



Australian Government

Department of Health

**Re-authorisation of the Marketing in Australia of Infant
Formulas: Manufacturers and Importers Agreement
(MAIF Agreement) by the Australian Competition and
Consumer Commission (ACCC) A91506 &A91507**

Submission to the ACCC Draft determination

DEPARTMENT OF HEALTH

The Department of Health supports the re-authorisation of the Marketing in Australia of Infant Formulas: Manufacturers and Importers Agreement (MAIF Agreement) based on the following comments being addressed prior to the authorisation being finalised.

1. Current Signatories

It is listed in both the Infant Nutrition Council's (INC) application and the Australian Competition and Consumer Commission's (ACCC) draft determination that the *Infant Food Co Pty Ltd* is a current signatory to the MAIF Agreement. Part of the Department of Health's (the Department) role is to facilitate companies becoming signatories to the MAIF Agreement and the Department would like to advise that the Infant Food Co Pty Ltd is not a current signatory and this should be corrected.

2. Associated Guidelines

The Department notes that the conduct for which authorisation is sought not only includes the MAIF Agreement but also includes the following documents:

- Interpretation and application of the MAIF Agreement;
- The marketing of infant formula via electronic media;
- Interactions with health care professionals;
- The provision of samples to health care professionals; and
- The complaints and review process (Terms of Reference).

With the exception of the last two documents mentioned above, these documents were developed by the Advisory Panel on the Marketing in Australia of Infant Formula (APMAIF). The APMAIF was a non-statutory body that monitored compliance with, and advised the Australian Government on, the operation of the MAIF Agreement. The APMAIF ceased to operate in November 2013. Since APMAIF ceased, a revised model for managing complaints in relation to the MAIF Agreement has been developed and established by the St James Ethics Centre, in consultation with INC and the Department of Health.

The MAIF Complaints Tribunal commenced in December 2014. The MAIF Complaints Tribunal has been established to receive and investigate complaints regarding the marketing in Australia of infant formulas and develop guidelines on the interpretation and application of the MAIF Agreement. The Terms of Reference for the MAIF Complaints Tribunal are at **Attachment A**.

Amendments or updates to all of the above listed documents would not necessarily require the agreement from all signatories to the MAIF Agreement and the MAIF Complaints Tribunal and therefore should not form part of the Agreement. Breaches of these documents

do not have to be considered by the MAIF Complaints Tribunal in its consideration of complaints and the Tribunal does not have to apply the documents when it makes a decision.

However, the Department notes that these documents may form a reference point to companies and industry. As stated in the Terms of Reference (**Attachment A**), part of the MAIF Complaints Tribunal's role is to develop its own guidelines on the interpretations and application of the MAIF Agreement.

The Department therefore recommends that re-authorisation of the MAIF Agreement should not include these documents.

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

Complaints Tribunal

Terms of Reference

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
- Bayer Australia Ltd
- H J Heinz Company Australia Ltd
- Nestlé Australia Ltd
- Nutricia Australia Pty Ltd
- A2 Corporation 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 St James Ethics Centre with a request that the 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: <http://www.health.gov.au/apmaif>

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:

- 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;
- represent the infant formula industry in Australia and New Zealand

Source: <http://www.infantnutritioncouncil.com/about-us/>

4. St James 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 St James 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 St James 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) St James Ethics Centre will establish the service so that the deliberations of the Tribunal are free from influence by any other organisation, including St James Ethics Centre.
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MAIF Complaints Tribunal

Terms of Reference

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; and
 - b) develop guidelines on the interpretation and application of the MAIF Agreement.

Proceedings:

- 2) All proceedings of the Complaints 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 23).

Composition:

- 5) 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.
 - b) A disinterested Public Health and Nutrition Expert with scientific and technical expertise in public health, nutrition, regulation around therapeutic goods and the food/drug interface.
 - c) A disinterested community representative.

Appointment:

- 6) Members of the Tribunal shall be appointed by the Executive Director of St James Ethics Centre.
- 7) The power of appointment may not be delegated to another person.
- 8) In making an appointment the Executive Director of St James 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).

Conflicts of Interest

- 9) 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.

Term of appointment

- 10) Each Member may be appointed for a period of three years.
- 11) Subject to clause 11, Members are eligible for appointment for one further term of three years.
- 12) 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.

Termination of Appointment

- 13) 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.

Casual Vacancies

- 14) The Executive Director of St James Ethics Centre must as soon as is practicable appoint suitably qualified persons to fill any casual vacancy that might arise on the Tribunal.
- 15) In filling a casual vacancy the Executive Director of St James Ethics Centre must apply the same criteria for selection as if making a regular appointment of a Member.

Chair of the Tribunal

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

Remuneration

17) Members of the Tribunal shall be paid a daily rate, as specified in Appendix 1.

18) The daily rate of remuneration is to be reviewed on an annual basis.

19) Members of the Tribunal are to be reimbursed for out-of-pocket expenses reasonably incurred in the conduct of their duties.

Basis for a determination

20) 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.

21) The Tribunal shall publish, by means that it deems appropriate, reasons for its determinations.

Process

22) 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.

23) Upon receipt, complaints will be assessed by the Department and are classified as being within or outside the scope of the MAIF Agreement. Those 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 member to the MAIF Agreement or was not a member 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").

24) The Department may, at its absolute discretion, seek further information (if required) in order to make a determination in relation to scope.

25) 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.

- 26) 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 to St James Ethics Centre (the Secretariat) for submission to the Tribunal at its next available meeting.
- 27) Upon receipt of a complaint that is deemed to be within scope, the Secretariat (St James Ethics Centre) will advise the manufacturer or importer of the product concerned that a complaint has been received alleging a breach of the MAIF Agreement. The manufacturer or importer (respondent) will be invited to respond with any evidence or other information it wishes to submit for consideration by the Tribunal in making its determination.
- 28) Complaints requiring consideration by the Tribunal will be summarised by the Secretariat prior to being forwarded to the Tribunal.
- 29) Summaries will be prepared using a standard format to present the key information relevant to making a decision. Where available, this information is to 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 (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).
- 30) The Tribunal is to consider the complaint and may decide initially that it does not represent a breach of the MAIF Agreement or that further consideration is required before a determination can be made.
- 31) Where further consideration is required, the manufacturer or importer is to be notified by the Secretariat and provided with relevant material and invited to respond with any further relevant information.
- 32) At its next available meeting, the Tribunal is to consider all relevant information provided and make a decision that the complaint is either 'in breach' or 'not in breach' of the MAIF Agreement.
- 33) In cases where a breach of the MAIF Agreement has been found, the Tribunal may make recommendations as to how the breach might best be remedied.
- 34) In all but exceptional circumstances, the deliberations of the Tribunal are to be concluded within a period of three months after an 'in scope' complaint has been received by the Secretariat.
- 35) When a decision is made, both the complainant and the subject company are to be advised of the final outcome of the complaint, including the Tribunal's reasons for the decision and any recommendations that the Tribunal may have made in relation to the matter.
- 36) Decisions that there has been a breach of the MAIF Agreement, along with any recommendations by the Tribunal, are to be reported to the Department and are to be recorded in the Tribunal's Annual Report.

- 37) 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.
- 38) Except with the consent of the complainants, the complainants' identities are not to be disclosed to parties other than the Members of the Tribunal.

Appeals

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

Residual Rights

- 40) 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.

Observer

- 41) A representative of the Commonwealth Minister for Health may attend a meeting of the Tribunal as an Observer.
- 42) 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.
- 43) An observer may not speak, nor otherwise contribute to, the deliberations of the Tribunal.

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	\$922 per day
Member	\$794 per day