility from complainant to the Ministry to investigate the complaint so that only in-scope complaints go before the CP; develop guidelines to assist understanding of grey areas in the Code; appoint more objective people to the CP; move the complaints process to a third party provider with a strong process such as the ASA.

Another suggestion by an INC representative was quarterly surveying of published materials for the purpose of giving industry feedback on what is acceptable.

[W]hat that does is educate the industry on what’s acceptable, what the panel’s thinking is, and set the standards for a proactive approach – INC Representative

The representative also suggested publishing complaint findings on a regular basis as a means of increasing transparency in the process.

One INC representative suggested no changes were necessary.

One complaint recipient repeated the call for guidelines, noting areas of the Code require clarification. They also noted that current process straddles self-regulation and formal regulation, and a decision ought to be made about which it is and then develop a process that fits.

A health worker commented that it was an “obvious omission” to not have a paediatrician on the CP, and expressed the view that the panel’s current composition seemed “loaded”.

Two NGOs commented, and recommended industry play no part in regulation, that legislation replace self-regulation, and government not contract for services from providers not compliant with the International Code. Another NGO suggested publishing findings to increase exposure for breach.

An enquirer noted:

in Fiji the government looks at every advertisement that comes out so they actually have to be cleared by them before it goes out. Now that would be a really good way of doing it. If you had a panel that looked at every single thing that industry wanted to put out and actually really, that would be great - Enquirer

Enquirers also suggested formal legislation replace self-regulation, the International Code replace the local interpretation to include bottles and teats, complementary foods and breast pumps.

Who should pay for improvements?

All four complainants who offered comment suggested government or the Ministry should pay the cost of improvements.

The INC representative who suggested the Ministry take the lead in investigating complaints indicated there would be no additional costs to pay. Another representative speculated on ways industry could finance regulatory oversight given the government is reluctant to accept money from industry, but couldn’t think of a way to convince government to take the money.

Two health workers voiced opinions on funding: one said there would be no cost increases for their idea of an expansion in Code scope. The second indicated the government should appropriately pay additional costs, having committed to implementing the Code in New Zealand.

All three NGOs to comment on the matter thought the government should fund changes.

5.2.8. Knowledge and information

Advice to mothers and caregivers

Complainants overall believe advice to mothers and caregivers promotes breastfeeding. One complainant felt at times the advice went too far, health workers “press the breastfeeding beyond torture sometimes”. One complainant drew a distinction between advice from midwives and lactation consultants (who offer advice that is in their words “excellent”), and practice nurses, pharmacy assistants and GPs who in the main give advice that is “really poor”. Pharmacies, the complainant says, are compromised by commercialism, and “very few GPs are well-informed about breastfeeding.”

INC representatives took a different view on the advice available to mothers and caregivers: “In a word, appalling,” said one. Representatives consistently made the same few points: mothers who cannot or choose not to breastfeed have considerable difficulty in obtaining the information they need. Mothers must instead rely on friends, information from manufacturers’ web sites, or package labelling to make feeding decisions. Some health care workers interpret their responsibilities as excluding the

provision of advice on infant formula creating, in the view of INC representatives, a public health risk.⁶⁸

INC representatives say insufficient numbers of health care professionals are willing to offer advice because health care workers face asymmetric incentives to offer advice on infant formula to mothers: a potentially large downside to offering advice on formula and being found to have breached the Health Workers' Code, but no corresponding upside to providing advice. According to most of the INC representatives, this means health workers are reluctant to offer any advice:

I think that the fact that a health worker can be breached against that Code makes them very wary about having anything to do with the infant formula industry and very wary about helping mothers who are using infant formula. Because it can be misinterpreted or misconstrued by those people who are extremist in their views – INC Representative

According to INC representatives, mothers who cannot or choose not to breastfeed must fall back on informal networks of friends and the labelling on formula for information. Representatives reported hearing frequent anecdotes of mothers in supermarket aisles genuinely confused about what to buy and who could not obtain access to information.

Representatives believe they have an obligation under the Code to provide information to health workers, and that the constraints on speaking to health workers are too strong. Health workers, representatives maintain, are trained, able to understand scientific data, and exercise judgment.

One representative expressed a company view that it is inappropriate for industry to provide advice directly to mothers. Another representative was highly complimentary of Ministry's food and nutrition guidelines.

Health workers were split on advice to mothers and caregivers. One health worker was adamant that there is enough information on formula being provided to mothers, and that more needs to be done on promoting breastfeeding. Another health worker, although they considered advice to mothers overall was good, took a different view, noting that hospitals are supportive of breastfeeding but offer insufficient information to mothers who cannot breastfeed. This worker reported seeing instances of babies who had lost 10 percent of their body weight because breastfeeding had not gone well and, they reported, intervention to supplement breastfeeding with formula for one to two days had been slow in coming. The worker suggested breastfeeding rates might improve if a more candid description of the breastfeeding experience – that it is normal for there to be some problems – was given to mothers.

Two NGOs commented on advice to mothers and caregivers: one felt the advice was sufficient. The second considered the advice to be unclear, with many different guidelines.

An enquirer commented the advice is poor and inconsistent, and said:

[I]t gets back to re-educating the health providers that they have a responsibility [to teach formula use] and they must teach that well and in a way that's safe to the mother and doesn't feel like she's being judged... Because it is awful, I think the mothers feel terribly judged, you know we've gone too far with the breastfeeding promotion in a sense. If we soft pedalled and actually had better communication around that, it wouldn't be seen as a battle – Enquirer

⁶⁸ The Code requires formula marketers only provide information that is of a factual or scientific nature to health care workers. Under the Code, marketers may not interact directly with mothers.

Health worker understanding

Complainants were approximately evenly divided on whether health workers have a clear understanding of the Code. Their responses included: “They absolutely don’t. They have no idea,” “I would say there is very poor, very, very poor understanding of the Code,” “we have nurses who deliver who have no idea there’s a Code,” “Oh gosh yes. They know that Code inside out and back to front,” “Yea absolutely. Honestly,” and “Yep.... that’s what we do as a group.” The Baby Friendly Hospital Initiative was cited by a number of complainants as responsible for greater awareness among health workers. One complainant noted health workers, as a result of misunderstanding requirements under the Code, don’t speak about formula, leaving a gap in understanding among mothers that, according to the complainant, is being filled by formula makers who are finding ways to provide information, or at least brand awareness, to mothers.

INC representatives did not generally indicate a strong position on health worker knowledge. One representative suggested health workers had alienated mothers by feeling unable to speak to them about formula. Another representative felt there needs to be more education for health workers about the Code. It was not enough, in their view, just to provide the Code – and suggested a travelling show to promote it might be in order. This comment echoed that of another, by an Enquirer:

I think at the moment it’s really very hard to be able to be complained about when there’s no one actually providing you with the education and the information in the first place – Enquirer

Three health workers commented on health worker understanding of the Code. One indicated most health workers do not know there is a Code, but most comply with it. According to this interviewee, health workers know not to speak to mothers about formula because if they do then the charge midwife will “come down on them”.

The two other health workers indicated health workers are aware of the Code, one noting this is part of staff training in their organisation. One cited the Ministry’s document on health workers and infant feeding as especially helpful.

A NGO said there is limited understanding among health workers in regards to feeding of babies six months to two years of age.

5.3. Other Comments

On knowledge of the Code in New Zealand:

[I]t shows you how well the Code was promulgated, the lawyers from medical protection had never heard of this Code... And had never heard that there was a panel empowered by the Ministry of Health to hear complaints – Health Worker

On educating health workers:

Either our Code or the health workers Code and I did offer, we did approach the Ministry of Health about doing a sort of a travelling show and going out and providing some education. Disseminating information about the Code. It’s not just producing the Code and saying there you are. But they seemed reluctant to do that – INC Representative

On external influences on the oversight process:

[T]he Ministry of Health is torn. It’s got one view in trying to increase breastfeeding for the enormous health benefit for all of the nation but on the other hand it’s protecting agriculture at the same time. It’s an economic thing – Complainant

I think we live in a dairying country and it’s not popular to have [the Code] widely promoted – Health Worker

[T]he New Zealand Code [is] diluted down too much to protect our agricultural industry – Complainant

New Zealand, tended to have a voluntary Code with a weak application because of our very strong dairy industry – Complainant

I think it's really important to acknowledge the work the Ministry's tried to do in terms of a breastfeeding campaign but it's a small drop in the ocean compared to the economic power that the dairy industry has – Complainant

Hidden in amongst all this is the fact that New Zealand's a small country and we don't advertise the fact that our dairy industry's so important to us and when we talk about milk quotas and milk products that a certain amount of our milk gets made into formula to feed Indonesia and India and those countries, so there is hidden amongst that there are some power stuff as well – Complainant

On the importance of process:

I'd say the Advertising Standards Authority [to oversee compliance]. Because they are very experienced at dealing with complaints in health care. They have a process that works. And no matter what the outcome is, it's okay. We know it's followed a good process... if something was in breach then you learn from it and you move on and you make sure you don't do it again. And so it's an acceptable objective process – INC Representative

On the difficulty of finding a health worker in breach:

I don't think you can find a health professional in breach of the Code which, unless you're quite clear that the Code prohibited that activity or that it, that they would have, yea, I don't think you can make a statement like that, that a health professional is in breach of a Code when you haven't clearly enunciated what it is they have to do and what they can't do – Complaint Recipient

On performance in other countries:

[I]n India they've actually banned all advertising of infant formula or baby food up to the age of two years. It doesn't mean that the violations aren't still happening. In England now because they've got such a fantastic active network like Baby Milk Action and the International Baby Food Action Network over there, they do a lot of work and a lot of lobbying and they're at all the Code meetings, they're all over the place. We don't really have anybody that's doing that level of work – Enquirer

On parents seeking advice on formula:

[O]ne group in our opinion that we feel that you might like to speak to now or in the future would be Media Editors, the parenting magazines... they receive a lot of letters from consumers requesting more information on infant formula – INC Representative

On motivation for advocacy and complaints:

I see that actively supporting the Code needs to be viewed in terms of protecting child rights and so I've just, there are a couple of, I'm not going to read all that's written there, but just basically that those documents actually quite clearly state that it's member states should be doing these things and we continue to just choose to do a voluntary – NGO

[J]ust recently we had a health worker giving samples to a mother and on the face of it, it looked like it was very helpful. But then when you said to her look, do you realize that by doing that, giving her just a few, chuck a couple of samples here and there, it's actually not helping that mother with her underlying issue? If she doesn't have enough money to feed her baby, that's what needs to be addressed. If you're going to be benevolent and give freebies, it has to be for the whole duration of that child's need so you're looking at least a year. You know? Are you going to give her free samples for a year? And so again it was health worker ignorance because giving samples is just actually sales inducement really. It's just health workers being beautifully manipulated to be industry, to do marketing – Enquirer

[B]ecause of the vulnerability of this particular population, the normal marketing tools are actually inappropriate... it's not like selling a car. It's different. The marketing strategies have to be different and we have to first protect health... They keep on moving to increase their marketing which is what a business is going to do. But what we're saying is it's not appropriate in this regard – Enquirer

On Commerce Act constraints:

in Australia, the marketing agreement which is the MAIF agreement, the WHO Code in Australia, has been endorsed by the ACCC so it is against our trade practices law and we've had official authorization to do that. In New Zealand there's no official authorization. So the trade practices commission is turning a blind eye to the fact that industry is acting in an illegal anti-competitive way. If the Code was extended in New Zealand up to 12 months, which is way beyond the WHO Code, then companies would feel that they would be put in quite a precarious position. And that, I think that's where they're sitting. So if you can, if someone's willing, and I don't know whether the New Zealand government is, if someone's willing to go down the track of getting authorization for the Code in New Zealand which no one's ever got, then I think the companies would be quite, would be willing to talk about that – INC Representative

On the misreporting of official statistics from one health worker:

I have quite a few women who tell me when they come to see me at the office that the midwife from the hospital who comes to see them, they tell the midwife that the baby's fully breastfed but in fact the baby is getting some top-up formula at times. And everybody's happy. The midwife's happy because she's got the statistic she wants, the mother's happy because the baby's pretty happy and you know it's a win-win situation. The stats are of course unreliable but at the end of it the mother couldn't care about that – Health Worker

On the substitution to other complaints processes:

[P]eople who are monitoring the Code now are tending to go to other agencies to make complaints under other Codes so predominantly we've been using the Advertising Standards Authority... I've just now had a complaint upheld by them about health claims about follow-on and toddler formula. [W]e can't use the WHO Code [which] isn't being implemented in New Zealand so we can't shut down advertising for 6 months and over so we find another avenue... Australia New Zealand Food Safety Authority and Codes for advertising of food and things like that... if we want to see a reduction in advertising of infant formula products which we would define as being up to 12 months and maybe even beyond because creating brand awareness is marketing... we feel that the only way that we can really try and get them out of circulation is to find that they're breaching food advertising Codes because we don't have full WHO Code implementation in New Zealand – Complainant

On the value of an open dialogue with the regulator:

[I]t all starts with having a level of collaboration between the manufacturers as represented by INC and the particularly the compliance panel to make sure that we are all working to a common aim, we're not working to the same where they want to catch us out and they believe that we exist to do the wrong thing. They're all really working to a common objective. No one wants to do the wrong thing. People want to be successful but they don't want to do the wrong thing in order to achieve that. And I think if the dialogue could start there, that could probably be the biggest change agent in terms of then the other things that need to happen. Because I'm sure the compliance panel have their ideas as well and we're not immune to those at all. That's probably the biggest, from my perspective, where it would start... I think we also mentioned the timeliness of the process and we've only had one recent experience and it wasn't a problem. But I think it may be more a problem from the non-industry perspective as things seem to drag on and that doesn't help us either if people think that it takes too long – INC Representative

[W]e previously had contact with the Ministry of Health about a process that the Ministry of Health felt that we hadn't followed and we thought that we had gone about it the right way. So there was previously some communication that had occurred. So this time when we knew that we had to communicate about a change, rather than us guessing how we should do it, we thought we would go to the source and go back to the person that we originally had contact with in the Ministry, which we found very useful because it helped guide us as to the best way to approach – INC Representative

6. Discussion

In this section we provide an analysis of the main issues identified in Sections 4 and 5 above.

6.1. Complaints process

Compliance is not mentioned in either the objective or the roles of the CP in its terms of reference. We presume, however, the fundamental purpose of the CP is to test for breach of the INC Code and Health Workers' Code, and to do so in an independent and transparent way.

In our view the complaints process is improperly designed for this purpose. The current process appears to be designed to satisfy the complainant: but satisfaction is, at best, an imperfect measure of compliance with the INC Code, and in fact may be unrelated to it given that complaints may be motivated by matters outside the Code, or by the general dissatisfaction of complainants with the New Zealand Code's scope.

The complaints process assigns a central role to the complainant. The complainant, after lodging their complaint, is a central figure in the rest of the compliance process. The complainant must decide whether they are satisfied with the initial response from the subject of their complaint. If they report satisfaction, the complaint is closed. If they do not, the complaint proceeds to the CP. The evidence is put before the CP, who may seek further information from the complainant or the subject, and a decision is made. It is then up to the complainant to decide whether to appeal.

In order to make a complaint, a complainant must have a) knowledge of the existence of one or more Codes in New Zealand; b) knowledge of the complaints process; c) awareness of, and evidence for, a possible breach in one or more of the Codes; d) sufficient familiarity with the detail of at least one of the Codes to identify the specific provisions to allege the subject has breached. Despite possessing expertise on the Codes and the complaints procedure, we understand the Ministry, who receives complaints, has taken the position that it does not support complainants in an effort to preserve its independence. Given the resulting lack of support and guidance on the complaints process, it is unsurprising that all complainants interviewed in the qualitative review were connected with either a NGO or the health sector. Even with this support, complainants report feelings of intimidation, frustration, and of being overwhelmed by the requirement to read, understand and respond to documents usually prepared by legal counsel, and which are usually technical.

Other things being equal, the perception of an onerous complaints process weakens monitoring and may reduce manufacturer and health worker compliance.

In our view, the complaints process misconstrues the role of the complainant. In effect, the complainant is asked to lead the process by which compliance with a code they are not party to is enforced. By placing onerous demands, as reported by complainants in the qualitative review, on those who lodge a complaint, the effectiveness of the complaints process as a means for monitoring formula manufacturers and health workers is likely to be reduced. The process facilitates a dialogue between the complainant and the subject, with adjudication available should the two sides not be able to agree. We think, the process attempts, in effect, to obtain

a mediated resolution of a dispute.⁶⁹ But there is no direct dispute between the complainant and the respondent to be resolved. We think the complainant is not an aggrieved party to be made whole, and without a compensation claim there is no possibility of early settlement between complainant and subject; the process, as documented,⁷⁰ has to date been seen out by both complainant and subject once it has been initiated.

The complaints process puts the complainant in the position of leading the case against the complaint's subject, but the complainant's value is as a holder of information that an agreement between third parties and written in the public interest may have been breached. In effect, the complaints process requires that, as a condition for sharing information of possible breach, the complainant take a leadership role in the complaints process which for one complaint lasted two years.⁷¹ This obligation on complainants should be expected to reduce the willingness of complainants to bring information to the attention of the overseeing authority, and may in part explain the low number of complaints. There is no dialogue to be usefully had between complainant and subject: the complainant's role in the process can end once the complainant has brought to the attention of the overseeing authority a possible breach in a Code, and provides the evidence they are able to bring to bear on the matter.⁷² As we note in section 8, provided the complaint meets a jurisdiction test, the complainant should subsequently be made aware of the decision of the overseeing authority, and the decision should be published.

By being onerous on complainants, the process provides advantage to those with access to technical expertise, particularly legal representation. By putting the complainant in the position of having to respond to professionally prepared documents, frequently of a technical nature, the process allows the well-resourced to confuse, frustrate and overwhelm the concerned individual who complained. Complainants are right to express frustration at subjects' use of lawyers, but their frustration is misdirected: the design of the process is responsible for allowing imbalances in access to legal resources to translate to advantage. A clearly-documented complaints process, rigorously followed at all times, protects against these imbalances and is likely to reduce the demands placed on complainants.

To address this imbalance, the enforcement of the Code should move towards either (i) a pure whistle-blowing process, where public officials investigate the issue and bring any action against those who have breached the Code, or (ii) retain the current role of the complainant, but provide support from a public official in the preparation of the complaint. In our view, the complainant's role ought to be confined to that of whistleblower: to bringing a possible breach in the Code to the attention of an independent panel for investigation and adjudication. This raises questions about funding, which is a subject for appropriate consideration in the Ministry's full review

⁶⁹ There are strong parallels between the CP process and that of other complaints processes aimed at dispute resolution, reviewed in section 4.4.

⁷⁰ Terms of Reference are available here: <http://tinyurl.com/387wj6w> Accessed 24 March 2011.

⁷¹ Complaint number 07-2008-04b lasted two years because of the appeal.

⁷² The Ministry has drawn our attention to the fact that the APMAIF complaints process operating in Australia provides for a preliminary decision to be released to the infant formula marketer but not to the complainant and asked us to comment on whether this process is consistent with natural justice. We do not think that natural justice requires a complainant who has brought a possible breach in a code of practice to the attention of an oversight body, and who has passed the information they have on the matter, to continue participating in the process. Natural justice may be undermined if a requirement to see out the process beyond initial whistleblowing creates a reluctance to complain in the first place. As previously noted, complainants report the requirement to participate in the complaints process is onerous, stressful and intimidating. Natural justice is better served by a process that is less onerous on complainants, which rigorously assesses complaints, and which makes public all decisions.

later this year. Prospectively, an agreed clearly-documented complaints process should be developed. This process should be rigorously followed at all times, the value of which we now discuss.

6.2. Due Process

There is dissatisfaction with the current complaints process from both complainants and INC representatives. Both groups feel the complaints process is weighted against them. The qualitative review identified an instance of complainant and the subject of that same complaint (independently) making the following comments:

[Y]ou're very aware that suddenly you're... David against a couple of Goliaths – Complainant

The process seems hopelessly loaded in favour of the complainant – Subject

In our view, this dissatisfaction is caused in part by a failure of the CP, firstly, to allegedly fully document the complaints process, and secondly to follow the process where it is documented. The terms of reference for the compliance panel provide some guidance on the complaints process, but much is left unstated. We make recommendations on how this might be improved in Section 8.

There are reported instances (in most cases unsubstantiated) in which the CP is believed to have departed from due process, or from participants expectations of due process and natural justice. These reports include:

- A change in the composition of the CP in the middle of a complaint, which the complaint recipient considered was in violation of the CP terms of reference which provides (Ministry of Health 2008):

Any member may at any time resign by advising the Director of Public Health in writing. However, the resigning member should complete any complaints process where he or she is involved.

The subject of a complaint alleges they were not notified of the change and discovered it occurred by noting a change in the names listed in a decision;

- Alleged inclusion of third parties in a complaints process without the knowledge of the person who is the subject of the complaint;
- Alleged failure to notify a person who is the subject of the complaint that an investigation of them was underway;
- Alleged investigation of complaints which are “clearly outside the scope of the agreement,” according to an INC Representative;
- CP alleged to have breached a formula manufacturer on a matter not complained about; company was alleged not have been given an opportunity to respond to the matter on which it was found to have breached;
- Formula manufacturer alleged to have been breached by the CP on a matter for which there was no evidence presented either way, leading one INC representative to comment, “so they were beached on being guilty unless they could prove themselves innocent”;
- A claim that not all evidence provided by a complainant was passed to the person who is the subject of the complaint, and that the subject claimed they only became aware of this evidence when it was referred to by the Adjudicator;

- A concern raised in an Adjudicator's decision that a CP decision was not drafted by a member of the CP and was not signed by any member of the panel, raising a concern about whether it could be demonstrated that the decision was made by the panel;
- A finding by the Adjudicator to quash a finding of breach by the CP for reasons including that the CP took irrelevant evidence into account, that none of the justifications cited by the CP in support of a finding of breach on one of two counts lead to the conclusion reached, and that the CP did not correctly apply a test in the other;
- Alleged concerns about or inaccurate advice being offered: advice to the effect that the Adjudicator's decision is final may be misleading because the decision can be open to judicial review; that the voluntary nature of the health workers' Code is not explained; that the consequences for a health worker choosing not to participate in a complaint is not explained.

In addition, concerns were expressed that the time taken by the process interferes with natural justice. One interviewee noted that providing anonymity for the complainant creates a perception of procedural bias. A number of interview participants noted that they consider the complaints process is incompletely documented, creating confusion.

Failure to adhere to due process, whether perceived or real, creates several problems. First, it appears to explain why several of the CP decisions have been overturned by the Adjudicator. Second, adherence to due process is the basis for a decision's legitimacy and acceptance by complainants, industry and health workers. Third, departure from due process limits the precedent value and learning that can be taken from a decision. Fourth, alleged departure from due process may create legal risk for the CP and the Ministry, and because of this exposure, may compromise (or give the appearance of compromising) the independence of the Panel's decision making. Fifth, departure from due process introduces an *ad hoc* component to decision-making, which in turn is likely to reward power, in this instance the party with access to legal representation. Because some interviewees consider the current procedure is not fully documented, and under a panel that some interviewees consider may not always adhere to its procedure as documented, advantage goes to those with sufficient access to expertise and knowledge to be in a position to remind the panel of their rights to judicial review and to access compensation through tort. In the current process, that is likely to be the subject of the complaint, to the disadvantage of the complainant. The result limits the effectiveness of the monitoring function of the CP, may undermine natural justice, and is understandably a source of complainants' frustration.

As we note in Section 8, these issues can be resolved either by arranging for an independent body to handle complaints, or by keeping the process in-house but appointing a chair with training and experience in due process. We suggest a retired High Court judge. Rigorous adherence to due process as documented is likely to reduce complexity for participants.

6.3. Conflict of interest

The Ministry is not in our view the appropriate organisation to be overseeing compliance with the INC and Health Workers' Codes. The current arrangement puts the Ministry in the dual positions of policy maker and overseeing compliance. The Ministry's objective is to promote national health outcomes. A conflict of interest arises when the organisation committed to the promotion of breastfeeding funds and

decides on the composition of an overseeing committee that checks compliance by the manufacturers of a product that can potentially undermine that objective. In spite of the Ministry's efforts to maintain objectivity in the process, this conflict has helped create a perception of bias in the CP among INC representatives. The inclusion of the INC CEO on the CP also creates the appearance of potential bias for some stakeholders.

The CP's terms of reference are quite unhelpful to protecting it from charges of bias: the Objective and the Roles do not make clear that the CP is there to oversee compliance. The CP's objective is "to contribute to the wider policy environment which supports the provision of safe and adequate nutrition for New Zealand infants," and its role is to, "make decisions on unresolved complaints."

We also note that New Zealand is a signatory to The United Nations Convention on the Rights of the Child:

The United Nations Convention on the Rights of the Child (CRC) is the most comprehensive international human rights framework in this regard. Numerous articles of the CRC are supportive of the aim of the Code, particularly the right of children to the highest attainable standard of health, by, inter alia, reducing infant mortality, and promoting breastfeeding. The CRC not only reflects the legal obligations of Governments towards all children and mothers under its jurisdiction, but also provides legal and normative guidance on protecting, promoting and supporting infant and young child feeding.

Countries having ratified the CRC are legally bound by its provisions. In other words, governments can be legally held accountable for action or inaction which hinders the enjoyment of the rights and freedoms set forth in it. Therefore, both national and international mechanisms for monitoring CRC implementation should address the implementation of the Code in their activities.⁷³

While it is a legal question beyond the scope of this paper, New Zealand as signatory to international arrangements means the Ministry, or the government, may be vulnerable to legal input. However, this would relate to the *existence* of a regulatory scheme, rather than individual outcomes of it. We think this may add to the value of moving oversight of Code compliance to a structure governed by an external process, separate to the Ministry.

A solution to the conflict is to outsource the evaluation of complaints. Having complaints heard by an external organisation will provide an important advantage for the Ministry: it is then free to advocate on behalf of or otherwise assist complainants, consistent with other policies to promote breastfeeding. This will eliminate the awkward balancing act of maintaining objectivity while balancing dual roles, while leaving the Ministry free to assist complainants or advocate on their behalf, eliminating the current requirement on complainants to understand the various Codes and to participate in each step of a legal process.

6.4. Transparency

Transparency is an important part of any process for three reasons. The first relates to natural justice, and the requirement that the Code be clear to all parties, and the identities of all parties to a complaint know the identity of all of the other parties.

⁷³ Source is Ministry of Health. website. WHO International Code - Questions and Answers from WHO. See Question #16 available from <http://www.moh.govt.nz/moh.nsf/indexmh/breastmilksubstitutemarketingcode-who-> Accessed 20 December 2010

Second, transparency is important because the nature of the complaints made and the resolution or decision on those complaints only has value to all stakeholders if it is freely available to all interested parties. Third, self-regulation relies on there being costs to those who breach the regulatory thresholds, and industry, stakeholder and public awareness of any breaches will substantially increase those costs. For this reason, publication of information about breaches is likely to increase the satisfaction of complainants with the process.

Against this standard, we consider that the current process lacks transparency. To facilitate this greater transparency, it seems likely that the process would need to provide for the publication of complaints received, resolutions achieved and all decisions reached by the Panel and Adjudicator, an absence of anonymity for complainants, anonymity for health workers personally but not their employers, and no anonymity for companies.

Transparency is not without risk for the operator of a complaints process: publication increases the potential for liability. However, this liability is insurable (we understand the ASA utilises professional insurance) and in any event the complaints process can protect itself through the careful application of due process and natural justice.

6.5. Scope of the Code

Complainants, NGOs and enquirers in the qualitative review repeatedly and strongly expressed the view that the scope of the New Zealand interpretation of the Code should be extended to cover formula for infants up to 12 months of age.

Every manufacturer interviewed is openly in favour of the Code and its principles. The Code prevents industry from marketing and discounting; but it is not a constraint on selling. Code compliance imposes substantial costs on manufacturers and, under the current compliance regime, risk. Costs are incurred in achieving compliance in product design, responding to consumer complaints, and in the reputation risks that go with operating under imperfectly-specified rules and inconsistent oversight.

Notwithstanding the merit of the goal of promoting breastfeeding, industry-wide restrictions on marketing and discounting are nominally anti-competitive. Were these restrictions achieved via an agreement between competing firms without the consent of a Ministry, it would be correctly labelled collusion and would probably violate section 27 of the *Commerce Act 1986*.⁷⁴ As we noted at page 17, monopoly rents can arise from advertising restrictions, and the Code's obligations have parallels to the restrictions advertising professional bodies impose on members.

The effect of the Code's restrictions is to increase search costs for consumers, and reduce price competition among members, thus raising prices to consumers. This may create economic rents (monopoly profits) for the industry. One way to think about the Code is that it enforces a collusive equilibrium in which firms have mutually agreed to avoid the substantial expense of marketing and providing free samples to a large segment of the market, without setting any constraint on sales.

Whether the economic rents this produces more than offset associated compliance costs and reduced size of the New Zealand market, is beyond the scope of this paper, but it is conceivable that, by targeting marketing but not sales, the effect of the Code

⁷⁴ INC representatives noted their awareness of Commerce Act obligations and that this constrained what they could discuss at INC meetings. The Public Health Commission(1995) emphasises that interpretation of the International Code in New Zealand needs to be consistent with the Commerce Act. Ministry of Health (2007) notes: "In New Zealand, it was not possible to legally restrict the advertising of products without contravening the Commerce Act 1986 and the Fair Trading Act 1986."

for each company is to reduce costs by more than revenues and thus raise profitability. The industry's acceptance of the Code is at least consistent with a rational economic framework of profit maximisation; suspicion of industry's motives among complainants and NGOs may be misplaced.⁷⁵ Efficiency considerations may be worth taking into account as discussion of appropriate scope of the Code continues.

Our advice to the Ministry on resolving the impasse between manufacturers and the Ministry and extending the INC Code of Practice to 12 months is as follows:

1. Seek an undertaking from the INC that its members will agree to 12 months provided the Ministry is able to obtain an undertaking from the Commerce Commission that no prosecution will occur under the Commerce Act for such an agreement. INC members should indicate the sections of the Commerce Act, and any other legislation, of concern to them.
2. Approach the Chair of the Commerce Commission for a letter of no action or an exemption from the relevant sections of the Commerce Act, in regards to the marketing (but not any other aspect of production, distribution, or price setting) of infant formula for infants to 12 months in New Zealand. The request should emphasise the particular circumstance in which the implementation of New Zealand's obligations under the UN Convention risks coming into conflict with one or more sections of the Commerce Act.

We note two caveats. First, private action under the Commerce Act is technically feasible, so that an undertaking by the Commerce Commission of no action is not a guarantee of protection. However, any such action would effectively be against the Commission as well as the private party, and so it would be complex and costly.

Second, we think, an extension to 12 months should only be contemplated if the complaints process is substantially improved, so as to rule out its use as a vehicle for expressions of concern that fall outside the conducts that are covered by both Codes of practice.

6.6. Vetting of Complaints

Complainants and NGOs are concerned about the limited scope of the Code in New Zealand, and it appears some express their concerns by making a formal complaint to the Ministry. This may explain why approximately 83 percent of complaints received in Australia are found to be out of scope.⁷⁶ All alternative New Zealand complaints processes reviewed included a jurisdiction test as a first step.

The Australian evidence suggests design of the complaints process should anticipate complaints that are out of scope, and prevent these complaints from proceeding. In interviews, INC representatives reported that a source of their dissatisfaction with the current complaints process is that it requires their participation in complaints that are, they report, outside the Code's scope. In our Key Findings, we recommend that the Ministry should discard the satisfaction test in the current process, and add a jurisdiction test to ensure only complaints which raise concerns in regards to compliance should be considered by the CP.

⁷⁵ The Ministry of Health has advised (personal communication, 1 March 2011) that manufacturers have rejected proposals to extend advertising restrictions on formula to 12 months. The main source of the industry's resistance appears to be concerns that an agreement among manufacturers not to advertise to 12 months may violate the Commerce Act. An INC representative expressed the view that if Commerce Act constraints could be settled then industry would consider extending Code provisions to 12 months (see quote regarding Commerce Act on page 48).

⁷⁶ See Table 6 on page 24.

In response to our recommendation in the draft version of this report to add a jurisdiction test, the Ministry sought comment on how out of scope complaints should be resolved. This raises questions about the objective of the complaints process. The complaints process operates to detect and respond to breaches in Codes of practice by health workers and infant formula marketers'. The objective of the CP and Adjudicator is not the acknowledgement and placation of interested people and groups. The inclusion of a satisfaction test in the complaints process, which we have previously noted is unrelated to compliance, may have the effect of confusing this issue, by inviting the interpretation that satisfaction of the concerns of all complainants is a legitimate goal of the complaints process.

Dealing with interested parties is a fact of life for officials, and it is understandable if there is a desire among Ministry officials to acknowledge and where possible resolve concerns, whether or not they relate to compliance with existing rules. However, a complaints process is a needlessly costly way to acknowledge and resolve concerns that do not raise questions about compliance with current rules. Failure to exclude out of scope complaints may breach the natural justice requirement in the CP's terms of reference. Out of scope complaints should not make demands on health workers or manufacturers who can only be asked to comply with the rules as written, particularly when the complaints process can take over 400 days to produce an adjudicated decision, and allegedly demands considerable time and expenditure by those, or on behalf of those, who are the subject of a complaint, whether they are guilty of a breach or not.

None of this should be taken to imply our dismissal of the views of those who have wider concerns about existing Codes of practice that is not related to compliance. We note that many participants in the qualitative review believe the scope of the Code implementation in New Zealand is too narrow. These are perfectly legitimate views to hold. However, it is our view that a process that is designed to test compliance is a costly and ineffective way to acknowledge those concerns, and the Ministry may wish to consider a separate process by which these concerns are received and considered. It is not clear to us that there is any value in troubling health workers and manufacturers with complaints which are out of scope.

6.7. Health Worker Issues

Compliance by health workers under the Health Workers' Code can be distinguished from compliance by manufacturers under the INC Code. Whereas INC members have understood and agreed to a Code of practice, health workers have not, and there is no guarantee that a health worker who is the subject of a complaint was aware of the health workers' Code at the time of the alleged breach. In the qualitative review, it was reported to us that many health workers are not aware of the Code.

We think industry norms appear to protect health workers against inadvertent breach. The health worker spoken to in the qualitative review who had been the subject of a complaint claimed to us that they had not heard of the Health Workers' Code, yet the worker still knew to include a statement in their presentation to the effect that breast feeding is superior. We also received repeated reports in the qualitative review that health workers protect themselves in another way, by using a 'rule of thumb' to not discuss infant formula at all.

Even where health workers understand their obligations under the Code, it was reported to us that workers risk reprisal from the charge nurse or midwife who, we understand, are encouraged to increase breastfeeding rates. By discussing formula feeding, it was reported to us that workers increase their risk of being the subject of a complaint; the health worker spoken to in the qualitative review who was subject of a

complaint went through a process lasting 21 months. After an initial finding of breach by the CP, the worker found not to have breached the Health Workers' Code. As this health worker's experience demonstrates, compliance costs are not necessarily avoided by providing advice on infant formula that is compliant with the Code of practice. Such costs are avoided with certainty by a health worker, however, if the worker chooses not to offer any advice on formula feeding. That is the position that it appears many health workers have adopted. This may be a response by health workers to policy settings which are hostile to the provision of advice on formula feeding, and may also reflect difficulties health workers have in obtaining access to updated product information from formula manufacturers. We received repeated though unsubstantiated and indirect indications that many mothers have difficulty obtaining timely information on, and access to, infant formula when they cannot or choose not to breastfeed. One interview respondent reported seeing repeated instances of babies who had lost over 10 percent of their body weight through malnourishment. Their testimony was as follows:

I think most people working in the hospital, in my experience, very supportive of breastfeeding and in some ways I think the hospitals have gone overboard in not giving women, if they're struggling, they're not given much support and information as to what else they might do. The more senior you are in the hospital the more people see it as well that's just what we have to do to satisfy the Code. And you know bad luck if some people come off worse. I'm private so I only see individual women and individual babies on referral. I now see lots of women, or lots of babies who've lost more than 10% of weight and that's because breastfeeding hasn't gone that well and there hasn't been much intervention... women are left to flounder and then eventually their [Lead Maternity Carer] says get somebody like me to come and have a look at them. And oftentimes we will recommend supplemental feeding for a day or two which is all I generally do and then back to, in most cases, full breastfeeding – Health Worker

The Health Workers Code requires health workers to provide information on infant formula "where necessary". The refusal by some and perhaps many health workers to provide advice on infant formula feeding to mothers may constitute a breach of the Health Workers' Code.

These findings with respect to health workers should be treated with caution. They rely mainly on second-hand reports from the qualitative review. Some interview respondents indicated non-compliance with the Code through inappropriate distribution of formula. We therefore flag the experiences of mothers and health workers in regards to access and provision of advice on infant formula as an area for further research. Our findings are broadly consistent with those of a study of health workers in Scotland by McInnes et al (2007). If there is widespread reluctance among health workers to provide information on infant formula, it is almost certainly a product of a mix of policy and institutional settings.

Because health workers may be unaware of their obligations under the Code of practice, and yet workers exhibit strong support for the principles of the Health Workers Code, it is possible and perhaps likely that any breach was inadvertent. It is therefore counterproductive to respond in the first instance to a complaint against a health worker by initiating a formal complaints process. Compliance and increased understanding of obligations under the Code of practice can be achieved much more quickly, after application of a jurisdiction test to the complaint, by simply alerting the health worker to the existence of the Code of practice and seeking agreement that they will in future be aware of their obligations under the Code. Only in the event of a second complaint should a more formal complaints procedure against a health worker be considered. Given the goodwill towards the principles of the Code no

formal complaints process for health workers may be necessary: Australia operates without any such process for health workers, at least at the Commonwealth level.⁷⁷

We think the Ministry should note that indications to us are that the most common form of non-compliance with the Code by health workers appears to be a failure to provide advice on formula feeding when sought by mothers, and not in a failure to promote breastfeeding. The Ministry should in our view be prepared to encourage compliance with all aspects of the Health Workers' Code.

6.8. Market for infant formula as a candidate for self-regulation

The economic literature lists the industry characteristics most suited for self-regulation, and these characteristics appear a good fit with the market for infant formula.⁷⁸ Compliance is likely to be high under self-regulation, for the following reasons:

- Monitoring costs are kept low by the inherently public nature of advertising and promotion. Rivals can easily monitor one another's activity;
- That breastfeeding is superior is an industry and interest group norm, and may be a wider social norm as well;
- There is organised monitoring of companies by interest groups;
- A high proportion of complaints in New Zealand, Australia and the United Kingdom are not upheld, suggesting over-reporting of complaints;
- The industry is supplied by a small number of companies that are large, multi-product firms that are relatively vulnerable to retaliation by consumers for misbehaviour;
- Infant formula is a credence good;⁷⁹ here brand value and reputation is especially important to convincing consumers to buy; behaviour which affects reputation is particularly costly for producers of credence goods;
- No one company is dominant in the market for infant formula, meaning a self-regulatory body is unlikely to be corrupted.

On the basis of this evidence, we conclude the market for infant formula is a strong candidate for self-regulation. Under the conditions listed above, compliance is achievable under self-regulation even though participation in the regulatory scheme is voluntary and there is limited scope for the levying of financial penalties. A number of complainants and enquirers expressed the view that without the ability to levy financial penalties on errant firms, a self-regulatory regime cannot produce compliance. Neither coercion or financial penalties are necessary to achieve compliance under self-regulation. Provided self-regulatory organisations are seen to be reasonably independent and credible, they are able to exact costs on non-compliant members through the use of reputation: sanctions such as public announcement of non-compliance or the threat of expulsion from the group impose large costs on firms that rely on their brands and reputation to signal quality to buyers.

⁷⁷ As noted in section 4.3.1.

⁷⁸ See Table 4 on page 15.

⁷⁹ A credence good is a type of good whose quality is difficult to signal in advance to consumers, and also difficult for consumers to gauge even after consumption. See Gehrig and Jost (1995).

Multi-product firms such as those supplying infant formula in New Zealand are especially vulnerable to this type of sanction, because consumers are able to punish the firm across multiple product categories, not just those to which non-compliance relates (Stefanadis 2003). Under these conditions, reputation costs translate to lost sales and therefore company bottom lines. By this means, a self-regulatory regime, making use of reputation rather than direct financial penalties, can produce compliance. For these reasons, the Ministry, complainants and enquirers should have confidence that full self-regulation will be effective. Compliance is more likely if the Ministry is able to credibly signal implementation of a full regulatory regime in the event of widespread non-compliance under self-regulation.

6.9. Current Compliance

In spite of the problems with the complaints process, there is strong evidence that there is compliance with the Codes in New Zealand. We are convinced by a combination of factors:

- The low proportion of complaints that are upheld as breaches;
- This low rate of breach is comparable to rates in Australia and the United Kingdom;
- In respect of the one instance of breach upheld on appeal, is doubt that the decision would survive a more robust decision process;
- A substantial proportion of complaints in Australia are out of scope, suggesting, if anything, over- rather than under-reporting;
- Companies back their stated support for breastfeeding with investment in systems and processes to achieve compliance;
- There is organised and credible opposition to, and scepticism of, formula manufacturers. These opponents monitor the activities of the formula manufacturers; formula manufacturers also report monitoring their rivals; the INC has an internal dispute process for companies to complain about rival manufacturers;
- Manufacturers face incentives to comply: protection of reputation; the threat of government intervention for non-compliance; and possibly the maintenance of a profitable collusive no-marketing equilibrium; and
- The qualitative review provided repeated anecdotes of insufficient information about formula reaching mothers, and insufficient access to formula in hospitals suggesting, if anything, excessive compliance by health workers with the requirement under the Code to promote breastfeeding.

6.10. Code-Related Problems

The qualitative review identified the following problems:

- By discussing formula with mothers, a health worker reported that health workers risked sanction from the charge nurse and risk being the subject of a complaint and participating in a protracted complaints process. Evidence provided in the qualitative review suggests some health workers are responding to these incentives by refusing to discuss formula feeding at all. We received numerous reports of mothers having difficulty obtaining information about formula from health workers;

- INC representatives report difficulty in providing product information, consistent with Code provisions, to health workers, meaning health workers are frequently uninformed about formula product updates;
- Statistics are reported by a health worker to be made unreliable as mothers under-report use of formula to avoid difficulties with midwives;
- One health worker reported instances of malnutrition and dehydration among newborn babies born to mothers who are unable to breastfeed because nurses are unwilling or unable to offer formula without the mother asking; and
- Reported feelings of guilt among mothers unable to breastfeed.

7. Knowledge Gaps

Knowledge among health workers of the Code appears patchy, and this may be causing unintended consequences, such as a refusal to discuss formula feeding with mothers. This may be a source of considerable harm, as there are reports of weight loss among infants from lack of feeding, and of mothers obtaining information on infant formula from alternative sources of unknown quality. It would be valuable to understand a) the depth of knowledge among health workers of the full set of requirements under the health workers' Code, and b) the experiences of a representative sample of recent mothers who did not breastfeed their child.

We are not aware of any systematic study of the effect of Code-related restrictions on industry profitability. A study may be able to demonstrate that providing limited exemptions for companies from competition requirements and allowing those companies to agree not to promote those products will produce a no-marketing equilibrium of infant formula requiring minimal oversight.

We are not aware of evidence on the share of the market that small producers of infant formula (in particular organic infant formula makers) outside the INC serve. What is their level of awareness and compliance with the Code? We have not seen evidence on the awareness and compliance of retailers in New Zealand, who are not covered by a Code of practice under existing arrangements. In the qualitative review, a complaint recipient noted some retailers are genuinely unaware it is not in accord with the Code to discount formula. Non-compliance among retailers may be significant.

Do Australian and United Kingdom complaints processes, which have upheld similarly few Code-related complaints against manufacturers, produce the same feelings of frustration and futility among complainants as occurs in New Zealand? Our hypothesis is that the cause of those feelings in New Zealand is the alleged failure to follow due process and to publish all findings, not the lack of success per se.

8. Conclusion and Key Findings

We conclude this report with what we consider are our key findings. Our key findings suggest a number of potential prospective actions:

1. For complaints under the INC Code, outsource compliance monitoring and the Adjudicator (collectively, “evaluation”) functions to an independent body, such as the Advertising Standards Authority, the Commerce Commission or a private disputes resolution provider such as Dispute Resolution Services Limited (DRSL).
2. For complaints under the Health Workers’ Code, outsource the evaluation functions to an appropriate and independent body, such as the Health and Disability Commissioner.
 - a. To avoid fragmentation of service from the perspective of complainants, the Ministry of Health should continue to operate a “one stop shop” to receive all complaints and then direct them to the appropriate body.
 - b. The Ministry of Health should, provided an independent body is responsible for complaints, where feasible provide assistance to complainants in preparing their complaint.
 - c. The industry is likely to be willing to fund this process. Industry funding is standard practice elsewhere. Provided a documented process is adhered to, and the process is transparent, an industry-funded process is likely to be credible and legitimate.
3. **If findings 1 and 2 are not adopted and adjudication is not outsourced then the Compliance Panel should:**
 - a. Appoint a retired High Court judge to chair the Panel to strengthen adherence to due process;
 - b. Appointments to the Compliance Panel should be assigned to an independent person or body, such as the President of the Law Commission;
 - c. The Ministry of Health should appoint an independent person (“the advocate”) knowledgeable in the Code to assist complainants in preparing their submission, to advocate on behalf of the complainant, including deciding on whether to appeal a decision;
 - i. The advocate is the point of contact for the Compliance Panel throughout the complaint.
 - ii. The advocate is responsible for lodging the complaint in a reasonable timeframe, for arranging to provide additional information if sought by the Compliance Panel or Adjudicator (with the help of the complainant if they agree to assist), and for deciding whether to appeal a decision (the process should not require the complainant to do more than allege breach of one or more aspects of the INC Code or Health Workers’ Code and to provide supporting evidence).
 - iii. The advocate may only decline to provide (or arrange) assistance for the complainant if the complaint is manifestly out of scope.

- d. A draft decision should be made available to the subject of the complaint and the complainant (if the complainant indicates they wish to receive it) for the purpose of obtaining feedback from the subject of the complaint in a reasonable time frame.

4. Regardless of whether outsourcing of complaints about either Code of practice occurs:

- a. Prepare new terms of reference that, among other things:
 - i. Defines the Objective of the Compliance Panel as being to determine compliance with the INC Code and the Health Workers' Code;
 - ii. Defines the forms of evidence the Compliance Panel may and may not consider;
 - iii. Requires transparency: the subject of the complaint should be made aware of the complainant's identity; all information provided by the complainant should be passed to the subject.
- b. The complaints process should be fully and publicly documented.
 - i. The process should provide guidance on options for remedy should complainants or subjects believe due process was not followed.
- c. The full text of all final decisions, excluding individuals' names, should be made publicly available at the time they are made:
 - i. Health workers' institutions should be named;
 - ii. An annual report that summarises these results should continue to be produced;
- d. The Minister of Health should table these results in Parliament, the aim being to increase sanction for breach by marketers who are members of INC.
- e. The complaints procedure should be updated, or replaced, and the following elements should be included:
 - i. A full description of the grounds for complaint and grounds for appeal;
 - ii. The number of available appeals a complainant or subject may make;
 - iii. A statute of limitations, specifying the timeframe since an event about which a complaint may be lodged;
 - iv. Explain the consequences of non-participation by health workers.
- f. The complaints procedure should eliminate the satisfaction test.
- g. The process should indemnify the complainant against legal risk. However, the Ministry of Health should reserve the right to prosecute a complainant for knowingly making a false declaration.
- h. Add a jurisdiction test at the start of the process.
 - i. If outsourced, the jurisdiction test should be undertaken by the independent body, otherwise by the Chair of the Compliance Panel.

- ii. Complaints found to be out of scope should be automatically and immediately excluded from any further consideration under the complaints process.
 - 1. A letter explaining this should be provided to the complainant.
 - 2. The subject of the complaint should be advised that a complaint was received but deemed out of scope, and that no action by them is required.
 - 3. The Ministry of Health may wish to develop a separate process for acknowledging and handling complaints which are out of the scope of the complaints process.
- i. For complaints against health workers:
 - i. The first complaint against a health worker:
 - 1. Should not cause a complaints process to be initiated, unless the alleged breach is particularly serious or deliberate.
 - 2. A letter should be sent to the health worker informing them of the complaint. Information about the Health Workers' Code should be included.
 - ii. A second complaint against a health worker should cause the complaints process to be initiated.

9. References

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Appendix A. Summary of other processes in New Zealand

Table 11: Other complaints and disputes processes in New Zealand

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
Coverage	Complaints received against advertisements, including print and broadcasting media and advertisers, which may be in breach of the ASA's Code of Practice.	Free independent investigation and dispute resolution process for resolving or determining complaints about banking service providers if unresolved after consideration by banking service provider.	Free, independent service for resolving consumer complaints about electricity and gas companies.	Dispute handling service for customers of member financial products and services.	A free independent dispute resolution service to help residential and small business customers with complaints about their telecommunications company. TRD covers major telecommunication companies in New Zealand.	Independent Crown Agency responsible for enforcing the Fair Trading Act. The Act protects consumers from misleading and deceptive conduct and unfair trading practices. The act applies to all aspects of the promotion and sale of goods and services – from advertising and pricing to sales techniques and finance agreements.
Codes/ Regulations/ Legislation	Members are bound ASA's 13 Specialised Codes of Practice including the overarching Code of Ethics against which all advertisements complained about are measured. The ASA introduces and amends Codes of Practice for specific categories of advertising where they are necessary. ASA Constitution.	Scheme participants are bound by the Banking Ombudsman's Terms of Reference. One of four current financial dispute resolution schemes approved by the Minister of Commerce under the Financial Service Providers (Registration and Dispute Resolution) Act 2008.	The EGCC Code of Conduct for Complaint Handling binds member companies. Code sets out the minimum standards that the companies agree to uphold in dealing with complaints. Members can elect to be bound by three Codes of practice (Electricity Code of Practice, Gas Code of Practice and the Land Code). Effective from 1 April 2011 EGCC is the single dual fuel complaints resolution scheme. It is under the provisions of the Electricity Act 1992 and Gas Act 1992 respectively.	Member's financial service providers are bound by FSCL Terms of Reference. One of four current financial dispute resolution schemes approved by the Minister of Commerce under the Financial Service Providers (Registration and Dispute Resolution) Act 2008.	The Customer Complaints Code governs all TDR's actions and all scheme members sign and thereby agree to comply with this Code. Term of Reference, Telecommunication Act 2001.	The Fair Trading Act 1986.

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
Funding	Subscriptions and special levies on members.	Scheme participants (17 as at 3/11 including the major banks in NZ) on a levy basis.	Levies on member companies. From 1 April 2011 membership will be compulsory for all energy companies (gas and electricity line companies and retailers).	All participating members pay fees based on the size and scale of the business. Participants also pay fees for any case that FSCL investigates against them.	Member companies are charged fees depending on how many cases the TDR handles against them.	Government funded but not subject to direction from the government for carrying out its enforcement control activities. Commission is accountable to Minister of Commerce and Associate Minister of Commerce for its performance. Commission delivers its outputs under an Output Agreement with the Minister of Commerce and the Minister of Communications and Technology. Work funded through Vote Commerce and Vote Communication and Information Technology.
Number of complaints	In 2009, 1339 complaints about 829 advertisements. In 2008, 1246 complaints about 703 advertisements.	In 2009/10, 1,924 new cases received of which 1021 were classified as complaints and 657 were disputes. In 2008/09 received 1888 cases– 202 enquiries, 1079 complaints and 607 disputes,	In 2009/10, 1826 customers contacted ECGG as a result of some difficulty with their electricity or gas company of which 653 were classified as ECGG complaints (71 deadlocked) In 2008/09 1562 contacts were made, of which 585 were ECGG complaints, (70 deadlocked) In 2007/08 1855 contacts, of which 822 were complaints.	Scheme began operating in 2009. Currently estimated to be running at about 4 or 5 investigations per month.	In 2009, handled 1621 matters of which 536 were referred back to Scheme Members internal complaints schemes, 34 progressed to facilitated negotiation, 18 to conciliation and 30 went to adjudication. In 2008, dealt with 1,396 matters, 815 of which were referred back to Scheme Members internal complaints handling process. 28 jobs progressed to level 2 (facilitated negotiation), 12 to level 3 (conciliation) and 1 to level 4 (adjudication). Scheme began operating on 30 November 2007.	Currently receives around 10,000 complaints about potential breaches under the Fair Trading Act each year and this level of activity is likely to continue. The Commission does not act on behalf of individual complaints, it investigates fair trading issues taking into account the complaints received.

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
Decision-maker	The Chairperson of Advertising Standards Complaint Board (ASCB) determines whether a complaint is suitable for the Board's consideration and within the Board's jurisdiction.	The Banking Ombudsman will determine whether the Scheme or another dispute resolution body is the most appropriate body to consider taking into account Terms of Reference.	The Commissioner receives, considers, investigates and facilitates resolution of complaints. Commissioner, an independent person qualified in dispute resolution, recommends a settlement if the parties are unable to resolve the complaint by agreement (deadlock).	The Chief Executive Officer duties include jurisdictional decisions and complaint recommendations and determinations. FSCL Panel, comprised of industry representative, a consumer representative and CEO, may determine complaints involving a claim of greater than \$50,000 or such amount as nominated by the Board and any complaint referred by the CEO.	Dispute Resolution Services Limited (DRSL), as Scheme Agent , decides whether deadlock has been reached with Scheme Member's and whether complaint is within jurisdiction.	The Commission decides whether to commence or continue enforcement action, the most appropriate type(s) of enforcement action and the most appropriate response to each case. The Commission considers the available information for its relevance to the commission's responsibilities and current work programme, the enforcement criteria and priority areas for new enforcement work in deciding the most appropriate response to each case. To assist in making these decisions, the Commissions applies the following enforcement criteria: Extent of detriment; Seriousness of conduct; Public interest.
Board/panel composition and processes	Complaints Board (ASCB) comprises 5 public representatives with no connection to media or advertising groups, one of whom is the chairperson with a right to exercise a casting vote, plus 4 persons nominated by the ASA. Public members appointed by appointments	To help maintain its independence and give it a legal entity the Banking Ombudsman Scheme is a company. Its governing body is a Board on which banks and consumer groups are represented without either having a majority (2 bank representatives, 2 consumer representatives). The	Effective 7 April 2011, Board comprised of 1 elected retail scheme member, 2 elected lines company members, 2 members appointed by Minister and 1 independent chair appointed by EGCC Board. The Board monitors how well the scheme is working and appoints the	FSCL is an independent not-for-profit External Dispute Resolution scheme. FSCL is governed by Board of Directors that appoints the Panel Members including an industry representative and consumer representative. Panel Members appointments follow a merit selection process that includes input by relevant	Scheme Agents is the independent body appointed to facilitate the efficient working of the Scheme. Current Scheme Agent is DRSL, a specialist dispute resolution company that is independent of all the telecommunication companies. The Scheme reports to a governing council. The	Commission comprises a Chair (current Chair is lawyer), Deputy Chair and up to 3 members. The Telecommunications Act created the position of a Telecommunications Commissioner. Assoc Members and up to 2 Cease and Desist Members may also be appointed. – Chair (lawyer), 4 commissioners

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
	<p>panel.</p> <p>Appointment Panel consisting of Chairman and Deputy Chairman of ASA, the Chairman of the ASCB and an independent person makes unanimous recommendations to Authority about public member appointments. Authority shall confer with Minister of Broadcasting, Minister of Consumer Affairs and any other person as considered appropriate.</p>	<p>Chair (a law professor) is independent of banks and consumer groups. The main function of the Board is to ensure the independence of the Banking Ombudsman and to make sure the scheme is well-run and effective.</p> <p>Participant representatives appointed by Council of NZ Bankers' Association. One consumer representative appointed by Minister of Consumer Affairs or, if no such portfolio, other Minister of Crown Chair considers appropriate and Executive Director of Consumers Institute of NZ or such person as Chair may consider appropriate. Terms indefinite if not specified by those appointing them.</p>	Commissioner.	consumer or industry groups. The consumer or industry representative must be well-informed, impartial and objective.	<p>Council is made up of 50% Scheme members and 50% consumer representatives. Three consumer representatives selected by panel comprised of representatives from the Consumers Affairs Institute and Telecom Users' Association of NZ (TUANZ). The fourth representative is appointed by Ministry of Consumer Affairs.</p>	<p>(economists), 2 associate commissioners and 2 cease and desist commissioners.</p> <p>The Governor General, on the recommendation of the Minister of Commerce, appoints the Commission members on the basis of their knowledge of, and experience in, areas of relevance to the Commission.</p>
Powers	<p>ASA members, in accordance with self-regulatory principles, are bound by the decisions of the ASA. If complaint upheld, advertisement modified or removed. Formal written decisions distributed to complainant, parties and media Decisions from 2003 available on ASA web site.</p>	<p>The Banking Ombudsman's decision is binding on participants but the complainant is free to accept or reject it. Participants can be required to pay compensation for direct loss or damage up to \$200,000 and for inconvenience (stress, embarrassment etc) up to \$9,000. Also powers to make other non-binding recommendations such as the correction of a mistake or return or disclosure of</p>	<p>All member companies are bound by the Commissioners decisions. Commissioner may make a decision ordering companies to pay money or take other steps to put the matter right, as is appropriate. (e.g. correction of bills, customer service payments and compensation for loss or damage that does not extend to punitive</p>	<p>CEO or Panel may direct Participant to carry out or refrain from specific actions. A Participant who does not comply with the recommendations that the Complainant has accepted may have its participation terminated in accordance with the provisions of the Deed of Participation. FSCL is not a regulator and cannot impose fines or discipline participants or employees. Compensation can be ordered up to \$100,000, can recommend</p>	<p>Scheme members are bound by policies and procedures of the TDR and any determinations made against them by the Scheme Agent. Members will refrain from conduct which may give rise to reasonable doubts about the independence and impartiality of the Scheme Agent. TDR can deal with complaints up to \$12,000, including compensation for direct loss. The Council issues breach notices and public censure or expulsion</p>	<p>The Commission has a number of enforcement response options for resolving investigations including compliance advice letters, warning letters, settlement, and a court order to stop the offending and prosecuting the trader. Penalties for non-compliance can be onerous.</p> <p>CC is able to use certain statutory powers to assist it in gathering information and evidence about</p>

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
		documents or the restoration of an account.	damages).	up to \$200,000 but cannot enforce orders above this cap. There is a \$500 cap for inconvenience. No monetary compensation for punitive damages or loss or damage not a direct result of complaint. CEO/Panel refers systematic issues (those that will have an effect on other persons beyond the parties to the Complaint) to relevant Participant for remedial action.	from the Scheme.	behaviour it considers is in breach of the Fair Trading Act. It can require written information and documents to be provided and extends to search warrant powers.
Complaint Process	<p>All complaints must be received in writing and bear name and address of complainant and sufficient information for the ASA to identify the advertisement that is the subject of the complaint.</p> <p>The Chairperson determines whether complaint is suitable for Board's consideration and within the Board's jurisdiction. If not, complainant and other parties and media advised. If it is, complaint sent to all parties concerned for comment. On receipt of comments and opinions, the Secretary shall place before the ASCB the full details of the</p>	<p>General advice provided. May assist complainant to put a complaint in writing (e.g. translator) but does not extend to advising on merits of complaint or advocating for the Complainant.</p> <p>Once complaint is determined to be within the terms of reference it is assigned to an investigator who will obtain all the information from complainant and scheme participant to assist in resolving complaint. If complaint is unable to be resolved informally with the assistance of the investigator, Banking Ombudsman personally reviews the complaint and makes a decision on it.</p>	<p>Commission contact personnel may provide general information about the Scheme and give advice on the procedure for referring a complaint to the Commissioner. Complainant can present case orally or in writing at discretion of complainant. Commission will arrange services to assist complainants (e.g. appropriate services for people with disabilities or non-English speaking backgrounds). If complainant unable to can assist with writing complaint and confirm with complainant.</p> <p>Once lodged, Commission will look into what happened. First, a Commission</p>	<p>FSCL can provide guidance on what information to provide when making a complaint, including clarifying what matters might be relevant. FSCL can provide assistance in to put the complaint in writing if the complainant has language difficulties or a disability but this does not extend to advocating for the complainant.</p> <p>FSCL has a two stage process for complaints. The first stage is investigation of the complaint with a view to facilitating an agreed resolution. If an agreed resolution can not be reached, FSCL may make a decision that is binding on the Financial Services Provider.</p>	<p>If complainant reasonably unable to submit a written complaint a Scheme Agent can help write complaint.</p> <p>Once TDR has written complaint formal process begins including contact with complainant, company and written dispute summary. If complaint accepted Scheme Agent checks details of complaint with company and writes up Dispute Summary. Conciliator tries to reach an agreement between complainant and company. If not, independent adjudicator appointed to make final decision which telecom company must accept under the Code. If complainant does not agree they can still go to other places for help such as the Courts or the Disputes Tribunal.</p>	<p>Complainants asked to provide as much detail as possible on the issue they want to report and must provide contact information and a description of the complaint. The Commission can record complaints, link complainant with information and suggest possible courses of action.</p> <p>The Commission does not act on behalf of individuals, it investigates fair trading issues. The Commission assesses the information it receives along with information from its own monitoring and surveillance activities, to determine the investigations that it carries out into unfair or misleading trading practices.</p>

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
	complaint. ASCB determines whether complaint is determined with or without attendance of parties. If complaint does proceed Board determine whether the Codes of Practice breached and all parties informed of outcome. A formal written decision distributed to complainant, parties and media Decision data base, from 2003, available on ASA web site.		<p>conciliator works with complainant and company to resolve complaint. If this is not successful the conciliator will do more in-depth investigation. If parties still unable to resolve the complaint Commissioner can review information and recommend a settlement.</p> <p>Scheme now has responsibility for monitoring and reporting on compliance and identifying and reporting on systemic issues.</p>			
Mediation	Board can act as mediator or arbitrator of disputes.	Banking Ombudsman can encourage settlement or withdrawal of complaint. In 2009/10 282 investigations were resolved using facilitation or conciliation, a 109 percent increase on 2008/09.	Goal is to help the parties resolve complaint by reaching agreement between the parties, rather than the Commissioner imposing a decision. To this end the Office of Commission uses a wide range of dispute resolution techniques such as mediation and conciliation. In 2009/10 Commissioner only gave notice of proposed recommendation on 17 deadlocked complaints, (9 of which were accepted) and formally recommended settlement on 8 complaints.	The primary focus is on resolving as many disputes as possible by facilitating an agreed resolution. If conciliation fails, CEO or Panel will make a recommendation that is binding on the Financial Service Provider.	TDR will try to resolve the complaint and work with complainant and company to reach a settlement. If that does not work an independent adjudicator will make a determination.	The CC may issue a trader with a compliance advice letter and/or warning letter with the aim of deterring future illegal behaviour. May issue a warning letter where likely breach to inform and stop behaviour. Settlement is an option where there is mutual agreement between the parties and the Commission holds the view that the terms of the settlement provide an appropriate outcome.
Appeal rights	Decisions of the ASCB may be appealed to	Customer can take complaint to courts or	Internal review of complaint handling	Complainant has 20 days to object to exclusion. CEO	When a complaint is completed, a draft	Enforcement response options include no further

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
	<p>Complaints Appeal Board on certain grounds. The main grounds are new evidence, the rules of natural justice were not followed. All rulings of the Chairperson of the ASCB are appealable to Chairperson of the Appeals Board. Appeals must be made to the Secretary within 14 days of ASCB's written decision. The Chairperson of the ASCB shall decide whether or not accept the appeal application. and the Chair will order rehearing or refer to appeal Appeals Board of 3 members (1 public, 1 industry, independent chair). Appeals against Chair decisions referred to Chair of Appeals Board.</p>	<p>other dispute resolution bodies.</p>	<p>process can be conducted by senior staff member not involved in case, reported to Commission who reports on the matter to Commission. Two such complaints received in 2009/10.</p> <p>Independent external review of sample cases undertaken to assess handling of complaints meeting requirements of natural justice and good complaints handling.</p>	<p>reviews decision.</p>	<p>determination is sent to the affected parties for comment. The adjudicator will consider these comments before issuing a final decision.</p>	<p>enforcement action when there is no contravention or possible or likely contravention. This option may include situations where the information received was incorrect, a business goes on to apply for an adjudication in respect of its activities, the behaviour is outside the jurisdiction of the Commission , or it is more appropriate for another agency or affected party to consider the matter. Settlements and withdrawals or discontinuances are also options.</p>
Complainant Rights	<p>In lodging a complaint with the ASCB the complainant accepts that he/she will not pursue the complaint in any other forum and is required to sign a waiver to that effect.</p>	<p>If legal proceedings commenced Banking Ombudsman will not consider complaint further and will advise both parties in writing.</p>	<p>Complainant is free to ask EGCC to stop work on complaint and/or take complaint elsewhere at any point in the EGCC consideration of the complaint. Complainant has right to reject Commissioners decision and pursue the complaint in other avenues, such as the</p>	<p>At any time complainant may choose to take complaint away from FSCL and pursue their rights in Court, but once you have done so it can not be brought back to FSCL. If dispute reaches determination stage, Complainant must elect whether or not accept recommendation in writing</p>	<p>TDR cannot consider a complaint that is currently being considered by Disputes Tribunal or other bodies. Complainants can pull out of the dispute process at any stage and take it through the court system or any other resolution body. If dispute reaches determination stage and the customer</p>	

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
			Disputes Tribunal. If the member is a state owned enterprise, the complainant may refer the complaint to the Office of the Ombudsman. The member may also pursue the complaint through disconnection, debt collection or the courts.	within one calendar month of the date the decision sent to Complainant. If accepts, Complainant is bound by all aspects of that decision.	accepts the determination, that determination is binding on the customer and scheme member. By accepting that determination the customer will be required to acknowledge that this is full and final settlement of the matter. If the customer does not accept the determination they retain their right to pursue the matter in another forum, such as the NZ courts.	
Time limits	Focussed on timeliness including various targets because conscious that advertising is very fast moving.	More than 50% of complaints are resolved within 3 months but more complex cases can take longer. Very occasionally, it may take more than a year to complete an investigation. Complainants are kept informed of progress.	Time limits for complainant, Member Company and Commissioner. Commission deals with most enquiries and complaints within 24 hours. Target to close 75% of cases within 90 working days.	Time limits but if gets to Panel stage, decisions "as soon as practicable".	Complaints through TDR can go through 4 levels each of which can take up to 15 days to a maximum of 70 days. Many complaints are resolved at an earlier stage in the process. Timeframes may be extended to help the resolution process.	Timeliness output measure is for 90% of : -routine Fair Trading (FT)/Credit Contracts and Consumer Finance (CCCF) investigations to be decided within 45 days. -substantial/complex cases FT/CCCF investigations to be decided within 9 months
Expert assistance and/or evidence	The ASCB determines whether the complaint will be determined by way of adjudication with attendance of parties, or without attendance of parties. Parties are free to seek legal and/or expert assistance. Lawyers with expertise for those "seeking legal advice on advertising with regards to the Codes of Practice of the ASA	Scheme is a free and informal alternative to going to court. Cases are decided by facts not on the way the complaint is presented. In most cases complainant should not need any legal or other expert assistance. If complainant decides to employ a professional then they will almost certainly have to pay these costs themselves and should not expect to get	Resolution relies on telephone and /or written communication not hearings. Complainants can use advisor(s), such as a support person or lawyer. Reimbursement of costs of a complainant using an advisor not normally awarded. If required Commissioner has in-house legal expertise and a technical advisory panel with particular knowledge of the	In the event of a hearing all parties are expected to attend. The Complainant may appoint a person to assist him or her but neither party shall be allowed legal representation except at the discretion of the CEO. If external legal representation is allowed for Participant, the Participant must pay the reasonable costs of legal representation for the Complainant. Any dispute	The TDR scheme is a free and informal alternative to the Disputes Tribunal, or the Court System, so lawyer is not needed.	Commission may take civil or criminal action against the business in question.

	Advertising Standards Authority (ASA)	Banking Ombudsman Scheme	Electricity and Gas Complaints Commission (EGCC)	Financial Services Complaints Ltd (FSCL)	Telecommunications Disputes Resolution (TDR)	Fair Trading, Commerce Commission
	or complaints to the ASCB” are identified on the ASA’s web site.	these costs back.	electricity and gas sectors.	about these costs will be determined by CEO. If the Panel holds a hearing Participant must meet Complainant’s reasonable costs of attendance including travel and accommodation.		

Appendix B. Complaints and Results

Table 12: Summary of Complaints and Outcomes From 2008

Complaint Reference Number	Complaint Description	Health Worker Complaint?	Date received	Complainant satisfied with response: Yes/No	Complaint 1st considered by Compliance Panel	Date Compliance Panel Decision	Date sent to Adjudicator	Date of adjudicator decision	Adjudicator decision	Complaint closed	Final decision
04-2008-01	Complaint about advert in pharmacy flyer (14 April to 11 May 2008)		15/04/08	No	26/08/08	12/12/2008	9/03/09	5/05/09	Quashed	Yes	
05-2008-02	Complaint about advert. in two pharmacy flyers		14/05/08	No	26/08/08	12/12/2008	9/03/09	5/05/09	Quashed	Yes	
06-2008-03	Advert in May 2008 magazine		10/06/08	No	26/08/08	12/12/2008					
07-2008-04a	Sponsored evening re. feeding options for women not fully breastfeeding		8/07/08	No	12/12/08	12/12/2008	9/03/09	7/05/09	Back to CP for redetermination at next meeting	No	Upheld
07-2008-04b	About a health worker presentation	Yes	8/07/08	No	12/12/08	11/08/2009	6/11/09	8/04/10	Quashed	Yes	
03-2009-01	Advert. in nurses' magazine		23/03/09	Yes							
03-2009-02	Advert. in nurses' magazine		23/03/09	Yes							
06-2009-03	Television advertisement		3/06/09	Yes							
10-2009-04	Advert for formula in supermarket flyer		22/10/09	Yes							
09-2010-01	Regarding pack including infant formula samples for mother of 6-week infant		10/09/10	No	9/11/10	9/11/2010					
09-2010-02	Complaint about an unnamed Practice Nurse	Yes	10/09/10	No	9/11/10	9/11/2010					
11-2010-03	Mailout (with sachet sample) about formula for all ages to a nurse		17/11/10								

Complaint Reference Number	Complaint Description	Health Worker Complaint?	Date received	Complainant satisfied with response: Yes/No	Complaint 1st considered by Compliance Panel	Date Compliance Panel Decision	Date sent to Adjudicator	Date of adjudicator decision	Adjudicator decision	Complaint closed	Final decision
11-2010-04	Follow-on formula advertisement.		18/11/10								

Appendix C. Search Strategy

Table 13: Search Terms and Sources for Literature Review

Search Term	Source	Criteria	Date
"self-regulation"	EconLit	All Text	
"self regulation" "government regulation"	EconLit	All Text	
"self regulation"	JSTOR > Economics, Finance Journals	All Text	
monitoring compliance "self-regulation"	JSTOR > Economics, Finance Journals	All Text	
"self-regulation" and signalling	JSTOR, JSTOR Arts & Sciences, LexisNexis Academic, ProQuest 5000, ProQuest Education, Science Direct: Subscribed Content, Wiley Interscience Journals, Worldwide Political Science Abstracts	Full Text + Subject	
signalling "self-regulation"	JSTOR > Economics	All Text	
compliance "self-regulation" Date >= 1995	JSTOR > Economics	All Text	
monitoring "self-regulation" Date >= 1995	JSTOR > Economics	All Text	
"dispute resolution" "self-regulation" Date>=1995	JSTOR > Economics	All Text	
"formal regulation" "self regulation" Date>=1995	JSTOR > Economics	All Text	
"dispute resolution" Zealand Date>=2000	Victoria University of Wellington Library Catalogue, Academic OneFile, Academic Search Premier, Australia/New Zealand Reference Centre, Digital Commons @ Victoria	All Text	
((("dispute resolution") AND (Zealand)) AND (regulation)) and Date >= 1995	JSTOR > Economics, Finance, Law, Political Science	All Text	
"Employment Tribunal" Zealand Date>=1995	JSTOR > Economics, Finance, Law, Political Science	All Text	
"Disputes Tribunal" Zealand Date>=1995	JSTOR > Economics, Finance, Law, Political Science	All Text	
"Banking Ombudsman" Zealand Date>=1995	JSTOR > Economics, Finance, Law, Political Science	All Text	
"World Health Organization" "International Code of Marketing of Breast-milk Substitutes"	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"World Health Organization" "infant formula" marketing	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"WHO Code" marketing	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"WHO code" compliance	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"WHO code" evaluation	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts,	All Text	From 2000 on

Search Term	Source	Criteria	Date
	ScienceDirect		
"WHO code" monitoring	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"WHO code" violations	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect	All Text	From 2000 on
"WHO code" Zealand	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, Sociological Abstracts, ScienceDirect, Australia/New Zealand Reference Centre, Index New Zealand	All Text	From 2000 on
"World Health Organization" "breast-milk substitutes" marketing compliance	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, LexisNexis Academic, Sociological Abstracts, Wiley Interscience Journals	All Text	From 2000 on
"World Health Organization" "breast-milk substitutes" marketing evaluation	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, LexisNexis Academic, Sociological Abstracts, Wiley Interscience Journals	All Text	From 2000 on
"World Health Organization" "breast-milk substitutes" marketing monitoring	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, LexisNexis Academic, Sociological Abstracts, Wiley Interscience Journals	All Text	From 2000 on
"World Health Organization" "breast-milk substitutes" marketing violations	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, LexisNexis Academic, Sociological Abstracts, Wiley Interscience Journals	All Text	From 2000 on
"World Health Organization" "breast-milk substitutes" marketing Zealand	Victoria University of Wellington Library Catalogue, JSTOR, JSTOR Arts and Sciences V Collection, LexisNexis Academic, Sociological Abstracts, Wiley Interscience Journals		From 2000 on
code substitutes marketing	www.who.int/en		From 2000 on
"economics of regulation"	JSTOR > economics	All Text	
theory of regulation	JSTOR > economics	Title	
"World Health Organization" "International Code of Marketing of Breast-milk Substitutes"	Google Scholar	All Text	From 2000 on
("World Health Organization" "infant formula" marketing) AND "2000"[Create Date] : "3000"[Create Date]	Pubmed (incl. MEDLINE)	All Text	From 2000 on
"World Health Organization" "International Code of Marketing of Breast-milk Substitutes"	Pubmed (incl. MEDLINE)	All Text	From 2000 on
"World Health Organization" "infant formula" marketing	Pubmed (incl. MEDLINE)	All Text	From 2000 on
"WHO Code" marketing	Pubmed (incl. MEDLINE)	All Text	From 2000 on

Search Term	Source	Criteria	Date
"WHO code" compliance	Pubmed (incl. MEDLINE)	All Text	From 2000 on
"WHO code" evaluation	Pubmed (incl. MEDLINE)	All Text	From 2000 on

Appendix D. Other Research Questions

The Ministry has asked for our comment on the following questions.

What would be the postulated effects of no implementation or monitoring of The International Code in New Zealand?

We respond to this question using the concept of equilibrium and to consider whether, under a hypothetical case of removal of implementation and monitoring of the Code in New Zealand, manufacturers might profitably deviate from a starting equilibrium in which the Code was generally adhered to, as broadly appears to be the case in New Zealand now.

Answering the question is complex because company behaviour, like most economic phenomena, depends on many factors, some of them capricious. We noted in section 6.8 that we have confidence that a fully self-regulatory regime will be effective because a number of aspects of the formula industry appear suited to producing compliance under self regulation, and we listed the various factors identified in the literature. An important qualifier in regards to our confidence in self-regulation in this particular case is that the Ministry of Health is able to credibly promise full regulation in the event of non-compliance under self-regulation. Such a promise is a low-cost means of generating compliance under self-regulation. Provided manufacturers believe misbehaviour will cause the imposition of a worse (for them) compulsory regime, compliance should in our view be reasonably expected given the structure and characteristics of the industry.

We can speculate on outcomes under pure self-regulation without the presence of a credible promise of full regulation from the Ministry for non-compliance. Consider the hypothetical first day of a new self-regulatory regime in New Zealand and a starting point of full compliance by manufacturers. Now imagine one firm decides to deviate from compliance, and runs advertising in contravention of the self-regulatory code of practice.

Is the deviating firm rewarded or punished for their misbehaviour? Many factors will decide this, and most are hard to predict in advance: the response of consumers both in New Zealand and overseas (the deviating firm is presumably a multi-national, multi-product firm), whether there is widespread understanding among consumers of what has occurred, and whether there is outrage. Do consumers, in New Zealand and overseas, buy more of the deviating firm's products, or less? The response of other manufacturers, suppliers and retailers is relevant. Do they expel the deviating firm from the industry body, refuse to supply the firm or distribute their products? Do they merely ask for better behaviour? Do they do nothing?

If the response to the deviating firm by consumers and other firms is to reward it with higher sales and punishments are insufficient to offset those sales, then other firms are likely to deviate as well, and quickly: they must, because the alternative is to see their misbehaving competitor capture the entire market. On the other hand, if consumers' response is to punish the deviating firm with fewer sales and reduced market share, then high compliance under self-regulation is likely to be achieved, at least initially.

Even if the initial response is to punish the firm for deviating, this may change over time. Standards and industry norms may slip, expectations among consumers may decline. Our reading of what occurred in the Philippines (see section 4.3.6) is that behaviour in equilibrium declined over time: each firm found it increasingly profitable to deviate ever further from a good-behaviour starting equilibrium, and as a result no firm could afford *not* to deviate. Equilibrium behaviour spiralled down, and full regulation was necessary to recover (and appears to have been successful). This is

reason for caution, but care should be taken to account for differences in circumstances between New Zealand and other countries. These differences are almost certainly relevant to compliance under self-regulation.

Deviation would be a major issue for a company, having previously and expressly agreed to the INC Code. A deviating firm could reasonably expect a global backlash from interest groups. The experience of Nestle and the boycott beginning in 1977 and continuing, in some quarters, today is relevant.⁸⁰ As noted earlier in this report, multi-national, multi-product producers of credence goods are vulnerable to brand damage because for these companies there is a strong relationship between reputation and sales. Under these conditions, the literature indicates self-regulation is likely to produce compliance at less cost than full regulation. The chance of producing compliance under self-regulation will be increased if a credible promise of compulsory regulation can be made should bad behaviour emerge. This is a low-cost but potentially effective way of enforcing compliance: the promise of regulation is sufficient to produce compliance without ever having to bear its substantial cost. Provided a credible response of full regulation should misbehaviour under self-regulation emerge, then we have confidence that firms will comply under a fully self-regulatory regime.

What are the risks to the current implementation and monitoring process of the Code in New Zealand?

If the CP continues to be viewed by some participants as not adhering to due process then the Ministry of Health may be exposed to risk of a substantial liability. In the qualitative review, one INC representative commented:

[W]e find that we're dealing with individuals who seem to not understand due process or even the legal risk they're putting themselves in. I think the way they're executing this, they, you know companies actually could have very strong legal grounds for suing the Ministry of Health for the way they've conducted a lot of these complaints and they have no awareness of this legal risk that they're carrying – INC Representative

What are the barriers and enablers to successfully implementing and monitoring The Code in New Zealand?

There may not be widespread awareness of the Code among health workers, possibly producing non-compliance with the Health Workers' Code in the form of alleged refusal among some health workers to provide information on formula feeding. Verifying whether this is true and identifying primary causes is a matter for further research.

There are some indications that Commerce Act constraint(s) may be the only barrier to agreement from manufacturers to an increase in INC Code to 12 months. These constraints might be relieved to the satisfaction of INC members by a letter of no action from the Commerce Commission, possibly clearing the way for an increase in the scope of the INC Code.

The INC Code and Health Workers' Code may perform an indirect function of producing industry norms in favour of breastfeeding. This has the effect that even among health workers who are not aware of the Code, such norms nevertheless produce substantial compliance, as these workers knew "breast is best". These

⁸⁰ See http://en.wikipedia.org/wiki/Nestl%C3%A9_boycott (accessed 25 March 2011).

norms may be thought of as enabling widespread effectiveness of Code implementation, even if direct knowledge of the Code is lagging.

Are there any specific New Zealand considerations, including cultural factors that should be explored (i.e. advice for Maori, Pacific and Asian populations)?

We received no comment as part of the qualitative review, or noted any issues in the reviewed literature, on cultural factors, and have no comment to offer on these matters.

Appendix E. Consent Form

The following letter was sent to all prospective interview participants:

20 September 2010

P.O Box 5013

Wellington

New Zealand

Dear Colleague

The purpose of this letter is to ask you if you would be willing to be interviewed by the Research Trust from Victoria University of Wellington (the Research Trust) about the marketing of breast-milk substitutes in New Zealand. This is in relation to the Ministry of Health's ("the Ministry") 2007 publication Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand (Ministry of Health, 2007). You can access this at <http://www.moh.govt.nz/moh.nsf/indexmh/breastmilksubstitutemarketingcode>.

The Research Trust is the independent third party contracted to undertake this work. If you agree to be interviewed please reply **by return email**, acknowledging that you have read this invitation and are happy to be contacted by the Research Trust.

You may be aware that the Ministry placed a Request for Proposal (RFP reference 29308) on the Governments Electronic Tenders Service in April 2010. This RFP was seeking proposals for an Information Gathering Exercise (the exercise) on The Code in New Zealand. Part of the exercise, is a qualitative interview component.

You are under no obligation to participate in the interview component. However, if you are willing to be interviewed, the process will work as follows:

1. I will pass your email details to the Research Trust (they have been contracted to interview a maximum of 30 individuals).
2. The Research Trust may contact you to arrange a convenient interview time. At this time they will forward the interview questions to you in advance of the formal interview (so that the dedicated interview time is maximized as you will have had time to consider your response). Interviews are due to commence on the 26 October and be completed by the 30 November 2010 and participants should set aside 40 to 60 minutes for the telephone interview.
3. All interviews will be recorded, transcribed, analysed, summarised (on an anonymous basis), securely stored and destroyed no later than 25 March 2011 by the Research Trust. The Research Trust will follow strict protocols consistent with Victoria University's privacy and ethical policies.
4. The anonymous interview summary will be included in a written report for the Ministry (due in the first quarter of 2011).

If you agree to participate initially and then need to withdraw from the interview, you may do so without question at any time before the scheduled interview by contacting the Research Trust.

I hope you are willing to be interviewed as the Ministry is looking for practical ideas to improve the implementation and monitoring of The Code in New Zealand.

If you would like to discuss this invitation further, please contact me on [phone] or [email]. Note, I am in the office Wednesdays, Thursdays and Fridays.

Yours sincerely

Barbara Hegan
Analyst
Nutrition & Physical Activity Policy

Appendix F. Questionnaire

The following questionnaire script was used for all interviews other than four pilot interviews, in which a slightly modified version of the script was used. ‘*’ indicates the questionnaire script called for the question to addressed only to a particular group or individual within a group: we have removed identifying information.

I am [interviewer name] your interviewer today on behalf of The Research Trust, Victoria University, Wellington.

1. As you are aware the Research Trust have been contracted by the Ministry of Health to interview 30 participants about the current implementation and monitoring of the *International Code of Marketing of Breast-milk Substitutes* as described in the Ministry’s 2007 publication *Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand (The Code in New Zealand)*.
2. Can you please confirm your name(s) and your organisation if applicable?
3. I expect this interview to take around 40-60 minutes and it will be:
 - temporarily recorded
 - then transcribed
 - the recording and transcription will be destroyed on completion of our report
 - in our report individuals will not be identified but organisations at a high level will (e.g. professional health groups, industry groups, consumer groups)
 - do you require a summary of the anonymous findings? Yes/No
 - if **yes**, we will retain your contact details until such time that our summary findings can be released,
 - you can withdraw your comments up to 10 days after this interview takes place which would be [date] by contacting me by email at: [interviewer email address],
 - can you confirm that you are happy to proceed with this interview?

F.1. Interview questions for Complainants

Complaints Process

How did you learn about The Code (if necessary: the International Code of Marketing of Breast-milk Substitutes)?

How did you find out about the complaints process? prompt – from the homepage/health worker/friend

How many complaints have you made since April 2008? (this is when the new Compliance Panel was appointed)

What was your complaint(s) about?

How did you lodge your complaint(s)? prompt – to who? How - by email/by mail?

What was the Ministry’s response to the lodgement of your complaint(s)? prompt – informative? timely? responsive? easy to understand?

Can you tell me about the response to your complaint(s) i.e. from the INC member &/or the health worker? prompt – informative? timely? easy to understand? ?

Could you suggest any improvements to the response step?

Did you ask for your complaint(s) to be referred to the Compliance Panel (the panel)?

If yes, what were your thoughts about the panel's decision? prompt - informative? timely? responsive? easy to understand?

Could you suggest any improvements to the panel step?

If no, why not?

Was the panel decision appealed?

If yes - by who? why?

What was the outcome of the appeal?

What did you think about the appeal decision?

What were your thoughts about the appeal process? prompt - informative? timely? responsive? easy to understand?

Could you suggest any improvements to the appeal process?

Outcome

How was your complaint resolved?

What did you think about the resolution of your complaint(s)?

Would you lodge a complaint again? If not – why not?

What would you estimate was the total time you spent on this complaint(s) i.e. from the time you lodged your complaint with the Ministry of Health, through to resolution i.e. number of hours/could you assign a monetary value to this estimate?

Could you suggest any improvements to the current complaints process? May not be required depending on earlier responses to each step in the current complaint process.

Did you lodge a complaint pre-2008?

If yes - how would you compare that complaint process to the current process?

Have you recently had interaction with one or more health workers about infant feeding advice in New Zealand?

If yes – did you feel that they had a clear understanding of the Code and their obligations under it?

Interview questions for Enquirers

How did you learn about The Code (if necessary: the International Code of Marketing of Breast-milk Substitutes)?

Process

How did you know to contact the Ministry of Health about your query?

What was your query about?

Are you aware there is a complaints process?

If yes - how did you find out about the complaints process? prompt – from the homepage/health worker/friend

If no – the link to the Ministry’s homepage on *The Code in New Zealand* is:
<http://www.moh.govt.nz/moh.nsf/indexmh/breastmilksubstitutemarketingcode>

Did you consider making a complaint? This question will depend on the query.

Have you ever made a complaint about either the infant feeding advice given by a health worker or the marketing of infant formula in New Zealand?

If yes can you tell me about your complaint(s) and resolution?

What did you think of the outcome?

Would you consider lodging a complaint in the future? If not, why not?

F.2. Interview questions for Complaint Recipients

Complaints and appeals data

What is your role in the administration of complaints relating to:

- The Ministry of Health’s Code of Practice for Health Workers (CP Chair and Adjudicator INC CEO as member of current Compliance Panel);
- The Infant Nutrition Council’s Code of Practice for the Marketing of Infant Formula (INC CEO and CP Chair and Adjudicator);
- Follow-on formula and/or toddler milk (ASA);
- Labelling, composition or quality of formula (NZFSA, now part of MAF).

Process

Please outline to me your internal procedure by which each complaint you receive is treated.

(if not already discussed) What is your policy on feedback – when and how do you contact the complainant/the responder to the complaint?

What would you estimate as an approximate cost of resolving a complaint?

What are you including/excluding in your estimate?

Can you provide a summary history of all complaints and decisions and if relevant, appeals, by email to me, for the years 2008, 2009 and 2010 or tell me where I could access this information?

Do marketers and manufactures monitor each other in regards to the advertising of infant formula?*

Are there examples of any breach in INC’s *Code of Practice for the Marketing of Infant Formula* being handled “in house” or “in industry” without resort to the Ministry of Health?*

What do you consider the strengths are of the INC *Code of Practice for the Marketing of Infant Formula* in New Zealand?*

What tools does the INC have at its disposal to enforce its rules?*

Do INC members threaten to withdraw from the INC?*

If yes, why?

How could compliance with the various Codes discussed in *The Code in New Zealand* be improved?

How does self-regulation work in practice from your perspective?*

F.3. Interview questions for INC Representatives

[Note: in this section, all references to “firm” means marketers and manufacturers of infant formula in New Zealand]

What are the functions of the INC?

Why is your firm a member of INC?

What are the benefits of membership in the INC?

What are the obligations and costs of membership in the INC? [prompt if necessary: referring to both financial costs and other costs like restraints of trade or greater scrutiny or higher compliance costs]

Are there marketers or manufacturers of infant formula in New Zealand who are not in the INC?

If yes: do you know if they comply with The Code? What sanctions do non-INC members face for non-compliance?

Does INC’s Code provide clear guidelines to your company for marketing infant formula?

How could the INC Code be improved?

Do you think some firms comply with *The Code* more than others? [prompt if necessary: and by “firms” I mean marketers and manufacturers of infant formula in New Zealand]

What potential sanctions from government do firms which are less compliant with the INC Code face?

What are the potential sanctions from the INC, or from other INC members, or from consumers, do firms which are less compliant with the INC Code face?

Does the INC constitution or rules provide for removal of a non-compliant member?

What sanctions have INC members actually suffered for non compliance with the INC Code? [prompt – this might include public shaming, censure by other members, expulsion from INC]

How seriously does your company take the threat of stronger government regulation and enforcement of *The Code*?

How costly would removal from the INC for non-compliance with *The Code* be for a member? [prompt: in lost reputation and lost business]

To your knowledge has removal from INC been threatened or actually occurred?

If yes – please elaborate

Do you know if INC members have threatened to withdraw from the INC?

If yes – please elaborate

Who is most active in monitoring compliance with *The Code* in New Zealand?

Do you know if formula marketers and manufactures monitor each other in regards to the advertising of infant formula?

If yes, how is any alleged breach against the INC’s Code handled?

In your view, would compliance with *The Code* in New Zealand occur without any government oversight?

If yes, why would compliance with *The Code* be in the interests of firms without government oversight?

In your view, do the public regulators' understanding, or lack of understanding, of your business affect the way they provide oversight? [prompt: by regulator I mean the Ministry of Health, ASA and NZFSA]

Complaints and appeals data since April 2008

How many complaints have been made about your organisation for alleged breach(es) to *the Code of Practice for the Marketing of Infant Formula* since the April 2008 appointment of the new New Zealand WHO Compliance Panel?

Can you describe how the complaint(s) was (were) resolved?

Have you used the appeal process since April 2008?

If yes – why?

What do you estimate it has cost your company to respond to each complaint and if applicable - appeal?

Can you provide some detail – i.e. what your estimate includes/excludes - staff time/legal fees?

What is your view of the current complaint process (including the appeal step) for handling alleged breaches to the *Code of Practice for the Marketing of Infant Formula*?

Internal Policy *

Can you outline your policy on marketing formula:

- made for infants less than 6 months formula?
- 6-12 months (i.e. follow-on formula)?
- 12+ months (i.e. toddler milk)?

How is your policy implemented and monitored?

Improvement

How would you improve the current complaint/appeal process for alleged breaches against the *Code of Practice for the Marketing of Infant Formula*? May not be required depending on earlier responses to each step of the current complaint process.

Who would pay for the improvements you recommend?

Aside from waiting for complaints – how else could compliance to the *Code of Practice for the Marketing of Infant Formula* be administered?

Do you know if there were any complaints lodged against your organisation pre-2008?

If yes - how would you compare that complaint process to the current process?

Self-Regulation

Are there examples of any breach in INC's *Code of Practice for the Marketing of Infant Formula* being handled "in house" or "in industry" without resort to the Ministry of Health?*

F.4. Interview questions for Health Workers and their Representatives

The Process

How did you find out about the complaint? prompt – from the Ministry of Health?

What was the complaint against you (your client) about?

The Ministry of Health manages the complaint process relating to alleged complaints about their *Code of Practice for Health Workers* and Infant Nutrition Council's *Code of Practice for the Marketing of Infant Formula*. Could you offer any suggestions as to how the Ministry could improve their role in the current complaint process?

I understand you were asked to respond to the complainant – how did you(your client) find this part of the process?

After the complainant considered your response, I understand the complainant asked for their complaint to be referred to the Compliance Panel (the panel) who upheld their complaint. After participating in the process could you suggest any improvements to the panel step? If yes – can you elaborate?

I understand you appealed the decision of the panel. How did you find the appeal process? Prompt – timely, informative

How could the appeal step be improved?

Outcome

What was the outcome of the complaint against you(your client) i.e. how was the complaint resolved?

What did you think about the resolution of the complaint against you(your client)?

Would you participate in this complaint process again?

If yes, can you tell me why?

If no, can you tell me why not?

What would you estimate was the total time you spent on this complaint, including lodging the appeal i.e. from the time you lodged your complaint with the Ministry of Health, through to resolution (i.e. number of hours)? What would you estimate to be the monetary cost of resolving the complaint?

In sum, could you suggest any improvements to the current complaints process? May not be required depending on earlier responses by health worker/representative.

Have you been involved in any other type of complaint process, in a professional capacity before? If yes- how did this complaint process compare?

The Code in practice

Do health workers understand their obligations and constraints under *The Code*? [prompt if necessary: Do health workers understand if and when they are allowed to talk about infant formula, and what advice they can and cannot offer?]

Do health workers comply with *The Code* requirements?

If yes, why? [prompt if necessary: believe in its value, threat of sanctions, protect personal or professional reputation?]

F.5. Closing (for all interviewees)

Final questions (all interviewees)

What is your overall impression of the current implementation and monitoring of *The Code* in New Zealand? prompts - working well – changes/improvements?

If not already discussed:

What changes in implementation and monitoring of *The Code* would you suggest?

Who would pay for the changes/improvements you suggest?

What organisation is best placed to administer complaints about infant formula advertising? Why do you suggest this?

The Health and Disability Commissioner's Office (HDC) has agreed in principle to handle complaints about health workers under the Ministry of Health's *Code of Practice for Health Workers*. What are your thoughts on this potential transfer of complaints about health workers to the HDC?

If not already discussed:

Do you know if there is any monitoring of *The Code* in New Zealand? If yes, can you tell me where I can access more information?

What do you think about the current marketing of infant formula in New Zealand?

What do you think about the infant feeding advice that's available to mothers/caregivers in New Zealand?

Would you like to make any further comments about the way the *International Code of Marketing of Breast-Milk Substitutes* is currently implemented and monitored in New Zealand?

All interviews

Can you suggest (refer us to) any organisation or individual who is interested in the marketing of infant formula and/or the advice about infant formula, in New Zealand that we should talk to, understanding that due to resource and time constraints we may or may not be able to contact them?

If you have any additional thoughts or comments on today's interview, please email me at: [interviewer email address]

May we contact you with follow-up questions if we have any?

Would you like the report sent to you when it is available?

Lastly, you have 10 days from today to withdraw your comments. If you chose to do this, please email me at: [interviewer email address] by [today's date +10 days]

Thank you for your support and time today.

Appendix G. List of parties/individuals who participated in interviews⁸¹

Table 14: Interview Participants

Category	Organisation
Complainant	Midwife
Complainant	
Complainant	
Complainant	Women's Health Action (WHA) now with IFANZ
Complainant	
Complainant	Maternity Services Consumer Council (MSCC)
Complainant	Waitemata DHB
Complainant	Nurse
Complainant	West Coast PHO
Complainant	Infant Feeding Association of New Zealand (IFANZ)
Complaint recipient	Chair, Compliance Panel
Complaint recipient	Adjudicator, Compliance Panel
Complaint recipient	New Zealand Food Safety Authority (NZFSA) official (now part of MAF)
Complaint recipient	Advertising Standards Authority (ASA) official
Enquirer	Dietitians New Zealand (formerly NZDA)
Enquirer	Nurse/midwife/lactation consultant
Enquirer	Breastfeeding advocate
Health worker	Health Worker and responder to complaint
Health worker	New Zealand College of Midwives (NZCOM)
Health worker	Plunket
INC member	Nestle
INC member	Infant Nutrition Council
INC member	Bayer
INC member	Nutricia
INC member	Wyeth
INC member	Heinz Watties
NGO	La Leche League (LLL)
NGO	New Zealand Lactation Consultants Association (NZLCA)
NGO	Women's Health Action (WHA)
NGO	New Zealand Breastfeeding Authority (NZBA)
Other	Health Worker's representative

⁸¹ Twenty-nine stakeholders were interviewed by telephone, one of which also provided a written response. Another two stakeholders responded solely in writing. The written responses were considered alongside the transcripts of the interviews.

Appendix H. Compliance Panel and Adjudicator Terms of Reference⁸²

Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand (including Terms of Reference for the Adjudicator for the Appeal Process) (Ministry of Health 2008)

Compliance Panel Name

WHO Compliance Panel for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand (the Code in New Zealand).(CP)

Objective

The overall objective of the CP, which was established by the Ministry of Health, is to contribute to the wider policy environment which supports the provision of safe and adequate nutrition for New Zealand infants. The CP is part of the complaints process for implementing and monitoring the Code in New Zealand.

Role of the CP

The role of the CP is to:

- make decisions on unresolved complaints relating to either the Code of Practice for Health Workers (Ministry of Health 2007) or the Infant Nutrition Council (INC) Code of Practice for the Marketing of Infant Formula (2007) (the codes)
- provide advice on appropriate action to remedy a breach of either code in New Zealand.

Role of the Adjudicator

The role of the Adjudicator has two parts: determining if what is alleged constitutes a legitimate ground for appeal; and (where required) determining (making a decision about) that appeal. The appeal process is detailed in Appendix 1.

Decision making principles

In making its decisions, the CP is expected to:

- properly apply the codes in consideration of complaints
- undertake rigorous debate and examination of the issues relating to the complaint
- make a reasoned decision in an open, fair and unbiased manner, based on the principles of natural justice
- when required seek further information before making a final decision (either from the Ministry of Health (the Ministry); health practitioners; INC; or others)
- ensure that all decisions reflect an appropriate balance between protecting the rights and well-being of consumers, of health practitioners, and INC members

⁸² Available from: <http://www.moh.govt.nz/moh.nsf/indexmh/breastmilksubstitutemarketingcode-compliancepanel-tor>
Accessed 12 December 2010.

- make all decisions and material relating to the decision available to the Adjudicator for ruling on an appeal, when required.

Duties and responsibilities as a CP member

The expectation of the Director of Public Health is that members operate in an effective manner within the parameters set out in these Terms of Reference (TOR).

General guidance

1. Members have a commitment to work for the greater good of the CP.
2. Members will make every effort to attend all meetings and devote sufficient time to become familiar with the affairs of the CP.
3. Members have a duty to act responsibly with regard to the effective and efficient administration of the CP and the use of CP funds.

Terms and conditions of appointment

Members have been appointed by the Director of Public Health for a term of office of at least three years.

The industry member is the Executive Director of the INC.

Any member may at any time resign by advising the Director of Public Health in writing. However, the resigning member should complete any complaints process where he or she is involved.

Any member may at any time be removed from office by the Director of Public Health (in his or her sole discretion) on grounds of misbehaviour, or incapacity to discharge the functions of his or her office.

The Director of Public Health may from time to time alter or reconstitute the CP, or appoint new members for the purpose of increasing the membership or filling any vacancies.

Composition of the CP

The CP has four members and an independent Chair. The CP consists of:

- one community/consumer representative
- the INC Executive Director
- one health practitioner
- one academic in a field related to infant and maternal nutrition.

The composition of the CP has been determined to ensure that the range of skills and expertise includes:

- an understanding of self-regulatory processes
- a working knowledge of meeting procedure and an understanding of due process
- knowledge of current scientific literature and the current evidence base relating to infant nutrition
- awareness of the WHO International Code of Marketing of Breast-milk Substitutes (1981)
- knowledge of The Code in New Zealand
- an ability to engage with colleagues for shared decision making

- an ability to exercise analytical and judgement skills, specifically when to seek external cultural or technical expertise
- knowledge of infant feeding practices including breastfeeding
- awareness of He Korowai Oranga and Whanau Ora
- awareness of different cultural contexts especially for Māori and Pacific peoples
- demonstrated links to ethnic minorities and/or to the disability sector
- demonstrated links to the community (including caregivers of infants)
- effective communication skills.

Chairperson

The independent Chair will work closely with the Secretariat (provided by the Ministry) to:

- ensure the agenda is prepared in time with appropriate input from the CP, where required
- ensure sufficient time is allocated in meetings for each agenda item to be adequately addressed
- ensure fairness in discussion amongst panel members
- ensure that key discussions/decisions are summarised
- ensure all decisions are clearly considered and actions are assigned in an agreed timeframe.

Conflicts of interest

1. Members must perform their functions in good faith, honestly and impartially and avoid situations that might compromise their integrity or otherwise lead to conflicts of interest. The CP is to perform its functions with a view to ensuring that it has the confidence of stakeholder groups.

2. Members attend meetings and undertake CP activities as independent persons responsible to the CP as a whole. Members are not appointed as representatives of professional organisations and groups, with the exception of the INC Executive Director. The CP should not, therefore, assume that a particular group's interests have been taken into account, with the exception of the INC Executive Director, because a member is professionally associated with that particular group.

3. When members believe they have a conflict of interest on a complaint, they must declare that conflict of interest and the Chair will decide what that person can contribute to the discussion and/or activity around consideration of that complaint.

Confidentiality and information sharing

1. The public has a right to be informed about the final decisions of the CP. The CP must follow its procedures regarding the release of final decisions and processing requests for information.

2. Members must observe the following duties in relation to CP information. These provisions ensure that the CP as a whole maintains control over the appropriate release of information.

- Meetings, including agenda material, notes and minutes, are confidential

- Members must ensure that the confidentiality of the CP is maintained and that CP documents are kept secure
- Members are free to express their own views within the context of the CP meetings
- Members must not publicly comment on decisions made by the CP
- The Director of Public Health requires advance notice of any media statements or adjuncts to reports to be published
- At no time should members individually divulge details of the CP or decisions of the CP to persons who are not part of the CP
- The provisions of the Official Information Act 1982 and the Privacy Act 1993 apply to information held by the CP, and CP information can only be released with the approval of the CP Chair on behalf of the CP, in consultation with the Ministry.

Performance Measures

The CP will be performing effectively when it provides relevant and timely decisions on unresolved complaints to the complainant and to the respondent and stays within its allocated budget.

Complaint timeline

The suggested timeline for processing complaints is:

- i. The complaint is received by the Ministry.
- ii. The Ministry has 20 working days from receipt of the complaint to invite the respondent to respond to the complaint.
- iii. The respondent has 20 working days from receipt of the complaint, to respond.
- iv. On receipt of the response, the Ministry has 20 working days to on-forward this to the complainant.
- v. The complainant has 20 working days from receipt of the response to advise the Ministry if they are not satisfied with the response and if they want the CP to consider their complaint.
- vi. If the complainant is not satisfied with the respondent's response and wants the CP to consider their complaint, the Ministry advises affected parties of that fact, and that the complaint will be considered at the next scheduled CP meeting.
- vii. The CP at its next meeting considers the complaint and either makes a decision, or seeks further information.
- viii. The CP secretariat sends written notification to the complainant and affected parties of the CP decision as soon as practicable.
- ix. All affected parties have 20 working days, from receipt of the CP written decision, to lodge an appeal as set out in Appendix 1.
- x. If no appeals are lodged after 20 working days from receipt of CP decision, the CP secretariat will initiate any action recommended by the CP.

Meetings of the Committee

Meetings shall be held at such times and places (including teleconferences) as agreed by the CP Chair, the majority of panel members and the secretariat.

The CP will agree on a quarterly meeting programme for the coming calendar year by no later than September of the preceding year. This is to ensure that unresolved complaints are considered within three months of lodgement.

At any meeting, a quorum shall consist of three members, including the CP Chair or the Chair's assigned deputy for that meeting.

Every complaint under consideration shall be determined by majority vote. Each panel member present (including the CP Chair) has one vote. Panel members not present or participating by teleconference, are not entitled to vote.

The CP must not publish any decision, until the appeal period has expired with no appeal lodged, or (where an appeal is lodged) the Adjudicator's decision has been made.

Correspondence arising from CP business will be drafted by the CP secretariat and reviewed by the CP Chair, on behalf of the CP. If changes are required these will then be made by the CP secretariat before the correspondence is sent to the recipient. All CP correspondence will be signed: Analyst XXXX, Secretariat for WHO Compliance Panel. Nutrition and Physical Activity Policy Team.

Subject to the provisions set out in these TOR, the CP may determine its own procedures.

Records and Reporting Requirements

The CP is required to keep minutes of all CP meetings including a clear record of any decisions or recommendations made about any complaint (secretariat to prepare minutes).

An annual report for the CP will be prepared by the secretariat. This will briefly summarise complaints and queries received in that calendar year.

Fees and Allowances

Members are entitled to be paid fees for attendance at meetings. Attendance fees are set in accordance with the State Services Commission's framework for fees for statutory bodies.

The Chair will receive \$430 per day. There is provision for an additional half day payment (\$215 per half day) for additional preparation and reading time, as determined by the Ministry. In addition, an additional allowance of an extra day per quarter for any other work undertaken by the Chair (if required), is available.

The attendance fee for members is set at \$320 per day. There is provision for an additional half day payment (\$160 per day) for additional preparation and reading time, as determined by the Ministry.

The INC Executive Director will be funded by the INC.

The Ministry will pay for actual and reasonable travel and accommodation (within New Zealand) for any expenses of members accrued on CP business, on receipt of supporting invoices, with the exception of the INC Executive Director.

The Adjudicator will be paid at a rate to be determined by the Ministry on a case-by-case basis. The Ministry anticipates that this remuneration is likely to be within the range of \$320 to \$430 per appeal.

Further information about the fees framework can be accessed at:

<http://www.dpmc.govt.nz/cabinet/circulars/co06/8.html>

Definitions

“Working day” means any day except a Saturday, a Sunday, Good Friday, Easter Monday, Anzac Day, Labour Day, the Sovereign’s birthday, and Waitangi Day; and a day in the period beginning on 20 December in any year and ending with 10 January in the following year.

Appendix 1

TERMS OF REFERENCE 2008

Adjudicator for WHO CP Appeal Process

Appeal process for Implementing and Monitoring the International Code of Marketing of Breast-milk Substitutes in New Zealand: The Code in New Zealand (the Code in New Zealand).

Role

The role of the Adjudicator has two parts: determining if what is alleged constitutes a legitimate ground for appeal; and (where required) determining (making a decision about) that appeal.

Any affected party can bring an appeal. Grounds for the Adjudicator accepting an appeal is where it appears that the CP, in making its decision:

1. did not follow a fair process based on the principles of natural justice
2. failed to take a relevant fact into consideration or took an irrelevant fact into account, or gave a relevant fact insufficient weight or
3. did not properly apply the relevant codes in its decision.

If there are grounds for an appeal, the Adjudicator may uphold, amend, or quash the CP decision. The Adjudicator may also refer the complaint back to the CP for re-determination.

Process for decision making

- The Adjudicator will receive all material relating to the CP decision that has been appealed
- The Adjudicator will undertake a rigorous examination of the material put before him/her in an open, fair and unbiased manner, based on the principles of natural justice
- The Adjudicator will determine whether one (or more) of the three grounds of appeal (set out in the preceding section) are established
- If the Adjudicator determines that there are established grounds for the appeal, he or she will consider the evidence (as presented to, and considered by, the CP) and decide whether the CP decision should be upheld, amended, quashed, or referred back to the CP for re-determination
- After receipt of the appeal, the Adjudicator has 30 working days to consider the grounds for the appeal, make a decision, and provide written reasons for his or her decision.

Any appeal is limited to the three grounds set out above. The Adjudicator does not consider new evidence, only the material that was considered by the CP.

Appeal process timeline

1. The CP secretariat sends written notification to the complainant and affected parties of the CP decision as soon as practicable.
2. All affected parties have 20 working days from receipt of the CP written decision to lodge an appeal.
3. If no appeals are lodged after 20 working days from receipt of CP decision, the CP secretariat will initiate any action recommended by the CP.
4. If an appeal has been lodged, no action (if required) will be taken apart from advising affected parties of the appeal, until the Adjudicator has considered the appeal.
5. After receipt of the appeal, the Adjudicator has 30 working days to consider the grounds for the appeal, make a decision, and provide written reasons for the decision.
6. The CP secretariat has 20 working days from receipt of the Adjudicator's written decision to inform affected parties and initiate any action recommended by the Adjudicator.
7. The Adjudicator's decision is final.