

Natural and Traditional Health Products Bill

A Proposal for the Regulation of:

- Natural and Traditional Health Products
- Manufacturers, Importers, Exporters, Distributors,
Marketers and Licensees

Natural and Traditional Health Products Bill

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Section I: Explanatory Notes

Introduction

This proposal is modelled, to a very large extent, on the recommendations of the Health Select Committee's first inquiry report into the Joint Trans-Tasman Therapeutic Goods Agency ("JTTTGA", later renamed Australia New Zealand Therapeutic Product Agency ("ANZTPA")). Where possible, this proposal has embraced and has been empathetic to the concerns of various stakeholders as expressed in submissions to the Health Select Committee inquiries/hearings into the JTTTGA.

The Health Select Committee inquiry report into the proposal to establish the JTTTGA to regulate, what are currently called "dietary supplements", made a number of recommendations relating to the regulation of "dietary supplements". The term Natural and Traditional Health Products ("NaTHPs") has been subsequently adopted as a result of stakeholder input, as the term NaTHP accurately describes the class of products. The term NaTHP is used throughout this proposal.

NaTHPs is a \$650 million industry, with approximately \$300 million in domestic sales and \$350 million in export sales.

This proposal establishes an industry specific regulatory agency, in addition to any agencies responsible for the regulation of foods and pharmaceutical medicines, but acknowledges that there will be interface issues that need to be appropriately and fairly managed.

- An example of potential interface issues is highlighted by the recent European Court of Justice ruling, which held in Case C-319/05 Commission v. Germany, that Germany had classified the product wrongly as a medicinal product thereby imposing a restriction on the free movement of goods, which is prohibited by Article 28 European Convention (EC). The European Court of Justice ruled that presenting a herbal extract in capsule form does not make a product a medicine. A capsule is simply a small container. In this case, garlic extract in a capsule is no more or less a food than whole garlic.
- The Court then turned to the question of whether the German measure was justified for reasons relating to the protection of public health in accordance with Article 30 EC. The Court held that there was no public health justification for such a measure.
- Under the proposal garlic extract would qualify as a NaTHP; the European Court of Justice ruling would also classify it as a food. It should be left to the company/enterprise as to whether they manufacture and market their products under food or NaTHP requirements.

The proposal provides for a co-regulatory model suitable for a very low risk industry. Agency costs will be shared by the Government and industry. [A small levy funding mechanism based on turn-over is proposed as the most efficient means of collecting industry contributions. It is also seen as a means of controlling or limiting the expansion of the regulatory agency via regulatory creep. Alternatively, a licensed fee based system may be appropriate depending on further consultation once a full economic impact assessment has been completed.]¹

This proposal recognises that there are unique regulatory issues relating to processed extracts that are different to pharmaceutical and food manufacturing requirements.

Products that meet the definitions of NaTHPs will be exempt from the Medicines Act 1981 and the Food Act 1981, including issues arising from Codex Alimentarius, unless the distributor of the NaTHP chooses otherwise.

Food or Medicine? Battle of Paradigms

- The regulation of NaTHPs has long been caught in the midst of a regulatory battle of paradigms; caught between those who believe that they should be regulated as medicines and those who believe that they should be regulated as foods. This debate has dragged on for several decades.
- NaTHPs have long been recognised in New Zealand as being not 'foods' or 'medicines' in the ordinary sense of those words and yet, as a range of products NaTHPs embrace both foods and medicines.
- The Dietary Supplement Regulations 1985 acknowledges this unique aspect of NaTHPs with the

¹ Explanatory note: [...square brackets...] that are used in this document Indicates that Industry has not reached a consensus and that further information and or consultation is required.

following explanation:

"This note is not part of the regulations, but is intended to indicate their general effect. These regulations, in a sense, fill the gap between the Food Regulation 1984 and the Medicines Regulation 1984, in that dietary supplements are not 'food' or 'medicine' in the ordinary sense of those words. However, they are 'food' within the meaning of the Food Act 1981, and will be 'related products' within the meaning of the Medicines Act 1981 if therapeutic claims are made for them."

- New Zealand industry has had the opportunity over the past 20 years to make therapeutic claims for its products by licensing its products as 'related products' under the Medicines Act.
- With very few exceptions, New Zealand industry chose not to license their products as related products. The primary reason being that, although doing so would have enabled them to make therapeutic claims, the economic impact of doing so would have been prohibitive.
- Government decisions on its future involvement in NaTHP regulation should be based on the principle of proportionality. NaTHPs, with a long recognised history of safe use, should not be regulated with the same mindset or philosophy as novel pharmaceutical products with no history of safe use.

Justification for a Light Regulatory Framework

Decision-making Process for Government Involvement in Regulation

The need for regulation and the most effective regime for it should be periodically reviewed to ensure that the regime in place continues to meet its intended objectives with minimal negative impact on competition, consumer choice and other important factors. As the current regulatory framework is generally recognised to need improvement, this Act provides for this review.

The Cabinet Office Manual contains a five-step framework for regulating occupations that can be applied to the regulation of NaTHP industry:²

➤ **Step One: Identify whether intervention in an industry is necessary**

- Consider the nature of the risk from the industry
 - Probability of significant irreversible harm occurring
 - Availability of other means of handling risk (e.g. insurance)

If significant irreversible harm is likely there is a case for intervention in the practice of the industry.

➤ **Step Two: Identify whether intervention by Government is justified**

- Consider whether existing means of protection from harm for consumers and third parties are sufficient (i.e. civil law, consumer legislation)
- Consider ability of industry to regulate itself;
- Consider likely effect of intervention by Government

If significant harm is likely, existing means of protection are insufficient, the industry is unable to regulate itself adequately and intervention by Government is likely to improve outcomes, there is a strong case for Government intervention.

➤ **Step Three: Identify the most effective form of Government intervention**

- Consider nature of problem posed by the industry. Would it be solved by:
 - Provision of information to consumers
 - Training of industry
 - Setting and enforcing standards
 - Specifying services Government will purchase

² Cabinet Office Circular: June 2008: http://www.dPMC.govt.nz/Cabinet/circulars/co99/COC_99_6.pdf
Cabinet Manual 2008: April 2008: <http://www.cabinetmanual.cabinetoffice.govt.nz/files/manual.pdf>

If any links shown within this documents footnotes do not connect to the appropriate reference, an alternative source can be found at: http://www.nzhealthtrust.co.nz/NTHP_footnotes.html this link can also be found at the bottom of page 44.

- Legislation regulating practice of industry?

If only a specific aspect of the practice of an industry poses a threat to consumers or third parties, the best solution is to target that aspect rather than legislate to regulate the industry.

➤ **Step Four: If legislation is required to regulate an industry, what form of regulatory regime is needed**

- Disclosure
- Registration
- Certification
- Licensing those entering an industry

Licensing participants in an industry imposes costs and reduces flexibility more than other means of control and should be reserved for industry where there is a high need for control for safety reasons. Any of the other methods are likely to be adequate control for industries, which do not affect health or safety.

➤ **Step Five: What legislative provisions are needed to regulate industries**

- Regulation should be guided by the following general principles drawn from the Code of Good Regulatory Practice approved by Cabinet in 1997. These are:
 - **Effectiveness:** Regulation should be designed to minimise an identified risk of significant harm to consumers or the public from market failures, such as information asymmetries and externalities in service markets
 - **Efficiency:** Taking into account alternative approaches, the benefits of regulation to society (consumer and public protection) should exceed the costs of regulation to society (i.e. higher prices and reduced competition)
 - **Equity:** Regulation should be fair; it should treat individuals in similar situations similarly and individuals in different situations differently
 - **Transparency:** In formulating and administering occupational regulation, the process should be transparent to both the decision-makers and those affected by those decisions
 - **Clarity:** Regulatory processes and requirements should be as understandable and accessible as practicable
- Institutional regulation should minimise the incentives for regulatory bodies to provide occupational protection rather than public protection
- An important additional point is that any regulation should be able to be enforced effectively³

When is there a Good Case for Regulatory Intervention?

The Cabinet Office Manual provides a model for regulatory intervention, as discussed immediately above, that when applied to NaTHPs, suggests that a light regulatory framework is appropriate in the vast majority of cases for the following reasons:

- Most of the limited examples of harm are not significant
- There are so few documented examples of irreversible harm
- Consumption of these products is voluntary

Overview of How this Bill's Graduated Risk-Proportionate Risk-Management Framework Operates

- A graduated risk-proportionate risk-management framework for the regulation of NaTHPs is proposed
- The framework embraces the Government's Code of Good Regulatory Practice⁴, which requires laws to meet standards of efficiency, effectiveness, transparency, clarity and equity

³ Policy Framework for Occupational Regulation: A Guide for Government Agencies Involved in Regulating Occupations; December 2005 http://www.med.govt.nz/templates/MultipageDocumentPage_9117.aspx#P110_4952

⁴ Code of Good Regulatory Practice: 28 Aug 2006 http://www.med.govt.nz/templates/MultipageDocumentTOC_22149.aspx

- The proposed Act shall establish NaTHPs as a legal category in its own right, meaning that it shall no longer be classified as a subset of foods or as a subset of medicines
- Nothing in the Act overrides the Treaty of Waitangi or any resolution of any claim under the Treaty of Waitangi
- It is acknowledged that there may, from time to time, be interface issues between NaTHPs and foods or medicines, which will require responsible and equitable risk management. It is contrary to Good Regulatory Practice for inequitable decision-making processes to be utilised in regulating the NaTHP industry
- It is inappropriate for a pharmaceutical mindset or philosophy to regulate NaTHPs through de facto means
- All NaTHPs shall be manufactured and distributed under an approved Risk-Management Programme (RMP) including, where appropriate, GMP
- In order to prevent unnecessary regulatory creep, there shall be a prescribed risk proportionate dispute resolution mechanism to be followed when there is conflict between the Regulator and any affected party
- The Act recognises the need for risks to be managed using the As Low As Reasonably Practicable (“ALARP”) principle. This does not mean that zero-risk is the standard for regulating NaTHPs. However, as a rule, NaTHPs have a very low risk profile resulting from extended use. This means that it is reasonable to assume that NaTHPs and their ingredients are safe until proven otherwise
- The Act recognises the significant diversity of the industry providing NaTHPs and the various potential competing interests that such diversity can cause. The Act provides a means of pre-empting issues relating to some of that diversity and provides a risk-proportionate dispute resolution mechanism to help resolve conflict in a fair and equitable way
- Some acknowledged potential competing interests include, but are not limited to:
 - Large companies/enterprises versus small companies/enterprises
 - Retailers wanting access to a wide range of product versus practitioners wanting exclusive prescribing rights
 - Proponents of standardized herbs versus proponents of non-standardized herbs
 - Consumers desire for freedom of choice versus Regulator's desire to protect the consumer
 - Science versus history of safe use
 - Pharmaceutical mindset or philosophy (i.e. no history of safe use - must be approved before use) versus food mindset or philosophy (i.e. generally recognised as safe – free sale subject to basic quality processes)
 - Proprietary ownership versus generic ownership
 - Qualified practitioners versus experienced practitioners
 - New Zealand made versus imported
- Such potential competing interests can introduce distortions to the market if allowed to influence decision making so they need to be formally acknowledged and managed appropriately
 - Where practicable, these potential competing interests need to be considered when appointing representatives to expert advisory groups or working parties
 - Potential competing interests must be identified during consideration of risk management options and avoided as much as reasonably practicable
 - Appointments must be based in the skills brought to the table but must also ensure a balance in representation
 - The annual Auditor General's audit will assess the management of such potential competing interests

- The Act does not restrict the extemporaneous⁵ prescribing, compounding and dispensing of NaTHPs unless an ingredient is prohibited for human use altogether:
 - Provision will be made in this Act for certain ingredients to be prohibited from industrial production, but able to be extemporaneously prescribed, compounded and dispensed by appropriately qualified practitioners
 - Such provision would usually be reserved for individual identified consumer use, but in certain circumstances, such as an epidemic or outbreak of a particular disorder, could provide for production sufficient for groups of individuals.
- This Act does not apply to the retailing of product, except for the requirement to comply with recall requests when a Class I recall is issued, but does apply to the manufacture, importation, storage and distribution of such products
- In recognition of their unique characteristics, NaTHPs will be legislated for as a separate class of products distinct from pharmaceutical products and food products, whilst acknowledging that there may be interfaces between all categories which may need to be specifically provided for in legislation and regulation
- The Act, in a sense, fills the gap between the Food Act 1981 and associated regulations and the Medicines Act 1981 and associated regulations, in that NaTHPs are not necessarily “food” or “medicine” in the ordinary sense of those words. However, dietary supplements, a large category of NaTHPs, are currently regulated as “food” within the meaning of the Food Act 1981, and “related products” within the meaning of the Medicines Act 1981 if therapeutic claims were made for them:
 - Historically, this regulatory environment has left dietary supplements poorly regulated and open to criticism from all sides, as they are not appropriately regulated. Some argue that they are unregulated in that there are no specific manufacturing requirements and that the ingredients are not officially approved, and others argue that they are over regulated in that to make legitimate evidence based claims these products have to go through an onerous and expensive medicines approval process as related products. The fact that very few products have been licensed as related products highlights the failure of that option provided in the Medicines Act
- The proposed Act blends elements of both medicines and food legislation in such a way that the inherent very low risks associated with most NaTHPs are carefully managed so that:
 - The Regulator knows who is in the market and what is in the market
 - The Regulator is able to respond in a risk-proportionate manner should a significant public health issue emerge
 - Businesses are required to maintain an appropriate level of product quality necessary to maintain public confidence in the industry as a whole
 - Businesses are able to manufacture and market existing and innovative products with the minimum of regulatory burden
 - Businesses are able to make evidence based health claims
 - Businesses are able to supply export markets in the knowledge that they have a supportive and efficient regulator
 - Politicians have a high degree of confidence that the industry is appropriately regulated and public confidence in NaTHPs is maintained
 - The Act will be guided by the overarching principles set out in Part I, Section 3 of the Act
- The Act provides that all products be manufactured and marketed under the umbrella of registered Risk Management Programme (RMP) including, where appropriate, GMP, which may range from a recognised pharmaceutical or dietary supplement style of Good Manufacturing Practice certificate, through to an RMP registered under the Animal Products Act (for example) with appropriate ‘add-ons’ to meet all the minimum requirements of the Act
 - For example, all RMPs including, where appropriate, GMP, must have a recall system in place and notify such to the Regulator. Some recognized overseas GMPs eg the recently announced USA Dietary Supplement GMP, and RMPs under the Animal Products Act do not

⁵ Definition: Products specifically tailored for an individual

require a recall system.

- The Act provides a mechanism for the Regulator to challenge/disallow a proposed new ingredient, where a less than tolerable public health risk is considered likely or insufficient evidence of safety or history of safe use is provided by the notifier, but enables an affected party, such as the distributor or industry group to initiate a dispute resolution mechanism based on a formal risk assessment and a prescribed dispute resolution process
- The Act provides a mechanism by which the Regulator can recall individual products or products containing specific ingredients on the market that pose a less than tolerable public health risk, but enables an affected party, such as the distributor or industry group to initiate a dispute resolution mechanism based on a prescribed dispute resolution process
- The Act prohibits the Regulator from applying the provisions of any regulation in a punitive manner
- The Act provides guidance as to the need for regulatory response to be commensurate with established level of risk and Good Regulatory Practice
- The Act exempts NaTHPs from the requirements of food law and medicines law when NaTHPs comply with the requirements of the Act
 - For the avoidance of doubt, NaTHPs are exempt from the requirements of Codex Alimentarius Guidelines and Rules as applied in New Zealand
- Regulatory decisions under this legislation may be open to challenge, through the World Trade Organisation, where they appear to create technical barriers to trade
- All New Zealand manufacturers and distributors of NaTHPs shall be required to register their presence in the market with the Regulator, which shall be via the simple online Risk Management System (RMS)
- Serious recidivist breaches of the Act and any subsequent regulations may result in a business being disqualified from manufacturing or supplying NaTHPs. However, the Act provides for an affected party to initiate a dispute resolution mechanism based on a prescribed dispute resolution process

Vision

- A viable Natural and Traditional Health Product (NaTHP) industry, recognised in its own right as a contributor to quality of life and wellness in New Zealand:
 - True-to-label health products
 - Sustainable employment to New Zealanders
 - Thriving domestic market and export trade
 - Freedom of choice for consumers
- Stand-alone legislation that provides a framework allowing scientifically and/or traditionally based health claims to be made on a wide choice of *quality, effective and safe* NaTHPs, which range from supplementing the diet to therapeutic cures
- Stand-alone legislation, administered by a separate industry-specific Government office providing a viable and innovative environment for the manufacture, export, import and research of NaTHPs
- Legislation which shall enable products that meet the definitions of Natural and Traditional Health Products to be exempt from the Medicines Act 1981 and the Food Act 1981, including issues arising from Codex Alimentarius, **unless the distributor of the NaTHP** chooses otherwise
- Industry and Government working cooperatively towards mutual recognition of New Zealand regulations with overseas Governments and accepting unilateral recognition, where practicable

A New Agency

- This proposal establishes an industry specific regulatory agency, apart from the agencies responsible for the regulation of foods and pharmaceutical medicines, but acknowledges that there will be interface issues that need to be appropriately and fairly managed

This proposal:

- Provides a degree of certainty for industry
- Offers consumers freedom of informed choice
- Gives regulators a robust process ensuring safety to consumers
- Minimises the potential for unnecessary technical barriers to trade
- Reduces ongoing compliance and regulatory costs to levels as low as reasonably practicable to not restrict innovation

Intent

The intention of the proposal is to put in place in New Zealand a risk responsive and risk proportionate, robust and sustainable regulatory environment for NaTHPs, whilst acknowledging that this class of products have a generally low risk profile.

This will provide a degree of certainty for industry, enable consumers freedom of choice, satisfy regulators of a robust process ensuring safety to consumers, minimise the potential for unnecessary technical barriers to trade and reduce ongoing compliance and regulatory costs to levels as low as reasonably practicable to not restrict innovation.

The proposal is designed to encourage consumers to accept primary responsibility for their own health and wellness, recognising that to empower them to do this, the consumer's access to good information and right to choose from a variety of options must be entrenched.

The intention is to create a sensible, cost effective approach to regulation of the NaTHP industry. As New Zealand is a small, diverse economy compared to most others and because New Zealand industry is comprised mainly of small to medium enterprises, adopting and recognising other selected countries and jurisdictions': (1) manufacturing standards; (2) health claims; and (3) ingredients lists, takes advantage of all the work already undertaken by those countries and jurisdictions. This provides an extremely good base to start from and consequently keeps costs low and overcomes any safety concerns.

The intention is to keep the Regulator's discretion to a minimum and ensure industry certainty is maximised, enabling consumers' maximum freedom of choice whilst maintaining an appropriate level of risk-proportionate consumer protection.

The Regulator must employ staff who are appropriately skilled and who are supportive towards NaTHPs.

It is intended that the new Regulator created by this proposal shall support robust growth of the industry and encourage diversity and innovation.

This proposal adopts and, where necessary, adapts appropriate best practice from around the world and in doing so embraces the concept of building knowledge on top of knowledge.

Enabling Legislation

The proposal would be given effect by an enabling Act of Parliament. Prohibition of ingredients would be the exception rather than the rule. The co-regulatory approach requires industry to ensure that products placed on the market are acceptably safe and to have evidence to that effect. The Regulator is not to disallow products unless it has strictly controlled grounds to do so. A robust dispute resolution mechanism is designed: (1) to allow the stakeholders to efficiently and cost effectively resolve conflicts over any regulator decisions with a minimum of disruption; and (2) to prevent abuse of power, negligence, or failure to uphold a duty of care. The Act seeks to maintain a healthy respect and tension between:

- The desire of industry to develop and market innovative products and the desire for safety
- Small cottage industry stakeholders and large industrial manufacturers

Safe Harbour

In essence, this proposal provides enabling legislation that operates to provide a safe harbour for qualifying products. If the answer to all four of the following questions is 'yes' then the product is regulated by this proposed Act:

- (1) Does the product fall within the definition of a NaTHP?

- The definition of a NaTHP determines whether ingredients are natural, or have a traditional use and therefore able to be considered for use in a NaTHP. Any conditions or restrictions of use will be contained in the ingredients central register
- (2) Is there an accepted Risk Management Programme (RMP) including, where appropriate, risk proportionate Good Manufacturing Practice (GMP) system in place?
 - (3) Is there the required evidence available for any health claims made regarding any NaTHP?
 - (4) Have the ingredients and product been lodged on the central register?
 - The database on the central register does not determine whether the ingredient can be used; the definition of NaTHP in the proposed Act does

Health Select Committee Recommendations⁶

In December 2003, the Health Select Committee Report recommended that the Government ensure that any system for regulating NaTHPs: (Please note the following pages refer to pages in the report itself)

- (a) is risk-based;
- (b) establishes a separate category for low-risk complementary healthcare products that do not make therapeutic claims distinct from categories for food and medicine (page 15);
- (c) requires all products and their ingredients to be listed by the distributor on a central register (page 24);
- (d) includes a simple electronic lodgement and notification system (page 30);
- (e) is based on a negative list that records which ingredients are not permitted to be used because a safety issue has been identified (page 29);
- (f) takes full account of the voluntary nature of risks accepted by consumers in this area and places an appropriate emphasis on disclosure of adequate and accurate relevant information to consumers (page 23);
- (g) has labelling requirements that govern the adequate and accurate disclosure of information (page 23);
- (h) requires compliance with good manufacturing principles (page 24);
- (i) includes monitoring, enforcement and review of quality assurance, with ongoing random sampling and auditing to ensure maximum compliance (page 24);
- (j) allows for innovation in products and processes and new product entry (page 29);
- (k) takes into account the impact of the cost of complying with any regulatory regime on the New Zealand complementary healthcare products industry (page 29).

This proposed Bill contains two variations to the Health Select Committee recommendations shown as (b) and (e) above. The two variations are as follows:

- (b) This proposal provides for evidence-based health claims utilising a schedule of sources of acceptable claims such as pharmacopoeia, certain overseas or international regulatory agencies (i.e. Australia, Canada, EU, Codex, WHO), scientific papers/reports, monographs and history of traditional purpose of use (evidence of traditional use may be oral in certain cultures). Other sources of evidence can be utilised but must be held by the claimant
- (e) This proposal includes a notification system embracing elements of both positive and negative listing systems and enabling additions of 'new' ingredients via a notification system that enables the Regulator to disallow the ingredient if it does not meet the definition of a NaTHP or poses intolerable safety concerns

This proposal assumes that:

- (1) Intervention by Government should generally be used only when there is a problem or potential problem that is either unlikely to be solved in any other way or inefficient or ineffective to solve

⁶ Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products and Petition 2002/2 of Sue Kedgley and 30,457 others (I.6D) (9 December 2003) http://www.parliament.nz/NR/rdonlyres/BC850BE7-8DD3-41B7-8CDC-47438279AF8F/14174/DBSCH_SCR_2633_2394.pdf

in any other way

- (2) The amount of intervention should be the minimum required to solve the problem
- (3) The benefits of intervening must exceed the costs

Optimal Co-regulatory Model

The proposal is for an optimal co-regulatory model of regulation requiring industry to accept its share of responsibility for maintaining confidence in its products.

To help maintain a balance between Regulator and industry responsibilities, the agency will be jointly funded by Government and industry.

There will be provision in the Act for a graduated dispute resolution mechanism that is commensurate with established risk.

Compliance of Proposal with Regulatory Guidelines

The Health Select Committee also recommended that any regulatory proposal of NaTHPs complies with all of the Committee's requirements with respect to best regulatory practice, including:

- (a) the five principles and guidelines (efficiency, effectiveness, transparency, clarity, and equity) set out in the 1997 Code of Good Regulatory Practice⁷ administered by the Ministry of Economic Development; and
- (b) the Cabinet Office and Ministry of Economic Development requirements relating to regulatory impact statements and business compliance cost statements.⁸

Impact on Existing Industry

Following enactment:

- No products currently on the market will be removed from the market unless unacceptable safety issues emerge during the transition period
- Compliance will be phased in progressively over five years
- Manufacturers, importers, exporters and distributors will have the choice of implementing Risk Management Programmes (RMPs) including, where appropriate, GMP, which will be submitted to the Regulator for approval
- An RMP including, where appropriate, GMP, will be required to meet certain safety standards and may be customised or be an acceptable risk proportionate GMP scheduled by the Act and chosen by the manufacturers, importers, exporters, or distributors; these programmes will ensure product integrity
- Simple Risk Management Programmes including, where appropriate, GMP, shall embrace well defined and sensible Hazard Analyses Critical Control Point (HACCP) principles⁹ and have requirements not unlike those required under the current Animal Product, Wine and Food Acts
- Health claims will be permitted subject to acceptable evidence being held by the manufacturers, importers, exporters or distributors, or the health claims must be contained in the schedule of sources of acceptable claims

How is this Proposal Different?

This Proposed Natural and Traditional Health Product Bill is different to both the New Zealand Dietary

⁷ Code of Good Regulatory Practice: 28 Aug 2006; http://www.med.govt.nz/templates/MultipageDocumentTOC_22149.aspx

⁸ <http://cabguide.cabinetoffice.govt.nz/procedures/regulatory-impact-analysis/ris-requirements>
Guidelines on Regulatory Impact Analysis Requirements: Sep 2007
http://www.med.govt.nz/templates/MultipageDocumentTOC_26448.aspx

⁹ Introduction to HACCP: Food and Safety Information for New Zealand Business: May 2003 <http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf>

Supplement Regulations 1985 (status quo) and the shelved proposed JTTTGA.

➤ **Status quo:**

- The Regulatory philosophy that applies in New Zealand is based on common law. This ensures that products are legal, allowed to be used and assumed safe until proven otherwise with no pre-vetting, minimal bureaucracy and restrictions
- Although the market is considered open and free, there have been very few safety problems occurring over time
- However, the Health Select Committee's inquiry report into the proposal to establish the JTTTGA to regulate therapeutic products expressed grave concerns that the few existing regulations were mostly unenforced

➤ **Shelved proposed JTTTGA:**

- The Regulatory philosophy was based on Napoleonic Law in the proposed JTTTGA where regulatory permission is required before a product can be marketed. This means that all products, beginning from the raw ingredients, the manufacturing process and all other steps, impose extensive pre-vetting and compliance costs, causing an expensive and time-consuming bureaucratic environment
- Therefore, the proposed JTTTGA meant that the Stakeholder/Applicant must first apply for a license to list a product. An initial application fee had to be paid, and if granted, a yearly license fee applied. If any of the ingredients were not on a pre-approved list, a prohibitively costly process had to be gone through to get the ingredient on the approved list.
- In addition, non-regulatory compliance costs (e.g. consultants, manufacturing processes requirements, laboratory testing and pre-vetting authorities) were significant and much higher than the regulatory costs (e.g. the license listing application fee and on-going yearly license). The proposed JTTTGA was based on the existing Australian system therefore, this often would involve replicating audits or approvals in overseas jurisdictions. This becomes an effective technical barrier to trade and to small to medium sized product runs, which effectively would stifle New Zealand's innovative, small-business based industry
- Furthermore, the Regulator would have had the power to ban an ingredient or suspend a license indefinitely for any reason with only circumstantial evidence, without due process or any significant independent appeal process

➤ **This Proposed Natural and Traditional Health Product Bill:**

- The Regulatory philosophy that applies in this proposal (but is not limited to the following) provides an appropriately structured framework to balance between Common law and Napoleonic Law. This, in essence, buffers the extremes of the status quo and the shelved proposed JTTTGA by maintaining an appropriate regulatory oversight of the industry to balance the right of the individual with the responsibilities of the state
- The NaTHP Bill is structured on a set of principles similar to a constitution whereby any regulations/policies have to be measured against those principles
- An important feature of this proposal is to ensure that the stakeholders know exactly what their regulatory obligations and freedoms are and regulator discretion is kept to a minimum

Some of the unique features:

- Regulators will be required to demonstrate an understanding not only of risk management, but also the need to balance risk management with the needs of consumers and comply with good regulatory practice
- In essence, the proposal provides for manufacturers, importers, exporters and distributors to sign a register notifying the regulator that they are about to enter the NaTHP market. One requirement is that they have to sign a declaration that they have an approved RMP including, where appropriate, GMP
- This proposal enables the Regulator to monitor who is in the market and what is in the market, but at the same time it provides certainty to all stakeholders relating to their various interests

Overall, major cost savings are accrued by recognising other selected countries' and jurisdictions'

ingredients, health claims and manufacturing standards because of reduced regulatory costs.

The major advantage of this proposal is that, by accepting and applying equivalency with other selected countries and jurisdictions, compliance costs and technical barriers to trade are minimised for manufacturers, importers, exporters and distributors.

This proposal would have the following additional advantages as well:

- Giving consumers freedom of choice of the widest possible range of quality assured NaTHPs at least possible cost
- Providing consumers the benefit of knowledge to enable informed choice
- Encouraging appropriately controlled innovation
- Enabling exporters and importers to rationalise inventory, without having to maintain slightly different formulae simply to satisfy a plethora of red tape

Consultation

This proposal has been developed following extensive ongoing informal consultation with a number of stakeholders representing different sections of industry and broader stakeholder groups. The consultation process was, and still is, open to any input from any interested party. For pragmatic and logistical reasons not all stakeholders have been able to be consulted and no offence is intended or should be taken if individuals or groups have been missed. As much as possible, representatives from all identified stakeholder groups, Maori, companies, organisations and individuals have been approached for input.

This proposal makes a genuine attempt to embrace the principles of the Treaty of Waitangi in particular, as it relates to the regulation of Rakau Rongoa (i.e. herbal remedies). The proposed Act will include a clause stating, "Nothing in the Act over-rides the Treaty of Waitangi or any resolution of any claim under the Treaty of Waitangi," or words to that effect.

The requirement under the Treaty of Waitangi to consult with Maori in an appropriate and meaningful way is recognised and is intended and has occurred both formally and informally during the development of this proposal. Such consultation has included consideration of various submissions to parliamentary select committees considering the establishment of the JTTGA, conversations and informal meetings with Rongoa practitioners and more formal meetings of individuals belonging to various groups.

It is provided for in the Act that evidence relating to medical practices, such as the use of Rakau Rongoa, is an orally based tradition, and as such, providing documented evidence of specific remedies could be problematic if a written western model was adopted as the sole means of evidence.

There is a strong and growing connection to Rakau Rongoa and that the benefits of its use need to be protected and perpetuated. There is a real desire to embrace and protect the future of Rakau Rongoa in the development of regulation.

The biodiversity of Aotearoa/New Zealand, the research and development of Rakau Rongoa and such products and the importation and exportation of bio diverse raw and processed NaTHPs should be allowed to be developed and supported by Government within the confines of Good Regulatory Practice.

Individual consumers have different micro nutritional requirements and therefore it is important that the market is able to respond to these needs with as wide as commercially possible a range of products for consumers to choose from as occurs with macro (i.e. unrefined) foods.

A one-size-fits-all approach to regulation of NaTHPs is not appropriate for an industry that requires a system that whilst flexible, maintains the integrity of the industry and products.

The Act recognises that consumers consume NaTHPs on a voluntary basis which highlights the need for communication of any possible emerging safety issues to the consumer via educational and/or risk management strategies. Consumers should be informed of any potential safety issues so as to enable informed choice.

Compliance Costs

This proposed Act is designed to keep regulatory and compliance costs to a minimum. The Cabinet Office

Circular (CO (01) 2) defines compliance costs as:¹⁰

- “3. ...the administrative and paper work costs to business in meeting Government requirements. They include both the administrative burdens and all other compliance costs, such as equipment purchases, retooling, and recurrent production cost. Compliance costs are distinct from the direct costs of any Government requirement, such as the amount of tax payable.
 4. Compliance costs include the costs associated with identifying and understanding the regulatory requirement and may include costs associated with buying in specialist services (such as legal training, computer systems, research) to satisfy regulatory obligations (or employing new staff generally). At a less tangible level, compliance costs can arise from increased liability through the establishment of new legal obligations (such as health and safety requirements).
 5. The need to comply with Government requirements can also have non-monetary effects such as stress and anxiety. These effects often arise from uncertainty about obligations and disproportionately affect smaller businesses with limited management resources that are most susceptible to such costs.”
- Compliance costs anticipated for the JTTTGA based on the Australian TGA system were submitted to the 2002 Health Select Committee Inquiry for six representative companies showing initial set up and year one direct and indirect compliance costs between \$500,000 and \$3 million.¹¹
 - The industries expectations are that the compliance costs for this proposal are significantly less than the anticipated cost for the proposed JTTTGA. However, until a formal economic impact assessment is undertaken, details are uncertain.
 - Approximately 90 percent of the compliance costs would have been non-regulator costs.
 - Blackmore's Australia Ltd are on record that the extra compliance costs due to regulation introduced into Australia post Pan Pharmaceuticals recall itself was approximately \$AUS 2 million to Blackmore's company alone.

Funding

Government funding reflects the fact that there is a considerable degree of public good created by consumers choosing to self-care in order to maintain wellness and to self treat low risk disorders.

The cost of the Regulator shall be split between the Government and the industry, with the industry's share being no more than fifty percent of total costs.

The level of fees/levies will be established after a thorough investigation and consultation with the industry.

Funding will include provision for public education and research.

Summary

The Summary provides a preview of the major points detailed in the text of the Act. The Act provides for a regulatory system that:

1. Is enabling and risk proportionate
2. Establishes NaTHPs as an important class of goods in their own right
3. Recognises legislative relationships with the Food Act 1981 and the Medicines Act 1981 that need to be pro-actively and fairly managed
4. Provides for streamlined audits amongst related agencies in conjunction with the NaTHP Regulator so all regulators, where practicable, have one mutually recognised audit
5. Recognises and provides for Treaty of Waitangi related matters
6. Provides political assurance and certainty
7. Provides clear guidelines as to the Regulator's discretionary powers

¹⁰ Business Compliance Cost Statement: March 2001; <http://www.dPMC.govt.nz/cabinet/circulars/co01/2.html>

¹¹ See appendix iv "Summary of 2002 compliance costs submitted to Health Select Committee Inquiry into the proposed JTTTGA."

8. Provides industry assurance and certainty
9. Provides for consumer choice, innovation and maintenance of product safety
10. Maintains quality assurance through approved Risk Management Programmes (RMPs) including, where appropriate, Good Manufacturing Practice (GMP)
11. Enables the Regulator to know who is in the market and what is on the market so that they can responsibly monitor the industry and enforce the Act effectively and efficiently
12. Ensures that the principles of the Government's Good Regulatory Practice (GRP) are complied with, especially the principle of equity (i.e. proportionality)
13. Requires the Regulator to be certified as GRP compliant by the Auditor General
14. Prohibits the adulteration of NaTHPs with synthetic pharmaceutical ingredients
15. Ingredients found in products are permitted only if they meet the definition of NaTHPs
16. Provides a mechanism to ensure that compliance and regulatory costs are kept to as low as reasonably practicable levels commensurate with GRP
17. Enables the entry of defined NaTHP ingredients onto the market whilst at the same time preventing the use of this Act to introduce novel, non-natural or non-traditional ingredients¹²
18. Recognises that, whilst NaTHPs have a long history of safe use, safety issues do emerge from time to time that need to be managed in a risk proportionate manner
19. Minimises compliance costs and reduces technical barriers to trade
20. Requires 'True to Label' manufacture and packaging
21. Provides a Proprietary Knowledge Labelling Exemption
22. Provides for evidence based health claims, but health claims are not mandatory
23. Provides marketing and quality certainty for New Zealand's burgeoning NaTHP industry
24. Provides a regulatory environment that maintains a healthy 'tension' or 'balance' between the operational needs of small cottage industry and large industry players
25. Enables the Regulator to undertake Post Market Monitoring and Auditing to maintain the integrity of the regulatory system:
 - Sensible ongoing monitoring is essential to ensure compliance with this Act
 - Post Market Monitoring of known and emerging issues related to the NaTHP industry is to be undertaken with priorities and resources being established utilising HACCP type principles
 - Post Market Auditing is to be risk responsive and involve some degree of testing of targeted ingredients and/or products as issues emerge
26. Directs Regulator to responsibly initiate the withdrawal of unsafe products or ingredients from the market place where the risk posed cannot be managed otherwise
27. Prevents the Regulator from choosing consultants/advisors philosophically opposed to the use of NaTHPs when considering risk management options or other regulatory matters
28. Provides for a robust dispute resolution system based on recognised dispute resolution models, so as to prevent regulatory creep, the excessive use of regulatory power, to ensure compliance, and to ensure that any safety issues are managed in compliance with Good Regulatory Practice, including in a risk proportionate manner.^{13,14}

¹² It is not the intension of this act to allow cart blanche entry of ingredients onto the market of novel, non-natural, or non-traditional ingredients not meeting the definition of a natural and traditional health product ingredient.

¹³ Benchmarks for industry-based Customer Dispute Resolution Schemes:
http://www.treasury.gov.au/documents/1124/HTML/docshell.asp?URL=03_%20principles.asp

¹⁴ Canadian Department of Justice Resolving disputes - think about your options <http://www.justice.gc.ca/eng/dept-min/pub/dr-rd/index.html> also see <http://www.justice.gc.ca/eng/pi/dprs-sprd/rd-dc.html>

Section II: Proposed Bill for Natural and Traditional Health Products in New Zealand

Part I: Introduction

1. Purpose

The purpose of this Act is to:

- (a) Provide a sustainable, risk proportionate co-regulatory system for the manufacture, import, export and distribution of NaTHPs at the minimum optimal regulatory and compliance cost;
- (b) Enable the regulator to know who is in the market and what is in the market;
- (c) Enable an innovative NaTHP industry to develop and provide the widest range of NaTHPs;
- (d) Further consumer wellness through freedom of choice and informed choice;
- (e) Ensure consumers maintain their traditional rights of access to natural and traditional health products;
- (f) Fund public education and research of NaTHPs; and
- (g) Facilitate the export of NaTHPs.

2. Object of this Act

The object of this Act is to build productive regulatory relationships through the promotion of good faith and natural justice in all aspects of the regulatory environment and of the regulatory relationship by:

- (a) recognising that regulatory relationships must be built not only on the implied mutual obligations of trust and confidence, but also on a legislative requirement for good faith behaviour;
- (b) acknowledging and addressing the inherent inequality of power in regulatory relationships;
- (c) protecting the integrity of individual choice;
- (d) promoting mediation as the primary problem-solving mechanism; and
- (e) reducing the need for judicial intervention.

3. Definitions

(a) **‘Natural and Traditional Health Product’ means:**

- i. A product intended to provide a health or nutritional benefit and intended for oral, nasal, or topical use or use via enema, but not intravenous, intramuscular, or subcutaneous use, and
- ii. Containing one or more ‘Natural or Traditional Health Product Ingredients’ and necessary acceptable excipients.

For clarity’s sake, products may consist of one or more ingredients.

(b) **‘Natural and Traditional Health Product Ingredient’ means:**

- i. An ingredient intended for use or used in a natural or traditional health product that is:
 - a. Natural or nature identical, including, but not limited to;
 - i. a vitamin;
 - ii. a mineral;
 - iii. a herb or other botanical;
 - iv. an animal product for human consumption;
 - v. an amino acid;
 - vi. a microorganism for human consumption;
 - vii. a dietary substance for use by humans to supplement the diet by increasing the total dietary intake; and

- viii. a substance normally present in the human body;
- b. A traditional remedy;
- c. A concentrate, metabolite, constituent, extract, or combination of any of the categories listed in 3(b)i.a.; and
- d. Is not included in the Misuse of Drugs Act or the Misuse of Drugs Amendment Act 2005.

Ingredients range from refined or pure substances (such as vitamin C) to substances that may or may not be processed containing many active (known and unknown) components such as whole herbs.

- ii. A traditional remedy with a recognized history of safe use, including, but not exclusive to, the following:
 - a. Rakau Rongoa¹⁵;
 - b. Ayurveda;
 - c. Chinese herbal medicines;
 - d. Western herbal medicines;
 - e. Homeopathics;
 - f. Essential oils;
 - g. Aromatherapy;
 - h. Apitherapy; and
 - i. Other ethnic traditional medicines.
- iii. An ingredient meeting the definitions in 3(a) that was legally marketed as a dietary or food supplement or related product, in New Zealand or any other country or as an approved low risk medicine in any other country at the date of this Act taking effect.

Topical use means a natural or traditional health product that is applied to body surfaces such as, but not limited to, the skin or mucous membranes, for example the vagina, penis, rectum, throat, eyes and ears and may include (as appropriate) and by way of examples, ointments, salves, poultice, paste, powders, inhalants, liquids or solids.

Explanatory Note: It has been suggested that sub clause iii sets a low hurdle. However, any ingredient can be challenged by the regulator under the provisions of this Act if they have sufficient reason to do so. As a rule, NaTHPs have a very low risk profile resulting from extended use. This means that it is reasonable to assume that an ingredient is 'innocent' until proven 'guilty'.

(c) 'Risk management programme' (RMP) means:

- i. A risk management programme (RMP) including where appropriate GMP is a system for identifying and managing risks relative to an individual, company or enterprise;
- ii. All RMPs including, where appropriate, GMP, will require notification to the regulator who will draw to the attention of the notifier any deficiencies;
- iii. The regulator shall be required to prepare generic off-the-peg (off the shelf) RMPs that may require being adapted to individual needs;
- iv. RMPs may be very simple for a single product company, or may be a GMP recognized in a schedule of acceptable GMPs;
- v. RMPs shall be audited by a recognized third party and a certificate of compliance by the auditor shall be submitted to the regulator at least once every three years. RMPs shall be audited by the following:
 - a. Any auditor approved in a selected country or jurisdiction whose manufacturing standards have been accepted under this Act; or

¹⁵ Rongoa Rakau refers to the flora and fauna that medicines are obtained from. Rakau rongoa refers to the medicines derived from rongoa rakau. Rakau rongoa may be manufactured from exotic ingredients. By way of example, puha is an accepted Rakau rongoa ingredient

- b. Any auditor established in New Zealand and approved by the regulator.
- vi. RMPs shall include an approved recall provision.

The licensee shall certify to the regulator that all required RMPs have been complied with during all steps of manufacturing, packaging or distribution processes.

Explanatory Note: An RMP for a distributor is unlikely to fulfil the requirements of a risk proportionate GMP programme designed for manufacturing companies; however the required minimum safety standards will be met by both systems. An acceptable GMP system would be an acceptable RMP with any additions such as a recall system additional to the US FDA dietary supplements GMP.

(d) **'Recognized history of safe use' means:**

- a. 15 years of use in any global market without significant safety issues; or
- b. Inclusion in the following recognised acceptable overseas and local sources of ingredients:
 - Substances That May Be Used in Listed Medicines in Australia¹⁶,
 - British Pharmacopoeia;
 - British Herbal Pharmacopoeia and associated Compendium;
 - Canada NHP;
 - EU Traditional Herbal Medicine Directive;
 - European Pharmacopoeia;
 - European Scientific Cooperative on Phytomedicines (ESCOP);
 - German Commission E Monographs;
 - Indian Herbal Pharmacopoeia;
 - Nga Ringa Whakahaere o Te Iwi Maori Incorporated Society;
 - Pharmacopoeia of the People's Republic of China: including traditional Chinese medicines;
 - United States Pharmacopoeia (USP): USP Verified Dietary Supplements;
 - World Health Organization: Monographs on Selected Medicinal Plants;
 - *Other Maori sources to be added;*
 - *Other recognised pharmacopoeia; and*
 - *Others to be added.*

(e) **'Health Claims' means:**

Health claims includes structure/function, risk reduction, prevention, treatment and curative claims that are true and not misleading and are subject to the Fair Trading Act 1986 and the Consumers Guarantee Act 1993.

(f) **'Industry' means:**

Industry means only manufacturers, packers, distributors, importers, exporters and licensees of NaTHPs.

(g) **'Licensee' means:**

The legal entity that holds a licence under this Act.

¹⁶ Substances that may be used in Listed Medicines in Australia: Dec 2007 <http://www.tga.gov.au/cm/listsubs.pdf>

(h) **'Level of risk':**

- i. Risk that is negligible or de minimis and can be accepted without specific management other than monitoring; and
- ii. Risk that is intolerable may require that the activity shall cease temporarily or permanently, unless the risk can be reduced to tolerable or acceptable levels.

Level of risk is categorised as:

- Intolerable. Ingredients with intolerable risk are unacceptable and access will usually be restricted temporarily or permanently in some way (i.e. recall or practitioner only) or manufacturing/testing standards, upper limits, etc will be introduced to reduce risks to as low as reasonably practical (ALARP) levels. Emerging intolerable risks would normally include voluntary or mandatory product recall at consumer or retail level, or the regulator disallowing such ingredients when notified.
- Tolerable. Ingredients will not usually have access restricted but there will usually be risk management requirements such as manufacturing standards, mandatory labelling and/or education.
- Acceptable. Ingredients with known, but acceptable levels of risk will normally have risk management by generic education and voluntary advisory statements.
- De minimis. Ingredients with de minimis levels of risk are deemed to be inherently safe and will have no special risk management requirements.

(i) **'As Low As Reasonably Practicable' (ALARP):**

- i. For the purposes of this Act, the ALARP principle shall apply¹⁷;
- ii. All ingredients and products shall have risk management programmes and labelling requirements that reduce generic risks to ALARP levels;
- iii. Some products may require specific risk management options to reduce risks to acceptable levels;
- iv. The ALARP principle shall be applied by industry when applying risk management strategies; and
- v. The ALARP principle shall be applied along with the principle of proportionality when the regulator is considering risk management options.

Explanatory Note: Most NaTHPs have a proven history of safe use and the levels of risk are de minimis. The ALARP principle encourages politicians, regulators and industry to consider the benefits of reducing a risk against the costs involved (time, trouble, money, resources, lost opportunity, loss of consumer choice etc). For example, if a potential hazard is identified which creates a de minimis to acceptable level of risk and there are systems in place to deal with the risk, then there are no real benefits to reducing the risk further.

(j) **'Advisory group' means:**

Advisory group means any group established pursuant to Part II, Section 7 of the Act.

(k) **'Safety' means:**

A demonstrable lack of significant harm.

(l) **'Safety Assessment and Risk Assessment' means:**

For the purposes of this Act, the terms "safety assessment" and "risk assessment" are interchangeable.

(m) **Classification of adverse events:**

The terms 'certain', 'probable' and 'possible', in relation to assessment of adverse events associated with the use of NaTHPs, shall have the same meaning as those definitions in current World Health Organisation causality classifications of medicines¹⁸.

¹⁷ *Edwards v National Coal Board* (1949) 1 KB 704 at 712, CA, per Asquith LJ

¹⁸ The use of the WHO-UMC system for Standardised case causality Assessment: <http://www.who-umc.org/graphics/4409.pdf>

4. Interpretation Note: Principles are Paramount

The Act creates a principles-based regulatory system in which overarching principles shall determine the implementation and administration of this Act.

In achieving the purpose of this Act, all persons exercising functions and powers under it shall take into account the principles. For the purposes of this section, the term “regulator” may include industry, officials and membership advisory groups created by the Act.

For the purposes of interpreting and applying the Act, the principles include the following:

- (a) Treaty of Waitangi (Te Tiriti o Waitangi)
- (b) Good faith
- (c) Natural justice
- (d) NaTHPs have, in general, a history of safe use and shall override regulations, rules or decisions that may assume such products are inherently unsafe
- (e) New Zealand is a multi-ethnic society and over the years many of these cultures have brought their traditional health products or medicines to New Zealand. Some of these products have been introduced to New Zealand relatively recently and whilst they may not have a tradition of safe use in New Zealand they do have such a tradition in their homelands. This Act recognises such traditions and in the absence of evidence of harm, these traditional products are deemed to be safe until proven otherwise:
 - i. Ethnic communities will be consulted and formal safety assessment will be undertaken if necessary; and
 - ii. The use of appropriate dispute resolution mechanism can be utilized in such circumstances bearing in mind that many such traditions have no written history of use.
- (f) Proportionality
- (g) ALARP
- (h) The regulator is ultimately accountable to the consumer
- (i) The regulation of NaTHPs embraces the principle that all consumers are different, that all consumers have different physiological requirements and may respond differently (i.e. there is no one size fits all). As such the regulator shall not seek to reduce ingredients to the lowest common denominator
- (j) The dissemination of information regarding treatments for all diseases, ailments, disorders and conditions is a public good
- (k) The regulator shall, at all times, maintain a neutral stance in respect of the wide range of modalities that fall under the category of NaTHPs, focusing only on outcomes for the individual consumer
- (l) A consumer's right to choose and to free and informed choice, is an important public good
- (m) The right of the individual to manage their quality of life and wellbeing
- (n) If any harm is reversible and use is voluntary, then the case for regulatory intervention is minimal and restricted to labelling and education. If the harm is irreversible and use is involuntary, then there is a high case for regulatory intervention¹⁹
- (o) The seriousness of an illness has no bearing upon any risks associated with NaTHP use. Therefore, the seriousness of illness cannot be used as a reason to restrict NaTHP use
- (p) Enforcement action shall be applied evenly, transparently and risk proportionately
- (q) The regulator will respond in a timely and meaningful manner to communications from consumers and industry
- (r) Where there is a conflict between this Act and the Bill of Rights, the Bill of Rights will take precedence
- (s) It is the role of the regulator to facilitate a regulatory environment where innovative NaTHP

¹⁹ When is there a case for intervention in an Occupation?: <http://www.med.govt.nz/upload/17932/diagram1.pdf>

- therapies can compete freely and openly with any other forms of therapy
- (t) Regulatory charges must be kept low to prevent them from acting as a trade barrier
- (u) The regulator shall be ultimately accountable to the individual consumer for unjustifiably restricting access to NaTHPs
- (v) Sensible risk management
- (w) Truth in labelling

Part II: Oversight of Regulator, Appeals and Technical Issues

5. Good Regulatory Practice Audits

- (a) The regulator will be audited [by the Auditor General's Office / CCMAU-type] annually against the principles of the Government's Code of Good Regulatory Practice;
- (b) Such audits will include a request for submissions from all stakeholders and include a formal annual report from the Board of Guardians; and
- (c) Audit report will be tabled in Parliament.

6. Board of Guardians

- (a) The Board of Guardians will consist of an independent chair appointed [by the Auditor General's Office] who is skilled in good regulatory practice, a person skilled in alternative dispute resolution nominated by the Chairperson of the New Zealand Chapter of Lawyers Engaged in Alternative Dispute Resolution and 8-10 members also appointed by the Auditor General's Office including members nominated by and representing the following sectors:
 - i. Maori;
 - ii. Importers;
 - iii. Exporters;
 - iv. Local manufacturers;
 - v. Distributors;
 - vi. Natural and traditional healthcare practitioners;
 - vii. Retailers;
 - viii. Raw products distributors; and
 - ix. Regulator.
- (b) The Board of Guardians will meet from time to time as required, but at least annually;
- (c) Any decision of the Board of Guardians shall not violate the objectives of this Act or the principles;
- (d) The Board of Guardians is to hear matters referred to it by stakeholders or the regulator and issue binding decisions;
- (e) When considering any appeal the Board of Guardians may refer the issue and/or specific questions to the Technical Advisory Group for their assessment of the issue being considered. The Board will consider the Technical Advisory Groups assessment in reaching any decision;
- (f) The Board of Guardians will report annually to the Auditor General regarding the performance of the regulator including a summary of all appeals heard by the Board; and
- (g) Payments to members of the Board of Guardians will be in accordance with State Services Commission guidelines.

7. Technical Advisory Group

- (a) The technical advisory group will focus on potential safety issues related to NaTHPs and will provide technical expertise to the regulator whenever the need arises;
- (b) The technical advisory group consists of two levels of membership:

- i. The first level, a core group (maximum of 5 persons), shall consist of individual members with appropriate expertise including applied public health, risk analysis, good regulatory practice including awareness of equity issues relating to potential trade barriers, NaTHPs and shall include a person representing the interests of the Treaty of Waitangi. The potential competing interests shall be considered when appointing the core membership and shall ensure fair and appropriate industry representation.
- ii. The second level (maximum of 4 persons) shall be co-opted from a pool of wide ranging expertise, from which appropriate expertise shall be drawn upon to match the type of risk being considered; and

Explanatory Note: For example, Rongoa practitioner for Rakau Rongoa, herbalist for an herb, Ayurveda practitioner for Ayurvedic medicine, homeopath for homeopathy, manufacturer for manufacturing issues. The same applies to compounding, importing, exporting, toxicology etc.

- (c) The core group and members of the pool shall be appointed by the Board of Guardians, from those persons nominated in writing and endorsed by any two levy paying bodies or NaTHP industry associations. Appointments will be for three years with an opportunity of reappointment for subsequent three year terms;
- (d) The core group shall ensure equitable risk management outcomes are achieved and that regulatory creep does not occur;
- (e) Members of the core group shall not include employees of the regulator but shall be appointed by the regulator following public notification of the positions; and
- (f) Payments to members of the Technical Advisory Group shall be in accordance with State Services Commission guidelines.

Explanatory Note: It is important that any risk management standards imposed are commensurate with known risks, and are equitable in that the outcome matches similar risk management practices for other products/ingredients of similar risk.

8. Technical Working Group

The Technical Advisory Group may, from time to time, form a Technical Working Group as a regulators resource to advise on issue-specific matters.

9. Licensee

- (a) The licensee is responsible for notifying products and ingredients to the regulator;
- (b) The licensee is primarily responsible for:
 - i. oversight of any product recall; and
 - ii. ensuring compliance with all rules and regulations under this Act.
- (c) The licensee is responsible for paying such fees / levies as shall be determined from time to time under this Act.

10. Dispute Resolution

- (a) If a dispute arises in relation to a specified decision referred to in this Act and the parties, including directly related parties, are unable, within a reasonable time, to resolve the dispute, they must, in the interests of natural justice and acting in good faith,—
 - i. endeavour to agree on a process for resolving the dispute, including (but not limited to) all or any of the following:
 - further negotiations:
 - mediation:
 - determination of the dispute by an independent arbitrator, in terms of the Arbitration Act 1996; and
 - ii. Parties must, before proceeding to take any other action under this Part, engage in the process agreed under paragraph (a).
- (b) Unless the Board of Guardians is a party to the dispute, a party may refer the dispute to the

Board of Guardians for determination if:

- i. the parties cannot agree on a dispute resolution process under (a) of this section; or
 - ii. the timetable for the dispute resolution process is not being complied with; or
 - iii. the dispute resolution process does not resolve the dispute.
- (c) All dispute resolution matters shall be reviewed by the Board of Guardians as part of its annual Good Regulatory Practice audit;
- (d) Parties to Continue to Perform: Pending resolution of any dispute or difference, the parties shall continue to perform their respective obligations pursuant to the Act.

11. Regulatory Management System (RMS)

- (a) Central to the regulation of NaTHPs is a Risk Management System (RMS) commensurate with the very low risk profile of the vast majority of NaTHPs;

Explanatory Notes:

- i. *The RMS is a simple online notification system that contains information for licensees relating to any regulatory requirements for individual ingredients.*
 - ii. *The RMS shall provide for the regulator to know “who is in the market and what is in the market” in order to monitor NaTHPs and assist with managing any emerging safety issue. The regulator shall provide a simple online database Risk Management System.*
 - iii. *The RMS will minimise technical and administrative barriers to commerce by combining elements of both ‘positive’ and ‘negative’ listing systems and at the same time requiring all new ingredients to be notified to the regulator via a simple online database, while enabling the regulator to challenge new ingredients within a certain statutory time frame.*
- (b) All ingredients shall be recorded in the RMS database before being provided for sale;
- (c) Licensees shall be required to notify the regulator of all products and new ingredients, by entry of required data into the online RMS database;
- (d) The licensee notifying a new ingredient shall be required to make an online statutory declaration that it has evidence to support the safe use of the ingredient and any stated or implied claims;
- (e) Some ingredients, including previously prohibited ingredients will be permitted if certain standards established under this Act are met;
- (f) Any new ingredient, including currently prohibited ingredients that comply with the NaTHP ingredient definition, shall be notified to the regulator by the licensee via the RMS Notification System;
- (g) The regulator may disallow any such notification if the regulator has reasonable cause for concern, based on reliable evidence, that shall be disclosed to the licensee at the time the disallowance is made;
- (h) The RMS will provide a simple immediate means of identifying the classification of ingredients based on known risk profiles and shall include any specific labelling, manufacturing, or marketing requirements including recommended or mandatory advisory or warning statements, upper safe limits, specific manufacturing standards or any other good risk management requirements;
- (i) Permission or approval from the regulator is not required for new products that include ingredients in the RMS which are not prohibited substances;
- (j) The RMS shall initially contain all known acceptable substances from the lists of recognised acceptable overseas and local sources of ingredients detailed in the definition of ‘Recognised history of safe use’ and related schedules;
- (k) The RMS database shall require the licensee to lodge all required details before any specific products can be notified;
- (l) New ingredients or currently prohibited substances shall be notified to the regulator via the

RMS 40 working days before commencement of proposed marketing. The regulator is to respond within 20 working days:

- i. The regulator may request copies of supporting evidence of safety to support new ingredient notifications.
- ii. Ingredients that have a recognised history of safe use will not normally be disapproved.
- iii. The regulator may only challenge such notifications when there are genuine safety issues and reasonable cause for concern, based on reliable evidence,
- iv. When assessing the risk profile of an ingredient, consideration shall be given to the fact that consumption of NaTHPs is a voluntary activity, and that the vast majority of adverse or unwanted effects are self-resolving and do not cause permanent disability or death.
- v. The regulator may only disallow such notifications when there are genuine safety issues that can not be managed via an appropriate standard,
- vi. Where the regulator disallows an ingredient or imposes a standard the issue must be referred to the Technical Advisory Group by the regulator along with all supporting documentation held by the regulator for the Technical Advisory Group's opinion unless the applicant decides otherwise,
- vii. Before considering the evidence referred to it under section (I)vi. the Technical Advisory Group shall request from the applicant any additional information that the applicant deems relevant.
- viii. Disapproval of notifications may be appealed as provided for in the dispute resolution provisions of the Act.

Explanatory Note: The Ministry of Economic Development and Cabinet Office model has been utilised to assist with determining risk classification of ingredients. See Appendix I 'When is there a case for intervention?'^{20 21} The system has been developed as a pragmatic and innovative alternative to the two common options for regulating NaTHPs.

- *The "Positive" list, referred to as a 'white' list in some countries or jurisdictions, is paradoxically a prohibitive system. As a positive list is an officially approved list it means that, effectively, if an ingredient is not on the list, it is banned.*
- *Getting new ingredients approved through such a prohibitive system has historically been administratively onerous, and the costs involved, imposes an effective technical barrier to commercial use of new ingredients. This is especially the case when the ingredients are generic with no commercial or proprietary protection for the applicant,*
- *A "Negative" list, sometimes referred to as a 'black' list, is paradoxically a permissive system in that unless an ingredient is specifically banned then it can legally be sold.*
- *The upside of this permissive system from a commercial point of view is that there are no market entry barriers thus facilitating innovation to the maximum.*
- *The downsides of this system is that new potentially hazardous ingredients can be introduced to the market without any effective monitoring or management of risk other than through adverse events or complaints.*
- *For example, in New Zealand, which uses the negative list system, it is very easy for unscrupulous manufacturers, importers, exporters and distributors to*

²⁰ When is there a case for Intervention in an occupation?: <http://www.med.govt.nz/upload/17932/diagram1.pdf>

²¹ This is the original document that includes the decision tree for regulating occupations
http://www.med.govt.nz/templates/MultipageDocumentPage_9117.aspx
Here it is in a Cabinet Circular... CO (99) 6
http://www.dpmc.govt.nz/cabinet/circulars/co99/COC_99_6.pdf
It has been referenced in this NSW Government Fair trading document
http://www.fairtrading.nsw.gov.au/pdfs/About_us/convlicrev.pdf

market uncontrolled products.

12. Principles of Sensible Risk Management

- (a) Any regulatory response shall apply the principle of proportionality and shall apply the least restrictive risk management response necessary to reduce risk to a level that is as low as reasonably practicable; and
- (b) Any safety concern shall be addressed using the principles of sensible risk management.

Explanatory Note:

Sensible risk management is about:

Ensuring that consumers are properly protected;

Providing overall benefit to society by balancing benefits and risks, with a focus on reducing real, rather than perceived risks;

Enabling, not stifling innovation;

Ensuring that those who create risks manage them responsibly and understand that failure to manage real risks responsibly is likely to lead to corrective action;

Enabling companies, enterprises and consumers to understand that as well as the right to protection, they also have to exercise responsibility;

Learning from experience.

*Sensible risk management is **not** about:*

Creating a totally risk free society;

Using the "Harm by omission" principle to raise the risk profile of NaTHP's

Restricting access to substances that do not pose unacceptable risks;

Generating useless paperwork mountains;

Imposing considerable compliance costs to manage de minimis or acceptable risks;

Closing a business down when there is no evidence of actual significant harm;

Scaring people by exaggerating or publicising trivial risks;

Falsely reassuring people by denying risk or attenuating real risk as if it did not exist;

Stopping consumer choice or commerce where the risks are manageable or negligible;

Diminishing the focus on risks that cause real harm and suffering.

13. Risk Management Categories²²

- (a) The RMS database shall provide for classifying appropriate levels of risk management required over and above any RMP including where appropriate GMP requirements:
- (b) All active ingredients will be identified on the label except as provided in section 25.
- (c) For the purposes of avoiding any unjust restrictions separate risk assessments will be required to differentiate any emerging risks associated with natural, nature identical or synthetic forms of ingredients including any manufacturing processes that apply to each of the above.
- (d) Ingredient labelling is in itself a risk management option meaning that all products have any inherent risks reduced via labels for people who may, for example, have specific allergies.
- (e) Where restrictions are required for risk management purposes these will be indicated in schedule X and Y (see appendix II and III)
- (f) Risk Management categories are as follows:

²² A useful guide to good and bad processes of determining appropriate risk management responses to emerging or 'noisy' evidence (i.e. known as a 'beat up') of a safety issue can be found in the Regulation Review Select Committee report to Parliament regarding the Complaint relating to Food Standard Number 11, and the subsequent Minister of Health's Expert Scientific Working Group's report into the labelling of Bee Products. Report on the Complaint relating to the New Zealand Food Standard 1996, Amendment No.11: http://www.victoria.ac.nz/nzcpl/Reqs_Review/regsReviewReports/Report%2041.aspx

- i. Risk Management Category 1 (RMC1): **de minimis level of risk** requiring no specific risk management. Indicators for this level of risk include:
 - less than one death possibly attributable to the ingredient per 500,000 person years of use worldwide;
 - less than one death probably attributable to the ingredient per 1 million person years of use; or
 - less than one death certainly attributable to the ingredient per 2 million person years of use.
- ii. Risk Management Category 2 (RMC2): **Possible very low risk** that warrants generic education and nominated voluntary advisory statements or similar. Indicators for this level of risk include ingredients known to cause:
 - mild irritation,
 - allergies or,
 - other manageable or reversible adverse or undesirable effects in some people..
 - o no specific mandatory labelling other than a requirement that these ingredients must be stated on the label.
 - o Recommended voluntary labelling will be flagged via the RMS and regulator and industry communications;
- iii. Risk Management Category 3 (RMC3): **Possible low level risks or probable risks** that warrant mandatory risk management provisions such as labelling, manufacturing standards and upper safe levels. Indicators for this level of risk include:
 - more than one death but fewer than five deaths possibly attributable to the ingredient per 500,000 person years of use worldwide;
 - more than one death but fewer than five deaths probably attributable to the ingredient per 1 million person years of use; or
 - more than one death but fewer than five deaths certainly attributable to the ingredient per 2 million person years of use.
- iv. Risk Management Category 4 (RMC4): **Certain moderate level risks that are tolerable** if certain risk management strategies such as those listed below are established following formal safety assessments, including, specific risk management options such as upper ingredient limits, mandatory combination of ingredients,²³ restrictions on certain extraction solvents or plant parts,²⁴ mandatory testing to ensure certain substances are within standard,²⁵ and limited to appropriate practitioners only in certain circumstances,²⁶ Indicators for this level of risk include:
 - five or more deaths possibly attributable to the ingredient per 500,000 person years of use worldwide;
 - five or more deaths probably attributable to the ingredient per 1 million person years of use; or
 - five or more deaths certainly attributable to the ingredient per 2 million person of use
- v. Risk Management Category 5 (RMC5): Ingredients prohibited from use in NaTHPs unless appropriate risk management options can be implemented or new evidence establishes that the risks can be reduced to tolerable levels. This level of risk includes:
 - ingredients considered too hazardous to allow in NaTHPs above certain natural/baseline levels (i.e. certain heavy metals such as lead, arsenic); and
 - substances normally requiring approval under food or medicines law such as:

²³ by way of example: folic acid products over 1,000ug must include at least 50ug of vitamin B12 to mitigate very rare anecdotal reports of masking of pernicious anaemia.

²⁴ by way of example: kava peel extracted with acetone.

²⁵ by way of example: Pyrrolidine Alkaloids in Comfrey, or aristolocic acid in certain Aristolochia spp

²⁶ by way of example, many currently banned substances, including substances currently classified under hr Medicine Act eg. Ephedra alkaloid and belladonna

- o novel substances or non-food synthetic ingredients; and
- o non-natural nanotechnology (defined for the purposes of this Act as being molecules generally less than 100nm).

14. Emerging Risks Protocol

- (a) Emerging safety concerns shall require a risk proportionate response that is evidence based and includes recognition of the ingredient's history of use. Any regulatory response shall apply the principle of proportionality and shall apply the least restrictive risk management response necessary to reduce risk to a level that is as low as reasonably practicable;
- (b) Any risk management responses considered by the regulator shall be risk proportionate and take into account cultural, economic and historic use of any ingredients or products potentially affected;
- (c) Absence of evidence of significant harm is, for the purposes of this Act, deemed to be proof of absence of significant harm;
- (d) "Safety" means a demonstrable lack of significant harm;
- (e) For the purposes of this Act, the terms "safety assessment" and "risk assessment" are interchangeable; and
- (f) For clarity's sake, the term "recognised" means recognition by the consumers, practitioners or industry rather than by a regulator or other authority.

Explanatory Note: There is nothing genetically unique relating to New Zealand consumers that would expose them to any more or less risk than residence in other countries. Therefore it is logical that NZ consumers are not denied access to ingredients commonly available in other countries when those ingredients have a history of safe use and that use is voluntary.

15. Medicines Act 1981 Exemption

Any product regulated under this Act is exempt from the provisions of the Medicines Act 1981.

16. Food Act 1981 Exemption

Any product regulated under this Act is exempt from the provisions of the Food Act 1981.

17. Fair Trading Act 1986 and Consumer Guarantee Act 1993

Fair Trading Act 1986 and Consumers Guarantee Act 1993 apply to products regulated under this Act.

18. Advertising

The industry will develop a voluntary advertising code of practice to be recognised by the regulator.

Part III: Risk Management Programmes (RMPs)

19. All Manufacturers, Importers, Exporters, Distributors, Marketers and Licensees are Required to have a Registered Risk Management Programme

Manufacture/Packaging:

- (a) As a minimum registered RMPs including where appropriate GMP are to be based on the HACCP method of risk management²⁷
- (b) RMPs shall be similar to those described in the Animal Products Act or based on off-the-peg ("template") RMP models that shall be made freely available by the regulator;

Explanatory Note: This provision will mean that many NaTHP businesses will not have to bear the costs of plan development, nor will their RMP require detailed evaluation.

- (c) The regulator will establish a schedule of acceptable GMPs

Explanatory Note: The impact of the introduction of Risk Management Programmes will be eased by the unilateral recognition of international Good Manufacturing Practice certificates.

²⁷ Introduction to HACCP: <http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf>

- (d) The existing scheduled Good Manufacturing Practice certificates are the following (current GMPs):
 - i. Australia
 - ii. Canada
 - iii. EU
 - iv. USA
 - v. South Africa
 - vi. Japan
 - vii. China
 - viii. India
 - ix. Others to be determined.
- (e) Template RMPs, will be available from the regulator at least nine months prior to the registration date for that NaTHP sector; and
- (f) The NaTHP business' RMP will be submitted for registration at least three months before the registration date.

Explanatory Note: Industry is therefore given at least six months to complete an off-the-peg RMP. The requirements for RMPs including, where appropriate, GMPs are described in the sections below.

Audits

- (g) RMPs including, where appropriate, GMPs shall be audited by a recognised third party.
- (h) A certificate of compliance by the auditor shall be submitted to the regulator at least once every three years, except that the regulator may authorise up to five year audits provided the applicant has a demonstrated history of compliance.
- (i) The certificate of compliance shall note any significant non-material breaches or imminent or potential breaches of the RMP including, where appropriate, GMP along with a recommended timeline for rectification.
- (j) RMPs including, where appropriate, GMP may be audited by the following:
 - i. Any auditor approved in a selected country or jurisdiction whose manufacturing standards have been accepted under this Act and listed in the Acceptable GMP Schedule; or
 - ii. Any auditor established in New Zealand and approved by the regulator or IANZ.

Explanatory Note: A manufacturer might want to export product to Australia or Europe so will be able to satisfy the requirements of an RMP including where appropriate GMP by use of an auditor recognised by the competent Australian or European authority.

- iii. The regulator may request a subsequent issue-specific audit where there have been material breaches, significant non-material breaches or imminent or potential breaches of the RMP including, where appropriate, GMP.

Quantify by Input

- (k) For multi-ingredient products certified quantify-by-input shall be an acceptable means of establishing content of product.
- (l) If a problem is indicated then manufacturing input records shall be examined to determine the problem (i.e. mixing) as an alternative to scientific testing.

Explanatory Note: If it is shown that ingredient levels need to be tested then testing will be limited to one easily, accurately and economically identifiable ingredient. It is acknowledged that once certain ingredients are mixed in a formula, the ability to identify them by scientific testing is extremely limited, time consuming and expensive. Further, this even applies to some individual ingredients. Hence, the most efficient way is to quantify by input.

Post Market Random Testing by the Regulator

- (m) The regulator shall undertake random testing of x percent [5 percent?] of products on the market each year with an expectation that, where specific safety issues emerge, either in New Zealand or in similar product overseas, targeted testing shall occur.

Explanatory Note: Recent examples of such testing include testing for DEG in toothpastes, heavy metals in herbs from certain sources, melamine in milk products, prescription medicine testing following evidence of certain products being adulterated.

- (n) Substances that may be randomly tested for, when appropriate, include the following:
- i. Heavy metals;
 - ii. Microbes;
 - iii. Oxidised oils / fats; and
 - iv. Adulterated substances.

Date Mark Requirements

- (o) A date mark shall be required, being an expression in one of the following forms:
- i. Best before (followed by a date); or
 - ii. At the date of manufacture (followed by a date) this product contained; or
 - iii. Use by/expiry (followed by a date); or
 - iv. Not to be consumed after (followed by a date) or
 - v. Words of similar meaning (followed by a date);—
 - vi. the relevant date in any case being no longer than 5 years after the date of manufacture unless required by RMS.
- (p) NaTHPs may continue to be distributed after the 5 year period if a new assay determines the product is still true to label and a valid date mark is displayed on the label.
- (q) For the purposes of this Act, ingredient levels may be within a range on average of +30 percent to -10 percent, provided that levels do not exceed any upper levels specified in Risk Management classifications RMC4 and RMC5, provided for in the Act.

Labelling

- (r) Each different product, including different pack sizes, shall have unique identification that is notified on the RMS. Unique identifiers shall be nominated at time of notification onto RMS.
- i. The unique identification may be the RMS unique product notification number or a combination of brand/product names, existing bar code, registration or other unique identifier from another regulatory system, etc.
 - ii. RMS shall have capacity to use multiple fields to generate unique identifiers.
- (s) Standard labelling requirements shall include a batch number on every container.
- (t) Mandatory advisory, warning or other specific labelling requirements specified in RMS shall be complied with.
- (u) Labels shall be printed in waterproof ink.
- (v) All product labels shall have a date mark as set out in Part III, Section 19 of this Act
- (w) Every package and container containing an NaTHP shall, unless otherwise provided in this Act or regulations, bear a label that includes the following:
- i. The common name of the NaTHP, or a description (other than the brand name of the NaTHP) sufficient to indicate the true nature of the NaTHP, or a description of the NaTHP including the common names of its principal ingredients.
 - ii. A statement of the net weight or volume or number of the contents of the package or container, whichever measure is appropriate for retail sale of the NaTHP concerned.
 - iii. The trading name and business address of the manufacturer or seller or packer of the NaTHP, or of the owner of the rights of manufacture, or of the principal or the agent of any of them.

- iv. A consumer information panel that complies with the requirements of this Act.
- v. The words “Natural and Traditional Health Product”; “NaTHP”; “Dietary Supplement”; “Food Supplement”; “Complementary Medicine”, “Homeopathic”, Traditional Remedies as listed in part I section 3(b)i or any similar terms used in the country of manufacture.
- vi. A batch number.
- vii. A statement of the recommended daily dosage (for an adult) both as to quantity and frequency, which for ingredients in Appendix II Schedule X Column 1, shall not exceed the maximum daily dose stated in Column 2 subject to any conditions in Column 3 and, if the NaTHP is suitable for children, the recommended daily dose for children.
- viii. A warning or caution statement required as in Appendix III Schedule Y.
- (x) Notwithstanding sub clause (y) of this section, where NaTHPs are packed in blister or strip packaging, the packaging shall be labelled with—
 - i. The common name; and
 - ii. A batch number.
- (y) For the purposes of sub clause (w) iii of this section),—
 - i. A postal address, not being a telegraphic or code address or an address at a Post Box, shall be given.
 - ii. The name and address of a person who is not ordinarily resident in New Zealand shall not be sufficient unless the NaTHP is wholly manufactured and packed outside New Zealand.
 - iii. In the case where the trading name is of a body corporate (whether registered inside or outside New Zealand), either the name of the town in which the body corporate has its registered office or the full postal address of the premises where the NaTHP is actually manufactured or packed by the body corporate shall be given as the address.
- (z) Where a package or container of a NaTHP is enclosed or wrapped in a transparent covering and the particulars with which that package or container is required to be labelled are clearly visible through that covering, that covering shall be exempt from the labelling requirements under this Act.
- (aa) No person who has in that person's possession any package or container of an NaTHP intended for sale by retail shall—
 - i. Remove any label required by this Act to be on the package or container; or
 - ii. Alter, erase, obliterate, or obscure any word or statement borne on such a label in accordance with any of the requirements of this Act.
- (ab) Every word or statement that is required by this Act to be borne on a label shall—
 - i. Be conspicuously printed and, for each statement separately required, be in uniform colour contrasting strongly with a uniform background.
 - ii. Be clearly, legibly, and durably marked either on the material of the package or container or on material firmly and securely attached to the package or container.
 - iii. Be presented with continuity.
- (ac) The lettering of every word or statement required by this Act shall be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.
- (ad) The lettering of every word or statement required by this Act to appear on labels shall be—
 - i. All capital letters; or
 - ii. All lower case letters; or
 - iii. Lower case letters with an initial capital letter

- (ae) In every case to which paragraph i. or paragraph ii. of sub clause (ad) of this section applies, the height of the lettering shall be uniform in every word or statement that separately required.
- (af) In every case to which paragraph iii. of sub clause (ad) of this section applies, the height of the lower case lettering shall be uniform in every word or statement that is separately required.
- (ag) Except as otherwise provided in this Act, the lettering of any word or statement required by this Act to appear on labels shall be not less than 1.5mm in height, except where the package or container to be labelled is so small as to prevent the use of letters of that height, in which case letters of not less than 0.75mm in height may be used.
- (ah) The height of the lettering for the common name or description that is required by this Act to appear in the principal display panel of a label shall be not less than one-third of the height of the largest lettering appearing in that panel, and—
 - i. Not less than one-twentieth of the height of the label, in the case of a label that is no longer than twice the width of the label; and
 - ii. Not less than one-thirtieth of the height of the label, in any other case.
- (ai) For the purposes of this section, the height of a label is the distance between the top and bottom of all printed or pictorial information on the label.
- (aj) The particulars that are required by paragraph (r) and paragraph (s) and paragraph (w) of this section to appear on a label shall appear in the principal display panel.
- (ak) Every word or statement that is required by this Act to appear in the principal display panel of a label shall be in lines that are generally parallel to the base on which the package or container rests as it is designed to be displayed.
- (al) In the case of a cylindrical package or container, the width of the principal display panel on the cylindrical surface shall not exceed one-third of the circumference of the package or container
- (am) The following information, when required by this Act to be on the label, shall be grouped together in one portion of the label (that portion being called the consumer information panel):
 - i. The statement of ingredients, which shall show—
 - a. The quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, where the dietary supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and
 - b. The inactive ingredients in the package or container, which shall be described either by their specific names or by their class names, being any of the following permitted class names:
 - Antioxidants
 - Artificial sweeteners
 - Colouring or colour
 - Encapsulating aids
 - Flavouring or flavour
 - Minerals
 - Preservatives
 - Tableting aids
 - Vitamins:
 - c. The storage instructions (where appropriate).
- (an) The consumer information panel may be any part of the label, but shall—
 - i. Be conspicuously placed in relation to other information included on the label; and

- ii. Be clearly differentiated from all other promotional material or illustrations.
- (ao) A Proprietary Knowledge Labelling Exemption is described in Section 25.

Packaging

- (ap) Tamper proof packaging is NOT mandatory unless specified in RMS.
- (aq) A single level of tamper evident packaging is mandatory.
- (ar) Child proof packaging is NOT mandatory unless specified in RMS.

Recalls

- (as) All manufacturers, importers, exporters, distributors or licensees shall notify the regulator that they have an approved product recall system within six months of enactment of this Act²⁸,

Bulk Materials Integrity Procedures: Local and Imports

- (at) The Act requires that the manufacturer provides a Certificate of Analysis to ensure that the bulk materials actually are what they are claimed to be by undertaking: An identity test, or
- (au) An assay to identify actives if a specific level of active ingredients is claimed.
- (av) Any identity test or assay of each batch must be performed by an approved laboratory listed on the Schedule of Acceptable Testing Facilities.
- (aw) The manufacturer can rely upon the tests conducted by a bulk materials broker or distributor so long as the requirement in section 19 (av) is complied with.
- (ax) A Schedule of Acceptable Testing Facilities will be established to identify testing facilities that are authorized to produce Certificates of Analysis for the purpose of this Act.
- (ay) Such a schedule will include the following;
 - i. Any authenticated Certificate of Analysis produced by a testing facility accredited by any of the following;
 - the International Accreditation New Zealand (IANZ),
 - any member of the International Laboratory Accreditation Cooperation (ILAC),
 - the Asia Pacific Laboratory Accreditation Cooperation (APLAC)
 - ii. Any other testing laboratory able to verify that it meets acceptable Good Laboratory Practice.
- (az) Any authenticated Certificate of Analysis produced by a testing facility accepted and listed in the Schedule of Acceptable Testing Facilities will be accepted at face value unless the regulator has reasons to doubt otherwise.
 - NOTE: IANZ is the accreditation body of the Testing Laboratory Registration Council, an autonomous Crown entity established by the Testing Laboratory Registration Council Act, 1972
 - IANZ is a full member of the International Laboratory Accreditation Cooperation (ILAC) and the regional body, Asia Pacific Laboratory Accreditation Cooperation (APLAC); and a signatory to the ILAC and APLAC Mutual Recognition Arrangements.
- (ba) It is acknowledged that small batch runs can incur substantial disproportionate costs relating to customs certificates, compliance and identity testing which need to be managed in accordance with the principles of good regulatory practice.
- (bb) False certificates and declarations will be considered to be serious breaches of a risk management programme and will attract the attention of the regulator.

²⁸ NZFSA [Recall Quick Reference Guide](#); and also see Recall guidance material

Part IV: General Provisions

20. Exports

- (a) Products exported from New Zealand shall meet the regulatory requirements of the importing country not the NZ regulatory requirements,
- (b) The regulator shall facilitate the issuing of export certificates to satisfy the importing authorities,
- (c) The regulator shall endeavour to establish mutual recognition arrangements with major export countries,
- (d) New Zealand domestic standards shall not be determined by export market requirements.

21. Health Claims Procedures

- (a) Evidence-based health claims shall be permitted during the transition phase once an RMP including where appropriate GMP has been implemented and registered.
- (b) RMS shall have a schedule of acceptable health claims, explained in section 22 that can be used without permission.
- (c) New or novel health claims shall be notified to the regulator via the RMS 40 working days before commencement of proposed marketing. The regulator is to respond within 20 working days.
- (d) The regulator may request copies of supporting evidence of safety to support new or novel health claims.
- (e) The regulator may only disallow or challenge such notifications when there are genuine evidence issues.
- (f) Health claims that have a recognised history of use shall not normally be disapproved.
- (g) Disapproval of notifications may be appealed as provided for in the dispute resolution provisions of the Act.
- (h) Provided the regulator does not disallow or challenge the claim after 20 working days; the claim may be used.
- (i) Such claims shall include a declaration on RMS that evidence is held by the notifier.
- (j) The regulator may request a copy of such evidence.
- (k) Any disallowance shall be subject to the provisions of the dispute resolution mechanism.
- (l) Health claims shall not be mandatory.
- (m) The Act provides for differing claims classifications based on levels of evidence. The classification system will assist consumers in evaluating the validity of the health claims.

Explanatory Note: This Act adopts and adapts the evidence based guidelines framework developed by the New Zealand Guidelines Group for the New Zealand health system for the effective use of credible evidence.

- (n) Seven levels of evidence can be graded as A, B or C indicating strength of evidence: ²⁹
 - A. Good evidence:
 - I. Evidence from large, well conducted Randomised Controlled Trials (RCTs)
 - II. Evidence from small, well conducted RCTs

²⁹ New Zealand Guidelines Group, please see the seven levels of evidence on page 2 of "A Guideline for the management of heart failure" http://www.nzgg.org.nz/guidelines/0026/CHF_Guide.pdf
The New Zealand Guidelines Group (NZGG) was set up in 1996 by the National Health Committee (NHC) as an informal network of expertise and information on guidelines development and implementation. As the network and work expanded the organisational infrastructure grew, and in July 1999 the NZGG became an independent incorporated society. The NZGG's main office is in Wellington and a satellite office is set up in Auckland. NZGG is funded by the Ministry of Health and through contracts with other health agencies such as ACC and the National Health Committee.

- III. Evidence from well-conducted cohort studies³⁰
- B. Fair Evidence
 - IV. Evidence from well-conducted case-control studies³¹ or traditional use
 - V. Evidence from uncontrolled or poorly controlled studies
 - VI. Conflicting evidence, but tending to favour the recommendation
- C. Weak Evidence
 - VII. Expert opinion or testimonial evidence

22. Schedule of Sources of Acceptable Claims

- (a) The Act recognises that it is unreasonable for health claims of such a diverse range of natural and traditional ingredients be confined to only a single reference or pharmacopoeia.
- (b) A schedule of sources of acceptable claims shall be maintained by the regulator in consultation with affected parties.
- (c) The schedule shall include international sources that are generally recognised as being acceptable reference material.
- (d) Acceptable sources may include evidence that has an oral tradition.
- (e) Consultation as to acceptable sources shall commence within 6 months of the establishment of the regulator's office, the schedule shall be completed within 18 months with ongoing reviews of new acceptable sources for addition to the schedule.
- (f) New reference sources may be nominated by any party at any time.
 - i. The regulator shall have 10 working days to request further information about the nominated source.
 - ii. The regulator shall only disallow the nominated source material if they have good reason to do so.
 - iii. Unless the material is disallowed within 20 working days net of any delays due to requests for further information, the reference shall be automatically accepted, added to the schedule and notified as such in the *Gazette*.
- (g) Regardless of any claim being included in the acceptable source in the schedule, any claim may be moderated or modified and lodged in the RMS database subject to consultation and dispute proceedings,
- (h) The following sources shall be the initial schedule of sources of acceptable claims:
 - American Herbal Pharmacopoeia and associated Compendium
 - Any claim approved by a regulator-approved third party such as TAPS
 - Australian (TGA) register of medicines
 - British Pharmacopoeia
 - British Herbal Pharmacopoeia and associated Compendium
 - Canada NHP
 - Codex Alimentarius
 - EU Traditional Herbal Medicine Directive
 - European Pharmacopoeia
 - European Scientific Cooperative on Phytomedicines (ESCOP)
 - German Commission E Monographs
 - Indian Herbal Pharmacopoeia

³⁰ Definition of Cohort Study: http://en.wikipedia.org/wiki/Cohort_study

³¹ Definition of a Case-Control Study: http://en.wikipedia.org/wiki/Case-control_study

- Nga Ringa Whakahaere o Te Iwi Maori Incorporated Society
- Pharmacopoeia of the People's Republic of China: including traditional Chinese medicines
- United States Pharmacopoeia (USP): USP Verified Dietary Supplements
- World Health Organization: Monographs on Selected Medicinal Plants
- Other Maori sources to be added
- Others to be added

23. Penalties

The intention of the penalties provision is to ensure compliance with the Act and to ensure the integrity of the products offered to consumers.

- The penalty for the first material breach of the Act may be education about the manufacturer's responsibilities under the Act and to consumers.
- Any further penalties shall be sufficient to encourage compliance (i.e. 'name and shame'), but also commensurate with levels of risk and degree of non-compliance.
- If any fine for an offence under the Act is imposed the fine shall not exceed an amount to be determined and, in the case of a continuing offence, a further fine shall not exceed an amount to be determined for every day on which the offence has continued.
- Any alleged non-compliance may be subject to the dispute resolution mechanism.
- No Court proceeding initiated under this Act shall rely upon evidence of expert hypothesis but shall rest on empirical evidence.
- In any proceedings under this Act instituted by the Crown or the Regulator, no person shall have imposed on them any reversal of the burden of proof or any onus of rebuttal.

Explanatory Notes:

Penalties to be imposed in this Act should be benchmarked to those in the Animal Products Act and the Misuse of Drugs Amendment Act 2005 as they relate to the section on restricted substances.

It is noted that the provisions of the Fair Trading Act 1986 apply to the marketing of NaTHPs.

24. Funding Mechanism

- Funding mechanism
 - Industry funding is proposed either by licence fees and/or via a levy.
NOTE: Industry see merits in both fee and levy based funding. Submissions will be made once the cost of the regulator is more certain.
 - In the case of a levy funding mechanism, the regulator may request confirmation of declared turnover from a suitably qualified professional.
 - Any industry funding mechanism shall be applied uniformly from the end of year **[three]**.
 - Any increases in the percentage of any levy or fees are to be approved by Parliament.
- The regulatory agency shall be funded jointly by the state and industry, with the industry's share being no more than 50 percent of the cost.

Explanatory Notes:

- *Joint funding is predicated on the potential health savings due to the preventative nature of NaTHPs (also called the 'public good factor'), and*
- *the dissemination of knowledge which allows people to take responsibility for their own health, and*
- *the simultaneous management of community exposure to potential harm as well as establishment of a safe business environment for industry participants.*

25. Proprietary Knowledge Label Exemption³²

- (a) Manufacturers or distributors may apply to the regulator for an exemption to list amounts of ingredients on products where the disclosure of such information may reasonably be regarded as proprietary knowledge.
- (b) Applications for this labelling exemption shall be in writing and a reasonable fee may be charged by the regulator, and ingredients and amounts advised to the regulator.
- (c) Such an exemption may not be withheld by the regulator without good reason, but granting of such an exemption does not exempt the manufacturer from displaying any advisory, warning or other risk management labelling requirements.
- (d) If the regulator withholds an exemption, it must provide the licensee with its reasons for withholding, within 20 working days.
 - i. The regulator may only withhold exemptions when there are genuine safety issues.
 - ii. Withholding of exemptions by the regulator may be appealed as provided for in the dispute resolution provisions of the Act.
- (e) When granting such an exemption, the regulator shall advise the manufacturer and/or distributor of a unique exemption number.
- (f) Where such exemptions are granted, products shall display a label stating that such an exemption has been granted along with the exemption number. However, the label cannot be worded in such a way that it might imply that the product was endorsed by the regulator.
- (g) Whilst proprietary ownership of ingredients is not regulated by this Act, the ingredient database may be used to determine breach of proprietary issues established by other legislation.

26. Sustainability

All RMPs shall include a statement regarding management practices to ensure the sustainable harvesting of naturally grown New Zealand indigenous flora or fauna.

27. Transition/Phase-in period

- (a) A five-year transition shall begin with a six-month period during which time the NaTHP Authority shall be established and notify affected sectors of dates for the various stages of the transition.
- (b) There shall be a progressive transition. The timeline for the transition shall be as follows:
- (c) Within 6 months of the date at which Act comes into force:
 - i. The NaTHP Authority shall be established
 - ii. Implementation of the transitional process shall be confirmed and publicly notified by the NaTHP Authority.
- (d) Six months following establishment of the NaTHP Authority:
 - i. An off-the-shelf recall plan shall be developed by the regulator and made available to industry.³³
 - ii. The schedule of acceptable GMPs with any 'plug-in' requirements shall be reviewed.
 - iii. The schedule of sources of acceptable claims shall be reviewed to expand it.
 - iv. Evidence based health claims codes utilising evidence-based principles may be permitted subject to claimants registering an appropriate RMP including, where appropriate, GMP.
- (e) Within 12 months of the date at which Act comes into force:

³² Explanatory Note: Should the Waitangi Tribunal endorse the WAI 262 claim, certain Rakau Rongoa would be subject to proprietary ownership. The ingredient database would be able to be used for legal purposes to provide the claimants with information regarding companies using such ingredient in their products and such information could be used in Court proceedings.

³³ Note: This can essentially be an adoption, with possible minor modifications, of the existing NZFSA food recall plan. Food Recall for Manufacturers: http://www.nzfsa.govt.nz/processed-food-retail-sale/recalls/index.htm#P18_979

- i. An online RMS NaTHP Notification database shall be developed.
- ii. An 'Off-the-shelf' RMP shall be developed by the regulator and made available to industry including the minimum requirements for a risk proportionate NZ GMP.
- iii. All manufacturers and distributors shall have a recall system in place and have notified the NaTHP Authority of their recall system via the online RMS NaTHP Notification database.
- iv. A Technical Advisory Group shall be established.
- v. A list of third party RMP, including GMP, auditors shall be established.
- vi. An Industry funding plan shall be developed developed as provided for in the Act for introduction within 36 months of the date at which Act comes into force.
- vii. Any other provision that can be implemented within this time period may be carried out.
- (f) Twelve months after the online RMS NaTHP Notification database is established:
 - i. All manufacturers and distributors and products shall be entered into the online RMS NaTHP Notification database.
- (g) Within 24 months of the date at which Act comes into force
 - i. All manufacturers and distributors shall have undertaken an RMP, including where appropriate GMP, verification to determine issues that require attention.
 - ii. All manufacturers and distributors shall have submitted a progress report to the NaTHP Authority including a description of the approach they are taking to implementation of the chosen RMP, including where appropriate GMP. The progress report shall include critical issues, if any, that have been identified in achieving compliance.
 - iii. The risk proportionate GMP standards shall be confirmed prior to an audit taking place.
 - iv. Verification may be undertaken by a recognised third party including verifiers recognised by jurisdictions responsible for GMPs listed in the Acceptable GMP Schedule.³⁴
 - v. All products shall be appropriately labelled.
- (h) Within 36 months of the date at which Act comes into force:
 - i. Manufacturers and distributors shall have applied for formal Audit of their RMP including where appropriate GMP and notified the regulator of issues, if any identified in the audit.
- (i) Within 48 months of the date at which Act comes into force:
 - i. Manufacturers and distributors shall have submitted a plan to the NaTHP Authority that addresses outstanding issues, if any, relating to RMPs including where appropriate GMPs.
- (j) Within 60 months of the date at which Act comes into force:
 - i. Manufacturers and distributors shall be fully compliant and have provided appropriate documentation to the NaTHP Authority.

³⁴ Explanatory note: By way of example, a manufacturer might want to export product to Australia or Europe so will be able to satisfy the requirements of an RMP including where appropriate GMP by use of an auditor recognised by the competent Australian or European authority. It may be possible for several businesses to combine resources, fly an auditor from Europe to New Zealand and undertake multiple audits at the same time.

Appendices

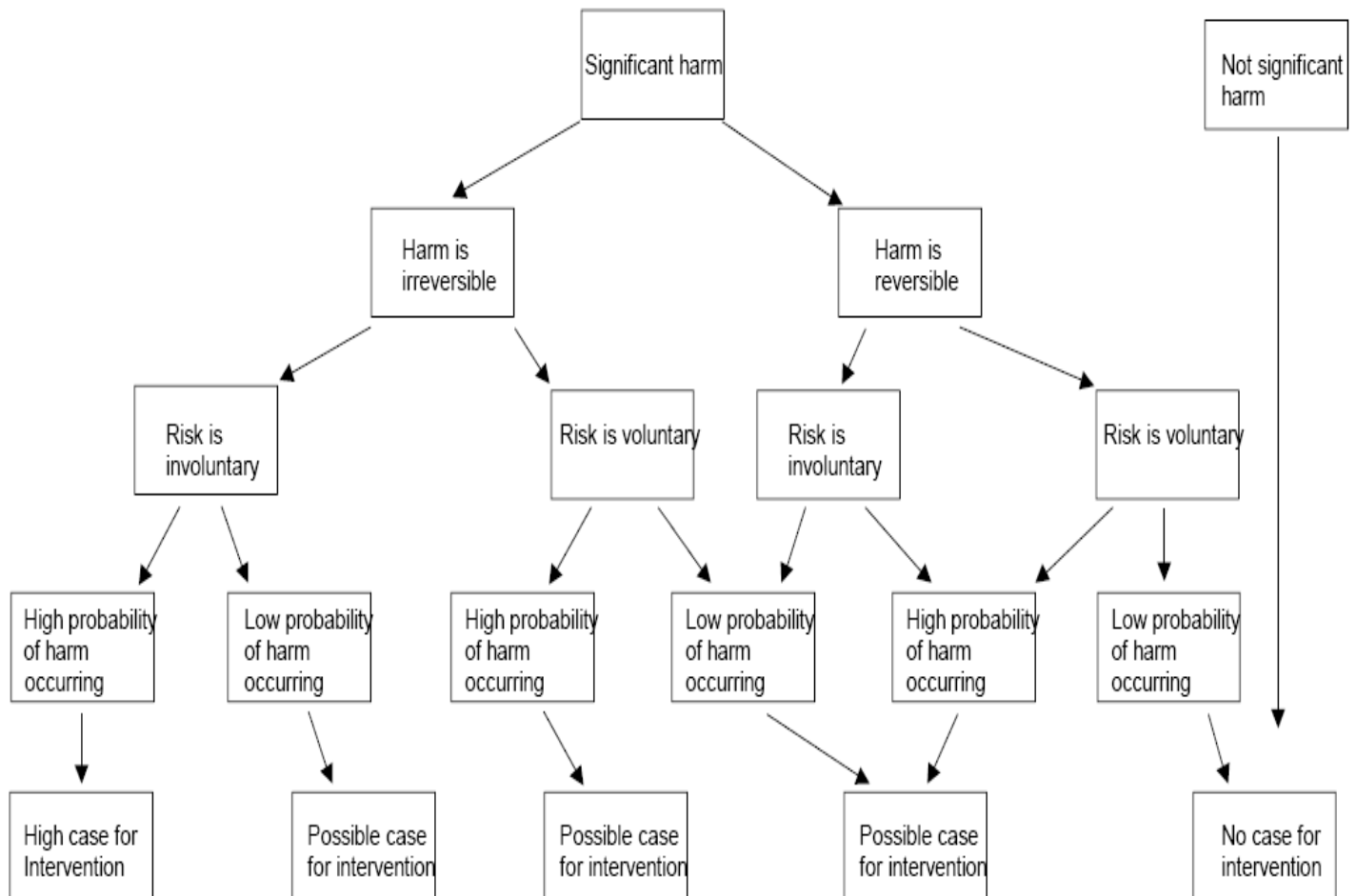
Appendix I: "When is There a Case for Intervention?"

1

CHART 2: WHEN IS THERE A CASE FOR INTERVENTION IN AN OCCUPATION?

Note:

(*) "Significant harm" covers significant harm to an individual and/or moderate harm to a large number of individuals.



Appendix II: Schedule X for Maximum Daily Dosages used where restrictions are required only for risk management purposes (to be developed further)

Column 1	Column 2	Column 3
Ingredient	Upper Limit per daily dose	Exception
Iron (elemental Fe as Ferrous sulphate)	5 mg	None
Iron (Elemental Fe as Non ferrous sulphate forms)	50 mg	Practitioner only
Folic acid	1,000 ug	Upto 5,000 ug if ≥ 50 ug B12 included
Selenium	200 ug	Practitioner only up to 400ug per day
Zinc	30 mg	Practitioner only
B6	50 mg	Up to 200 mg with Caution statement; Practitioner only if greater than 200 mg

Appendix III: Schedule Y for Cautions, Warnings, and Standards used where restrictions are required only for risk management purposes (to be developed further)

Column 1	Column 2	Column 3
Ingredient	Voluntary	Mandatory
Comfrey		Pyrrolidine Alkaloids < x mg per dose
Aristolochic spp		Aristolochic acid < x mg per dose
Vitamin B6 >200 mg		Practitioner only
Vitamin B6 50-200 mg		The following or similar statement: Caution: If your fingers start tingling reduce intake.
St John's Wort		The following or similar statement: Caution: St John's Wort affects the way some drugs work. If taking prescription medicines consult a health practitioner for advice.
Vitamin A		> 3000 mg RE. Do not consume if pregnant
Ephedra spp		If a species that contains ephedra alkaloids: Practitioner only
Ephedrine (synthetic)		Prohibited.

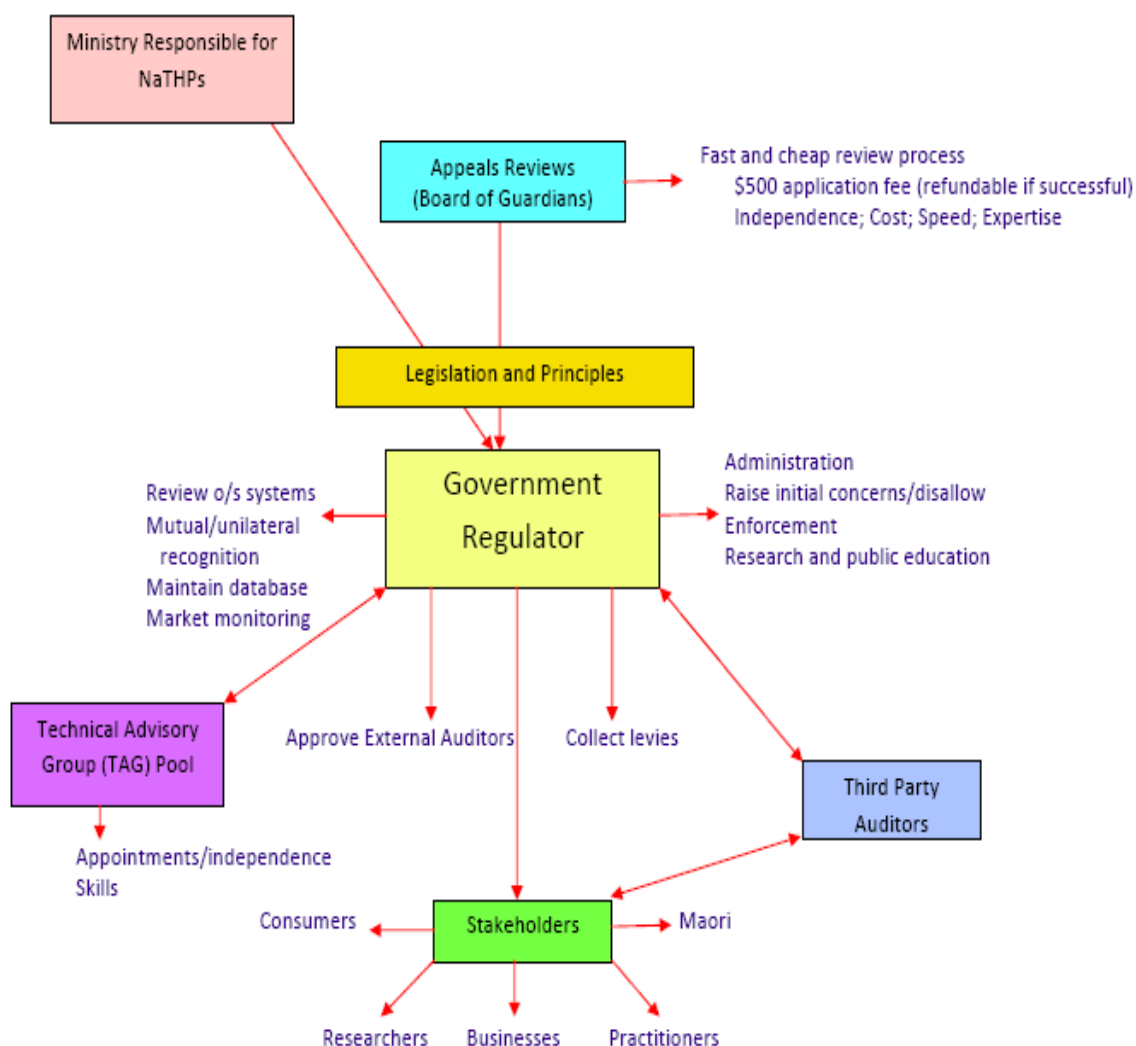
Appendix IV: Summary of 2002 Compliance Costs Submitted to Health Select Committee Inquiry into the Proposed JTTTGA.

Costs to convert from New Zealand regulatory system to proposed system including transition and first year compliance costs based on existing TGA fees and invoiced costs of companies in the Australian market.

Case #	Description of Supplier	Comments	Compliance costs
1	Medium-large NZ manufacturer with some imported products. Significant number of product in the Australian market.	Mostly based on actual costs with some estimates	\$791,500
2	Medium-large NZ Manufacturer with limited range of predominantly innovative food/medicine interface products, 10% of product on the Australian market.	Mostly based on actual costs with some estimates	\$561,200
3	Medium NZ Manufacturer not in Australian market due to cost of entry. Exports to	Estimated costs based on contracted consultant report.	\$607,300
4	Medium NZ (only) Importer: not in Australian market	Estimated costs based on schedule of fees and estimated costs.	\$924,750
5	Small NZ Importer: Not in Australian market	Estimated costs based on schedule of fees and estimated costs.	\$1,870,000
6	Large overseas supplier with significant market penetration in NZ but very limited in Australia.	Costs are based on actual market entry experience, though estimated to differentiate extra costs incurred over and above normal market entry costs.	\$3,000,000

Appendix V: Flow of Authority

FLOW OF AUTHORITY



NOTE: If any links shown within this document's footnotes do not connect to the appropriate reference, an alternative source can be found at: http://www.nzhealthtrust.co.nz/NTHP_footnotes.html