Natural and Traditional Health Products Bill

A Proposal for the Regulation of:

- Natural and Traditional Health Products

- Manufacturers, Importers, Exporters and Distributors

Natural and Traditional Health Products Bill

Explanatory Note

Introduction

This proposal is modeled, 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 $600 million industry with approximately $300 million in domestic sales and $300 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 an 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 ECJ 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 low risk industry. Agency costs will be shared by the government and industry. A levy 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.

This proposal recognizes 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 and food legislation, including international issues such as Codex Alimentarius, unless the distributor of the NaTHP chooses otherwise.

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 demonstrated extremely 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, minimize 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 recognizing 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. Because New Zealand is a small, diverse economy compared to most others and because NZ industry is comprised mainly of small to medium enterprises, adopting and recognizing 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 regulator discretion to an absolute minimum and keep industry uncertainty to an absolute minimum.

The regulator must employ staff who are appropriately skilled and who are not antagonistic toward NaTHPs.

It is intended that the new regulator created by this proposal will understand the principle of unity in diversity rather than unity in conformity.

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 (i.e. the Maori idea of "continuity of consciousness").

Enabling Legislation

The proposal would be given effect to 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 the regulator 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 Bill seeks to maintain a healthy respect and tension (1) between the desire of industry to develop and market innovative products and the desire for safety and (2) between 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 Bill and is exempt from compliance with both medicines and food law.

(1) Does the product comply with the definition of a NaTHP?

- The definition of a NaTHP determines whether ingredients are natural or have a traditional use and is therefore able to be considered for use in a NaTHP. Any conditions or restrictions of use will be contained in the ingredient central register.

(2) Does the product manufacturer and distributor have an accepted Risk Management Programme (RMP) or Good Manufacturing Practice (GMP) system in place?

(3) Does the manufacturer and distributor have available the required evidence for any health claims made?

(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 Bill does.

Health Select Committee Recommendations[1]

In December 2003 the Health Select Committee recommended that the government ensure that any system for regulating NaTHPs:

(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 lodgment 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 labeling 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 that relate to Health Select Committee recommendations (b) and (e).

b) This proposal provides for evidence-based health claims utilizing a schedule of sources of acceptable claims such as pharmacopoeia, certain overseas or international regulatory agencies (e.g. 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 utilized but must be held by the claimant.

e) This proposal includes a hybrid 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:

- 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 any other way;
- the amount of intervention should be the minimum required to solve the problem;
- the benefits of intervening must exceed the costs.

Co-regulatory Model

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

[1] 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

To help maintain a balance between regulator and industry responsibilities, the agency will be jointly funded via government funding and an industry levy.

There will be provision in the Bill 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 Practice[2] 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.[3]

Impact on Existing Industry

Following enactment:

- No products currently on the market will be removed from the market unless unacceptable safety issues emerge.
- Compliance will be phased in progressively over five years.
- Manufacturers, importers, exporters and distributors will have the choice of implementing Risk Management Programmes (RMPs) which will be submitted to the regulator for acceptance.
- A RMP will be required to meet certain safety standards and may be customised or be an acceptable GMP scheduled by the Bill and chosen by the manufacturers, importers, exporters, or distributors; these programmes will ensure product integrity.
- Simple Risk Management Programmes will embrace well defined and sensible Hazard Analyses Critical Control Point (HACCP) principles[4] 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 proposal is different to both the NZ Dietary Supplement Regulations 1985 (status quo) and the shelved JTTTGA.

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.

Status quo

(1) In essence, in New Zealand at present, the market is a free-for-all but in reality there have been very few safety problems occurring over time.

(2) However, the Health Select Committee's inquiry report into the proposal to establish the JTTTGA to regulate therapeutic products expressed grave concerns that existing regulations were mostly unenforced.

Shelved JTTTGA

(1) In essence, the shelved JTTTGA (based on Australia's TGA system) meant that

[2] http://www.med.govt.nz/templates/MultipageDocumentTOC____22149.aspx
[3] http://cabguide.cabinetoffice.govt.nz/procedures/papers/RIA ; http://www.med.govt.nz/templates/MultipageDocumentTOC____26448.aspx
[4] http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf

the manufacturer must first apply for a new ingredient (that may have been used for thousands of years in other parts of the world) to be licensed and then apply for a license to manufacture a product. Finally, the manufacturer may only manufacture approved products.

(2) In addition, non-regulatory compliance costs are approximately four times the regulatory costs and often 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.

(3) 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 trial or any significant independent appeal process.

(4) There is no evidence that the Australian restrictive regime delivers safer product. The Pan debacle demonstrated that this system offers no guarantee of quality of product even with one of the most restrictive GMP systems in the world for NaTHPs.

Proposed Natural and Traditional Health Product Bill

(1) This proposal in essence 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.

(2) Like the New Zealand status quo system, this proposal does not allow manufacturers, importers, exporters and distributors to use ingredients on the black list.

(3) However, unlike the shelved JTTTGA, manufacturers, importers, exporters and distributors are not limited to using ingredients on a preapproved white list so long as they notify the regulator and the ingredients meet the definition of an NaTHP. Further, the regulators created by this proposal can only disallow ingredients if their decisions are established on strictly controlled grounds. The manufacturer, importer, exporter or distributor can appeal any such decision via an independent dispute resolution process if they choose.

(4) 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.

The major advantage of this proposal is that in accepting and applying equivalency it minimizes compliance costs and reduces technical barriers to trade for manufacturers, importers, exporters and distributors.

Overall, major cost savings are accrued by recognizing other selected countries' and jurisdictions' ingredients, health claims and manufacturing standards because of reduced regulatory costs.

This proposal would have the following additional advantages as well:

a. giving consumers freedom of choice of the widest possible range of quality assured NaTHPs at least possible cost,

b. providing consumers the benefit of knowledge to enable informed choice,

c. encouraging appropriately controlled innovation,

d. enabling exporters and importers to rationalize inventory without having to maintain slightly different formulae simply to satisfy a plethora of red tape.

Consultation

This proposal has been developed following ongoing informal consultation with a number of stakeholders representing different sections of industry. 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 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 Bill 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 JTTTGA, conversations and informal meetings with Rongoa practitioners and more formal meetings of individuals belonging to various groups.

It is recognized and provided for in the Bill that evidence related to medical practices such as the use of Rakau Rongoa are orally based traditions 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**.**

It is recognized and appreciated that 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.

It is recognized that the biodiversity of Aotearoa/New Zealand, the research and development of Rakau Rongoa and such products and the importation and exportation of biodiverse raw and processed NaTHPs should be allowed to be developed and supported by government within the confines of Good Regulatory Practice.

It is recognized that 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. It is recognized that 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.

It is recognized 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.

Compliance Costs

1) One of the strong industry objections to the shelved JTTTGA was focused strongly around the prohibitive costs that were likely to have occurred in line with the current pharmaco-centric Australian TGA system relative to the established very low risk profile of NaTHPs.

2) Given the similarities of the Australian and shelved JTTTGA regimes, it was very reasonable to accept that similar costs would have forced many safe and effective products from the market for no reason related to safety.

3) This proposed bill is designed to keep regulatory and compliance costs to a minimum. The Cabinet Office Circular (CO (01) 2) defines compliance costs as:[5]

> "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

[5] http://www.dpmc.govt.nz/cabinet/circulars/co01/2.html

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 who are most susceptible to such costs."

Funding

The proposed co-regulatory model is to be funded 50/50 by government and industry.

Government funding is cognizant of 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.

Industry funding is proposed to be via a parliament approved levy of possibly 0.5 [to 1%] wholesale or possibly 0.25 [to 0.5%] export value based on self declared turnover similar to the way IRD operates. Exporters would pay only 50 percent of the actual costs with no cross subsidizing either direction.

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 Bill. The Bill provides for a regulatory system that:

(1) Is enabling;

(2) Establishes NaTHPs as an important class of goods in their own right via the proposed Natural and Traditional Health Products Bill,

(3) Recognises that there will be interface issues relating to the Food Act and the Medicines Act that need to be pro-actively and fairly managed;

(4) Recognises and provides for Treaty of Waitangi related matters;

(5) Provides political assurance and certainty;

(6) Provides clear guidelines as to the regulator's discretionary powers;

(7) Provides industry assurance and certainty;

(8) Provides for consumer choice, innovation and maintenance of product safety;

(9) Maintains quality assurance through approved Risk Management Programmes (RMPs);

(10) 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 bill effectively and efficiently;

(11) Ensures that the principles of the government's Good Regulatory Practice (GRP) are complied with especially the principle of equity (i.e. proportionality);

(12) Requires the regulator to be certified as GRP compliant by the Auditor General;

(13) Prohibits the adulteration of NaTHPs with synthetic pharmaceutical ingredients;

(14) Ingredients found in products are permitted only if they meet the definition of NaTHPs;

(15) Provides a mechanism to ensure that compliance and regulatory costs are kept to as low as reasonably practicable levels commensurate with GRP;

(16) Enables the entry of defined NaTHP ingredients onto the market whilst at the same time preventing the use of this bill to introduce novel, non-natural or non-traditional ingredients such as occurred with benzylpiperazine, known as party pills, under the Food Act;

(17) 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;

(18) Minimizes compliance costs and reduces technical barriers to trade:

(19) Requires 'True to Label' manufacture and packaging;

a. Recognises verifiable QBI (Quantify By Input);

b. Requires certain post manufacture testing where appropriate such as microbiological, heavy metals, rancidity of oils;

c. If it is shown that ingredient levels need to be tested then testing will be limited to one easily, accurately and economically identifiable ingredient.

i. If a problem is indicated then manufacturing input records are examined to determine the problem (e.g. mixing).

(20) Provides a Proprietary Knowledge Labeling Exemption based on the following reasons:

i. It is acknowledged that consumers choose products voluntarily so if they do not want to purchase products without proprietary formula ingredients listed on the label then they can choose not to. Market forces will dictate the success or otherwise of this aspect of the regulations. Given the generic aspect of the ingredients used in NaTHPs it is intended that this provision will allow distributors to develop innovative formulas knowing that their products are somewhat protected from copycats.

ii. This provision does not provide exclusive use of ingredients or formula. By way of example, the painted apple moth spraying campaign in Waitakere City utilised a spray consisting of a proprietary mix of generic ingredients that were kept secret by the government for commercial reasons. Whilst Foray 48B may have contained safe ingredients as claimed by health authorities, residents of Waitakere could not avoid its potential effects unless they moved house for several days. In the case of NaTHPs, consumers can simply choose not to buy the products without all ingredients listed on the label if they do not want to.

(21) Provides for evidence based health claims, but health claims are not mandatory;

(22) Provides marketing and quality certainty for New Zealand's burgeoning NaTHP industry;

(23) Provides a regulatory environment that maintains a healthy 'tension' or 'balance' between the operational needs of small cottage industry and large industry players;

(24) Enables the regulator to undertake Post Market Monitoring and Auditing to maintain the integrity of the regulatory system;

a. Sensible ongoing monitoring is essential to ensure compliance with this bill;

b. Post Market Monitoring of known and emerging issues related to the NaTHP industry is to be undertaken with priorities and resources being established utilizing HACCP type principles;

c. Post Market Auditing is to be risk responsive and involve some degree of testing of targeted ingredients and/or products as issues emerge. For example,

i. Recently it emerged overseas that certain toothpastes contained diethylene glycol.

ii. Cooperation between international regulators identified a limited number of countries as being the likely source of these products.

iii. The regulators' risk management response was to initiate recalls where specific products were identified and to test a range of high risk products for adulteration and withdraw any unacceptable products.

iv. Similar regulatory responses occurred with regards to certain soya sauces.

v. These regulatory responses were risk proportionate and appropriate for NaTHP regulation.

(25) Prevents the heavy-handed approach such as the recall and mandated destruction of Pan Laboratory's products in 2003.

a. Even though there was not, and still is not, any evidence of harm due to the consumption of a single NaTHP manufactured by Pan, or that any product was shown to

pose an actual health threat, the largest recall of any medicine or food occurred at an established cost of over $600 million to the industry and investors;

b. The only evidence of harm or unsafe product was a pharmaceutical product that was voluntarily recalled following consultation with the distributors some three months earlier;

c. Attempted prosecutions were rejected by the Courts through lack of evidence of both faulty product and wrongdoing.

(26) Prevents the regulator from abusing their power, though it would enable it 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 Australian Treasury Department and Canadian Justice Department models to prevent regulatory creep, to prevent 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.[6,7]

[6] http://www.treasury.gov.au/documents/1124/HTML/docshell.asp?URL=03_%20principles.asp

[7] http://canada.justice.gc.ca/en/dept/pub/rd/index.html

Proposed Bill for Natural and Traditional Health Products in New Zealand

1. Objectives

- To provide a sustainable, risk proportionate co-regulatory system for the manufacture, import, export and distribution of NaTHPs at least regulatory and compliance cost;
- To enable the regulator to know who is in the market and what is in the market;
- To enable an innovative NaTHP industry to develop and provide the widest range of NaTHPs;
- To further consumer wellness through freedom of choice and informed choice;
- To ensure consumers maintain their traditional rights of access to natural and traditional health products;
- To fund public education and research of NaTHPs;
- To facilitate the export of NaTHPs;

2. Definitions

- **'Natural and Traditional Health Product' means;**

  (a) A product intended for oral, nasal, or topical use or use via enema, but not intravenous, intramuscular, or subcutaneous use, and

  (b) containing one or more 'Natural or Traditional Health Product Ingredients' and necessary acceptable excipients.

To assist with understanding this definition, products consist of one or more ingredients.

- **'Natural and Traditional Health Product Ingredient' means;**

  (a) An ingredient intended for use or used in a natural or traditional health product that is:

  i. Natural or nature identical, including, but not exclusive to, the following

  (a) a vitamin,

  (b) a mineral,

  (c) a herb or other botanical,

  (d) an animal product for human consumption,

  (e) an amino acid,

  (f) a microorganism for human consumption,

  (g) a dietary substance for use by humans to supplement the diet by increasing the total dietary intake,

  (h) a substance normally present in the human body, or

  ii. a traditional remedy, or

  iii. a concentrate, metabolite, constituent, extract, or combination of any of the categories listed in (a)i.(a)-(h) and (b)i.-ix.

  iv. and is not included in the Misuse of Drugs Act

  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.

(b) A traditional remedy with a recognized history of safe use, including, but not exclusive to, the following;

i. Rakau Rongoa,[8]

ii. Ayurveda,

iii. Chinese herbal medicines,

iv. Western herbal medicines,

v. Homeopathics,

vi. Essential oils,

vii. Aromatherapy,

viii. Apitherapy, or

ix. Other ethnic traditional medicines.

(c) An ingredient meeting the definitions in (a) and (b) 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 Bill 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.

It has been suggested that clause (c) sets a low hurdle. However, any ingredient can be challenged by the regulator under the provisions of this Bill 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.'

- **Risk management programme (RMP)**

(a) A risk management programme (RMP) is a system for identifying and managing risks relative to an individual, company **or enterprise.**

(b) All RMPs will require notification to the regulator who will draw to the attention of the notifier any deficiencies.

(c) The regulator will be required to prepare generic off-the-peg (off the shelf) RMPs that will require being adapted to individual needs.

(d) RMPs can be very simple for a small single product company, or may be a GMP recognized in a schedule of acceptable GMPs.

(e) RMPs will be audited by a recognized third party and a certificate of compliance by the auditor is to be submitted to the regulator at least once every three years. RMPs may be audited by the following:

a. Any auditor approved in a selected country or jurisdiction whose manufacturing standards have been accepted under this Bill; or

b. Any auditor established in New Zealand and approved by the regulator.

(f) RMPs will include an approved recall provision.

An RMP for a small distributor is unlikely to fulfill the requirements of a GMP programme designed for larger companies; however the required minimum safety standards will be met by both systems. An acceptable GMP system would be an acceptable RMP with any additional 'patches' such as a recall system patched to the US FDA dietary supplements GMP.

[8] 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.

- **Recognized history of safe use**

  (g) Recognized history of safe use means;

  i. 10 years of use in any global market without significant unmanageable safety issues, or

  ii. Inclusion in the following recognised acceptable overseas and local sources of ingredients:

  ii. 'Substances That May Be Used in Listed Medicines in Australia'[9]

  iii. British Pharmacopoeia,

  iv. British Herbal Pharmacopoeia and associated Compendium,

  v. Canada NHP,

  vi. EU Traditional Herbal Medicine Directive,

  vii. European Pharmacopoeia,

  viii. European Scientific Cooperative on Phytomedicines (ESCOP)

  ix. German Commission E Monographs,

  x. Indian Herbal Pharmacopoeia,

  xi. Nga Ringa Whakahaere o Te Iwi Maori Incorporated Society,

  xii. Pharmacopoeia of the People's Republic of China: including traditional Chinese medicines,

  xiii. United States Pharmacopoeia (USP): USP Verified Dietary Supplements,

  xiv. World Health Organization: Monographs on Selected Medicinal Plants,

  xv. Other Maori sources to be added

  xvi. Others to be added

  - If a safety concern emerges then any risk assessment response must be evidence-based and include reasonable cognizance of the ingredient's history of use.
  - Any risk management options considered by the regulator must be risk proportionate and take into account cultural, economic and the history of use aspects of any ingredients or products potentially affected.
  - Absence of evidence of significant harm is for the purposes of this Bill deemed to be proof of absence of significant harm until proven otherwise.
  - Absolute safety is defined by an absence of harm. Safety itself can only be defined by demonstrating relative lack of harm. As such, a safety assessment is essentially a synonym for the more correct term 'risk assessment'.
  - Whilst it is recognized that new or emerging evidence relating to ingredients that were once deemed to have a recognized history of safe use may raise safety concerns, any regulatory response must apply the principle of proportionality and must apply the least restrictive risk management response, in the circumstances, to reduce risk levels to as low as reasonably practicable.
  - For clarity the term "recognized" means recognition by the consumers, practitioners or industry rather than by a regulator or other authority. There is nothing genetically unique relating to New Zealand consumers that would expose them to any more or less risk than residents of other countries. Therefore it is logical that New Zealand consumers are not restricted from having access to ingredients commonly available in other countries when those ingredients have a history of safe use.

- **Health Claims**

  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 and the

[9] http://www.tga.gov.au/cm/listsubs.pdf

Commerce Act.

- **Industry**

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

- **Levels of risk**

  It is acknowledged that there is a continuum of risk bounded by two extremes which are provided for in this Bill:

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

  Levels of risk are defined as;

  (a) Intolerable. Ingredients with intolerable risk are unacceptable and access will usually be restricted temporarily or permanently in some way (e.g. 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.

  (b) Tolerable. Ingredients will not usually have access restricted but there will usually be risk management requirements such manufacturing standards, mandatory labeling and/or education.

  (c) Acceptable. Ingredients with known, but acceptable levels of risk will normally have risk management by generic education and voluntary advisory statements.

  (d) De minimis. In a more formal legal sense, de minimis means something that is trivial or unworthy of the law's attention. Ingredients with de minimis levels of risk are deemed to be inherently safe and will have no special risk management requirements. In risk assessment "de minimis" refers to a level of risk which is too small to be concerned with which is a "virtually safe" level.

- **As Low As Reasonably Practicable (ALARP)**

  (a) The ALARP principle is when you balance up the benefits of reducing the risk, and think about ways you can reduce the risk level to a reasonable level, at a reasonable cost.

  (b) Most NaTHPs have a proven history of safe use and the levels of risk are de minimis. Some may have acceptable risks, some may have tolerable risks and some may have intolerable levels of risk and should be prohibited or severely restricted. Therefore, it becomes necessary to consider how you can reduce the risks to a level 'as low as reasonably practicable' (ALARP).

  (c) 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, imagine a potential hazard has been identified that creates a de minimis to acceptable level of risk. There are systems in place to deal with the risk and there are no real benefits of reducing the risk further.

  (d) All ingredients and products will have risk management programmes and labeling requirements that will reduce generic risks to ALARP levels.

  (e) Some products will require specific risk management options to reduce risks to acceptable levels.

  (f) The ALARP principle, also known as the ALARA (reasonably achievable), must be applied by industry when applying risk management strategies.

  (g) The ALARP principle must be applied along with the principle of proportionality when the

regulator is considering potentially restrictive risk management options.

- **Advisory group**

  Advisory group means any group mentioned or referred to in sections 7 – 10 of the Bill.

- **Reasonably practicable**

  Defining the term 'reasonably practicable' is critical to ensure that the regulator and industry have a deeper understanding of the ALARP principle and the resources required for compliance with the principle.

  (a) Definition 1 – Case Law

  The following opinion given by Lord Justice Asquith in 1949 is offered as the cleanest and simplest definition of the expectation of industry and the regulator's duty to do things in so far as is reasonably practicable. If decisions are based on the following definition then there will be strong argument to suggest appropriate duty of care has been discharged.

  > *'Reasonably practicable' is a narrower term than 'physically possible' and it seems to me to imply that a computation must be made by the owner, in which the quantum of risk is placed on one scale and the sacrifice involved in the measures necessary for averting the risk (whether in money, time or trouble) is placed in the other; and that if it be shown that there is a gross disproportion between them - the risk being insignificant in relation to the sacrifice - the defendants discharge the onus on them. Moreover, this computation falls to be made by the owner at a point of time anterior to the accident.*

  Source: Edwards v National Coal Board (1949) 1 KB 704 at 712, CA, per Asquith LJ. The following two examples illustrate the matters to be considered in determining whether this definition of 'reasonably practicable' has been met.

  (b) Example 1 - Queensland Workplace Health and Safety Act 1989

  The Queensland Workplace Health and Safety Act 1989 specifies that the following matters should be considered:

  - the severity of any potential injury or harm to health or safety that may be involved, and the degree of risk that exists in relation thereto
  - the state of knowledge about the injury or harm to health or safety that may be involved, about the risk of that injury or harm to health or safety occurring and about any ways of preventing, removing or mitigation that injury, harm or risk
  - the availability and suitability of ways to prevent, remove or mitigate that injury or harm to health or safety or risk, and
  - whether the cost of preventing, removing or mitigating that injury or harm to health or safety or that risk is prohibitive in the circumstances.

  (c) Example 2 - Legal opinion

  A legal opinion from a barrister active in the Occupational Health and Safety area in Victoria specifies that the following matters should be considered:

  - the severity of the hazard or risk in question
  - the state of knowledge about that hazard or risk and any ways of removing or mitigating that hazard or risk
  - the availability and suitability of ways to remove or mitigate that hazard or risk, and
  - the cost of removing or mitigating that hazard or risk.

  This definition relates to the duties imposed in the Bill. It means ALL these factors must be taken into account when determining whether the duty has been met rather than only looking at any single factor, e.g., the fact that a hazard or risk may or may not exist, or cost.

3. Interpretation Note: Principles to take Precedence over Regulations and Rules

(a) The Bill creates a principles-based regulatory system in which the principles take precedence over the rules. Under such a system the regulator, industry, officials and members of advisory groups created by the Bill are required to use their reason and judgment in support of the principles in the interpretation and application of the rules.

(b) For the purposes of interpreting the Bill and any regulations and/or rules promulgated under the Bill, the principle that NaTHPs in general have a long history of safe use and are inherently very safe products shall over-ride regulations, rules or decisions that assume such products are inherently unsafe.

(c) Levels of risk have been defined in general terms to assist in the interpretation and application of the Bill.

(d) The terms 'certain', 'probable' and 'possible' have the same meaning as those definitions in current WHO causality classifications of medicines.[10]

(e) It is acknowledged that 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. The principles of this Bill recognize such traditions and in the absence of evidence of harm, these traditional products are deemed to be safe until proven otherwise.

1. Like all ingredients and products, the ingredients and products identified in 10(d) shall be formally notified via the HyRMS when produced and marketed commercially.
2. Ethnic communities will be consulted and formal safety assessment will be undertaken if necessary.
3. 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) Where reasonable concern of significant public health safety issues emerge the principle of equity (i.e. proportionality) contained in the Government's Code of Good Regulatory Practice must be applied.

(g) The regulations are intended to encourage the dissemination of evidence based knowledge regarding natural treatments for all known diseases, ailments, disorders and conditions.

(h) The regulator is ultimately employed by and 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 will not seek to reduce ingredients to the lowest common denominator.

(j) The regulator will 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.

(k) The regulator will actively seek, collate and present to the consumer and other interested parties information regarding the results obtained during the use of the NaTHPs it regulates.

[10] http://www.who-umc.org/graphics/4409.pdf

(l) The bill respects and ensures a consumer's right to choose and to informed choice.

(m) 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 intervention. [11]

(n) The seriousness of an illness has no bearing upon any risks associated with NaTHP use. Therefore, the seriousness of illness cannot be used as an excuse to restrict NaTHP use.

(o) Enforcement action must be applied evenly, transparently and risk proportionately.

(p) The protection of life and well being must always be uppermost in the mind of the regulator when applying the regulations.

(q) The regulator will respond in a timely and meaningful manner to communications from consumers and industry.

(r) It is the role of the regulator to facilitate a regulatory environment where innovative NaTHP therapies can compete freely and openly with any medical establishment therapies.

(s) Regulatory charges must be kept low to prevent them from acting as a tariff barrier.

(t) Where there is a conflict between this Bill and the Bill of Rights, the Bill of Rights will take precedence.

(u) The method used to resolve disputes should be commensurate with the established risks.

(v) As a general guide, the costs and efforts associated with decision-making should be proportionate to the risks**.**

4. Findings: Foods or Medicines? Battle of Paradigms

(a) 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.

(b) This debate has dragged on for several decades and recently reached a crescendo in New Zealand with the attempt to introduce a Joint Trans-Tasman Therapeutic Goods Agency (JTTTGA, later renamed Australia New Zealand Therapeutic Product Agency (ANZTPA)), modeled on the Australian Therapeutic Goods Agency.

(c) NaTHPs have long been recognized 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.

(d) The Dietary Supplement Regulations 1985 acknowledges this unique aspect of NaTHPs with the 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."

(e) What has received little discussion throughout the debate relating to the attempted establishment of the JTTTGA is that New Zealand industry has had the opportunity over

[11] See http://www.med.govt.nz/upload/17932/diagram1.pdf

the past 20 years to make therapeutic claims for their products by licensing their products as 'related products' under the Medicines Act. This would have resulted in a regulatory system not too different to that in Australia.

(f) With a very few exceptions, New Zealand industry chose not to license their products as medicines. The primary reason being that although doing so would have enabled the ability to make therapeutic claims, the economic impact of doing so would have been prohibitive.

(g) Government decisions on its future involvement in NaTHP regulation should be based on the principle of proportionality. NaTHPs with a long recognized history of safe use should not be regulated with the same mindset or philosophy as novel pharmaceutical products with no history of safe use.

5. 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. Because the current regulatory framework is generally recognized to need improvement, this Bill provides for this review.

The Cabinet Office manual contains a five-step framework for regulating occupations that can be applied to the regulation of NaTHPs.[12]

- **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 (e.g. 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;
  • 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

[12] http://www.dpmc.govt.nz/Cabinet/circulars/co99/COC_99_6.pdf

• 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 (e.g. 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 effectively.[13]

When is there a Good Case for Regulatory Intervention?

The Cabinet Office Manual provides a model for regulatory intervention, as discussed immediately above in section 3, that when applied to NaTHPs suggests that a light regulatory framework is appropriate in the vast majority of cases for the following reasons:

(a) Most of the limited examples of harm are not significant,

(b) There are so few documented examples of irreversible harm,

(c) Consumption of these products is voluntary.

6. Overview of How the Bill's Graduated Risk-proportionate Risk-management Framework Operates

(a) A graduated risk-proportionate risk-management framework for the regulation of NaTHPs is proposed.

(b) The framework embraces the Government's Code of Good Regulatory Practice[14] that require laws to meet standards of efficiency, effectiveness, transparency, clarity and equity.

(c) The proposed Bill will establish NaTHPs as a legal entity in their own right meaning that they will no longer be classified as a subset of foods, or as a subset of medicines.

(d) Nothing in the Bill overrides the Treaty of Waitangi or any resolution of any claim under the Treaty of Waitangi.

(e) It is acknowledged that there will from time to time be interface issues between NaTHPs and foods or medicines which will require responsible and equitable risk management. It

[13] See also http://www.med.govt.nz/templates/MultipageDocumentPage____9117.aspx#P110_4952
[14] http://www.med.govt.nz/templates/MultipageDocumentTOC____22149.aspx

is contrary to Good Regulatory Practice for inequitable decision-making processes to be utilized in regulating the NaTHP industry.

(f) It would be wrong if the pharmaceutical mindset or philosophy continued to regulate NaTHPs through de facto means.

(g) All NaTHPs will be manufactured and distributed under an approved Risk Management Programme.

(h) In order to prevent unnecessary regulatory creep, there will be a prescribed risk proportionate dispute resolution mechanism to be followed when there is conflict between the regulator and any affected party.

(i) The Bill recognizes 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 'innocent' until proven 'guilty.'

(j) The Bill recognizes the significant diversity of the industry providing NaTHPs and the various potential competing interests that such diversity can cause. The Bill 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.

a. Some acknowledged potential competing interests include, but are not limited to;

i. Large companies/enterprises vs. small companies/enterprises ,

ii. Retailers wanting access to a wide range of product vs. practitioners wanting exclusive prescribing rights,

iii. Proponents of standardized herbs vs. proponents of nonstandardized herbs,

iv. Consumers desire for 'freedom of choice' vs. regulator's desire to 'protect the consumer,'

v. 'Science' vs. 'History of safe use,'

vi. Pharmaceutical mindset or philosophy (i.e.no history of safe use - must be approved before use) vs. Food mindset or philosophy (i.e. Generally recognized as safe – free sale subject to basic quality processes),

vii. Proprietary ownership vs. generic ownership,

viii. Qualified practitioners vs. experienced practitioners,

ix. NZ made vs. imported.

b. 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,

i. Where practicable, these potential competing interests need to be considered when appointing representatives to expert advisory groups or working parties.

ii. Potential competing interests must be identified during consideration of risk management options and avoided as much as reasonably practicable.

iii. Appointments must be based in the skills brought to the table but must also ensure a balance in representation.

iv. The annual Auditor General's audit will assess the management of such potential competing interests.

(k) The Bill does not restrict the extemporaneous prescribing, compounding and dispensing of NaTHPs unless an ingredient is prohibited for human use altogether,

i. Provision will be made in this bill for certain ingredients to be prohibited from industrial production, but able to be extemporaneously prescribed, compounded and dispensed by appropriately qualified practitioners,

ii. 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.

(l) This Bill 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.

(m) In recognition of their unique characteristics, NaTHPs will be legislated as a separate class of product distinct from pharmaceutical products and food products, whilst acknowledging that there will be interfaces between all categories which need to be specifically provided for in legislation and regulation.

(n) The Bill, in a sense, fills the gap between the Food Act and associated regulations and the Medicines Act and associated regulations, in that NaTHPs are not necessarily "foods" 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.

(o) Historically this illogical regulatory environment has left dietary supplements poorly regulated and open to criticism from all sides that 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.

(p) The proposed bill 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,

i. the regulator knows who is in the market and what is in the market,

ii. the regulator is able to respond quickly and responsibly should a significant public health issue emerge,

iii. businesses are required to maintain an appropriate level of product quality necessary to maintain public confidence in the industry as a whole,

iv. businesses are able to manufacture and market existing and innovative products with the minimum of regulatory burden,

v. businesses are able to make evidence based health claims,

vi. politicians have a high degree of confidence that the industry is appropriately regulated and public confidence in NaTHPs is maintained,

vii. The principles relating to the Bill over-ride any rules or regulations where there are conflicts.

(q) The Bill acknowledges those historical criticisms and provides for a risk proportionate regulatory environment that;

i. Provides the regulator with a record of 'who is in the market' and 'what is in the market,'

ii. Requires all products to be manufactured and marketed under the umbrella of registered Risk Management Programme (RMP) which may range from a recognized pharmaceutical or dietary supplement style of Good Manufacturing Practice certificate through to an RMP registered under the Animal Products or Dairy Products Acts (for example) with appropriate 'add-ons' to meet all the minimum requirements of the Bill.

- For example, all RMPs must have a recall system in place and notify such to the regulator. Some recognized overseas GMPs [e.g. the recently announced USA Dietary Supplement GMP] and RMPs under the Animal Products Act do not require a recall system.

iii. 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,

iv. 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 an prescribed dispute resolution process,

v. Prohibits the regulator from applying the provisions of any regulation in a punitive manner,

vi. Provides guidance as to the need for regulatory response to be commensurate with established level of risk and good regulatory practice.

(r) The Bill exempts NaTHPs from the requirements of food law and medicines law when NaTHPs comply with the requirements of the Bill.

(s) As such, and to remove any doubt, NaTHPs are exempt from the requirements of Codex Alimentarus Guidelines and Rules, but are open to challenge through the World Trade Organisation where they create apparent technical barriers to trade.

(t) All New Zealand manufacturers and distributors of NaTHPs will be required to register their presence in the market with the NaTHP Agency (NaTHPA) which will be via the simple online Hybrid Risk Management System (HyRMS).

(u) Very serious recidivist breaches of the Bill and subsequent regulations may result in a business being disqualified from manufacturing or supplying NaTHPs, but the Bill enables an affected party to initiate a dispute resolution mechanism based on a prescribed dispute resolution process.

Part II: Oversight of Regulator, Appeals and Technical Issues

7. Good Regulatory Practice Audits

(a) The regulator will be audited by the Auditor General's Office 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.

8. 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.

- Maori
- Importers
- Exporters
- Local manufacturers
- Distributors
- Natural and traditional healthcare practitioners

- Retailers
- Raw products distributors

(b) Any decision of the Board of Guardians shall not violate the objectives of this bill or the principles.

(c) The Board of Guardians is to hear appeals referred to it by stakeholders or the regulator and make binding decisions.

(d) 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.

(e) 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.

(f) Payments to members of the Board of Guardians will be in accordance with State Services Commission guidelines.

9. Technical Advisory Group

(a) The technical advisory group will focus on potential risk issues related to NaTHPs and will provide technical expertise whenever the need arises.

(b) The technical advisory group consists of two levels of membership

i. A core membership of 4-5 persons will 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 will include a Maori person representing the interests of the Treaty of Waitangi.

ii. Where practicable, the potential competing interests identified in section 4(j)a need to be considered when appointing the core membership. Appointments must be based in the skills brought to the table but must also ensure an actual and perceived balance in representation.

iii. A pool of a wide range of expertise will be established from which appropriate expertise will be drawn upon to match the type of risk being considered. For example, Rongoa practitioner for Rakau rongoa, herbalist for a herb, Ayurveda practitioner for Ayurvedic medicine, homeopath for homeopathy, manufacturer for manufacturing issues. The same applies to compounding, importing, exporting, toxicology etc.

(c) Core members and members of the pool shall be chosen by the State Services Commission or equivalent 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 a right of reappointment for a subsequent three years. Normal practice to be that no person shall be a member of the pool for more than six years; however, this may be extended in special circumstances to a maximum of nine years.

(d) 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. It is the responsibility of the core group to ensure equitable risk management outcomes are achieved and that regulatory creep does not occur.

(e) Members of the core group will not include employees of the regulator but will be appointed by the regulator following public notification of the positions.

(f) Payments to members of the Technical Advisory Group will be in accordance with State Services Commission guidelines.

10. Technical Working Group

(a) From time to time it is acknowledged that there will be specific operational regulatory issues that need to be addressed. Any technical working group will be focused on providing pragmatic, low cost solutions to these regulatory issues.

(b) In such cases specific ad-hoc working groups will be established by the regulator in consultation with appropriate interested parties ensuring that members have an appropriate mix of skills and experience required to address the particular issue.

(c) Such working groups may include employees of the regulator. Payments to the nonemployee members of the Technical Working Group will be in accordance with State Services Commission guidelines.

(d) Given the very low risk profile of NaTHPs, where there is a difference of view among the working group, every endeavour must be made to recommend the adoption of the least onerous risk management option.

11. Dispute Resolution Process

(a) The regulator will establish a dispute resolution process. When a stakeholder is unhappy with a decision that has been made and has not been able to resolve it directly with the regulator within a reasonable time the dispute resolution process will facilitate resolution.

(b) Stakeholders retain full rights to apply to either the Board of Guardians or the court system at any time to review any decision of the regulator.

(c) Any party may appeal to the Board of Guardians for a review of the decision of the dispute resolution process prior to commencing court action.

(d) All dispute resolution cases shall be reviewed by the Board of Guardians as part of their annual GRP audit.

(e) In the event that the dispute resolution process is used, the following provisions will apply:

i. The party claiming that the dispute has arisen concerning any decision made by the regulator must give notice to the other party (parties) in writing specifying the matter in dispute.

ii. **Negotiate:**

1. After a party has given notice under (d)i. and failing good faith efforts to resolve the dispute, each party must nominate one person who will have authority to settle the dispute:
2. These two persons will independently and jointly appoint and agree a third person to act as an independent Chair.
3. The parties will use their best endeavours to resolve the dispute by negotiation in good faith and will attend at least one meeting to discuss and attempt to resolve the dispute as a condition precedent to taking any other steps concerning the dispute (including but not limited to commencing any legal proceedings other than an application for injunctive relief).

iii. **Mediation:**

1. If the dispute is not resolved under the above clauses within 15 business days of notice of the dispute being given under clause (d)i., then any party may at any time within the next 10 business days invite the Chairperson of the New Zealand Chapter of Lawyers Engaged in Alternative Dispute Resolution, to appoint a mediator to enable the parties to mediate and settle the dispute:
2. All discussions in the mediation will be without prejudice and will not be referred to in any later proceedings.
3. The parties will bear their own costs in the mediation and will share equally the mediator's costs.

iv. **Arbitration:** If the dispute is not resolved under clause iii. within a further 15 business days after the appointment of a mediator, any party may then require the dispute to be referred to arbitration in accordance with the Arbitration Act 1996.

v. **Parties to Continue to Perform:**

1. Pending resolution of any dispute or difference, the parties shall continue to perform their respective obligations pursuant to the Bill.

12. Hybrid Risk Management System (HyRMS)

(a) The 'hub' of these NaTHP regulations is a 'Hybrid' Risk Management System (HyRMS) commensurate with the very low risk profile of the vast majority of NaTHPs.

(b) The HyRMS is a simple online notification system.

(c) The HyRMS will provide for the regulator to know "who is in the market and what is in the market" in order to monitor NaTHPs.

(d) The HyRMS will be established by the regulator to lodge ingredient and product notifications.

(e) The HyRMS will provide a simple real-time means of identifying the classification of ingredients based on known risk profiles and will include any specific labeling, 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.

(f) Permission or approval from the regulator is not required for new products that include ingredients in the HyRMS which are not prohibited substances.

(g) The HyRMS will initially contain all known acceptable substances from the lists of recognised acceptable overseas and local sources of ingredients detailed in the definition of 'Recognized history of safe use'.

(h) New ingredients or currently prohibited substances must be notified to the regulator via the HyRMS 60 calendar days before commencement of proposed marketing.

(i) The regulator may request copies of supporting evidence to support new ingredient notifications.

(ii) The regulator may only disallow or challenge such notifications when there are genuine safety issues and the regulator cannot act frivolously or vindictively.

(iii) Ingredients that have a recognised history of safe use will not normally be disapproved.

(iv) Disapproval of notifications may be appealed as provided for in the dispute resolution provisions of the Bill.

(v) The HyRMS database will require manufacturer/distributor details to be lodged before any specific products can be notified.

(i) When assessing the risk profile of an ingredient, cognizance will 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. As such, the Ministry of Economic Development and Cabinet Office model is used to assist with determining risk classification of ingredients. [See appendix x][15,16]

[15] 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/corporate/convlicrev.pdf

(j) The hybrid system has been developed as a pragmatic and innovative alternative to the two common options for regulating NaTHPs.

i. The "Positive" list, referred to as a 'white' list in some countries or jurisdictions, is paradoxically a prohibitive system. Because the '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,
- The hybrid system means that the regulator knows what ingredients are in the market, and if all products also have to be notified, then the regulator also knows who is in the market.
- As an example, in Australia, which uses the positive list system, it is extremely onerous and expensive to get any new ingredient approved for market even when that ingredient has been used for hundreds of years overseas with no problems.

ii. The "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 market uncontrolled products.

(k) Such a hybrid system will minimize technical and administrative barriers to commerce by combining elements of both the 'positive' and 'negative' listing systems while 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.

- This means that all ingredients are recorded in the HyRMS database.
- New ingredients including currently prohibited ingredients that comply with the NaTHP ingredient definition may be notified via the HyRMS Notification System, but the regulator has the statutory right to challenge such a listing if the regulator has genuine concerns based on evidence that is disclosed to the notifier at the time the challenge is made.
- The business notifying a new ingredient is required to make an online statutory declaration that they have evidence to support the safe use of the ingredient that the regulator may request if the regulator has concerns.
- Prohibited ingredients may be permitted if certain requirements are met. For example, Comfrey might be prohibited unless the product complies with a standard relating to levels of Pyrrolidine Alkaloids.

[16] http://www.med.govt.nz/upload/17932/diagram1.pdf

13. Principles of Sensible Risk Management

(w) Any safety concern that emerges must be addressed using the principles of sensible risk management.

(x) 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.

(y) Sensible risk management **is <u>not</u> about**:

- Creating a totally risk free society;
- 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.

14. Risk Management Categories[17]

(a) To remove any doubt, and to minimize the potential for regulatory creep, levels of risk have been defined ranging from de minimis through to intolerable.

(b) The HyRMS database will provide for classifying appropriate levels of risk management required over and above any RMP requirements.

i. All active ingredients will be identified on the label except as provided in section 23..

ii. Ingredient labeling 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.

- Risk Management Category 1 (RMC1): **de minimis level of risk** requiring no specific risk management. This level of risk includes:

i. less than one confirmed death due to the ingredient per two million person years of use worldwide, or,

[17] A useful guide to good and bad processes of determining appropriate risk management responses to emerging or 'noisy' evidence (e.g. 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. http://www.victoria.ac.nz/nzcpl/Regs_Review/regsReviewReports/Report%2041.aspx

ii. less than one probable death due to the ingredient per million person years of use, or,

iii. less than one possible death due to the ingredient per 500,000 person years of use.

- Risk Management Category 2 (RMC2): **Possible very low risk** that warrants generic education and nominated voluntary advisory statements or similar. No specific mandatory labeling other than a requirement that these ingredients must be stated on the label. Recommended voluntary labeling will be flagged via the HyRMS and regulator and industry communications. This level of risk includes:
    i. Ingredients known to cause mild irritation, allergies, other reversible adverse or undesirable effects in some people.
- Risk Management Category 3 (RMC3): **Possible low level risks or probable risks** that warrant mandatory risk management provisions such as labeling, manufacturing standards, upper safe levels, etc.
- Risk Management Category 4 (RMC4): **Certain moderate level risks that are tolerable** if certain risk management strategies such as those listed below are established.
    i. Require specific risk management options such as upper ingredient limits.
    ii. Mandatory combination of ingredients, e.g. folic acid products over 1,000ug must include at least 50ug of vitamin B12.
    iii. Restrictions on certain extraction solvents or plant parts, e.g. kava acetone/peel.
    iv. Mandatory testing to ensure certain substances are not present such as Pyrrolidine Alkaloids in Comfrey, or aristolocic acid in certain species such as Aristolochia.
    v. Limited to appropriate practitioners only in certain circumstances. These ingredients would include many currently banned via a euphemistic 'prescription only' classification under the Medicines Act e.g. Ephedra alkaloid and belladonna.
    vi. All ingredients sourced from GE plants or animals must be labeled as such.
- Risk Management Category 5 (RMC5): Ingredients prohibited from use in NaTHPs unless appropriate risk management options can be implemented or new evidence proves that the risks can be reduced to tolerable levels. This level of risk includes:
    i. Ingredients considered too hazardous to allow in NaTHPs above certain natural levels (e.g. certain heavy metals such as lead, arsenic, selenium (over 400ug)).
    ii. Substances normally requiring approval under food or medicines law such as:
        - Novel or non-food synthetic ingredients.
        - GE ingredients.[18]
        - Non-natural nanotechnology (defined for the purposes of this Bill as being molecules generally less than 100nm.).

15. Medicines Act Exemption

(a) Any NaTHP regulated under the Bill is exempt from the provisions of the Medicines Act.

[18] The issue of ingredients such as vitamin C being made from starch from GE corn needs to be reviewed. It is understood that manufacturers are able to readily source non-GE sourced ingredients in which case GE sourced ingredients should be banned.

16. Food Act Exemption

(a) Any NaTHP regulated under the Bill is exempt from the provisions of the Food Act.

17. FTA and CGA

(a) Fair Trading Act and Consumers Guarantee Act apply to NaTHPs.

Part III: Risk Management Programmes (RMPs)

18. All Manufacturers are Required to have a Registered Risk Management Programme

(a) As a minimum registered RMPs are to be based on HACCP, an internationally recognized method of risk management.[19]

(b) The impact of the introduction of Risk Management Programmes will be eased by the unilateral recognition of international Good Manufacturing Practice certificates, RMPs (e.g. as prescribed in the Animal Products Act) and the use of off-the-peg RMP models freely available from NaTHPA.

(c) 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, and
ix. Others to be determined.

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

(d) It is intended that off-the-peg RMPs will be available from the regulator at least nine months prior to the registration date for that NaTHP sector, and 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 are described below in sections A - H.

A. Audits

1. RMPs will be audited by a recognized third party and a certificate of compliance by the auditor is to be submitted to the regulator at least once every three years, except that the regulator can authorize up to five year audits where the applicant has a demonstrated history of compliance.

[19] For example: http://www.nzfsa.govt.nz/processed-food-retail-sale/fsp/haccp.pdf

2. The certificate of compliance will note any significant non-material breaches or imminent/potential breaches of the RMP along with a recommended timeline to fix.

3. RMPs may be audited by the following:

   (a) Any auditor approved in a selected country or jurisdiction whose manufacturing standards have been accepted under this Bill and listed in the Acceptable GMP Schedule; or

   (b) Any auditor established in New Zealand and approved by the regulator or IANZ.

   For example, a manufacturer might want to export product to Australia or Europe so will be able to satisfy the requirements of an RMP 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.

4. The regulator may request a partial follow-up audit where there have been material breaches, significant non-material breaches or imminent/potential breaches of the RMP.

B. Quantify by Input

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

C. Post Market Random Testing by the Regulator

Regulator will undertake random testing of x percent [?5%] 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 will occur. Recent examples of such testing include testing for DEG in toothpastes, heavy metals in herbs from certain sources, prescription medicine testing following evidence of certain products being adulterated. Aspects to be randomly tested for when appropriate are limited to the following:

Heavy metals,

Microbes,

Rancidity of oils,

Or adulterated substances (e.g. pharmaceutical content if evidence to suspect) based on safety concerns. 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.

D. Date Mark Requirements

(a) A date mark will be required, being an expression in one of the following forms:

   a. Use by (followed by a date); or

   b. Not to be consumed after (followed by a date) or

   c. Words of similar meaning (followed by a date);—

   d. the relevant date in any case being no later than 2 years after the date of manufacture.

(b) Recognizing that some ingredients are inherently stable, a product can continue to be distributed after the 2 year period if a new assay determines the product is still in good condition, but a new date mark will have to be added to the label.

(c) If the manufacturer and/or distributor claims a relevant date more than 2 years after the date

of manufacture then evidence of stability will be required at the date of manufacture.

E. Labelling

(a) All products shall be true to label.

(b) Each different product, including different pack sizes, must have unique identification that is notified on the HyRMS. Unique identifiers must be nominated at time of notification onto HyRMS.

i. The unique identification may be the HyRMS 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. HyRMS will have capacity to use multiple fields to generate unique identifiers.

(c) Standard labeling requirements include a batch number on every container.

(d) Mandatory advisory, warning or other specific labeling requirements flagged in HyRMS must be complied with.

(e) Labels must be printed in waterproof ink.

(f) All product labels shall have a date mark (e.g. a 'best before'/'use by' or similar statement) as appropriate.

(g) Every package and container containing an NaTHP shall, unless otherwise provided in this Bill 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 subsection (cc) and (dd) of this section.

v. The words ``Natural and Traditional Health Product'; "NaTHP"; "Dietary Supplement"; "Food Supplement"; "Complementary Medicine", "Homeopathic; or a similar term 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 Column 1 of Schedule X shall not exceed the maximum daily dose in Column 2 of Schedule X subject to any conditions in Column 3 of Schedule X, and, if the NaTHP is suitable for children, the recommended daily dose for children.

viii. A warning or caution statement required as in Schedule Y.

(h) Notwithstanding subclause (m) 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.

(i) For the purposes of subclause (m) iii. of this regulation,—

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.

(j) 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 these regulations.

(k) 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 these regulations 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 these regulations.

(l) Every word or statement that is required by these regulations 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; and

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; and

iii. Be presented with continuity.

(m) The lettering of every word or statement required by these regulations shall be clear, distinct, and legible with no decoration, embellishment, or distortion that could interfere with the legibility of the words.

(n) The lettering of every word or statement required by this section 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.

(o) In every case to which paragraph (i) or paragraph (ii) of subclause (m) of this section applies, the height of the lettering shall be uniform in every word or statement that is separately required.

(p) In every case to which paragraph (iii) of subclause (m) of this section applies, the height of the lower case lettering shall be uniform in every word or statement that is separately required.

(q) Except as otherwise provided in these regulations, the lettering of any word or statement required by these regulations 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.

(r) The height of the lettering for the common name or description that is required by these regulations 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.

(s) 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.

(t) The particulars that are required by paragraph i. and paragraph ii. and paragraph v. of subsection (n) of these regulations to appear on a label shall appear in the principal display panel.

(u) Every word or statement that is required by these regulations 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.

(v) 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.

(w) The following information, when required by these regulations 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—

1. 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

2. 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:

a. Antioxidants:
b. Artificial sweeteners:
c. Colouring or colour:
d. Encapsulating aids:
e. Flavouring or flavour:
f. Minerals:
g. Preservatives:
h. Tabletting aids:
i. Vitamins:

ii. The storage instructions (where appropriate).

(x) 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.

(y) A Proprietary Knowledge Labeling Exemption is described in section 23.

F. Packaging

(a) Tamper proof packaging is NOT mandatory unless specified in HyRMS.

(b) Child proof packaging is NOT mandatory unless specified in HyRMS.

G. Recalls

(a) All manufacturers, importers, exporters or distributors shall notify the regulator that they have an approved product recall system within six months of enactment of this bill.[20]

H. Bulk Materials Integrity Procedures: Local and Imports

i. The Bill requires that the manufacturer provide a Certificate of Analysis to ensure that the bulk materials actually are what they are claimed to be by undertaking:An identity test, or

ii. An assay to identify actives if a specific level of active ingredients is claimed.

(b) Any identity test or assay of each batch must be performed by an approved laboratory listed on the Schedule of Acceptable Testing Facilities.

(c) The manufacturer can rely upon the tests conducted by a bulk materials broker or distributor so long as the requirement in section 22(b) is met.

(d) 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 bill.

(e) Such a schedule will include the following;

- Any authenticated Certificate of Analysis produced by a testing facility accredited by any of the following;
  - the International Accreditation New Zealand (TELARC),
  - any member of the International Laboratory Accreditation Cooperation (ILAC),
  - the Asia Pacific Laboratory Accreditation Cooperation (APLAC)
- Any other testing laboratory able to verify that it meets acceptable Good Laboratory Practice.

(f) 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.

(g) 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

[20] For an example of a food recall system see Recall Quick Reference Guide or http://www.nzfsa.govt.nz/processed-food-retail-sale/recalls/guidance/index.htm

accordance with the principles of good regulatory practice.

(h) False certificates and declarations will be considered to be serious breaches of a risk management programme and will attract the attention of the regulator.

Part IV: General Provisions

19. Health Claims Procedures

Explanation Note: The Bill recognizes it is an affront to legitimate commerce and to natural justice to prevent honest and truthful health claims being made. As such the Fair Trading Act and Consumers Guarantee Act both apply to the regulation of NaTHPs.

This Bill acknowledges that, with respect to health claims, the focus is on what benefits the individual, rather than on the one-size-fits-all mindset.

(a) Evidence-based health claims will be permitted once an RMP has been implemented and registered.

(b) HyRMS will have a schedule of acceptable health claims, explained in section 19, which can be used without permission once an RMP has been registered.

(c) New or novel health claims can be lodged on HyRMS along with the appropriate claims classification, 40 working days prior to intended use of the claim. If the regulator does not disallow or challenge the claim after 20 working days, it can be used.

(d) Such claims will include a declaration on HyRMS that evidence is held by the notifier.

(e) The regulator can request a copy of such evidence.

(f) Any disallowance is subject to the provisions of the dispute resolution mechanism.

(g) Health claims are not mandatory.

(h) The Bill 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 Bill 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.

(i) Seven levels of evidence can be graded as A, B or C indicating strength of evidence: [21]

A. Good evidence:
   - I. Evidence from large, well conducted Randomized Controlled Trials (RCTs)
   - II. Evidence from small, well conducted RCTs
   - III. Evidence from well-conducted cohort studies[22]

B. Fair Evidence
   - IV. Evidence from well-conducted case-control studies[23] 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

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[21] New Zealand Guidelines Group, on page 2 of 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.

[22] http://en.wikipedia.org/wiki/Cohort_study

[23] http://en.wikipedia.org/wiki/Case-control_study

20. Schedule of Sources of Acceptable Claims

(a) The Bill recognizes 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 will include international sources that are generally recognized as being acceptable reference material.

(d) Acceptable sources can include evidence that has an oral tradition.

(e) Consultation as to acceptable sources is to commence within 6 months of the establishment of the regulator's office and is to be completed within 18 months of the establishment to update the schedule.

(f) New reference sources can be nominated by any party at any time.

i. The regulator will have 10 working days to request further information about the nominated source.

ii. The regulator can 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 will 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 HyRMS database subject to consultation and dispute proceedings,

(h) To remove any doubt, the following sources are included in 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,
- 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
- Others to be added

21. Penalties

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

ii. The penalty for the first material breach of the Bill would be education about the manufacturer's responsibilities under the Bill and to consumers.

iii. Any further penalties need to be sufficient to encourage compliance (e.g. 'name and shame'), but also commensurate with levels of risk and degree of non-compliance.

iv. If any fine for an offence against the Bill 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 offense has continued.

v. Any alleged non-compliance would be subject to the dispute resolution mechanism.

vi. This Bill acknowledges that no Court proceeding initiated under this Bill can rely upon evidence of expert hypothesis but must rest on empirical evidence.

22. Costs

(a) It is proposed that the regulatory agency be part funded by the state and part funded by industry.

(b) The administration costs will be shared 50/50 by the state and industry because of:

i. the potential health savings due to the preventative nature of NaTHPs (also called the 'public good factor'), and

ii. the dissemination of knowledge which allows people to take responsibility for their own health, and

iii. the simultaneous management of community exposure to potential harm as well as establishment of a safe business environment for industry participants.

(c) Turnover Levy

i. Industry funding is proposed via a levy of 0.5 [to 1%] wholesale or 0.25 [to 0.5%] export value authorised under the Bill up to a maximum sum which is based on self declared turnover, not unlike what occurs with tax and GST regimes. Exports and local levies will reflect the true cost and not cross subsidized in any way

ii. The regulator has the right to request confirmation of declared turnover from a suitably qualified professional.

iii. The levy should be applied uniformly from the end of year [three].

iv. Any increases in the percentage of levy are to be approved by Parliament.

23. Proprietary Knowledge Label Exemption

(i) 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.

(ii) Applications for this labelling exemption would be in writing and a reasonable fee can be charged by the regulator.

(iii) Such an exemption will normally be granted but granting of such an exemption does not exempt the manufacturer from displaying any advisory, warning or other risk management labeling requirements.

(iv) When granting such an exemption the regulator will advise the manufacturer and/or distributor of a unique exemption number.

(v) Where such exemptions are granted products must 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.

(vi) Whilst proprietary ownership of ingredients is not regulated by this bill, the ingredient database may be used to determine breach of proprietary issues established by other legislation.

i. For example 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.

24. Sustainability

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

25. Transition/Phase-in Period

a. The important feature of the transition/phase-in period is that there are periods of time in the transition plan to ensure everyone can move at a comfortable pace to the new system.

b. A five–year transition period is proposed which begins first with a six–month period during which the NaTHP Authority will be established and notify affected sectors of firm dates for the various stages of the transition.

c. There will be a progressive transition with the following timeline proposed as guidance;

d. 6 months following enactment of bill.

i. NaTHP Authority established

ii. Proposed Implementation timeline confirmed and publicly notified.

e. Six months following the setting up of the NaTHP Authority

i. Off-the-shelf recall plan developed. This can essentially be an adoption, with possible minor modifications, of the existing NZFSA food recall plan.[24]

ii. Schedule of acceptable GMPs with any 'plug-in' requirements reviewed [e.g. some GMPs do not include recall provisions.]

iii. Schedule of sources of acceptable claims to be published (including pharmacopoeia, unilateral recognition of approved overseas claims [e.g., Australia, Canada, EU, USA, South Africa.])

iv. Evidence based health claims codes utilizing Evidence-based medicine principles to be permitted subject to registration of appropriate RMP.

f. End of Year 1 following enactment of bill

i. It is proposed that the first twelve months will see the development of the HyRMS NaTHP Notification database with businesses then having six months to record their product range into the new online risk management system.

i. NaTHP Authority will have developed 'Off-the-shelf' RMPs including the minimum requirements for a NZ GMP.

ii. All manufacturers and distributors will have notified the NaTHPA how they intend to achieve RMP requirements. Options include:

[24] http://www.nzfsa.govt.nz/processed-food-retail-sale/recalls/index.htm#P18_979

1. Scheduled GMP [with add-ons such as recall system where appropriate]
2. Off-the-shelf RMP
3. Custom designed RMP

iii. Recall system in place and notified to regulator via document lodging facility in HyRMS.

iv. Technical advisory committee established.

v. List of Third Party RMP, including GMP, auditors to be established.

vi. Mechanics of funding issues to have been developed utilising either of the two options described in section 26.

vii. Any other provision that can be implemented within this time period.

g. Six months after HyRMS going live online

i. All manufacturers and distributors and products lodged into the HyRMS.

h. End of Year 2 following enactment of bill

i. All manufacturers and distributors will have undertaken an RMP audit to determine issues that require attention.

ii. All manufacturers and distributors will have submitted a progress report to the regulator including notification of the approach the business is taking to implementation of the chosen RMP and critical issues identified in achieving compliance.

iii. The GMP standards would need to be confirmed prior to audit taking place.

iv. Audits can be undertaken by a third party including auditors recognised by jurisdictions responsible for GMPs listed in the Acceptable GMP Schedule.

1. For example, a manufacturer might want to export product to Australia or Europe so will be able to satisfy the requirements of an RMP 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.

v. Funding mechanism in place for introduction in year 3.

vi. All products are to be appropriately labelled.

i. End of Year 3 following enactment of bill

i. Manufacturers and distributors must have applied for formal Audit for RMP purposes and notified the regulator of issues [if any] identified in the audit.

j. End of Year 4 following enactment of bill

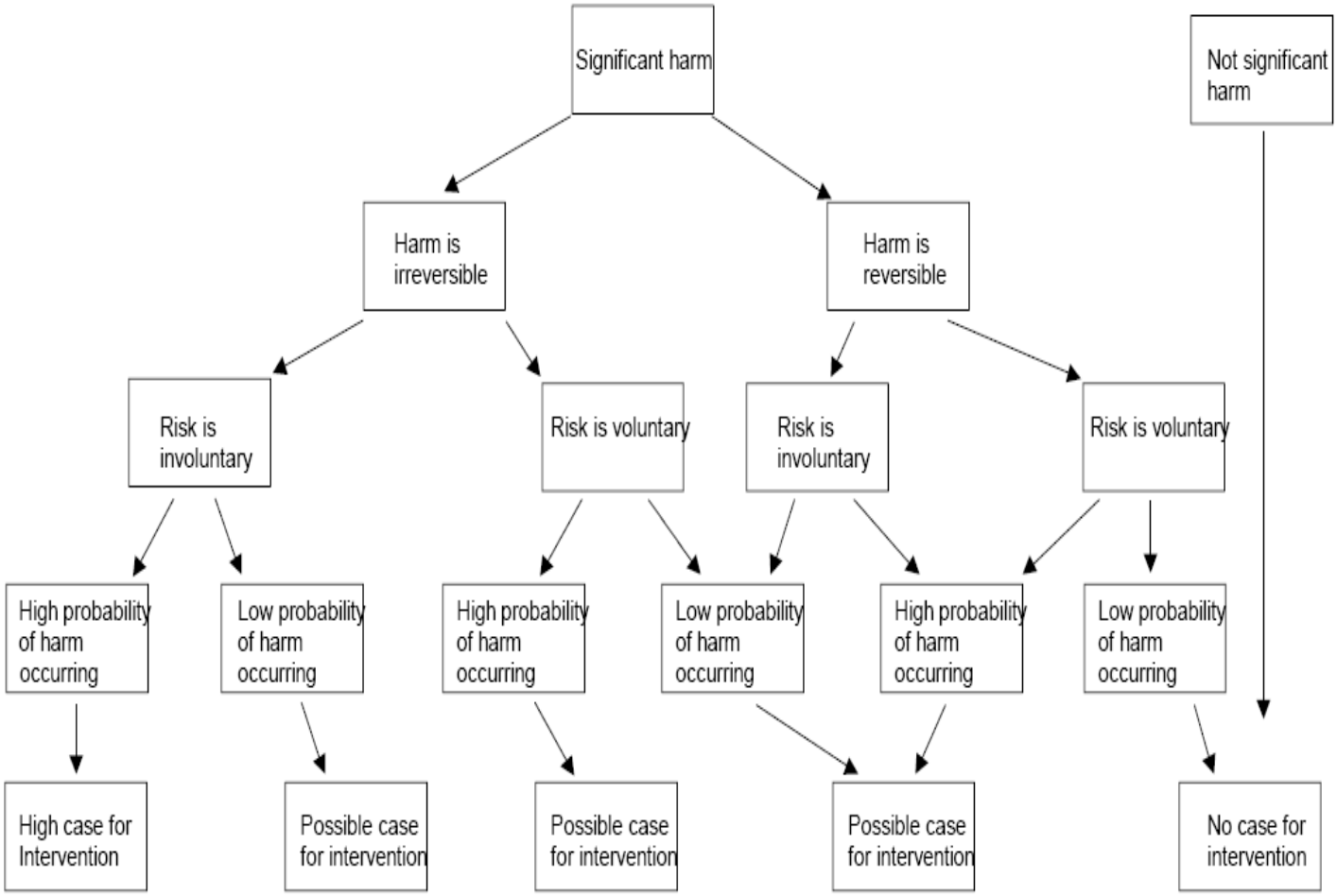
i. Must have submitted a plan to address any outstanding RMP issues [if any] to the regulator,

k. End of Year 5 following enactment of bill

i. Must be fully compliant and have provided appropriate documentation to the regulator.

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: Figure 1: When is there a case for intervention?

[25] http://www.med.govt.nz/upload/17932/diagram1.pdf

Appendix: Schedule X for Maximum Daily Dosages (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
Zinc	30 mg	Practitioner only
B6	50 mg	Up to 200 mg with Caution statement in Schedule Y; >200 mg Practitioner only

Appendix: Schedule Y for Cautions and Warnings (to be developed further)

Column 1	Column 2	Column 3
Ingredient	**Voluntary condition**	**Mandatory condition**
Comfrey		Pyrrolidine Alkaloids < x mg per dose
Aristolochic spp		Aristolochic acid < x mg per dose
Vitamin B6 >50 mg per daily dose		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.
B6	50 mg	Up to 200 mg with Caution statement in Schedule Y; >200 mg Practitioner only
Ephedra spp		If a species that contains ephedra alkaloids: Practitioner only
Ephedrine (synthetic)		Prohibited.

FLOW OF AUTHORITY