

Independent review of the MAIF Complaints Handling Process – Review Report

Department of Health

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1 Glossary

Throughout this document, the following terms have the meaning prescribed in the table below.

Term	Meaning
ACCC	Australian Consumer and Competition Commission
APMAIF	Advisory Panel on the Marketing in Australia of Infant Formula
FSANZ	Food Standards Australia New Zealand. FSANZ is a bi-national Government agency which develops and administers the Australia New Zealand Food Standards Code
INC	Infant Nutrition Council, representing industry members
MAIF Agreement	Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement
TEC	The Ethics Centre
WHO	The World Health Organisation
WHO Code	International Code of Marketing of Breast-milk Substitutes (WHO)

Executive Summary

When the Australian Government signed the WHO International Code of Marketing of Breast-milk Substitutes in 1981, it took on a responsibility for monitoring compliance with the Code. The Code aims to ensure safe and adequate nutrition for infants through protection and promotion of breastfeeding and by ensuring the proper use of breast-milk substitutes (when necessary) through adequate information and appropriate marketing and distribution.

Like New Zealand, (but unlike many other signatories) Australia chose not to legislate to require manufacturers and importers to comply with the Code. It was not until 1992, at the initiative of the industry, that the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) was developed as a voluntary, self-regulated code. Under the MAIF Agreement, the signatories voluntarily agree in essence not to promote formula as an equivalent alternative to breastmilk for children under 12 months old - through advertising, product distribution, education or other means. In 1992 there were six signatories to the Agreement – there are now fourteen, including all of Australia's major manufacturers and importers of infant formula.

1.1 The objective of this review

This independent review was commissioned by the Australian Department of Health in 2017 to examine the complaints handling process under the MAIF Agreement. The review was intended to inform Australia's current and future commitment to the WHO Code and to ensure best practice in the complaints handling process. In particular the review was asked to:

- assess the efficiency and effectiveness of the existing arrangements, including their scope and coverage
- understand stakeholder awareness and perception of the MAIF Agreement and Tribunal arrangements
- identify areas for improvement in the complaints process.

This review was conducted three and a half years after the complaints handling process underwent significant change: in 2013 the former Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF), which sat within Government, was disbanded and in 2014 the current independent Complaints Handling Tribunal was established. The timing of this review provided an opportunity to assess the effectiveness and the efficiency of the complaints handling process in light of this change, and identify opportunities for improvement to the end-to-end process.

The review drew on evidence from complaints data, a literature review and consultations with a broad range of interested stakeholders. An important context for the consultation process is that the voluntary, self-regulated nature of the MAIF Agreement does not sit well with breastfeeding advocates and other public health professionals consulted through this review. They hold a firm view that the Agreement does not go far enough and that voluntary regulation is not an effective means of compliance with the WHO Code. Their desire to see the Government step more heavily into regulation of its obligations under the WHO Code played out in the views of these stakeholders about the effectiveness of the complaints handling process.

1.2 The role of Government in the complaints handling process has varied over time

Until 2013 the Government played a key role in the monitoring of the MAIF Agreement through the Department of Health's role in the complaints handling process. From the outset, the Government took on the responsibility of setting up a mechanism to monitor industry's compliance with the Agreement and

determine whether a breach had in fact occurred. APMAIF was established as a non-statutory panel which monitored compliance with - and advised the Australian Government on - the MAIF Agreement.

The APMAIF used a collaborative process to determine breaches under the Agreement. Panel members were appointed by the Government and the secretariat sat within the Department of Health. Funding was initially shared by industry and government however in 2007 industry funding was ceased apparently due to the perceived conflict of interest. At that time the Department of Health became solely responsible for funding and managing the compliance process.

In 2013, the APMAIF was disbanded as part of a Government desire to remove 'red tape' regulation. While the Department maintained some of its previous functions in relation to monitoring compliance with the Agreement, it ceased other functions. This meant there was no longer a mechanism for the determination of breaches of the MAIF Agreement. The change in Departmental responsibilities is outlined below in Table 1.

Table 1: Changing Government responsibilities in complaints handling

Government role	Pre 2013	Post 2013
Maintain website with information on the MAIF Agreement and complaints process	✓	✓
Manage complaints lodgement process	✓	✓
Determine whether a complaint is in or out of scope	✓	✓
Establish and appoint body (APMAIF) to determine breaches	✓	
Report publicly on breaches and complaints statistics	✓	
House and staff secretariat	✓	
Fund the cost of the determining body and the secretariat	✓	

1.3 Industry set up an independent Tribunal to determine complaints

After a hiatus of some 12 months, the Infant Nutrition Council (INC), on behalf of the MAIF signatories, sought to fill the void by negotiating an arrangement with an independent body, The Ethics Centre, to establish and convene an independent non-statutory Tribunal to determine complaints. The task was complicated by the fact that industry would be funding the body it proposed to set up, and the perception of conflict of interest would need to be addressed.

The arrangement put in place between the INC and The Ethics Centre commenced in 2014 and is governed by a Terms of Reference determined at the sole discretion of The Ethics Centre. This review understands that the Terms of Reference have been under revision for the entire period of this review. The Terms of Reference and Tribunal have been explicitly excluded from examination by this review at the request of The Ethics Centre, given the Government's 2013 decision to opt out of the complaints determination role.

The Tribunal has been set up to be completely independent from industry influence. The head of the Ethics Centre is solely responsible for the appointment of the three Tribunal members. The Ethics Centre provides a secretariat function for the Tribunal.

Under the current arrangements, there are multiple communication and decision points. Complaints are lodged with the Department of Health, which determines whether they are in or out of scope of the Agreement, then passes them to the Ethics Centre and the Tribunal for final determination. In the period since 2013 there have been a total of 43 complaints made and 6 have been determined as in breach by the Tribunal. Of these breaches, 3 were for toddler milk advertisements and one company was breached twice for the same marketing activity.

1.4 Assessed against the key attributes of best practice regulation, the complaints process falls short

The review examined a number of sources that provide guidance on the key attributes of an effective and efficient complaints handling process. These included the WHO advice on implementation of the Code, ACCC guidelines for developing effective voluntary industry codes of conduct and the Australian and New Zealand Standard guidelines for complaint management. The key attributes of an effective complaints process drawn from this review are summarised below.

- ✓ Overarching responsibility for the complaints handling process should come from one single entity.
- ✓ Clearly identified end to end process.
- ✓ Clear communication of the complaints handling process to complainants and the public.
- ✓ Clear functional monitoring and enforcement mechanisms.
- ✓ Timely response and action taken from submission to resolution of complaints.
- ✓ Partnerships and cooperation with civil society and non-governmental organisations.
- ✓ Sufficient resources for effective operations.
- ✓ Documentation and reporting of Code violations.

Through stakeholder consultation the review found that many unsatisfactory aspects of the process have not changed from the findings of the 2012 Review of the MAIF Agreement. These include:

- **awareness and visibility** of the process – despite recent changes to the Department of Health website, there is room for improved information and access to lodging a complaint
- the **timeliness** from lodgement to determination and reporting has been extremely poor, with the Tribunal taking over 18 months to publish its first determinations
- The **transparency** of the process would be improved by more frequent real-time reporting. Industry signatories also expressed concerns about being kept abreast of the Tribunal's precedents.

The stakeholder consultation also found a significant difference of view between industry and public health stakeholders about the appropriateness of the consequences of a breach. Industry signatories appear to take the threat of a breach very seriously. Public health stakeholders, on the other hand, are cynical about the impact of a breach on industry behaviour.

The review has made a number of suggestions for improvement including:

- **More active education of consumers and health professionals as well as increased engagement with new market entrants**
- **Further improvement to the Department's website, with:**
 - **clearer information on the complaints handling process and easier navigation of the site**
 - **improved information on the role of the Tribunal**
 - **a simplified, well located and electronic complaints submission process and lodgement.**
- **Clear and realistic timeframes including the use of an on-line tracking system.**
- **Increasing the timeliness and frequency of reporting, including the publication of breaches on the Department's website as soon as determined.**
- **Providing the company subject to a complaint with an opportunity to respond prior to going to a formal hearing.**
- **Improved education about the impact of breaches on industry.**

1.5 The lack of overarching responsibility for the process militates against effectiveness and efficiency

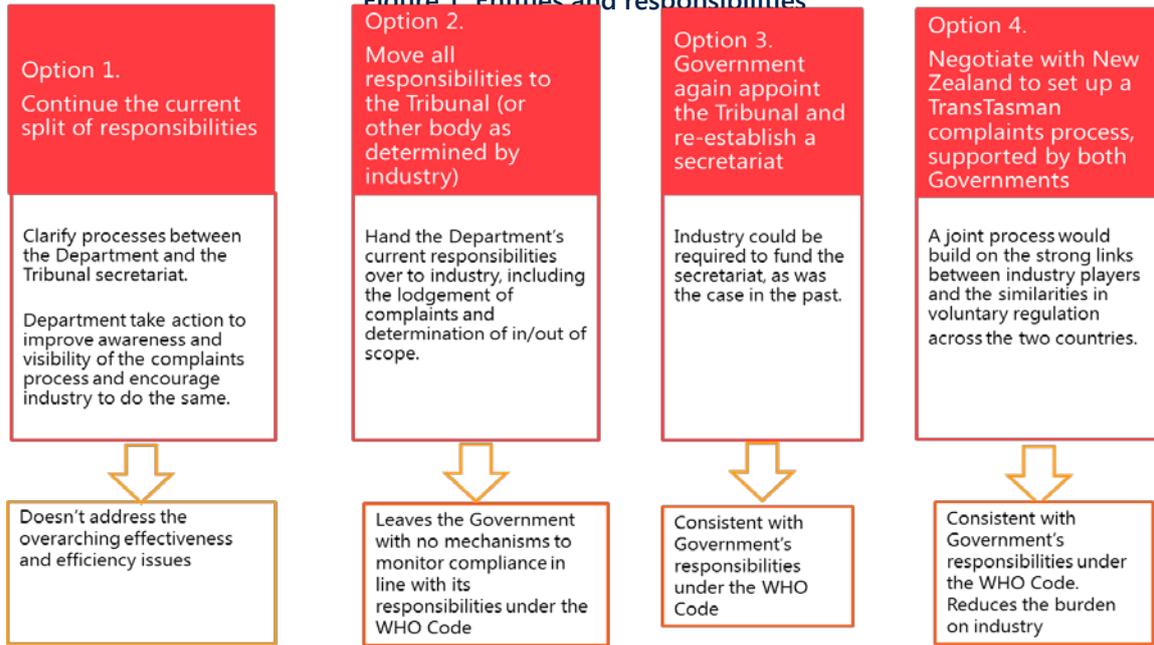
The current complaints process involves four entities: the Department, the INC, the Ethics Centre and the Tribunal. This disparate distribution of responsibility, coupled with the lack of an overarching mechanism for complaints handling, has resulted in a disjointed set of processes and decision-makers, with a lack of clarity between them. Key challenges emerging from this arrangement include:

- **inconsistency in reporting**, with no single source of truth – each entity across the complaints handling process has a discrete reporting methodology, which has led to inconsistencies in reporting of complaints data.
- **dissipation of corporate knowledge** across four entities – spreading responsibility for various aspects of the complaints handling process has weakened corporate knowledge about the MAIF Agreement and the complaints context.
- **no shared understanding** between the Department and Tribunal about their respective responsibilities for determining in and out of scope complaints
- a lack of certainty as to who – if anyone - **has responsibility for maintaining and updating guidelines**
- **an absence of a mechanism to facilitate collaboration** – the disjointed nature of the process has discouraged collaboration, and has acted as a barrier to some stakeholders participating in complaints determination.
- **a lack of institutional sustainability** of the third party – it is unclear what would happen to the process if the TEC decided to cease their involvement.

1.6 Options for improving the process

The review has found there are four possible approaches Government could take to improve the current disjointed complaints handling process. These are set out in Figure 1.

Figure 1: Entities and responsibilities



Option 1 would deliver minimal change, as it is limited to the actions the Department can take. On the other hand, Option 4 represents a new opportunity to reduce the burden on industry and on government by aligning the complaints process across both countries.

1 Introduction and context

The Department of Health (the Department) engaged Nous Group (Nous) to undertake an independent review of the complaints handling process under the Marketing in Australia of Infant Formula: Manufacturers and Importers Agreement 1992 (MAIF Agreement).

The review aimed to inform Australia's current and future commitment to the WHO's International Code of Marketing of Breast-milk Substitutes (WHO Code), and ensure best practice in the complaints handling process.

The objectives of the review were to:

- assess the efficiency and effectiveness of the existing arrangements, including their scope and coverage
- understand stakeholder awareness and perception of the MAIF Agreement and Tribunal arrangements
- identify areas for improvement in the complaints process.

The findings against each of these objectives are discussed in Sections 4 to 6.

This review was conducted three and a half years after the complaints handling process underwent significant change, following the abolition of the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF) and the establishment of the current Tribunal. The timing of this review provided an opportunity to assess the effectiveness and the efficiency of the complaints handling process in light of this change, and identify opportunities for improvement to the end-to-end process.

The review drew on evidence from complaints data, a literature review and consultations with a broad range of interested stakeholders. A summary of the consultation findings is presented in a separate report, the Consultation Summary Report, July 2017. As the final report in the complaints handling process review, this report covers Nous' analysis of the effectiveness and efficiency of the arrangements, stakeholder awareness and our findings in relation to areas for improvement.

1.1 The MAIF Agreement is Australia's response to the WHO Code

In 1981, the World Health Organization introduced the *International Code of Marketing of Breast-milk Substitutes* (WHO Code) as part of the effort to improve child and maternal health. The Code aims to ensure safe and adequate nutrition for infants through protection and promotion of breastfeeding and by ensuring the proper use of breast-milk substitutes (when necessary) through adequate information and appropriate marketing and distribution. The Code provides a model set of recommendations for the marketing (and related practices) of breast milk substitutes, and other milk products, foods and beverages.

Implementation and enforcement of the WHO Code varies globally. Whilst some countries have introduced legislative enforcement of all Articles under the WHO Code, other countries (including the USA, Canada and Germany) have partially implemented the WHO Code through a mixture of legislative and voluntary regulation.

New Zealand has adopted a similar voluntary regulatory arrangement as Australia – although in New Zealand, the Ministry of Health has maintained responsibility for monitoring the implementation of the Code. Implementation in New Zealand is through two relevant voluntary codes: the Code of Practice for Health Workers and the Infant Nutrition Council Code of Practice for the Marketing of Infant Formula in New Zealand.

Australia signed the WHO code in 1981, however, it was not until 1992 that the *Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement* (MAIF Agreement) was developed at the initiative of industry as a voluntary code. The Agreement was developed by the Australian government, the infant

formula industry, breastfeeding advocates and other stakeholders and was implemented in 1992. The Australian Trade Practices Commission participated in discussions with industry and consumer groups on the implementation of the WHO Code in Australia, and authorised the MAIF Agreement on its inception. The basis of the authorisation is that the anti-competitive aspects of the MAIF Agreement (such as the restrictions on advertising) are outweighed by the public benefits. The full WHO Code could not be adopted because of Australia's competition laws.¹

The MAIF Agreement is a voluntary, self-regulated agreement between the signatories to the Agreement. The signatories voluntarily agree to abide by a set of standards for the advertising of infant formulas in Australia. In essence the signatories agree not to promote formula as an equivalent alternative to breastmilk for children under 12 months old, through advertising, product distribution, education or other means. The Agreement does not apply to toddler milk drinks suitable from 12 months, complementary foods and feeding bottles and teats.

While the MAIF Agreement acts as Australia's primary method for implementing the WHO Code, it is complemented by a range of other mechanisms, including regulations, guidelines and education and awareness strategies that promote breastfeeding and reduce the inappropriate use of formula. These include the Infant Feeding Guidelines for health workers and labelling laws relevant to infant formula.

In 1992 when the Agreement was first signed, there were six signatories². As at July 2017, there were fourteen signatories to the Agreement. This includes all of Australia's major manufacturers and importers. Current signatories are listed at Appendix F. All but one of the signatories are members of the Infant Nutrition Council (INC) which acts as the industry body in relation to the MAIF Agreement.

Following some minor changes to the Agreement it was re-authorised by the ACCC in July 2016 for a further five year period³. This authorisation provides signatories with statutory protection from prosecution under the *Competition and Consumer Act 2010*.

1.2 The role of Government in the complaints handling process has varied over time

As a signatory to the WHO Code the Australian government under Article 11 of the Code has an obligation to monitor compliance with the application of the WHO Code in Australia i.e. the MAIF Agreement.

WHO Code Article 11

11.1 Governments should take action to give effect to the principles and aim of this Code, as appropriate to their social and legislative framework, including the adoption of national legislation, regulations or other suitable measures.

11.2 Monitoring the application of this Code lies with governments acting individually and collectively through the World Health Organisation as provided in paragraphs 6 and 7 of this Article. The manufacturers and distributors of products within the scope of this Code, and appropriate nongovernmental organisations, professional groups, and consumer organisations should collaborate with governments to this end.

¹ Advice provided by the INC

² Advice provided by the INC

³ In 2007 Nestlé Australia sought a variation to the original authorisation to provide for the addition of future parties to the MAIF Agreement; and the introduction of an 8-10 year time limit on the authorisation to allow for more regular review. This was granted by the Australian Competition and Consumer Commission (ACCC) on 30 August 2007.

From the outset, the Australian Government took on the responsibility of setting up a mechanism to monitor industry's compliance with the MAIF Agreement and to determine whether a breach had in fact occurred. The Government put in place a complaints lodgment process and set up the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF).

The APMAIF was a non-statutory advisory panel which monitored compliance with - and advised the Australian Government on - the MAIF Agreement. The APMAIF used a collaborative process and had an independent chair and included an industry representative, nutritional expertise and a consumer representative associated with the Australian Breastfeeding Association. Panel members were appointed by the government at first by the Minister for Justice and Consumer Affairs and later by the Parliamentary Secretary for Health.

In 1998, the MAIF signatories and the Treasury, who at the time provided APMAIF secretariat services, both funded the APMAIF expenses⁴. When the APMAIF secretariat moved to the Department of Health in 2001, this funding arrangement still continued informally. In 2007 industry involvement in directly funding the APMAIF was discontinued, apparently because it was seen to be a conflict of interest, and the Department of Health became solely responsible for funding the compliance process.

Government funding of APMAIF continued for approximately 6 years. Then in 2013, the APMAIF was disbanded as a response to a Government desire to remove 'red tape' regulation. At that point the Government ceased to support the APMAIF and there was no longer a mechanism for the determination of breaches of the MAIF Agreement.

1.3 The Complaints Tribunal is now managed by The Ethics Centre

After the disbandment of APMAIF, no complaints determination body was in place for approximately one year. During that time the Infant Nutrition Council (INC), on behalf of the MAIF signatories, sought to fill the void by putting in place a body that could determine complaints. The INC represents the major manufacturers and marketers of infant formula in Australia and New Zealand. INC members and associate members are responsible for the manufacture of over 95% of the volume of infant formula sold in Australia and New Zealand. The INC assists members to meet regulatory requirements.

The INC has advised this review that it that approached the Australian Breastfeeding Association inviting discussion of a proposed model and seeking to continue their involvement in the MAIF Agreement compliance monitoring process. The ABA did not respond.

The task of the INC was complicated by the fact that it would be funding the body it proposed to set up, and the perception of conflict of interest would need to be addressed.

The INC approached the St James Ethics Centre (now The Ethics Centre) to establish and convene an independent and credible complaints handling process for the MAIF Agreement. The Ethics Centre agreed to do this under certain conditions. It required that:

- The process was to be established and managed according to Terms of Reference determined solely by the Ethics Centre
- Funding of the process will be by industry (signatories to the MAIF Agreement) in an unrestricted form (retainer) that ensures operational independence to the Ethics Centre in the operation of the Tribunal, and is of an amount sufficient to fund the effective operation of such a body

⁴ The review was not able to source any information of how the complaints process was funded prior to 1998

- The Ethics Centre will establish the service so that the deliberations of the Tribunal are free from influence by any other organisation, including the Ethics Centre.⁵

From November 2014 the Ethics Centre (TEC) took on the responsibility of setting up the MAIF Complaints Tribunal and acting as its secretariat. The arrangement between the INC and the TEC provides in the broad that the TEC will receive and investigate “in-scope” complaints regarding the marketing in Australia of infant formulas; and develop guidelines on the interpretation and application of the MAIF Agreement.

The Tribunal is a non-statutory dispute resolution body appointed by the head of the Ethics Centre. There are three Tribunal members with extensive experience in the legal, health professional and child advocacy sectors.

The Terms of Reference negotiated by the INC and TEC provide that:

- all proceeds will be in accordance with the principles of natural justice
- Tribunal members will be the sole determinants of any complaints, as determined by the evidence presented by the Secretariat
- the Tribunal shall publish reasons for determinations
- complaints will be lodged with the Department of Health who will initially assess complaints and forward to the Tribunal if they are deemed in scope.⁶

The Terms of Reference then set out the complaints handling and appeals process, with timeframes.

The Ethics Centre is currently revising the Terms of Reference in negotiation with the INC and the industry signatories. The new Terms of Reference were expected to be finalised by July 2017 but had not been finalised by the time of this report. A copy of the latest available version is provided for information at Appendix E.

The matters covered by the Terms of Reference in setting up the Tribunal were explicitly removed from the statement of requirement for this review. Given that the Government has opted out of the determination of complaints, the Ethics Centre takes the view that the Terms of Reference are a matter between the INC (representing industry signatories) and The Ethics Centre, and could not be considered as part of a review commissioned by Government.

1.4 The current complaints handling process has multiple steps

The current complaints process involves a number of steps, carried out by the Department of Health, the Tribunal Secretariat (TEC) and the Tribunal itself. This process is shown below at Figure 2. Since preparation of this report, the Tribunal has published a new flow chart with timeframes, attached to its latest revised Terms of Reference. However it is understood that this is not yet finalised.

To meet the government’s obligations under Article 11 of the WHO Code, the Department maintains responsibility for the complaint lodgment information and lodgment form on its website. The form is available for download on the website. Interested parties, such as breastfeeding advocacy groups, health professionals and members of the public monitor compliance with the Agreement and submit alleged breaches to the Department via telephone, email or post.

On receipt of a complaint the Department determines whether the complaint is in scope and if so, sends it to the Tribunal secretariat. If the Department decides that a complaint is out of scope, it writes to the complainant, acknowledging their complaint and advising that it is out of scope. An out of scope decision

⁵ MAIF Agreement Complaints Tribunal Terms of Reference 2013

⁶ MAIF Agreement Complaints Tribunal Terms of Reference 2013

may be due to it relating to a non-signatory or not falling within the scope of the Agreement e.g. toddler milk advertising.

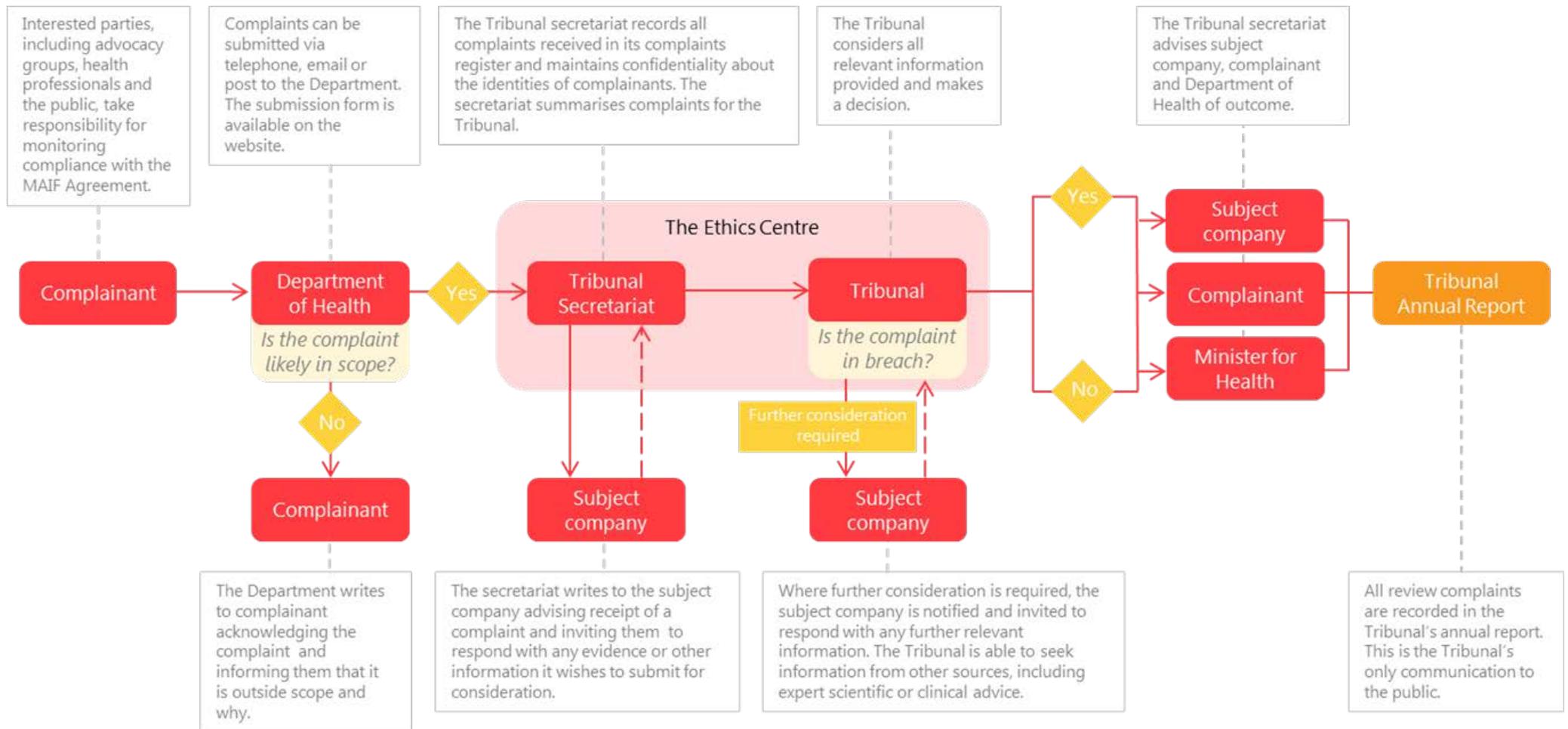
The Tribunal secretariat records the details of all complaints received from the Department and organises the documentation required for the Tribunal to make decisions about potential breaches. This involves summarising all complaint details. The Tribunal secretariat then invites the subject company to respond with any evidence or other information it wishes to submit for consideration.

The Secretariat then arranges for the Tribunal to meet to decide whether a signatory has breached the MAIF Agreement. If further consideration is required, they may contact the subject company. When investigating alleged breaches, the Tribunal has no formal powers to obtain information about a complaint and relies on voluntary cooperation from the parties to the MAIF Agreement and on other stakeholders.

If the complaint is deemed in breach then the secretariat informs the subject company, complainant and Department of Health of the outcome. If the complaint is not in breach then only the subject company and complainant will be informed. All reviewed complaints, whether deemed in breach or not in breach, are included in the Tribunal's annual report.

The annual reports for 2014-15 and 2015-16 are available on the Department of Health and the INC's websites.

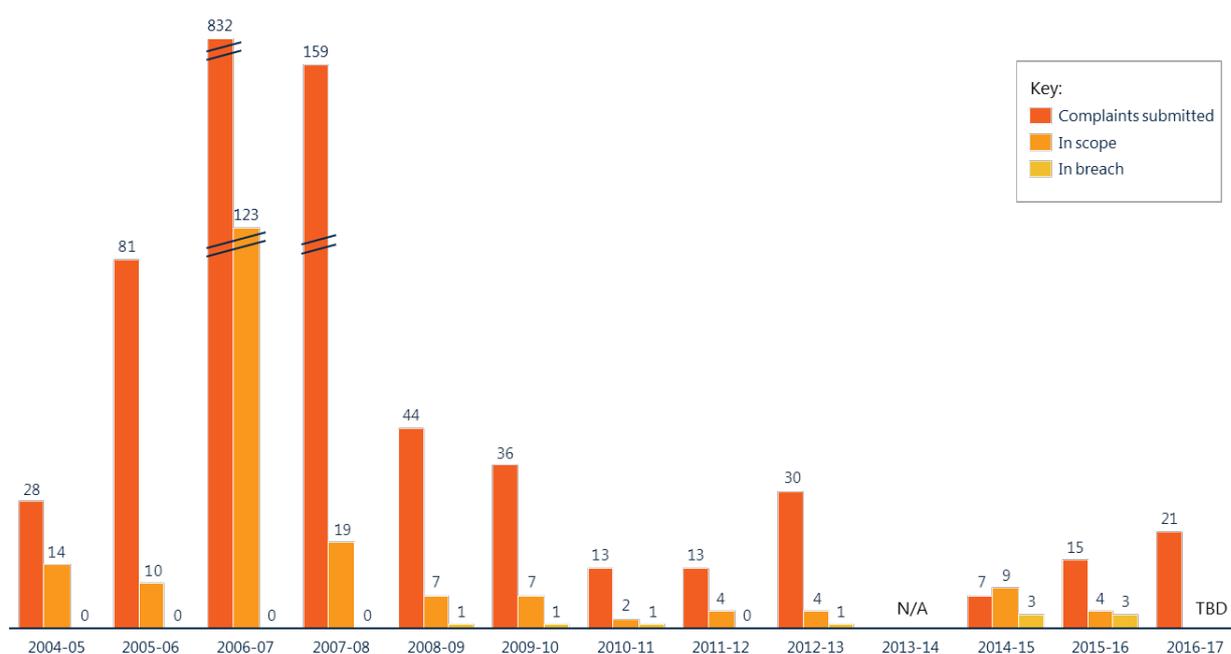
Figure 2: Overview of the MAIF complaints handling process



1.5 The volume of complaints has fluctuated but remains small

Throughout the history of the MAIF Agreement, the annual number of complaints has remained small, with an average of 35 complaints a year under APMAIF and 14 complaints under the Tribunal arrangements. This excludes 2006-07 and 2007-08 where 832 and 159 complaints were received respectively. Anecdotal evidence suggests that this spike was as the result of a campaign to test the complaints process. Figure 3 shows the fluctuations since 2004-05. The previous APMAIF complaints statistics are available in Appendix D.

Figure 3: Complaints submitted, deemed in scope and in breach



Since the former APMAIF was disbanded, complaints statistics have been maintained separately by both the Department and the Tribunal and are not in alignment. This issue is discussed further in section 5. The information presented here is drawn from the Tribunal's Annual Reports.

Since the establishment of the Tribunal in 2014 there has been a slow rise in the number of complaints submitted, with 21 submitted to the Department in 2016-17. According to the Tribunal's Annual Reports, the Tribunal received nine complaints determined as in-scope from the Department in 2014-15, which includes the complaints submitted to the Department in the period between the disbandment of the APMAIF and the establishment of the Tribunal and cover a period of 18 months. The Tribunal received 4 complaints from the Department in each of 2015-16 and 2016-17.

While the number of complaints submitted has declined since the disbandment of the APMAIF, the number of complaints decided to be in breach of the MAIF Agreement has increased under the Tribunal. Over its nine years of operation, the APMAIF received 1,236 complaints and decided that four were in breach of the MAIF Agreement. In comparison, in its first two years of operation, 22 complaints were submitted and the Tribunal decided that 6 were in breach. Of these breaches, 3 were for toddler milk advertisements and one company was breached twice for the same marketing activity.

The complaints statistics since 2013 are set out in Table 2 below.

Table 2: Tribunal Complaints Statistics

	2013-14 ⁷	2014-15	2015-16	2016-17
Number of MAIF Agreement signatories	-	7	10	14
Complaints submitted to the Department	-	7	15	21
Out-of-scope (Department decision)	-	N/A	11	17
Complaints received by Tribunal	-	9 ⁸	4	4
In breach	-	3	3	TBA

⁷ Statistics for 2013-14 are unavailable as this was the period when APMAIF was disbanded and the Tribunal was set up.

⁸ Includes complaints received in 2013-14 prior to the establishment of the Tribunal.

2 Our review methodology combined desk top research with interviews and an online survey

This section provides an overview of the key lines of enquiry and methodology used for undertaking the review.

These lines of enquiry were as follows:

1. How effective and efficient is the complaints handling process?
1. How fair, timely and transparent is the complaints handling process?
2. What changes should be made to improve the complaints handling process?

Each key line of enquiry was supported by a series of guiding and research questions which are shown in Appendix A.

The review methodology focused on three main data sources, each of which is outlined below.

2.1 Literature review

This provided insights into how the WHO Code is implemented overseas, the effectiveness of voluntary industry regulation, and what the complaints handling process looks like in overseas jurisdictions. As part of this, the review documented the relevant and useful guidelines to complaints handling processes, from the 'AS/NZS 10002:2014 Australian/New Zealand Standard™ Guidelines for complaint management in organisations' (the Standard) provides. Findings from the literature review are largely discussed in Section 3 of this report. The full Literature Review can be found at Appendix G.

2.2 Existing data

A review of the existing data provided some quantitative insights about the number of complaints, the number of complaints considered in and out of scope, and the number of breaches committed by signatories.

2.3 Consultations

During the review, Nous used two types of stakeholder consultation activities – individual interviews and an online survey. This ensured that all stakeholders were able to share their views with confidence and allow fair representation of perspectives. All responses have been kept confidential with the results attributed to stakeholder groups, as well as some key individual stakeholders. The interview and survey participants included a mix of stakeholders who had lodged complaints, been the subject of complaints or been involved with delivering the complaints process during the APMAIF and/or current Tribunal process. A report on the stakeholder consultations has been provided separately with a list of the stakeholders provided at Appendix B.

2.4 Interviews

Nous conducted 20 interviews in-person and via teleconference from 23 May to 19 July 2017.

2.5 Online survey

The online survey was open from 12 June to 30 June 2017 and received 180 responses. The survey was publicly available on the Department of Health website and distributed through key stakeholders including industry stakeholders, health professionals and organisations. Nous also provided interviewees with the survey to input any additional views and share it with other relevant stakeholders within their organisations or networks. Nous also offered survey respondents the opportunity for a follow up interview, with an additional five interviews being conducted with consumers and health industry representatives.⁹

The key lines of enquiry guided the development of the survey questions which included Likert scale and open response questions. The survey primarily focused on understanding community levels of awareness and collected high level perspectives about the current operations and future areas for improvement.

The survey provided the opportunity for any interested stakeholders, who otherwise would not be interviewed or be available for an interview, to participate in the review. Of the respondents, only about 4 respondents (about 2%) were from industry. The remainders were largely health professionals, breastfeeding advocates or consumers (70%). Of the total respondents, approximately 32% had lodged a complaint.

The full details of the survey are found in the Consultation Summary Report which is attached separately.

⁹ As above

3 The review examined what constitutes an effective complaints process

In order to determine the key characteristics of a good complaints handling process in a voluntary, self-regulated environment, the review investigated a number of guidelines and best practices. This included the WHO advice on implementation of the Code, ACCC guidelines for developing effective voluntary industry codes of conduct and the Australian and New Zealand Standard guidelines for complaint management. Best practice examples of complaints handling mechanisms were also examined. The full literature review outlining these can be found at Appendix G.

3.1 The WHO recommends three key elements for successful implementation

The implementation of the WHO Code is the responsibility of individual signatory governments who can take action appropriate to their social and legislative framework.

In the *'Country Implementation of the International Code of Marketing of Breast-milk substitutes: Status Report 2011'*, the WHO recommends the following elements for successful implementation:

- **Functional monitoring and enforcement mechanisms** to strengthen implementation, enforcement, monitoring and sanctions. Without this, weak or lack of appropriate laws, implementation, sanctions and monitoring results in systematic violations and aggressive marketing.
- **Partnerships with civil society and non-governmental organisations** to help governments in advocating for the enactment, implementation, enforcement and monitoring of the Code, as well as providing practical and community level breastfeeding support. Cooperation from food manufacturers, distributors, health-care professionals, non-governmental organisations and consumer groups is essential in implementation of the WHO Code and in protecting, promoting and supporting breastfeeding.
- **Documentation and reporting of Code violations** for effective tracking, compilation and systematisation of information and evidence needed for future action and advocacy

3.2 The ACCC provides guidelines for voluntary industry codes of conduct

The Australian Competition & Consumer Commission (ACCC) is Australia's competition regulator and national consumer law champion. According to the ACCC, well designed, effectively implemented and properly enforced codes can improve consumer protection and reduce industry regulatory burdens. Conversely, ineffective codes may result in unnecessary compliance burdens on business and even reduce market competition.

The ACCC provides 'guidelines for developing effective voluntary industry codes of conduct'. These guidelines highlight key areas of focus to ensure effective implementation of the WHO Code and state that voluntary industry codes of conduct tend to be more effective when the self-regulatory body:

- has **widespread support** of industry
- comprises **representatives of the key stakeholders**, including consumers, consumer associations, the government and other community groups
- operates an **effective system** of complaints handling.

Specific to effective complaints handling, the ACCC recommends that the code incorporates the following:

- a **definition of complaint** that includes any expression of dissatisfaction with a product or services offered or provided
- a procedure whereby **complaints should first be considered by signatories** to the code
- if the signatories cannot resolve a complaint it should be lodged with the **administration committee or an independent decision-maker** appointed by the committee
- **performance criteria** for effective complaints handling.

3.3 The AS/NZS 10002:2014 Australian/New Zealand Standard™ provides guidelines for complaints management

The 'AS/NZS 10002:2014 Australian/New Zealand Standard™ Guidelines for complaint management in organisations' (the Standard) provides relevant and useful guidelines to complaints handling processes. Although the Standard is a guide to complaint management within an organisation, it still contains many relevant structures and procedures which are applicable to industry-wide complaints handling processes and hence for the MAIF Agreement. The key relevant complaint management system recommendations from the Standard are outlined below.

3.3.1 Complaints handling bodies need to consider their role in the existing environment

This may include existing statutory or regulatory requirements, the value of the complaints process, the number and demographics of customers, the nature and breadth of public interaction, the number and type of complaints received, and input from staff and other stakeholders.

3.3.2 Communication of the process should be clear to complainants and the public

A complaints handling body should ensure that its complaint management policy, processes and outcomes informs and is consistent with its communication, public relations and media activities. Information about the complaints process should be readily available and accessible to the public. This includes being written in plain English and provided in a range of formats and languages. The complaint management policy should be accessible from the relevant website homepage, at a reception area of any relevant physical location, and in leaflets, newsletters or other relevant media generated by the complaints handling body.

Public information about the complaint management system should include:

- where, how and when complaints can be made
- what information should be provided by the complainant
- the organisation's process for handling complaints including acknowledgement of receipt and redress
- time periods associated with various stages in the process and how the complainant can obtain feedback on the status of their complaint.
- issuing a unique identifier, with key information on the complaint and the mechanism to track the complaint to resolution.

3.3.3 Sufficient resources is vital for effective operations

Throughout the complaints handling process, it is important to have adequate resources, including adequately trained staff, materials and equipment.

3.4 Best practice in complaints handling for self-regulated bodies

One relevant case study of best practice is the Advertising Standards Bureau (ASB). The ASB successfully follows many of the key guidelines outlined by the ACCC. It has clear overarching responsibility, reviews complaints in a timely manner, has an independent Board, and widespread support of industry. The ASB process is explored in detail in the below case study.

Best practice case study 1: Advertising Standards Bureau has widespread industry support, is timely and has an effective complaints handling process.

The self-regulation of advertising in Australia has occurred for over 40 years. The Association of National Advertisers (AANA) set up the current system in 1997 and the Advertising Standards Bureau (ASB) administer the complaints system that underpins the various Codes and ensures achievement of the Code objectives. In 2015, the ASB received 4,430 complaints and the proportion of advertisements found to breach the Codes was 17%. The ASB has a record of nearly 100 per cent compliance by industry with decisions of the Board.

One key area of success for the ASB is their timely review of cases. In 2015, the average time from a submission of a complaint to the publication of the final case report was 36.5 calendar days.

The Board is set up to be independent from industry, government and consumer lobby groups, and representative of the diversity of Australian society. The Board is unaware the method of funding of the complaints system which ensures that decisions are made without influence.

Furthermore, the majority of advertisers found to have breached a Code quickly remove or modify the advertising subject to complaint. In the case that the advertising does not comply, the ASB can take further action. If the advertising has breaches government regulation or law, the case can be referred to an appropriate government agency or industry body. The ASB can also liaise with industry and media bodies which will either negotiate with the advertiser direction or take action to remove the advertisement. ASB will always publish an advertiser's failure to respond in the final case report which is made public on the ASB website which is an incentive to act to avoid brand reputational damage.

3.5 An effective complaints handling process within an environment of self-regulation has key characteristics

Based on the research presented above, the review has found that an effective complaints handling process within an environment of self-regulation has the following characteristics:

- ✓ **Overarching responsibility for the complaints handling process should come from one single entity.**
- ✓ **Clearly identified end to end process.**
- ✓ **Clear communication of the complaints handling process to complainants and the public.**
- ✓ **Clear functional monitoring and enforcement mechanisms.**
- ✓ **Timely response and action taken from submission to resolution of complaints.**

- ✓ Overarching responsibility for the complaints handling process should come from one single entity.
- ✓ Partnerships and cooperation with civil society and non-governmental organisations.
- ✓ Sufficient resources for effective operations.
- ✓ Documentation and reporting of Code violations.

4 Many aspects of the complaints handling process could be improved

The review has found that aspects of the complaints handling process remain less than optimal, particularly when measured against best practice as described in Section 3. The review also found that many of these aspects have not changed from the findings of the 2012 Review of the MAIF Agreement.¹⁰ These include:

- **Awareness and Visibility** – awareness and visibility of the complaints handling process remains less than optimal. Under current arrangements, responsibility for improvement of visibility primarily rests with the Department as the body responsible for adherence to the WHO Code, but is shared to some degree by the Tribunal and industry.
- **Timeliness** – the timeliness of the complaints process is still under revision through the Tribunal's Terms of Reference review however all stakeholders were concerned that the process is not timely. Industry has been active in attempting to push the Tribunal to improve in this respect. Responsibility for improvement of timeliness predominantly lies with the Tribunal; however under current arrangements, the Department also has responsibility to complete their role of scope determination in a timely manner, which appears to have been occurring satisfactorily.
- **Transparency** – since the closure of APMAIF, transparency of the process appears to have decreased, with the delayed reporting of breaches and other statistics contributing to this lack of transparency.
- **Informal pre-determination resolution** – the current system does not include a mechanism whereby complaints could be resolved informally without proceeding to the Tribunal. The review suggests that the New Zealand process could be adopted.
- **Clarity about appeals within the Tribunal process** – the review heard concerns from industry about the fairness of the current appeals process. The review understands that clarification of the appeals process within the Tribunal arrangements is being clarified through the Terms of Reference revision.
- **Education about consequences of a breach** – Given that the MAIF Agreement is voluntary and self-regulated, the consequences for breach are a matter for industry. Industry signatories were clear that they take a breach very seriously. However it is clear that a majority of public health stakeholders interested in the Agreement believe the consequences are not sufficient to influence industry behaviour.

Each of these aspects is discussed in turn below.

¹⁰ Reference Nous report

4.1 There is room to improve the awareness, visibility and accessibility of the complaints handling process

4.1.1 Awareness

The majority of stakeholders Nous consulted are aware of the role of the Tribunal and MAIF complaints handling process but a clear majority of survey respondents do not think enough has been done to increase awareness of the complaints handling process in the general community.¹¹ This view was shared by a number of stakeholders who were consulted including the Tribunal, state government employees, health professionals and organisations, consumers and members of the general public.

The small number of complaints lodged supports the view that there is no great awareness of the Agreement itself or how to submit complaints under it.

Consistently across all groups, stakeholders called for greater education on the MAIF Agreement and its complaints handling process to health professionals and organisations as well as consumers and the general public.¹² This may include direct promotion to consumers, such as information packs for new parents and flyers in frequented stores, information given to families when they leave hospital and greater media coverage, including television, radio and social media advertising.¹³

With regards to non-signatories, currently the Department will contact non-signatory organisations and inform them of the MAIF Agreement only if they are subject to a complaint. To increase the awareness and visibility of the MAIF Agreement and complaints handling process, stakeholders believed that the Department could proactively and formally reach out to new market entrants and existing non-signatories informing them of the MAIF Agreement and its importance.

There was a general consensus among stakeholders that locating and accessing information about the MAIF Agreement, complaints handling process and submission of complaints was difficult. The complaints form was not located in the main body of text describing the complaints handling process. This issue was raised by many stakeholders during interview, including the Tribunal, who noted even with their advanced knowledge of the complaints handling process they could not locate the form. It is possible this difficulty of access has discouraged prospective complainants.

However with the recent upgrade of the Department of Health's website, there have been improvements to the MAIF site and access to information on both the Agreement, complaints handling process and submissions process.

In addition, there remains room for search engine optimisation and inclusion of the website in other relevant forums beyond the Infant Nutrition Council website.

4.1.2 Accessibility

Stakeholders reported that the submission of a complaint is fairly complex and difficult, with room to simplify and streamline the process. The lodgment form is currently available for download on the Department website. It requires the complainant to identify which clause of the MAIF Agreement their complaint pertains to. This requirement may be particularly challenging for some complainants. As the Department of Health's website expressly states that all fields in the complaint form must be completed for the complaint to be considered, complainants may be put off submitting a complaint if they are confused or intimidated by the requirement to identify a clause within their complaint.

¹¹ 96% of survey respondents.

¹² Survey

¹³ Survey

Improvements and a simplification of the complaint form and submission process would make the MAIF complaints handling process more accessible to a wider proportion of the Australian population. Stakeholders called for an easier complaints submission process through a fully electronic submission form which is accessible for some people with disabilities or from Culturally and Linguistically Diverse (CALD) backgrounds.

One suggestion commonly raised by stakeholders across various interest groups was for the Department to allow for submission of complaints via e-forms. While e-forms should not replace the existing submission options of post and email, they would greatly increase the ease of submitting a complaint. Beyond the accessibility implications associated with a more user-friendly complaints handling process, e-form functionality was also suggested by the Tribunal as a potential improvement to the timeliness of the process. This would also allow the Department and the Tribunal to investigate options for online tracking of complaints, and uniform use of reference numbers.

Industry wide support is a key factor of a successful voluntary industry

agreement¹⁴. Currently the Department will contact non-signatory organisations and inform them of the MAIF Agreement only if they are subject to a complaint. To increase the awareness and visibility of the MAIF Agreement and complaints handling process, stakeholders believed that the Department could proactively and formally reach out to new market entrants and existing non-signatories informing them of the MAIF Agreement and its importance.

The Department could more actively educate consumers and health professionals as well as increase engagement with new market entrants, existing non-signatory manufacturers and importers.

Further improvement to the Department's website, with:

- ***clearer information on the complaints handling process, easier navigation***
- ***improved information on the role of the Tribunal***
- ***a simplified, well located and electronic complaints submission process and lodgement.***

4.2 The effectiveness of the complaints process is reduced by poor timeliness

Across the stakeholder groups, there is general consensus that the complaints handling process has not been timely enough. Delays in the determination of a complaint reduce the effectiveness of the whole complaints process and take away from the transparency of the process. The majority of interviewed stakeholders and survey respondents believed there is poor timeliness from complaint to resolution.

In its 2016 re-authorisation of the MAIF Agreement,¹⁵ the ACCC commented that:

¹⁵ ACCC A91506 & A91507 - Infant Nutrition Council Limited - Revocation and Substitution

“the MAIF Complaints Tribunal currently publishes its decisions in its annual report. The ACCC understands the Tribunal has discretion under its Terms of Reference to publish its decisions in whatever manner it sees fit, and considers it is important to ensure public confidence in the MAIF Agreement that the Tribunal publish its decisions shortly after they are finalised as this will provide transparency and help ensure effective oversight of the MAIF Agreement.”¹⁶

Non-industry stakeholders who had submitted a complaint in the past were particularly privy to the length of time it can take for a complaint to reach a decision point. These stakeholders suggested that the greatest time period of perceived inaction has occurred between the Tribunal receiving the complaint and meeting to discuss it, and from when the Tribunal makes a decision to when it is publicly reported.

The signatories to the Agreement were also concerned about timeframes, particularly the length of time the Tribunal has taken to determine a breach. The original Terms of Reference for the Tribunal provided that complaints should be resolved within three months after an ‘in scope’ complaint has been received by the Secretariat.¹⁷ However, industry stakeholders commented that the Tribunal had not been able to adhere to these timeframes. Negotiations are underway in the revision of the Terms of Reference for the time limits to be reduced and specified at each step. The review encourages the Tribunal to ensure it is resourcing and managing the process in a way that ensures complaints can be determined as rapidly as possible.

Most industry signatories indicated that when they were subject to a complaint, the timeframes that the Tribunal and Secretariat provided for them to respond with information and to rectify the breach were fair. The Tribunal commented that the signatories are always extremely timely with their submissions in response to the Tribunal’s requests.

Many stakeholders in interviews and the survey believed that the Tribunal has taken far too long to publish its decisions in its annual report. The Tribunal’s first Annual Reports were released 12 to 14 months after the end of the year being reported.

The Tribunal acknowledged that its timeframes had been less than optimal and noted that a steep learning curve and a lot of ‘teething’ issues had impacted adversely on their timeframes in the initial years of operation.

Interviewees in particular called for reporting in greater frequency, suggesting publication of decisions and their rationale on the Department website or other relevant platforms as they are made by the Tribunal. The review could see no reason why the decisions of the Tribunal could not be passed immediately to the Department for publication on its website, accompanied by a short rationale.

Establish clear and realistic timeframes including the use of an on-line tracking system.

There is room to increase the frequency of reporting of both annual reports and breaches, including the publication of decisions and reporting a breach and its rationale on the Department’s website as soon as it is determined.

¹⁶ ACCC A91506 & A91507 - Infant Nutrition Council Limited - Revocation and Substitution, Final Determination

¹⁷ MAIF Agreement Complaints Tribunal Terms of Reference (www.infantnutritioncouncil.com/wp-content/uploads/2014/11/MAIF-Agreement-Committee-ToR-FINAL-.pdf)

4.3 Transparency of the complaints handling process

The majority of stakeholders were dissatisfied with the overall transparency of the complaints handling and reporting process,¹⁸ with a number of stakeholders expressing views that they are less trusting of the Tribunal and the overall effectiveness of the complaints handling process since the APMAIF was disbanded. Less than half of survey respondents felt that the decision about whether a complaint was in breach and the rationale is communicated effectively.¹⁹

Several stakeholders commented that they were unsure whether it was the Department or the Tribunal who made decisions on which complaint submissions were in and out of scope and why, with 38% of the survey respondents believing that whether a complaint is in or out of scope is not communicated effectively.

Some of the interviewed signatories requested that the Tribunal share information about breaches and the rationale for their decision more broadly within the industry so companies can learn from each other's mistakes.

4.4 Informal pre-determination resolution

Potential complainants are advised by the website information that they might wish to contact the subject company directly to discuss their complaint prior to a formal complaint being lodged. The review was not made aware of any instances where this has occurred.

The review suggests an alternative approach would be to adopt the New Zealand process, whereby prior to a complaint being formally considered by the Panel, the subject company has an opportunity to respond to the complaint. If the complainant is satisfied with this response, they have the option of closing the complaint before it reaches the Panel. In this instance, nothing is published on the Ministry of Health's website, and the matter is considered resolved. This process has settled a few complaints, with companies usually responding with their intention to remove the relevant advertising. Complaints settled in this manner are often closed within 4-6 weeks.

Provide the company who is subject to a complaint with an opportunity to respond, prior to going to the Tribunal.

4.5 Fairness in relation to appeal processes

The review understands that the process for appeals is under consideration in the revision of the Terms of Reference and therefore is not able to provide further comment.

4.6 Consequences of complaints handling decisions

The potential for reputational damage is currently the only external consequence for breach, and this is widely understood by stakeholders.²⁰ However the appropriateness of the current consequences for breach is an issue of concern amongst health professionals, public health bodies, breastfeeding advocates and

¹⁸ Interviews.

¹⁹ Survey

²⁰ During interview, the majority of stakeholders across groups identified potential reputational damage as the only consequence of breach.

other non-industry stakeholders, who do not believe that signatories take the potential for a breach very seriously²¹. They generally expressed the view that the consequences are insufficient to influence industry behaviour.

Conversely, signatories were convincing during interviews that they take the potential for a breach very seriously and can be subject to significant internal sanctions if a breach is found.²² Signatories to the MAIF Agreement consider findings of breach to carry significant weight within the industry.²³ The INC noted that signatories also lodge complaints against one another through an internal complaints process managed by the INC; which mediates and resolves these complaints internally, or with the assistance of external facilitation²⁴. This would seem to add weight to the argument that breaches do influence industry behaviour.

These opposing positions have remained unchanged since the 2012 Review of the MAIF Agreement.²⁵

The review considers that better education about the impact of breaches on industry may help to bridge this divide.

Improve education about the impact of breaches on industry, to non-industry stakeholders.

²¹ This view was both expressed during interview and through online submission. Of those stakeholders interviewed, 50% (all non-industry stakeholders) felt that reputational damage was an inadequate consequence of breach.

²² All interviewed signatories identified the additional internal consequence of significant changes to company practice.

²³ These views were expressed by all signatories interviewed by Nous, as well as the INC during interview.

²⁴ Information provided by the INC

²⁵ An independent review also conducted by the Nous Group.

5 The lack of overarching responsibility militates against effectiveness and efficiency

Under current arrangements, the complaints handling process is now split between four entities: the Department of Health, the INC (representing the industry signatories), TEC and an independent Tribunal. The responsibilities of each of these parties are outlined in Figure 4.

Figure 4: Responsibilities of entities involved in the complaints handling process

Department of Health	Infant Nutrition Council (representing signatories)
<ul style="list-style-type: none"> the provision of information on its website, including management of the format and receipt of complaints educate industry, health professionals and consumers receipt of complaints and an initial filtering process to determine whether complaints are in or out of scope responses to complainants advising the outcome from the initial filtering observer status on the MAIF Tribunal receipt of complaints determinations (breaches) from the Tribunal a running record of complaints statistics 	<ul style="list-style-type: none"> responsible for setting up independent body to establish the MAIF Tribunal
The Ethics Centre (independent body)	MAIF Tribunal
<ul style="list-style-type: none"> set arm's length conditions for involvement. determine Terms of Reference for operation of the Tribunal appoint Tribunal members provide Tribunal secretariat 	<ul style="list-style-type: none"> review complaints from the Department determine breaches publish annual reports in relation to breaches only

This disparate distribution of responsibility, coupled with the lack of an overarching mechanism for complaints handling, has resulted in a disjointed set of processes and decision-makers, with a lack of clarity between them. Key challenges emerging from this arrangement include:

- Inconsistency in reporting**, with no single source of truth – each entity across the complaints handling process has a discrete reporting methodology, which has led to inconsistencies in reporting of complaints data.
- Dissipation of corporate knowledge across four entities** – spreading responsibility for various aspects of the complaints handling process has weakened corporate knowledge about the MAIF Agreement and the complaints context.

- **No shared understanding** between the Department and Tribunal about relative responsibilities for determining whether a complaint is in or out of scope.
- **A lack of certainty** as to who – if anyone - has responsibility for maintaining and updating guidelines
- **An absence of a mechanism to facilitate collaboration** – the disjointed nature of the process has discouraged collaboration, and has acted as a barrier to some stakeholders participating in complaints determination.
- **A lack of institutional sustainability of the third party** – it is unclear what would happen to the process if the TEC decided to cease their involvement.

Each of these challenges is discussed in turn below

5.1 Reporting is inconsistent across the complaints handling process, with no single source of truth

Both the Department and the Tribunal Secretariat assign complaints reference numbers, however use different systems to do so. Hence there is no one line of sight of individual complaints.

The Department tracks complaints as they are submitted and records the total number of complaints received, the number of complaints the Department considered to be in and out of scope, and the number of breaches committed by signatories. When the Department is notified of the outcome of a complaint, in theory the Departmental database is updated, however anecdotal evidence suggests that this does not always occur.

The Tribunal tracks the number of complaints it receives from the Department and those subsequently deemed in scope, out of scope and whether or not an in-scope complaint was deemed in breach or not. The Tribunal records this information in the Annual Report of the MAIF. As a result of only tracking the number of complaints received from this point, the proportion of out-of-scope complaints published in the annual report is much lower than the total out-of-scope complaints submitted to the Department.

This leads to confusion by complainants on the status of their complaint. The bigger issue is the inconsistencies in reporting on the number of total complaints received, either in or out of scope, as evidenced by the data provided to this review by the Department and via the Annual Reports..

As an additional comment on the lack of consistency, the Tribunal reported that it has previously asked the Department for pre-Tribunal complaints data, which the Department was unable to provide due to perceived difficulty of the request

To increase the transparency of the process, the Department and Tribunal should consider utilizing a consistent and electronic complaint number tracking system. This will allow people and organisations who submit complaints to request information at any time on what stage of the complaints handling process their submission has reached

5.2 Corporate knowledge of the MAIF Agreement and the complaints handling process is dissipated across the four entities

The suggestion was made that the Department had lost considerable expertise since the closure of APMAIF, coupled with the appointment of the Tribunal members who were also new to the process, this has led to dissipated corporate knowledge of the process and precedents.

The Tribunal agreed that it has been difficult to operate efficiently without prior knowledge of the context of the MAIF Agreement, the operational requirements of the process or experience at servicing a Tribunal.

The disagreement between the Tribunal and industry as to whether some decisions were correctly made is also indicative of dissipated corporate knowledge

5.3 The Department and Tribunal lack a shared understanding of the role of scope determination

The review found that confusion exists between the Department and Tribunal as to the Department's current role in scope determination. When a complaint is received in the Department, a preliminary assessment is made by Department officials as to whether the complaint is in or out of scope of the Agreement. According to the Tribunal Terms of Reference, the signatories and the Government have agreed that matters considered outside the scope of the MAIF Agreement may include, but are not limited to, the following:

- a) an infant formula manufacturer or importer that is not a current signatory to the MAIF Agreement or was not a signatory at the time the complaint was made;
- b) retailer activity where there is no involvement by the manufacturer/importer (e.g. price promotions in retail catalogues);
- c) infant merchandise (e.g. infant feeding bottles, teats, dummies, etc.); and/or d) foods, including milk products formulated for children over 12 months of age (sometimes referred to as "toddler milks")²⁶.

The Department takes the view that when it has doubts about whether a complaint is in or out of scope, it is best to send the complaint to the Tribunal for the Tribunal to make that decision. Otherwise, the Department risks de facto making a determination. This is in line with the process under the previous APMAIF, when scope decisions would at times be debated within the APMAIF. It is also in line with the process in New Zealand, whereby the NZ Ministry of Health officials can seek the advice of the Panel Chair if they have questions of scope²⁷.

On the other hand, the Tribunal takes a clear view that every complaint sent to it by the Department is, by definition, in scope. The Tribunal believes it has no discretion to consider a complaint forwarded to it as out of scope and that every such complaint must be considered by the Tribunal.

Industry stakeholders pointed to instances of the Department forwarding toddler formula complaints to the Tribunal as evidence of this confusion. The Tribunal noted that uncertainty around the role of scope determination was particularly an issue in its first year of operation, with the INC and the Department often holding different views as to why complaints had been forwarded to the Tribunal. The Department also noted that they are unable to provide reasons as to why they are forwarding a complaint, and that this adds to the confusion of complaints being in and out of scope.

The Department and the Tribunal have so far been unable to clarify this misunderstanding, noting that the current arrangement is in part due to the scope in the Terms of Reference. However the latest version of the Tribunal Terms of Reference received by the review contains a clause that the Department "may, at its absolute discretion, seek further information (if required) in order to make a determination in relation to scope. This may include consulting with the Tribunal as to its view on whether the complaint falls within the scope of the MAIF Agreement or not"²⁸.

²⁶ Terms of Reference of the Tribunal, received by the review August 2017

²⁷ This arrangement was explained at interview by representatives of the New Zealand Ministry of Health.

²⁸ Tribunal Terms of Reference clause 25

5.4 It is unclear whether the Tribunal will continue to hold responsibility for creating and updating guidelines associated with the MAIF Agreement

One of the roles of the Tribunal, as described in the Terms of Reference, includes the development of guidelines on the interpretation and application of the MAIF Agreement. However, some confusion seems to exist as to whether developing guidelines is the responsibility of the Tribunal.

The Tribunal indicated during interview that it was uncomfortable with its role in updating guidelines, noting that instead the INC has been updating the guidelines, with the Tribunal approving or rejecting the proposed changes. The suggestion was also made by the Tribunal that if it were to update the guidelines, this may require additional funding. A potential compromise may be made in adopting the New Zealand approach, whereby the Panel does not create guidance material, but in its decisions often advises subject companies on how they might change their practices to remedy a breach.²⁹ The INC takes responsibility in New Zealand for updating the guidance material.

Responsibility for creating guidance material must be clarified, as currently stakeholders operate with very little certainty as to what constitutes a breach of the MAIF Agreement. This uncertainty prevents signatories from making fully informed decisions about marketing practices, and inherently undermines the effectiveness of the complaints handling process as a deterrent to breach-creating behaviour. Similarly, consumer uncertainty as to what constitutes a breach undermines their ability to identify breach behaviour in the marketplace. This further impedes the effective operation of the complaints handling process.

5.5 The limited perspectives represented by Tribunal membership hinders collaboration

Current membership of the Tribunal includes a public health and nutrition expert, a legal professional, and a community representative. Perspectives absent from membership, and called out by stakeholders during consultation, are representatives from industry, breastfeeding advocacy groups, and formula feeding parents. These suggestions were consistent with a perceived strength of the former APMAIF, which was perceived as more collaborative approach to complaints resolution. Stakeholders considered this collaborative approach as potentially fairer than the current approach, as it considered a variety of perspectives. This expansion would be more in line with the New Zealand approach, which includes an academic, a health practitioner, an INC representative, and a consumer representative.³⁰

5.6 There is no institutional sustainability of the third party, currently fulfilled by The Ethics Centre

Concerns were raised regarding the future of the complaints handling process and Tribunal should the TEC decide to cease their involvement. There is no natural successor to the TEC.

The review was advised that the Advertising Standards Bureau has indicated interest and willingness to take on the complaints determination role, should an alternative be sought.

²⁹ This practice was explained at interview by representatives of the New Zealand Ministry of Health.

³⁰ This arrangement was explained at interview by representatives of the New Zealand Ministry of Health.

6 The review has identified four options that could improve the overall process

Given the difficulties encountered by the current split arrangements, the review considers there are four possible approaches the Government could take to improve the efficiency and effectiveness of the complaints handling process. These are discussed in turn below.

6.1 Option 1: Keep the existing arrangement with improved visibility, timeliness and transparency

This option represents the most minimal change. If the current split of responsibilities is to continue, the Department will continue to have limited leverage to make improvements. These improvements could include:

- further upgrades to the website and complaints lodgement process, as identified in section 4
- negotiations with The Ethics Centre to seek improved timelines and to clarify the current impasse in relation to the responsibility for classifying a complaint as in or out of scope.

While the Department could attempt to negotiate these matters, there is no direct relationship between the Department and The Ethics Centre, which has sole discretion over the Terms of Reference for its involvement in the process.

Other improvements would be up to the INC, the TEC and the Tribunal.

6.2 Option 2: Government cease exercising its current partial responsibilities for the complaints process

Improvements to the effectiveness and efficiency of the complaints process require a single body to have overarching responsibility for the end-to-end process. To achieve this, Government could exclude itself entirely from the complaints handling process by no longer managing the complaints lodgment and receipt process as well as the initial determination of whether a complaint is in or out of scope. In this event, there would be no complaints process unless industry decided to manage the whole process itself. Government cannot guarantee that industry would pick up the whole process.

By adopting this option, Government would be taking a significant step away from being able to exercise its responsibility under the WHO Code to monitor compliance with the Code. It would be able to observe but not intervene. If government was dissatisfied with the process it would have no leverage to make change.

6.3 Option 3: Government resume the role of determining complaints, as per the previous APMAIF arrangements

To ensure a more efficient and effective complaints process Government could make a decision to again manage the complaints process in its entirety. This would bring the process back together under the Department and eliminate the need for a third party decision-maker.

Under this option, the members of the complaints determining body would be determined and appointed by Government rather than by the head of the Ethics Centre. This would mean that the complaints

determining body could again be established under administrative law, thus providing protections that do not exist with the independent arrangement.

A secretariat skilled in supporting a tribunal would be re-established within the Department, thus ensuring a return to a depth of corporate knowledge and expertise.

While this option will re-establish a greater role for government, there should be no barrier to the industry signatories funding the complaints process. Any perception of a conflict of interest should be alleviated by the role of government in ensuring an impartial and highly experienced complaints determining body is in place.

6.4 Option 4: Negotiate a new Trans-Tasman Approach

Most manufacturers and importers of infant formula operate on both sides of the Tasman. New Zealand and Australia have adopted a similar approach to enforcement of the WHO Code through voluntary industry regulation but have separate yet broadly similar complaints handling processes.

A precedent for a joined up process exists in the joint approach adopted for food standards across the two countries through Food Standards Australia and New Zealand (FSANZ).

There would be significant advantages for industry and for government in having a single complaints process operating across both countries. The compliance burden on industry of responding to two separate processes would be reduced as would the administrative cost of the process.

In the course of consultations for the review, officials from the NZ Ministry of Health expressed an interest in exploring collaboration with Australia in relation to the complaints process. Although the systems are slightly different, there is potential for shared learnings and effectiveness and efficiency gains through collaboration.

At present the NZ Code only covers the marketing of formula up to 6 months of age, but the review was advised that industry has indicated a preparedness to negotiate an extension to 12 months. This would bring the two systems closer together.

Appendix A Key Lines of Enquiry

Key Lines of Enquiry	Guiding Questions	Research Questions
<p><u>KLE 1:</u> How effective and efficient is the complaints handling process?</p>	How many complaints and breaches have been reported?	How many complaints were reported to the Department? How many were considered in and out of scope?
		What communications did complainants receive during this process? Did they receive a rationale for the decisions made?
		How many complaints were passed on from the Department to the Tribunal?
		How many were in breach? How many were out of scope?
		Who committed the breaches? What was the nature of the breaches? Do the same signatories keep committing the breaches?
	How appropriate are the consequences for breaches?	What are the consequences for a breach?
		How appropriate are the consequences? Should a breach incur a tougher consequence?
		Are signatories provided with suitable guidance after a breach?
		Is there an appeals process in place? Should this be considered?
	To what extent are stakeholders aware of the complaints handling process?	How aware are stakeholders of the role of the Department and the Tribunal and the whole complaints handling process?
What has been done to increase communication with the community and raise awareness about the MAIF Agreement and complaints handling process? How effective has this been?		
Are stakeholders aware how they register a complaint?		
How effective is the complaints handling process in overseas jurisdictions or other industries?	How effective are models of voluntary industry regulation? What is the complaints handling process in these models?	
	How effective are international models for implementation of the WHO Code and their associated complaints handling process?	
<p><u>KLE 2:</u> How fair, timely and transparent is the complaints handling process?</p>	How timely and transparent is the decision making process?	How timely is the decision making process from initial complaint to the Department to a resolution?
		How timely is the Department in responding to complainants about the progress and outcomes of their complaint? (whether it is in/out of scope)

Key Lines of Enquiry	Guiding Questions	Research Questions
<p>KLE 3: What changes should be made to improve complaints handling process?</p>		How transparent is the Department's role in defining in- and out of scope complaints? How appropriate and transparent is their response to complainants?
		How transparent is decision making? Are stakeholders aware of the rationale for decisions?
		How are complaints, breaches and decisions reported? Are these sufficiently transparent?
		To what extent are stakeholders satisfied with the transparency of the whole complaints and reporting process? What actions can be taken to increase stakeholder satisfaction?
	How effective is the Department in supporting the Tribunal?	To what extent does the Department have a clear understanding of the MAIF Agreement and its scope?
		How appropriate is the Department's current role in supporting the MAIF Agreement and the MAIF Tribunal?
		What guidance does the Tribunal receive from the Department? Is there a need for more guidance material? If so, what should this guidance cover?
		What is the value of the Department overseeing the Tribunal?
	What suggestions do stakeholders have to improve the effectiveness of the complaints handling and reporting process?	What are the main strengths and weaknesses of the complaint handling and reporting process?
		What improvements should be made to improve the effectiveness of the complaint handling and reporting process?
	How can the quality and efficiency of the complaints process be improved?	What improvements should be made to improve the efficiency and quality of the whole complaints process?
	How can the timeliness, transparency and fairness of the process be improved?	What changes should be made to improve the timeliness, transparency and fairness of the whole complaints handling process?

Appendix B Stakeholders consulted in this review

B.1 Interviews

Stakeholder	Interview Status
Commonwealth Government	
Preventive Health Policy Branch, Australian Government Department of Health	Completed
Food and Nutrition Policy Section, Australian Government Department of Health	Completed
Australian Competition & Consumer Commission	Submitted feedback via email
Other Health Departments*	
Victorian Department of Health and Human Services	Submitted feedback via email
Department of Health and Human Services Tasmania	Completed
New Zealand Ministry of Health	Completed
Signatories	
Abbott Australasia	Completed
Aspen Nutritionals Australia	Completed
Bayer Australia	Completed
Bubs Australia Ltd (The Infant Food Company)	No response
H J Heinz Company Australia	Completed
Nestle Australia	Completed
Nutricia Australia	Completed
The a2 Milk Company	Completed
Australian Dairy Park Pty Ltd	Declined - Do not sell infant formula
Nature One Dairy	Unavailable for interview
Murray Goulbourn Co-operative	No response
Freadom Foods	No response
Wattle Health	Declined - only 1 month as signatory

Stakeholder	Interview Status
Tribunal	
The Ethics Centre (MAIF Tribunal Secretariat) Simon Longstaff – Executive Director Leigh Woodgate – Tribunal Secretariat	Completed
MAIF Complaints Tribunal Members Graeme Innes – Tribunal Chair	Completed
Other	
Australian Breastfeeding Association	Completed, additional information provided
Australian College of Midwives	Completed
Consumers	Completed
Infant Nutrition Council Jan Carey – CEO	Completed
Dietician’s Association of Australia	Completed
Lactation Consultants of Australia and NZ	Completed
New Zealand Department of Health	Completed
Venessa Tripp – Former APMAIF Chair	Completed

*All State and Territory Health Departments were offered the opportunity to participate in the consultation process.

Survey

We received 180 online submissions in response to the survey.

Detailed survey results, including respondent groupings, are provided in the Consultation Summary Report, attached as a separate document.

Appendix C Consultation notes – NZ Ministry of Health

C.1 Receiving a complaint

Prior to a complaint being lodged with the Panel, the subject company has an opportunity to respond to the complaint. If the complainant is satisfied with this response, they have the option of closing the complaint before it reaches the Panel. In this instance, nothing is published on the Ministry's website, and the matter is considered resolved. This process has settled a few complaints, with companies usually responding with their intention to remove the relevant advertising. Complaints settled in this manner are often closed within 4-6 weeks.

If a complaint is lodged against a company that is not a member of the INC, the Panel cannot hear the complaint. In this instance, the Ministry writes to the subject company to educate them about the expectations around the marketing of infant formula, and encouraging them to become members of the INC. If the subject company does not take up this offer and multiple complaints are received about their practices, the Ministry asks the company to come in for a meeting to discuss the matter. At all times the company is kept up to date with the complaints being lodged against it.

A recommendation was made in the past to include a complainant advocate in the process, however this was not adopted by the then Minister and has not been substantively reconsidered.

C.2 Determining uncertain issues of scope

The Panel Chair is consulted on issues of uncertain scope within 10 days of the complaint being received. If necessary, the Chair will take the issue of scope determination to the Panel.

If the Panel receives a complaint to consider it deems out of scope, it dismisses the matter.

C.3 Guidance material

The Panel does not produce any guidance material for industry. They are quite clear that their role is to determine complaints on a case by case basis only. The Panel will often advise companies about potential changes to their practices to ensure future compliance when handing down a decision of breach, however. In some instances the Panel has also made recommendations that the Ministry should follow something up and provide more information to industry, but not on how the code should be interpreted.

The INC has produced guidance material in the past, but this is not formally endorsed by the Panel.

C.4 Panel composition

The NZ Panel comprises:

- An academic
- A health practitioner
- An INC representative
- A consumer/community representative
- An independent Chair.

C.5 Role of the Secretariat

The Ministry previously provided the role of the Secretariat to the Panel. They considered the administrative burden associated with the role too high, however, despite the small number of complaints. As a result, the role of the Secretariat was contracted out to an independent body with expertise in servicing a tribunal. The Ministry continues to attend Panel meetings, however.

C.6 Role of precedent

The Panel informally adopts a doctrine of precedent, and industry representatives have often pointed to past decisions in arguing their cases. Their use of precedent could not be considered as strict as a legal doctrine of precedent, however. The Panel considers complaints to have slight nuances that warrant review in isolation.

C.7 Timeliness

On average, the Panel takes 6 months to issue a complaint decision. As the Panel only meets quarterly, timeframes vary depending on when the complaint is received. This arrangement was put in place on the basis of legal advice around what is required for natural justice. As it stands currently, after a complaint is received the INC has 20 days to provide the company response, and the complainant has a further 20 days after receiving this response to decide whether or not they wish to pursue the complaint. If the decision goes to the Panel and is appealed, the adjudicator has 30 days to make a decision.

C.8 Consequences of breach

The name of a company found to be in breach is published on the Ministry website with a short summary of the breach details. Companies have complained in the past about the damage this has to their reputation. Companies have particularly been concerned in the past about the risk of Chinese authorities discovering the breach, and sanctioning the company in the Chinese market.

C.9 Appeals

After a complaint is decided, the decision is sent to the parties. Both parties have an option to request the decision is appealed. The decision is sent to the adjudicator, who is independent from the Panel. The adjudicator can either uphold the decision on appeal, or send the complaint back to the Panel to re-determine.

C.10 Potential for collaboration with Australia

There is a desire from the NZ Ministry to collaborate with the Australian Department of Health. Although the systems are slightly different, there is potential for shared learnings and effectiveness and efficiency gains through collaboration.

At present the NZ Code only covers the marketing of formula up to 6 months of age, but industry has indicated they're prepared to negotiate the extension to 12 months. This would bring the two systems closer together.

Appendix D Complaints Statistics

D.1 APMAIF Complaints Statistics

	2004-05	2005-06	2006-07	2007-08	2008-09	2009-10	2010-11	2011-12	2012-13
Signatories	-	-	-	-	-	6	6	6	6
Complaints submitted	28	81	832	159	44	36	13	13	30
Out-of-scope	14	71	709	140	37	29	11	9	26
In-scope	14	10	123	19	7	7	2	4	4
In breach	0	0	0	0	1	1	1	0	1
Proportion of complaints submitted									
Out-of-scope	26%	58%	79%	88%	84%	81%	85%	69%	87%
In breach	0%	0%	0%	0%	2%	3%	8%	0%	3%

D.2 Tribunal Complaints Statistics

	2013-14 ³¹	2014-15	2015-16	2016-17
Signatories	-	7	10	14
Complaints submitted to the Department	-	7	15	21
Out-of-scope (Department decision)	-	N/A	11	17
Complaints received by Tribunal	-	9 ³²	4	4
Out-of-scope (Tribunal decision)	-	1	0	TBA
In-scope	-	9	4	TBA
In breach	-	3	3	TBA
Proportion of complaints submitted to Department				
Out-of-scope	-	-	73%	TBA
In breach	-	-	20%	TBA

³¹ Statistics for 2013-14 is unavailable as this was the period when APMAIF was disbanded and the Tribunal was set up.

³² Includes complaints received in 2013-14 prior to the establishment of the Tribunal.

Appendix E Tribunal Terms of Reference (draft)

Marketing in Australia of Infant Formulas (MAIF): Manufacturers and Importers Agreement

Complaints Tribunal

Terms of Reference

E.1 Background¹:

1. The MAIF Agreement is a voluntary self-regulatory code of conduct between the manufacturers and importers of infant formula in Australia. It is Australia's response to the World Health Organization's *International Code of Marketing of Breast-milk Substitutes 1981* (WHO Code). The MAIF Agreement applies to those Australian manufacturers and importers of infant formula who are signatories to the MAIF Agreement. The MAIF Agreement aims to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary, on the basis of adequate information through appropriate marketing and distribution.

Current signatories to the MAIF Agreement include:

- Abbott Australasia Pty Ltd
- Aspen Nutritionals Australia Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Australia Ltd
- Bubs Australia Ltd (The Infant Food Company)
- Freedom Foods Group Trading Pty Ltd
- H J Heinz Company Australia Ltd
- Murray Goulburn Co-operative Co Ltd
- Nature One Dairy Pty Ltd
- Nestlé Australia Ltd
- Nuchev Pty Ltd
- Nutricia Australia Pty Ltd
- The a2 Milk Company Ltd
- The Infant Food Company
- Wattle Health Australia Ltd

2. Prior to 8 November 2013, industry compliance with the MAIF Agreement was monitored by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF). Part of APMAIF's role was to hear and determine complaints made under the terms of the MAIF Agreement. As of 8 November 2013, the APMAIF ceased to operate.
3. As a result of APMAIF becoming inoperative, the Infant Nutrition Council (INC)² approached the Ethics Centre with a request that the Ethics Centre establish and convene an independent and credible process by which complaints might continue to be heard and determined under the terms of the MAIF Agreement.

¹ Source: Australian Government Department of Health: [Department of Health Marketing in Australia of Infant Formula website](#)

² The Infant Nutrition Council (INC) represents the major manufacturers and marketers of infant formula in Australia and New Zealand as well as local manufacturers who are producing product for export
The members of the Infant Nutrition Council work with key stakeholders to support the public health goals of

promoting breastfeeding and good nutrition for infants. The Council aims to:

- D improve infant nutrition by supporting the public health goals for the protection and promotion of breastfeeding and, when needed, infant formula as the only suitable alternative;

Drepresent the infant formula industry in Australia and New Zealand Source: [Infant Nutrition Council website](#)

4. The Ethics Centre has agreed to this request under the following conditions:
 - a. The process will be established and managed according to *Terms of Reference* determined solely by the Ethics Centre.
 - b. Funding of the process will be by industry (signatories to the MAIF Agreement) in an unrestricted form (retainer) that:
 - i. ensures operational independence to the Ethics Centre in the operation of the Tribunal, and
 - ii. is of an amount sufficient to fund the effective operation of such a body.
 - c. The Ethics Centre will establish the service so that the deliberations of the Tribunal are free from influence by any other organisation, including the Ethics Centre.
-

MAIF Complaints Tribunal

Terms of Reference

E.2 Purpose:

- 1) The MAIF Complaints Tribunal (the Tribunal) has been established to:
 - a) receive and investigate complaints regarding the marketing in Australia of infant formulas pursuant to the MAIF Agreement; and
 - b) develop guidelines on the interpretation and application of the MAIF Agreement.

E.3 Proceedings:

- 2) All proceedings of the Tribunal must be conducted in accordance with the principles of natural justice.
- 3) The Members of the Tribunal shall be the sole determinants of any complaint.
- 4) The Tribunal may not take into consideration any interests other than those to be served under the MAIF Agreement (see clause 24).
- 5) The Tribunal Secretariat (Secretariat) will record the findings (including determinations and guidelines) of the Tribunal. Members of the Tribunal shall ensure confidentiality in relation to all of the Tribunal's deliberations.

E.4 Composition:

- 6) The Tribunal shall be composed of three members being:

- a) A disinterested person with legal qualifications and demonstrable experience in hearing and determining complaints that have involved both private and public interests. Ideally, the person will have a knowledge of relevant food legislation – or a commitment and capacity to develop that knowledge.
- b) A disinterested Public Health and Nutrition Expert with scientific and technical expertise in public health, child nutrition, regulation around therapeutic goods and the food/drug interface. Ideally, the person will have expertise in evidence-based medicine, with paediatric training.
- c) A disinterested community representative, ideally with knowledge and experience in the areas of child welfare and evidence-based decision making.

E.5 Appointment:

- 7) Members of the Tribunal shall be appointed by the Executive Director of the Ethics Centre.
- 8) The power of appointment may not be delegated to another person.
- 9) In making an appointment the Executive Director of the Ethics Centre must be satisfied that the appointee is:
 - a) Competent to perform the assigned role,
 - b) Disinterested (i.e. free from any conflict of interest or duty that might affect the independence of judgement to be exercised in the discharge of their duties).

E.6 Conflicts of Interest

- 10) Members of the Tribunal shall be under a standing obligation to declare any conflict of interest or duty that might affect the independence of judgement that they are required to exercise in the discharge of their duties. Where a conflict is declared, the Tribunal may, at its absolute discretion, determine the extent (if any) to which the person making the declaration may be involved in considering any relevant matter before the Tribunal.

E.7 Term of appointment

- 11) Each Member may be appointed for a period of three years.
- 12) Subject to clause 11, Members are eligible for appointment for one further term of three years.
- 13) If serving a second term, then one third of those appointed to the Tribunal at its

establishment will be required to retire by way of annual rotation according to a process agreed by the Tribunal.

E.8 Termination of Appointment

- 14) Appointment to the Tribunal may be terminated by:
- a) the resignation of the Member;
 - b) the expiry of their term of appointment;
 - c) for proven misconduct, including a failure to disclose a conflict of interest as determined by the Executive Director of the Ethics Centre.

E.9 Casual Vacancies

- 15) A casual vacancy arises on the Tribunal when a member either resigns or is terminated before the expiry of their term.
- 16) The Executive Director of the Ethics Centre must as soon as is practicable appoint suitably qualified persons to fill any casual vacancy that might arise on the Tribunal.
- 17) In filling a casual vacancy the Executive Director of the Ethics Centre must apply the same criteria for selection as if making a regular appointment of a Member.

E.10 Chair of the Tribunal

- 18) The person with legal qualifications shall serve as Chair of the Tribunal.

E.11 Remuneration

- 19) Members of the Tribunal shall be paid a daily rate, as specified in Appendix 1.
- 20) The daily rate of remuneration is to be reviewed on an annual basis.
- 21) Members of the Tribunal are to be reimbursed for out-of-pocket expenses reasonably incurred in the conduct of their duties.

E.12 Basis for a determination

- 22) In normal circumstances, all complaints are to be determined by the Tribunal solely on the evidence presented to it by the Secretariat and thus 'on the papers'. In exceptional circumstances, the Chair may seek expert oral testimony in order to aid

the Tribunal in reaching a well-informed and fair determination.

E.13 Process³

Initiation of complaint

- 23) A person wishing to make a complaint arising under the MAIF Agreement will do so, in the first instance, by lodging their complaint with the Commonwealth Department of Health (the Department). Complaints may be submitted online at - maif@health.gov.au or may be posted to MAIF Agreement Officer, Department of Health, MDP 802, GPO Box 9848, Canberra ACT 2601.

Assessment by Department of Health

- 24) Upon receipt, complaints will be assessed by the Department and classified as being within or outside the scope of the MAIF Agreement. The Signatories to the MAIF Agreement and the Commonwealth Government have agreed that matters considered outside the scope of the MAIF Agreement may include, but are not limited to, the following:
- a) an infant formula manufacturer or importer that is not a current signatory to the MAIF Agreement or was not a signatory at the time the complaint was made;
 - b) retailer activity where there is no involvement by the manufacturer/importer (e.g. price promotions in retail catalogues);
 - c) infant merchandise (e.g. infant feeding bottles, teats, dummies, etc.); and/or
 - d) foods, including milk products formulated for children over 12 months of age (sometimes referred to as "toddler milks").
- 25) The Department may, at its absolute discretion, seek further information (if required) in order to make a determination in relation to scope. This may include consulting with the Tribunal as to its view on whether the complaint falls within the scope of the MAIF Agreement or not.
- 26) The Department is to write to Complainants acknowledging receipt of a complaint and will advise Complainants in writing if their complaints are outside the scope of the MAIF Agreement. The Department shall reach a determination as to scope within 21 business days of receiving the complaint.
- 27) Complaints that have been assessed as falling within the scope of the MAIF Agreement ('in scope' complaints), along with any supporting documents will be forwarded within 10 business days by the Department to the INC and the Secretariat for submission to the Tribunal at its next available meeting.

Secretariat to gather evidence

- 28) Within 5 business days of receiving a complaint that is deemed to be within scope, the Secretariat will advise the manufacturer or importer of the product concerned that a complaint has been received alleging a breach of the MAIF Agreement and will provide details of the complaint. The manufacturer or importer (Respondent) will be invited to respond within 1 calendar month with any evidence or other information it wishes to submit for consideration by the Tribunal in making its determination.

29) The Secretariat will collate and send to the Tribunal in advance of the Tribunal's next meeting, all information relevant to the Tribunal making a decision on the complaint, including details of the complaint and the full response provided by the Respondent. Such information will, where available, include:

- a) how and where the Complainant obtained the complaint material,
- b) the Complainant's concerns regarding the material,
- c) an identification of relevant clause(s) of the MAIF Agreement that are alleged to have been breached or that are otherwise deemed to be relevant,
- d) the results of any enquiries made by the Department or Secretariat, on behalf of the Tribunal, (e.g. responses from formula companies or health professionals) and
- e) any previous consideration of a similar complaint or relevant guidelines on the interpretation of the MAIF Agreement which has been made by the APMAIF (the predecessor to the Tribunal) or the Tribunal.

³ An illustrative flowchart of the complaints process is set out at Annex2.

Consideration by Tribunal

- 30) The Tribunal is to consider the complaint at its next meeting and must within 1 calendar month of receiving the complaint information determine that
- a) the evidence before the Tribunal indicates it does not represent a breach of the MAIF Agreement, or
 - b) the evidence before the Tribunal indicates it does represent a breach of the MAIF Agreement, or
 - c) the Tribunal requires further information in order to make a determination.

'No breach' Determination

- 31) Where the Tribunal determines under paragraph 30(a) that the evidence currently before it indicates that the complaint does not represent a breach, the Complainant shall within 10 business days be notified of that determination and provided with a written explanation of any preliminary view that the Tribunal has reached together with the evidence or other material upon which that view has been reached, and the Complainant will be invited to make additional representations to the Tribunal. The Complainant may provide an additional response, which shall contain only new and/or additional information to that contained in its original response, and any such additional response must be provided to the Secretariat within 1 calendar month of the Complainant receiving the invitation to make additional representations.

'Breach' Determination

- 32) Where the Tribunal determines under paragraph 30(b) that the evidence currently before it indicates that the complaint does represent a breach, the Respondent shall within 10 business days be notified of that determination and provided with a written explanation of any preliminary view that the Tribunal has reached together with the evidence or other material upon which that view has been reached, and the Respondent will be invited to make additional representations to the Tribunal.
- 33) The Respondent may provide an additional response, which shall contain only new and/or additional information to that contained in its original response, and any such additional response must be provided to the Secretariat within 1 calendar month of the Respondent receiving the invitation to make additional representations.

Further Consideration by the Tribunal

- 34) At its next meeting The Tribunal is to further consider the complaint, taking account of any additional response provided by a Complainant or Respondent pursuant to paragraphs 31 and 32, and must within 1 calendar month of receiving the additional response determine that the complaint either:
- a) does not represent a breach of the MAIF Agreement, in which case the provisions of paragraph 35 shall apply, or
 - b) does represent a breach of the MAIF Agreement.
- 35) In cases where a breach of the MAIF Agreement has not been found, the Complainant, the Respondent, the Department shall within 10 business days be notified of that determination, including the Tribunal's reasons for reaching that determination. No further action shall be taken in respect of the complaint.

- 36) In cases where a breach of the MAIF Agreement has been found:
- a) the Tribunal may make recommendations to the Respondent and the INC as to how the breach might best be remedied; and
 - b) the Complainant, the Respondent, the Department and the INC shall within 10 business days be notified of the determination, including the Tribunal's reasons for reaching that determination, and of any recommendations. The Complainant, the Respondent, the Department and the INC shall be subject to the requirements of confidentiality set out at paragraph 39.
 - c) Potential remedies that the Tribunal might wish to recommend include (but are not limited to);
 - I. Changes to labelling, advertising and marketing materials,
 - II. Product recalls,
 - III. Public statements acknowledging error.

Tribunal requires further information to reach a determination

- 37) Where the Tribunal determines under paragraph 30(c) that it requires further information in order to make a determination, the Complainant and/or Respondent shall within 10 business days be notified of the further information requested by the Tribunal. The Complainant and/or Respondent shall provide a further response containing the further information requested by the Tribunal, and such further response must be provided to the Secretariat within 1 calendar month of the Complainant and/or Respondent receiving the request for further information.
- 38) At its next meeting The Tribunal is to further consider the complaint, taking account of the further information provided by the Complainant or Respondent pursuant to paragraph 37, and must within 1 calendar month of receiving the further information determine that either:
- a) The evidence before the Tribunal indicates it does not represent a breach of the MAIF Agreement, in which case the provisions of paragraphs 31 and 35 shall apply, or
 - b) the evidence before the Tribunal indicates it does represent a breach of the MAIF Agreement, in which case the provisions of paragraph 32 and 36 shall apply.

Reporting of Tribunal's determinations; confidentiality

- 39) Determinations that there has been a breach of the MAIF Agreement, along with any recommendations by the Tribunal, are to be publicly reported in the Tribunal's *Annual Report*. Notifications under paragraph 36(b) are made on a confidential basis and other than as allowed for under paragraph 40, the Complainant, the Respondent and the Department must not disclose to any person the determination and/or any recommendations, pending publication of the Tribunal's *Annual Report*.
- 40) A Respondent may disclose to the INC any determination and/or any recommendations of the Tribunal.

- 41) The Department will record all complaints received in its complaints register and forward relevant information concerning these (including statistics noting the total number of complaints received) to the Secretariat for incorporation in the Tribunal's Annual Report.
- 42) Except with the consent of the Complainants, the Complainants' identities are not to be disclosed to parties other than the Members of the Tribunal.

E.14 Appeals

- 43) There shall be no appeal from a decision of the Tribunal.

E.15 Guidelines

- 44) In developing and publishing any Guidelines, the Tribunal must:
 - a) take into account the decisions and guidelines published by earlier members of the Tribunal or its predecessor, APMAIF;
 - b) ensure that the guidelines are relevant to the aims of the MAIF Agreement;
 - c) include consultation with key stakeholders, including the INC, peak professional bodies and consumer organisations;
 - d) seek technical advice where deemed by the Tribunal to be either useful or necessary.
- 45) The Tribunal shall publish and maintain a record of its Guidelines in an easily accessible form.

E.16 Residual Rights

- 46) Nothing in these Terms of Reference should be taken to limit the legal rights of any party in relation to matters heard by the Tribunal.

E.17 Observer

- 47) As part of the Australian Government's obligation under Article 11.2 of the WHO Code, a representative of the Commonwealth Minister for Health will attend all meetings of the Tribunal as an Observer
- 48) The Observer must undertake to be bound by the conditions of confidentiality that apply under these *Terms of Reference* and more generally, in relation to the conduct of the Tribunal. As such, the Observer may provide to the Minister a general report of the Tribunal's activities but may not report specific details of its deliberations – unless specifically authorised to do so by the Chair of the Tribunal.
- 49) An observer may not speak, nor otherwise contribute to, the deliberations of the Tribunal.

E.17.1 APPENDIX 1

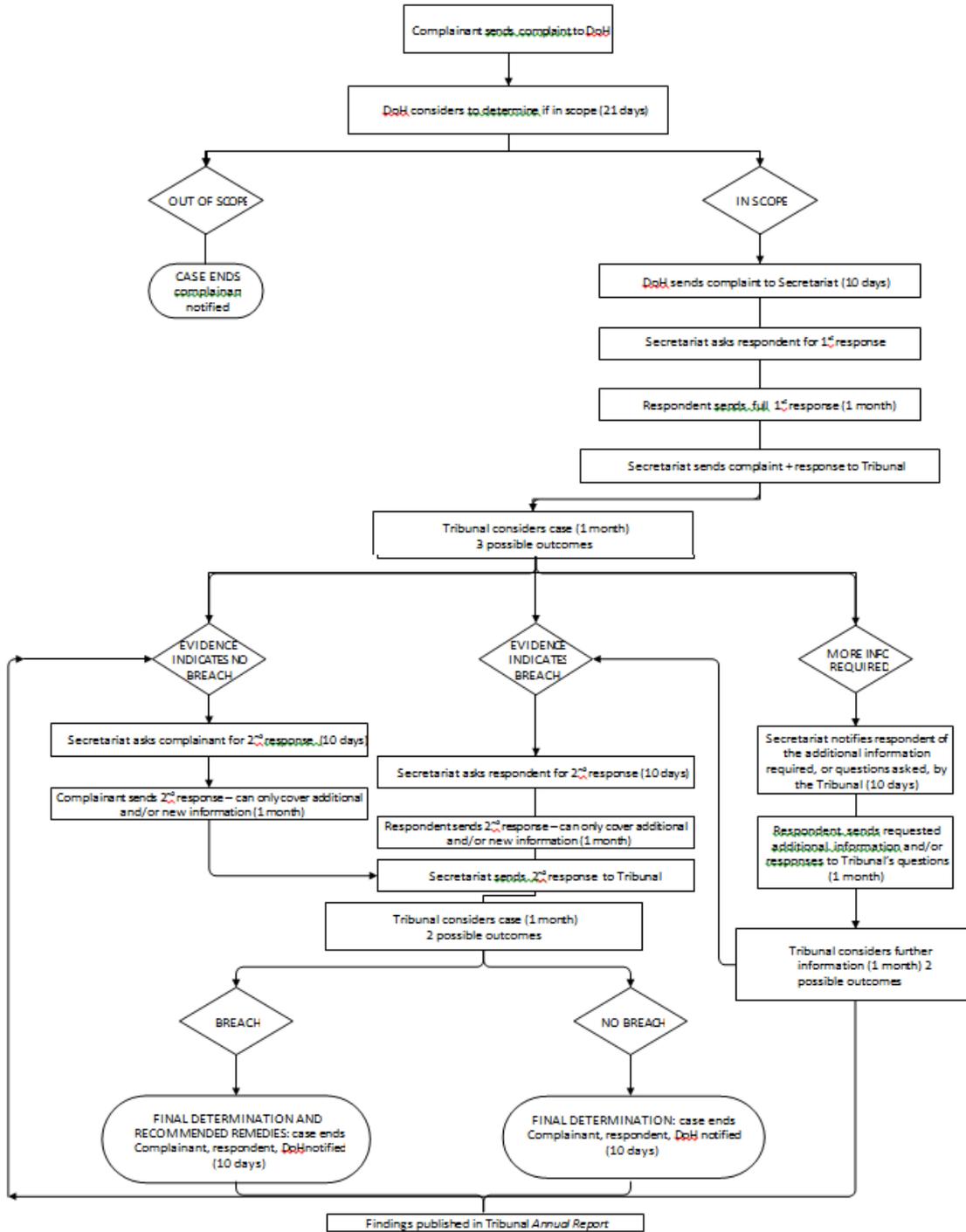
REMUNERATION OF COMPLAINTS TRIBUNAL MEMBERS

Remuneration rates have been set with reference to the scale of fees payable to persons performing similar roles within the administrative remit of the Commonwealth of Australia.

Chair	\$1098 per day
Member	\$824 per day

E.18 APPENDIX 2

MAIF COMPLAINTS TRIBUNAL PROCESS FLOWCHART



Appendix F **Current MAIF Agreement Signatories**

- Abbott Australasia Pty Ltd
- Aspen Nutritionals Australia Pty Ltd
- Australian Dairy Park Pty Ltd
- Bayer Australia Ltd
- Freedom Foods Group Trading Pty Ltd
- H J Heinz Company Australia Ltd
- The Infant Food Co. Pty Limited
- Murray Goulburn Co-operative Co. Limited
- Nature One Dairy Pty Ltd
- Nestlé Australia Ltd
- Nuchev Pty Ltd
- Nutricia Australia Pty Ltd
- A2 Corporation Ltd
- Wattle Health Australia Limited

Appendix G Literature Review

G.1 Introduction

The Commonwealth Department of Health has engaged Nous Group (Nous) to complete an independent review of the efficiency and effectiveness of the Marketing in Australia of Infant Formula (MAIF) complaints handling process. The Review commenced in April 2017 and is due for completion in August 2017.

Nous Group undertook this literature review in May 2017 as part of the review. The literature review covers the international implementation of the International Code of Marketing of Breast-milk Substitutes (the WHO Code) with a focus on the complaints handling process, the Australian guidelines for voluntary industry regulation and Australian/New Zealand Standard Guidelines for complaint management in organizations. It covers current knowledge relevant to the review of the MAIF complaints handling process but does not draw recommendations. This will be reserved for the final report.

The key findings are:

G.1.1 The WHO Code: international implementation

- The majority of WHO Member States have implemented the WHO Code through legislation.
- There are varying levels of adoption of the WHO Code provisions.
- The WHO recommends three key elements for successful implementation.

G.1.2 The WHO Code: international complaints handling processes

- Few WHO Member States report having a functioning monitoring system.
- In most countries, the health sector is responsible for monitoring and enforcement.
- Few WHO Member States meet the national code legislation requirements on monitoring and enforcement.
- UN agencies and non-governmental organisations play a substantial role but should not be relied upon in the long-term.
- There are a number of identified common challenges in complaints handling processes.

G.1.3 International Case Studies for WHO Code complaints handling processes

- USA has not taken any legal measures to implement the WHO Code.
- New Zealand follows voluntary industry regulation.
- UK has partially implemented some provisions in law.

G.1.4 Australian voluntary industry regulation

- An effective code has widespread awareness and support from consumers and industry.
- An effective code has a clear, transparent and independent procedures for monitoring.

- An effective code has clear, transparent and independently reviewed procedures for complaints handling.
- An effective code has enforcement and appropriate sanctions for non-compliance.

G.1.5 Case Studies in voluntary regulation in Australia

- The Australian Self Medication Industry has led to generally high compliance and breaches are publicly available.
- The Telecommunications Industry Ombudsman and the Financial Ombudsman Service are optimised to be simple and fast.
- The effectiveness of the Food and Grocery Industry Code of Conduct has been varied due to poor enforcement.

G.2 Complaints handling processes guidelines

- The 2014 Australian/New Zealand Standard™ Guidelines for complaint management in organisations' has a number of relevant guiding principles and recommendations.

G.2.1 The WHO Code: international implementation

The implementation of the WHO Code is the responsibility of individual signatory governments who can take action appropriate to their social and legislative framework. The WHO Code was reviewed as part of this literature review, to provide context to the complaints handling process sections and agreement compliance.

6.4.1.1 The majority of WHO Member States have implemented the WHO Code through legislation

Around 70% (135) of surveyed WHO Member States ("countries", n=194) had at least some form of legal measure in place covering some provisions of the WHO Code (WHO 2016). This was an increase from 64% of countries in 2011 (WHO 2011).

One quarter of countries have non-legal, including voluntary regulation, or no measures in place (WHO 2016). The remaining 5% (10) of countries did not provide information (WHO 2016).

6.4.1.2 There are varying levels of adoption of the WHO Code provisions

Countries have implemented the WHO Code to different levels. Only 20% of countries have comprehensive legal measures which cover all or most of the provisions of the WHO Code (WHO, 2016).

Only one third of countries with specified age ranges for products explicitly cover products for children up to 12 months old (WHO 2016).

Just over half of the surveyed countries ban marketing of infant formula to the general public, and giving financial incentives or products to health workers or their family members (WHO 2016). Fewer than half of the countries ban manufacturers or distributors from providing free or low cost infant formula supplies to health facilities (WHO 2016). One third of countries prohibit manufacturers or distributors from directly contacting pregnant women and mothers (WHO 2016).

A limited number of countries have strict labelling and marketing restrictions around providing information on the benefits and superiority of breast-feeding, age recommendations, preparation instructions, the need for medical advice, and the inclusion of nutrition and health claims (WHO 2016).

Table 3: Implementation of the WHO Code of selected countries³³

Full provisions in law	Many provisions in law	Few provisions in law	No legal measures
<ul style="list-style-type: none"> • Brazil • Fiji • Ghana • India • South Africa 	<ul style="list-style-type: none"> • Argentina • Cambodia • Egypt • Indonesia • Mexico 	<ul style="list-style-type: none"> • Canada • France • Germany • Ireland • Norway • United Kingdom 	<ul style="list-style-type: none"> • Australia • Japan • New Zealand • Singapore • United States of America

6.4.1.3 The WHO recommends three key elements for successful implementation

In the 'Country Implementation of the International Code of Marketing of Breast-milk substitutes: Status Report 2011', the WHO recommends the following elements for successful implementation:

1. **Functional monitoring and enforcement mechanisms** to strengthen implementation, enforcement, monitoring and sanctions. Without this, weak or lack of appropriate laws, implementation, sanctions and monitoring results in systematic violations and aggressive marketing.
2. **Partnerships with civil society and non-governmental organisations** to help governments in advocating for the enactment, implementation, enforcement and monitoring of the Code, as well as providing practical and community level breastfeeding support. Cooperation from food manufacturers, distributors, health-care professionals, non-governmental organisations and consumer groups is essential in implementation of the WHO Code and in protecting, promoting and supporting breastfeeding.
3. **Documentation and reporting of Code violations** for effective tracking, compilation and systematisation of information and evidence needed for future action and advocacy.

WHO Member States follow these elements to a varying degree.

G.2.2 The WHO Code: international complaints handling processes

The complaints handling process, or monitoring of the implementation, of the WHO Code varies internationally. The responsibility for monitoring the implementation of the WHO Code rests with governments, both individually and in collaboration with other parties (e.g. WHO, UNICEF, non-governmental organisations, and professional groups).

6.4.1.4 Few WHO Member States report having a functioning monitoring system

Of the 55 countries which provided updated information on formal monitoring and enforcement mechanisms, only 32 have one that is operational (WHO 2016). Most of these (88%) have mechanisms which monitor complaints with national legislative or other appropriate measures.

Weak or poor monitoring systems, irregular monitoring activities and inadequate mechanism for reporting violations continue to be the main issues. The causes of these are insufficient funding and capacity of staff. Only 19% of countries indicated that they had a dedicated budget or funding for their monitoring operations (WHO 2016). This lack of adequate and reliable funding from governments is problematic.

³³ WHO, 2016

6.4.1.5 In most countries, the health sector is responsible for monitoring and enforcement

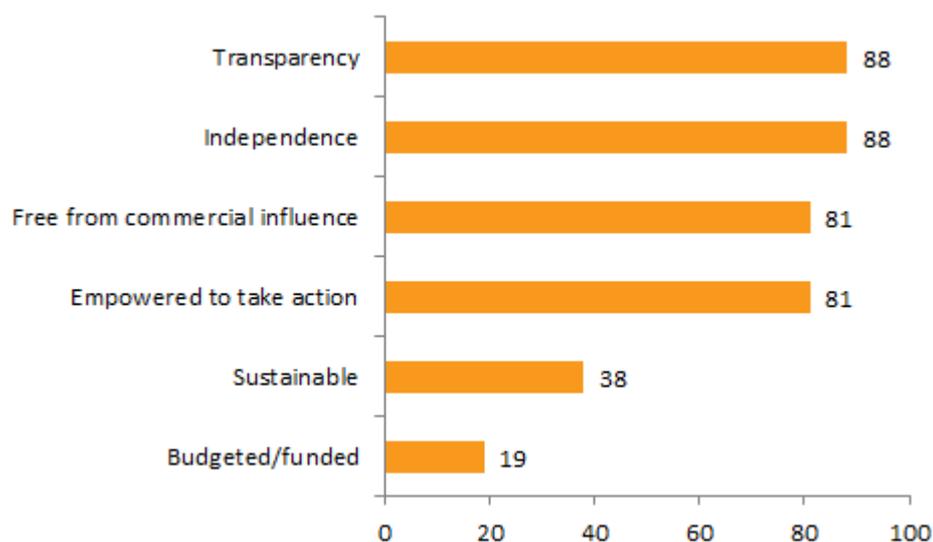
The health sector has overall responsibility for monitoring Code implementation in 24 out of the 32 (75%) countries with formal mechanisms in place (WHO 2016). This includes entities such as the ministry of health, the ministry of food and drug safety, and food and veterinary boards. Other sectors that hold responsibility in some countries are the food and agriculture sector and the trade sector.

6.4.1.6 Few WHO Member States meet the national code legislation requirements on monitoring and enforcement

Code legislation or regulations should have clear provisions that ensure robust and sustainable monitoring mechanisms and processes, which are transparent, independent and free from commercial influence (Resolution WHA49.15). Responsible government entities should be empowered to monitor compliance, identify breaches of the Code, and take corrective action breaches through administrative, legal or other sanctions.

Of the 135 countries that have Code-related legal measures, only 82 countries (61%) provided information on these provisions (WHO 2016). Of these, 66 countries (80%) have provisions that facilitate the establishment of a formal monitoring mechanism (WHO 2016). Furthermore, only 6 of the 66 countries have provisions that meet all of the criteria for the operationalisation of formal monitoring mechanisms (WHO 2016).

Table 4: Proportion of countries meeting criteria for operationalisation of formal monitoring mechanisms (n=32) (WHO 2016)



6.4.1.7 UN agencies and non-governmental organisations play a substantial role but should not be relied upon in the long-term

The majority of the surveyed countries reported that non-governmental organisations (NGOs) have a role in advocacy, monitoring and educating legislators (WHO, 2016). UN agencies, notably UNICEF and WHO, also provide support to Code monitoring, including building the capacity of government officials, and establishing monitoring processes. This support from the UN agencies and NGOs, including local and international infant health-focussed NGOs, provides short-term assistance but should not be seen as a replacement for the role of the government and should not be relied upon in the long-term. This is further explored in the international case studies in section 4.

Some NGOs including the International Baby Food Action Network (IBFAN), Save the Children and Helen Keller International (HKI) have devised their own monitoring mechanisms. IBFAN through its International Code Documentation Centre (ICDC) publishes periodic global, regional and national monitoring reports

focusing on marketing practices that violate the Code as a minimum standard, while Save the Children and HKI have published country specific reports that measure the level of adherence to national laws.

6.4.1.8 There are a number of identified common challenges in complaints handling processes

Many countries face difficulties in effectively implementing and enforcing the WHO Code. Commonly identified challenges include:

- **Consistent, repeated and systematic violations by the industry.** One of the most common breaches is through aggressive direct or indirect marketing to pregnant women and mothers. In some cases, manufacturers and distributors exert pressure on government to limit the implementation and enforcement of the WHO Code. Consumers and non-governmental organisations, particularly in countries which rely on voluntary regulation, often campaign against punishments which they view as unfair and not harsh enough.
- **Difficulty in submitting complaints of breaches of the WHO Code.** Whether the WHO Code is implemented through legislation or other forms of regulation, consumers and organisations may be unaware of the Code and their country's implementation and enforcement mechanism.
- **Long process time and poor transparency from submission of complaint to outcome.** This can often discourage consumers and organisations from submitting complaints.
- **Lack of sufficient data and expertise of the WHO Code.** The lack of resources and limited funding of many implementing bodies of the WHO Code intensify this.

G.2.3 International Case Studies for WHO Code complaints handling processes

Three case studies on the implementation of the WHO Code as it relates to the complaints handling process and monitoring and evaluation of the code are presented below. The information for these has been drawn from Baby-Friendly USA (2012), Breastfeeding Online (2015), the Infant Nutrition Council (2017) and the New Zealand Ministry of Health (2017).

6.4.1.9 Case study 1: No legal measures (USA)

The United States of America (USA) has agreed to take steps to implement the WHO code but has not introduced any legislative enforcement. Instead, the USA government has formally provided the WHO Code and the government's views of it to US manufacturers of breast-milk substitutes.

Adherence to the WHO Code is left to the discretion of manufacturers

The three major manufacturers declared that they will abide by the WHO Code when operating in developing countries but only review their practices in industrialised countries. Each of these manufacturers has developed their own code of conduct for the marketing of infant formula.

Monitoring and advocacy is left to non-governmental organisations

Several non-governmental organisations and individuals have worked to discourage businesses and consumers from interacting with manufacturers and organisations which violate the code. For example, the American Academy of Paediatrics will not accept the support from any company which promotes infant formula directly to the public. The Baby-Friendly Hospital Initiative, a worldwide program of the WHO and UNICEF, does not grant 'Baby-Friendly' accreditation to hospitals and birthing centres which do not abide by the provisions of the WHO Code. We could not find evidence of a formal complaints

6.4.1.9 Case study 1: No legal measures (USA)

handling or reporting process.

US laws only cover the safety and sanitary condition of infant formula

The Anti-Drug Abuse act of 1986 and the Infant Formula Act of 1980 outline the legislation around the safety and sanitary condition of infant formula but not its marketing.

6.4.1.10 Case study 3: Few provisions in law (United Kingdom)

Since 2016, the WHO Code has been partially implemented in the UK through legislation. Specifically it enforces EU Regulation 609/2013 on food intended for infants and young children, food for special medical purposes, and total diet replacement for weight control. Prior to 2016, the Code was implemented through the UK's Infant Formula and Follow-on Formula Regulations. Industry must also adhere to Ofcom's (the UK's independent regulator and competition authority) product placement rules and the Advertising Standards Authority's voluntary Advertising code.

It is a criminal offence for a company to not act on 'Improvement Notices'

Companies which have breached legislation are issued with an 'Improvement Notice'. It is a criminal offence for a company to not act on the Improvement Notice by the supplied deadline. If the company does not act, they are liable to a fine. The industry and relevant non-governmental organisations are supportive of this. Representative bodies and non-governmental organisations play an important role.

The public and NGOs play an important role in monitoring

Baby Milk Action and the Baby Feeding Law Group are two major players in the UK baby food industry. Baby Milk Action (BMA) is a not-for-profit organisation that aims to end the suffering and death caused by inappropriate infant and young child feed. They are a part of the International Baby Food Action Network. BMA is the secretariat of the Baby Feeding Law Group, a group of professional organisations and mother-support groups.

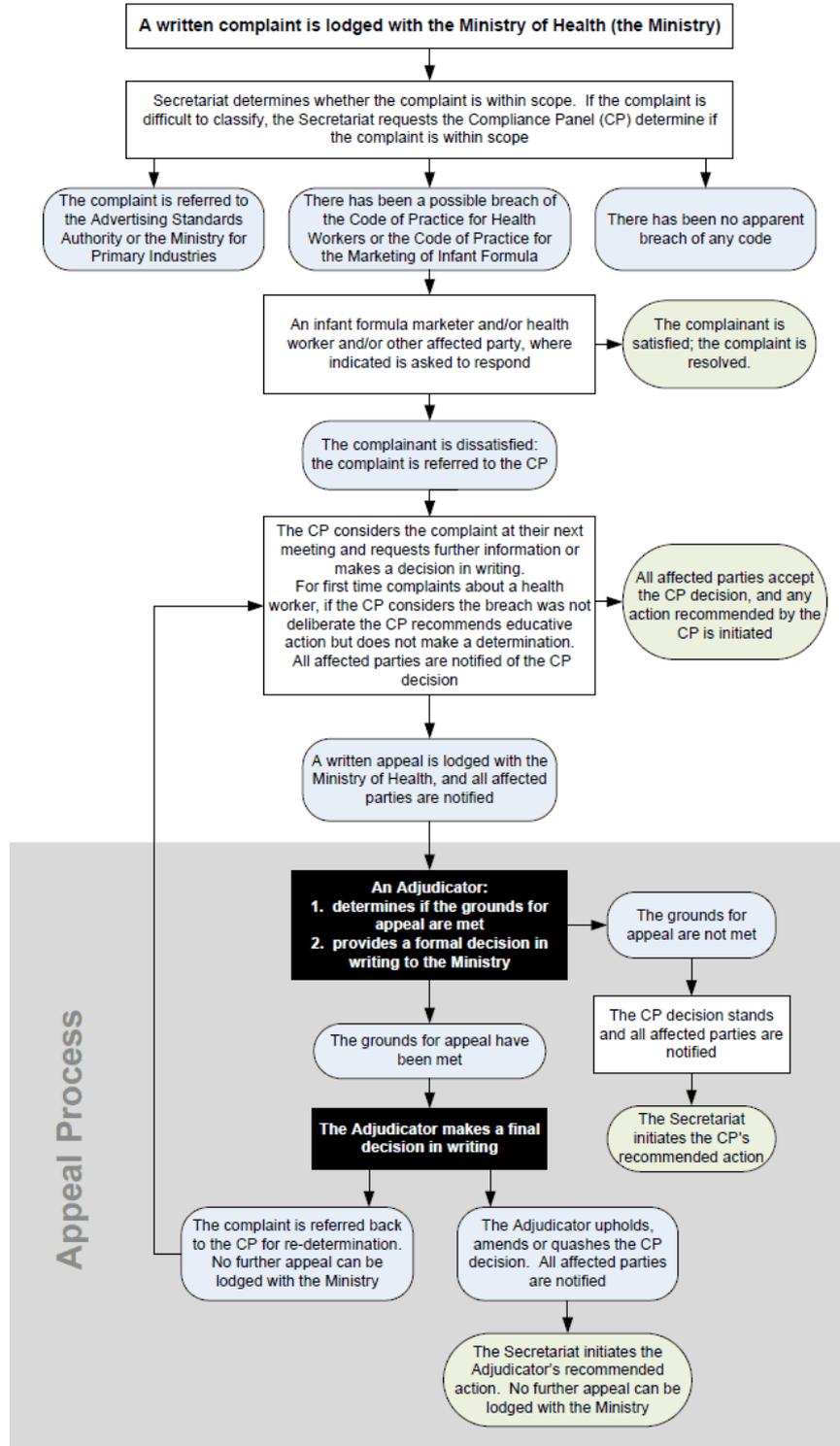
The public and interested parties are encouraged to monitor the baby food industry and submit to the Baby Feeding Law Group. In March 2016, BMA led a successful campaign against the Department of Health due to concerns that the 'Infant Formula and Follow-on Formula Regulations 2007' are disrespected in the UK. This was evidenced by a number of breaches, including repeat offenders, without prosecution. This campaign resulted in the changes from the Infant Formula and Follow-on Formula Regulations to the current legislation.

There is still room for improvement

Baby Milk Action supports the current legislation around the marketing of baby formula, however still wants further action as "...the Regulations (still) fall far short of international minimum standards repeatedly called for by UN human rights bodies." One of the requests of BMA is to make Improvement Notices public.

Figure 5: Flow diagram of the New Zealand WHO Code complaints process

The Code in New Zealand Complaints Process



Australian voluntary industry regulation

The Australia Competition & Consumer Commission (ACCC) is Australia's competition regulator and national consumer law champion. On 15 July 2016, the ACCC authorised the MAIF Agreement for the next five years.

The ACCC provides standards for regulation including for voluntary industry codes of conduct which are informative and relevant to ensuring that the MAIF Agreement is successfully implemented. The ACCC states that voluntary industry codes of conduct (code) should outline specific standards of conduct for an industry in relation to the manner in which it deals with its members and customers. Well designed, effectively implemented and properly enforced codes can improve consumer protection and reduce industry regulatory burdens. Ineffective codes may result in unnecessary compliance burdens on business and even reduce market competition. The following are guidelines for successful voluntary industry codes of conduct.

An effective code has widespread awareness and support from consumers and industry

The wider the industry coverage of a code, the more effective it will be. This is measurable through the number of signatories compared to potential signatories across an industry, as well as the breadth of issues the code addresses.

A common pitfall of code success occurs when employees or industry members are unaware of the code or fail to adhere to it in implementation. Therefore it is vital that a part of the implementation of the code involves ongoing education and instruction of its principals and procedures.

The same is also important to raise the awareness of consumers and the general public of the code. An effective code should incorporate a strategy which increases awareness of the code, issues it addresses, signatories, and its complaints handling process.

An effective code has a clear, transparent and independent procedures for monitoring

The code administration committee should have a system in place to regularly monitor and evaluate whether signatories are complying and that the code is assisting in the achievement of desired outcomes. This process may involve collecting and evaluating data to identify and resolve issues of non-compliance as well as improve levels of compliance. Monitoring and action sends a clear message to all stakeholders that the body is serious about and committed to adherence to the code.

For the monitoring body to be effective, they need to operate in a transparent and independent manner, free from commercial influence. The body will need to be:

- able to perform its duties and tasks without external pressure, fear or influence
- have the authority and sufficient resources to investigate Code violations
- empowered to take remedial action in line with national laws and regulations following investigation and verification of alleged violations
- make information related to monitoring activities, final results and remedial actions taken publicly available and accessible
- have safeguards to detect and exclude persons or bodies that have a conflict of interest and thus preserve its independence, integrity, trustworthiness and credibility.

Finally, the committee should regularly assess its effectiveness and strive continually improve process and compliance. This can occur through data collection and annual reporting. Data should be collected on the details of the complainant, business or organisation complained about, the type and frequency of complaint, how the complaint was resolved, time taken to deal with complaint, and type of sanction(s) imposed. The annual report may include an analysis of the data and outlines any systemic issues and recommendations for improvement. Reports should be readily available to all stakeholders and interested parties.

An effective code has clear, transparent and independently reviewed procedures for complaints handling

An effective complaints handling procedure will incorporate the following:

- a definition of complaint that includes any expression of dissatisfaction with a product or service offered or provided;
- a procedure whereby complaints should first be considered by signatories to the code if the signatories cannot resolve a complaint it should be lodged with the administration committee or an independent decision-maker appointed by the committee; and
- an independent review of complaints handling decisions for when a member of the public or industry is dissatisfied with the initial attempt to resolve the complaint.

An effective code has enforcement and appropriate sanctions for non-compliance

Commercially significant sanctions are necessary to achieve credibility and compliance. These sanctions should fairly reflect the nature, seriousness and frequency of the breach. Examples of commercially significant sanctions may include:

- supplying an item free or any meaningful remedy to the aggrieved party when a code rule is broken
- censures and warnings
- corrective advertising
- fines
- expulsion as a signatory to the code
- expulsion from the industry association.

Case Studies in voluntary regulation in Australia

Four case studies across the self-medication, telecommunications, financial, and food and grocery services industries are presented below. These provide a reference point for the practical implementation of voluntary regulated codes within Australia.

Case study 4: Australian Self Medication Industry (Australia)

The Australian Self Medication Industry (ASMI) is the peak body representing companies involved in the manufacture and distribution of non-prescription consumer healthcare products in Australia. It also represents related businesses including advertising, public relations, legal, statistical and regulatory consultancy companies, and individuals. ASMI is a member of the World Self-Medication Industry (WSMI) made up of over 50 member associations globally with affiliations to the World Health Organization (WHO).

The ASMI supports a full range of regulatory and non-regulatory approaches

In their view, the ideal set of controls includes judicious use of self-regulatory, co-regulatory and non-regulatory approaches consistent with the COAG Principles of Best Practice Regulation. When an alleged breach of the ASMI Code of Practice arises but where direct negotiation between the parties fails, Members are encouraged to seek to resolve their differences by mediation, irrespective of the nature of the dispute. There is a Panel of Mediators who are selected both for their expertise as mediators and for their long experience in the therapeutic goods industry.

A panel reviews and encourages compliance with the ASMI Code of Practice and Therapeutic Goods Advertising Code

The Promotional Monitoring Panel (PMP) meets four times a year to review compliance with the ASMI

Case study 4: Australian Self Medication Industry (Australia)

Code of Practice and the Therapeutic Goods Advertising Code (TGAC). It provides a long-standing self-regulatory review process, which helps demonstrate the effectiveness of self-regulation of advertising, and improve compliance generally across the industry for all 'below-the-line' advertising (material not requiring formal pre approval). A full list of the promotional categories considered by the Panel is published in the ASMI Code of Practice, and includes point-of-sale material, digital media, and training materials (for both healthcare professionals and pharmacy assistants).

Compliance is generally high and breaches are publicly available

Compliance with the TGAC and ASMI Code of Practice was generally high. In 2015/16 the Panel reviewed 422 submitted items, of which 164 were found to contain one or more possible breaches of the ASMI Code of Practice and/or the TGAC. Breaches are published as media releases on the ASMI website with the subject company, product and other details named. In the annual report, there are details on the most common breaches which are useful for industry and education knowledge.

Case study 5: Telecommunications Industry Ombudsman (Australia)

The Telecommunications Industry Ombudsman (TIO) provides an independent dispute resolution service for small business and residential customers who have a complaint about their telephone or internet service in Australia. The TIO was established in 1993 under legislation and is independent of industry, the government and consumer organisations. In 2015-16, they received 112,518 new complaints, handled 46,778 enquiries, commenced 9,161 new conciliations, and 48 new investigations. In addition to handling complaints they alerted providers to 47 issues of interest that were potential systemic issues and made 17 submissions to government to improve policy, regulation, legislation and industry best practice.

Carriers and eligible carriage service providers are required by law to enter the TIO Scheme

The Telecommunications (Consumer Protection and Service Standards) Act 1999 requires carriers and eligible carriage service providers to enter into the TIO scheme to provide a dispute resolution service for complaints about telecommunications services. The TIO Industry Engagement section contacts carriers and eligible service providers to inform them about their obligations to join and comply with the TIO Scheme. They refer non-compliant organisations to the industry regulator, the ACMA. The TIO are committed to having effective communication with the ACMA, the ACCC and other regulators about non-compliant conduct to enhance effective compliance and enforcement.

The TIO are flexible and fast in their approach

The TIO are flexible in their approach and are not bound by previous decisions, considering each matter on its own merits. They only handle complaints made by consumers (person or business), after the complaint has been made to the provider.

Consumers can complain through the phone number, email or website which has clear instructions on the homepage. The TIO will then promptly inform the provider and work with both parties to agree on a resolution. If not resolved by agreement, the TIO will investigate further and then dismiss or decide the resolution with written reasons. The provider must consider recommendations but is not obliged to accept. The consumer cannot lodge a complaint if the provider does not accept the recommendations. For each complaint the total value of any actions and recommendations must not exceed \$100,000. If the total value exceeds this, they may arbitrate the complaint.

The TIO can publish details in any forum they consider appropriate

The TIO can publish details about any complaint they have decided or dismissed. The TIO can publish the name and details of non-compliance of a provider where they consider they do not comply with the TIO

Case study 5: Telecommunications Industry Ombudsman (Australia)

scheme. They can publish the information in any forum they consider appropriate, including but not limited to the TIO Annual Report, the TIO website, or a Member News bulletin.

Case study 6: Financial Ombudsman Service (Australia)

The Financial Ombudsman Service (FOS) provides accessible, fair and independent dispute resolution for consumers and financial services providers. They are governed by an independent board of consumer representatives and financial services industry representatives. They deal with a broad range of financial services providers (big and small), professional associations, consumer representatives such as financial counsellors and community lawyers, Australian Securities Investments Commission (ASIC) and other government agencies, as well as the broader Australian community. In 2015-16, FOS received 34,095 disputes and closed 32,871 disputes in 2015-2016.

Complaints handling process is optimised to be simple and fast

In 2015, the FOS updated their process for resolving disputes to a simpler, faster and improved experience for both applicants and financial services providers. Changes include:

- fast-tracking decisions for simpler and low-value disputes
- opportunities for financial services providers to resolve their dispute directly with their customers before the FOS investigation
- provision of specialist expertise earlier in the dispute process
- the reduction of multiple 'touch points' and process stages.

The FOS work with the consumer and the financial services provider to resolve disputes and act independently by not taking sides. FOS aims to get a fair outcome for both parties to a dispute. They communicate with both parties by phone, email and letters. Dispute resolution methods may involve negotiation, conciliation, or reaching a decision. It is important that all information relating to your dispute is provided to assist in a timely resolution.

The FOS can only assist with complaints for members ('signatories')

Complaints about non-FOS members must be directed to the Credit and Investments Ombudsman. In 2015-16, FOS had 5,540 members.

The FOS is improving its service and growing

THE FOS recently introduced a new format for decisions that more effectively communicates the outcomes of disputes to both applicants and financial services providers. A key focus in 2015-16 was actively identifying and managing systemic issues. FOS identified and referred 129 possible systemic issues to FSPs for response and resolved 64 definite systemic issues. This area will continue to be a priority in 2016-17.

Case study 7: Food and Grocery Industry Code of Conduct (Australia)

The Competition and Consumer Regulation 2015 – the Food and Grocery Industry Code of Conduct (the Code), is a legally enforceable, voluntary prescribed code under the Competition and Consumer Act. The intent of the Code is to establish a level playing field by providing a framework for doing business that respects contractual freedom, ensures competitiveness, trust and continuity. The current signatories are Coles, Woolworths, Aldi and About Life. The Australian Competition and Consumer Commission (ACCC) is

Case study 7: Food and Grocery Industry Code of Conduct (Australia)

responsible for enforcing the Code. An important component of the Code is the dispute resolution provisions. A number of options will be available for suppliers' including; a retailer's complaints process; mediation/arbitration; legal avenues; or ACCC.

The ACCC is responsible for regulating compliance

The ACCC is responsible for regulating compliance with the Code and can take enforcement action where appropriate. When the ACCC receives a complaint about an alleged breach of the Code it undertakes a preliminary assessment of the complaint. Ensuring compliance with the Code is a current priority for the ACCC. While there are no financial penalties for a breach of the Code, other remedies are available. Conduct that breaches the Code could also breach the [unconscionable conduct](#) provisions of the Australian Consumer Law, which carries penalties of up to \$1.1 million per contravention. The ACCC conducts audits of retailers and wholesalers to ensure that they are complying with the Code. The ACCC cannot provide legal advice on the Code or provide dispute resolution services.

There are three main dispute resolution options

Under the Code, a supplier can choose the dispute resolution option that meets their needs. A supplier can:

- raise the complaint with a retailer or wholesaler's Code compliance manager
- request the immediate elevation of the complaint to senior management, or
- take the complaint directly to mediation or arbitration.

The effectiveness of the code has been varied due to poor enforcement

There have been varied opinions of the effectiveness of the Code since its inception in 2012. In 2015, the ACCC chairman Rod Sims said the initial implementation of the Code had been "disappointing" due to the lack of strict adherence. However, there has been some improvement in the ACCC enforcing the code since that time.

Complaints handling processes guidelines

This section of the literature review summarises the relevant insights from the 2014 'AS/NZS 10002:2014 Australian/New Zealand Standard™ Guidelines for complaint management in organizations' (the Standard). Although the Standard is a guide to complaint management within an organisation, it still contains many relevant structures and procedures which are applicable to industry-wide complaints handling processes.

Guiding principles

Focus on people and enable them to make complaints

Organisations need to ensure that they best enable complaints by focusing on the experience of complainants. This should be done through treating all complainants with respect, demonstrating commitment to addressing complaints in an appropriate and timely manner, having a visible and transparent process, ensuring accessibility, and not charging any submission fees.

Manage complaints with professionalism and clear communication

Organisations should ensure that they manage complaints with responsiveness, objectivity and fairness, equitably, protect complainant privacy, and communicate explanations and resolutions well. The organisation should establish a clear complaint management policy with procedures of complaint

management, including the parties involved in each process and their roles. This policy should be accessible to both staff and the general public.

Manage staff and stakeholders appropriately

Organisations should ensure that they have appropriate policies and guidelines around expected conduct of parties, work health and safety, facilitation for complaints involving multiple parties, and that staff are empowered to implement the complaint management system.

Ensure clear accountability, learning and prevention of ongoing disputes

Organisations should ensure that they have clear accountability, are continuously improving the quality of their complaints process, and develop and implement systems to minimise the number of complaints which escalate into ongoing disputes. Complaints handling bodies should continually strive to improve their effectiveness and efficiency. On a regular basis, the senior management should, or engage an external party to, audit, monitor and evaluate its process, including surveying satisfaction. The organisation should also recognise and learn from best practices in complaint management, empower staff, encourage innovation.

Complaint management system recommendations

Complaints handling bodies need to consider their role in the existing environment

Firstly, the organisation should consider any existing statutory or regulatory requirements, the value of the complaints process, the financial, operational and organisational requirements, the number and demographics of customers, the nature and breadth of public interaction, the number and type of complaints received, and input from staff and other stakeholders.

Complaints should be resolved as early on in the process as possible

Where possible, complaints should be managed and resolved at the first point of contact with the organisation. The organisation should aim to have the majority of complaints resolved by frontline with appropriate staff training and procedures provided to enable early resolution this. If the complaint is still unresolved at the front line, then they can be escalated to a second formal level of review. If still unresolved, complainants should have the option to seek a review by an appropriate external complaint management mechanism or body.

Communication of the process should be clear to complainants and the public

Information about the complaints process should be readily available, written in plain English and provided in a range of formats and languages. The complaint management policy should be accessible from the website homepage, at a reception area of any relevant physical location, and in leaflets, newsletters or other relevant media generated by the organisation.

Public information about the complaint management system should include:

- where complaints can be made
- how complaints can be made
- when complaints can be made
- when acknowledgement of complaints can be expected
- what information should be provided by the complainant
- the organisation's process for handling complaints
- time periods associated with various stages in the process
- where appropriate, possible options for redress
- the complainant's options for review, both internally and externally

- how the complainant can obtain feedback on the status of their complaint.

The organisation should acknowledge receipt of each complaint promptly. The organisation should record any complaint with supporting information and a unique identifier. The record of the complaint should identify the following as a minimum: the complainant's contact information, issues raised, outcome sought, any other information required to properly respond to the matter, and any support requirements needed by the complainant.

The organisation should also track complaint progress until resolution and provide an up-to-date status to the complainant upon request.

The organisation should ensure that its complaint management policy, processes and outcomes informs and is consistent with its communication, public relations and media activities.

Sufficient resources is vital for effective operations

The organisation should ensure that it has adequate resources for staff and complaint management. Resources include the number of staff appropriate to the number and complexity of complaints, the appropriateness of training provided to staff, the clarity of complaint management procedures, the simplicity of complaint management documentation, the sufficiency of the specialist support provided to staff, and the adequacy of materials and equipment, including technology and finances.

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Appendix I MAIF Agreement

I.1 Preamble

This document sets out the obligations of manufacturers in and importers to, Australia of infant formulas and gives effect in Australia to the principles of the *World Health Organization's International Code of Marketing of Breast Milk Substitutes* (WHO Code).¹

I.2 Clause 1: Aim

The aim is to contribute to the provision of safe and adequate nutrition for infants, by the protection and promotion of breastfeeding and by ensuring the proper use of breast milk substitutes, when they are necessary², on the basis of adequate information and through appropriate marketing and distribution. (WHO Code Article 1)

I.3 Clause 2: Scope

This document applies to the marketing in Australia of infant formulas when such products are marketed or otherwise represented to be suitable, with or without modification, for use as a partial or total replacement of breast milk. It also applies to their quality and availability, and to information concerning their use. (WHO Code Article 2)

I.4 Clause 3: Definitions

'Breast milk substitute' - any food marketed or otherwise represented as a partial or total replacement for breast milk, whether or not suitable for that purpose.

'Container' - any form of packaging of infant formulas for sale as a normal retail unit, including wrappers.

'Health care system' - governmental, non-governmental or private institutions engaged, directly or indirectly, in health care for mothers, infants and pregnant women and nurseries or child-care institutions. It also includes health workers in private practice. For the purposes of this document, the health care system does not include pharmacies or other retail outlets.

'Health care professional' - a professional or other appropriately trained person working in a component of the health care system, including pharmacists and voluntary workers.

'Infant formula' - any food described or sold as an alternative for human milk for the feeding of infants up to the age of twelve months and formulated in accordance with Australian Food Standard R7 - Infant Formula.

'Label' - any tag, brand, mark, pictorial or other descriptive matter written, printed, stencilled, marked, embossed or impressed on, or attached to, a container of infant formulas.

'Marketing' - includes the promotion, distribution, selling, advertising, public relations and information services related to infant formulas.

'Marketing personnel' - any persons whose functions include the marketing of infant formulas.

'Samples' - single or small quantities of an infant formula provided without cost. (WHO Code Article 3)

I.5 Clause 4: Information and Education

4(a) Manufacturers and importers of infant formulas in Australia agree that informational and educational materials, whether written, audio or visual, dealing with the feeding of infants and intended to reach pregnant women and parents of infants and young children, should always include clear information on all the following points:

- i. the benefits and superiority of breastfeeding;
- ii. maternal nutrition, and the preparation for and maintenance of breastfeeding;
- iii. the negative effect on breastfeeding of introducing partial bottle-feeding;
- iv. the difficulty of reversing the decision not to breastfeed; and
- v. where needed, the proper use of infant formula, whether manufactured industrially or home prepared. (WHO Code Article 4.2)

4(b) When such materials contain information about the use of infant formulas, they should include the social and financial implications of its use, the health hazards of inappropriate foods or feeding methods and, in particular, the health hazards of unnecessary or improper use of infant formulas. Such materials should not use any pictures or text which may idealise the use of infant formulas. (WHO Code Article 4.2)

4(c) Manufacturers and importers of infant formulas should not donate informational or educational equipment or materials unless it is at the request of, and with the written approval of, the appropriate government authority or within guidelines given by the Commonwealth, State or Territory Governments for this purpose. Such equipment or materials may bear the donating company's name or logo, but should not refer to a proprietary infant formula, and should be distributed only through the health care system. (WHO Code Article 4.3)

I.6 Clause 5: The general public and mothers

5(a) Manufacturers and importers of infant formulas should not advertise or in any other way promote infant formulas to the general public. (WHO Code Article 5.1)

5(b) Manufacturers and importers of infant formulas should not provide samples of infant formulas to the general public, pregnant women, parents or members of their families. (WHO Code Article 5.2)

5(c) Manufacturers and importers of infant formulas should not distribute to pregnant women, or parents of infants and young children, any gifts of articles or utensils which may promote the use of breast milk substitutes or bottle-feeding. (WHO Code Article 5.4)

5(d) Marketing personnel, in their business capacity, should not seek direct or indirect contact with pregnant women or with parents of infants and young children. This does not prevent appropriately qualified personnel from responding to complaints or unsolicited requests for information. For these requests, parents should be referred to a health care professional whenever health advice is required. (WHO Code Article 5.5)

I.7 Clause 6: Health care system

6(a) Manufacturers and importers of infant formulas should not use any facility of the health care system for the purpose of promoting infant formulas. This does not, however, preclude the dissemination of information to health care professionals as provided in clause 7(a). (WHO Code Article 6.2)

6(b) Manufacturers and importers of infant formulas should be aware that facilities of health care systems should not be used for the display of products within the scope of this document, for placards or posters concerning such products, or for the distribution of material provided by a manufacturer or distributor other than that specified in clause 4(c) above. (WHO Code Article 6.3)

6(c) The use by the health care system of pharmacies or retail outlets, 'professional service representatives', 'mothercraft nurses', or similar personnel, provided or paid for by manufacturers or importers of infant formulas is not permitted. (WHO Code Article 6.4)

6(d) Manufacturers and importers of infant formulas should be aware that feeding with infant formulas, whether manufactured or home prepared, should be demonstrated only by health care professionals. Such demonstrations should be made only to the parents or other persons who need to use it, and the information given should include a clear explanation of the hazards of improper use. (WHO Code Article 6.5)

6(e) Manufacturers and importers of infant formulas may make donations, or low-priced sales, of infant formulas to institutions or organisations, whether for use in the institutions or for distribution outside them. Such provisions should only be used or distributed for infants who have to be fed on breast milk substitutes. If these provisions are distributed for use outside the institutions, this should be done only by the institutions or organisations concerned. Manufacturers or importers should not use such donations or low-price sales as a sales inducement. (WHO Code Article 6.6)

6(f) Manufacturers and importers of infant formulas should note that, where donated infant formulas are distributed outside an institution, the institution or organisation should take steps to ensure that these provisions can be continued as long as the infants concerned need them. Donors, as well as the institutions or organisations concerned should bear in mind this responsibility. (WHO Code Article 6.7)

6(g) Equipment and materials, in addition to those referred to in clause 4(c), donated to a health care system may bear a company's name or logo, but should not refer to any proprietary infant formulas. (WHO Code Article 6.8)

I.8 Clause 7: Health Care Professionals

7(a) Manufacturers and importers of infant formulas providing information about the formulas to health care professionals should restrict the information to scientific and factual matters. Such information should not imply or create a belief that bottle-feeding is equivalent or superior to breastfeeding. It should also include the information specified in clause 4(a) above. (WHO Code Article 7.2)

7(b) Manufacturers and importers of infant formulas should provide members of the medical profession and related health care professionals with information about the products, and this information should accurately reflect current knowledge and responsible opinion. Such material should be clearly identified with the name of the manufacturer or importer, the brand names of the infant formulas, and the date of publication.

7(c) Manufacturers and importers of infant formulas should not offer any financial or material inducement to health care professionals or members of their families to promote infant formulas, nor should such inducements be accepted by health care professionals or members of their families. (WHO Code Article 7.3)

7(d) Manufacturers and importers of infant formulas should not provide samples of infant formulas, or of equipment or utensils for their preparation or use, to health care professionals except when necessary for

the purpose of professional evaluation or research at the institutional level. (WHO Code Article 7.4)

7(e) Manufacturers and importers of infant formulas should disclose to institutions, to which a recipient health care professional is affiliated, any contribution made to him/her, or on his/her behalf, for fellowships, study tours, research grants, attendance at professional conferences, or the like. (WHO Code Article 7.5)

I.9 Clause 8: Persons employed by manufacturers and importers

8(a) In systems of sales incentives for marketing personnel, the volume of sales of infant formulas should not be included in the calculation of bonuses, nor should quotas be set specifically for sales of these products. This should not be understood to prevent the payment of bonuses based on the overall sales by a company of other products marketed by it. (WHO Code Article 8.1)

8(b) Personnel employed in marketing infant formulas should not, as part of their job responsibilities, perform educational functions in relation to pregnant women or parents of infants and young children. This does not prevent such personnel from being used for other functions by the health care system. (WHO Code Article 8.2)

I.10 Clause 9: Quality and Labelling

9(a) Manufacturers and importers of infant formulas must ensure that infant formulas sold in Australia conform to Australian Food Standard R7 - Infant Formula. (WHO Code Articles 9.2, 9.4, 10.1 and 10.2)

9(b) Manufacturers and importers of infant formulas must ensure that labels provide the information required to be provided by the Australian Food Standard A1 - Labelling and Advertising and Standard R7 - Infant Formula, and also provide the necessary information about the appropriate use of infant formula and should not discourage breastfeeding. (WHO Code Article 9.1)

I.11 Clause 10: Implementation and monitoring

10(a) Independently of any other measures taken to implement their obligations under this document, each manufacturer and importer of infant formulas should regard itself as responsible for monitoring its marketing practices according to the principles and aim of this document, and for taking steps to ensure that its conduct at every level conforms to those principles and aims. (WHO Code Article 11.3)

10(b) Manufacturers and importers of infant formulas agree to be represented on APMAIF and to participate fully in the work of the Advisory Panel.

10(c) Each manufacturer and importer of infant formulas should apprise its personnel of the existence of this document and of their responsibilities under it. (WHO Code Article 11.5)

Appendix J **Consultation Summary Report**

The Consultation Summary Report including the on-line survey data is attached as a separate document.