Health Select Committee

Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products

---

Submission from the Dietary Supplements Consultative Group –
a coalition of organisations representing New Zealand manufacturers, distributors, retailers, exporters, importers, direct sellers and direct marketers, natural health practitioners and consumers of complementary healthcare and therapeutic products

November 2002

Letter of Transmittal

This submission is made jointly by the Dietary Supplements Consultative Group (DSCG).

The DSCG represents a broad coalition of manufacturers, distributors, retailers, exporters, importers, direct sellers and direct marketers, natural health practitioners and consumers of complementary healthcare and therapeutic products (CHTPs). Its membership includes:

- National Nutritional Foods Association
- Charter of Natural Health Practitioners
- International Nutritional Products Association
- Direct Selling Association
- Citizens for Health Choices
- New Zealand Health Trust
- Integrated Medical Group.

Further details on these groups are attached to this transmittal.

This submission accordingly reflects an unprecedented degree of industry unanimity concerning the proposed establishment of a trans-Tasman agency and the related issues being considered by the Health Select Committee ("the Committee").

By way of preface to our submission on the proposed established of a trans-Tasman regulatory agency, the DSCG notes the inadequacies of the current policy, regulatory and legislative framework governing CHTPs. We believe that these should be the subject of substantive review, and that recourse to a trans-Tasman solution in the name of harmonisation as an end in itself is premature and ill-advised.

We acknowledge that there are issues of legitimate public interest associated with the regulation and management of CHTPs. As the government's Code of Good Regulatory Practice mandates, any regulatory response should be commensurate with risk and take proper account of compliance costs.

The DSCG considers that the government has not taken sufficient cognisance of these issues and have failed to consider alternative policy options that better address the public and industry interests.

Accordingly, we have taken the constructive step of providing the Committee with an alternative proposal for a regulatory and legislative regime that addresses deficits in the current system and obviates the risks that we believe are associated with the current proposal for a trans-Tasman agency. We have

attached working drafts of possible interim regulations and describe in this submission the structure and elements of broader industry-specific legislation.

We also want to emphasise that the proposals herein are compatible with trans-Tasman harmonisation or "mutual recognition" in New Zealand's Code of Good Regulatory Practice (reproduced at Appendix 1). The system we propose provides a model that could be promoted to Australia for adoption; it need not be a stand-alone solution for New Zealand.

We thank the Committee for the opportunity to comment, and to participate in developing a regulatory system for our industry that is fair, affordable, evidence-based, risk proportionate and commensurate with good regulatory practice.

The DSCG would like to appear before the Committee to present this submission. Each of the undersigned would also like the right to appear individually in order to present their particular perspectives.

Given the complexities of the policy issues that remain to be resolved, the DSCG may submit additional information that we think may be helpful to the Committee before the eventual hearing.

Yours sincerely

Bill Bracks, President
National Nutritional Foods Association

Paddy Fahy, Executive Director
Charter of Natural Health Practitioners

Gary Mabey, Chair
International Nutritional Products Association

Bruce Murray
Direct Selling Association

Dave Sloan, Director
New Zealand Health Trust

Jan Mabey, Secretary
Citizens for Health Choices

Mike Cushman
Integrated Medical Group

Members of the Consultative Group making this submission

National Nutritional Foods Association
President: Bill Bracks (07) 573 7000

The National Nutritional Foods Association of New Zealand (NNFA) is by far the broadest-based industry group in the complementary healthcare and therapeutic products sector. It has been the major industry association since its formation in 1983, and has worked consistently to improve the status and professionalism of its manufacturer, supplier, distributor and retailer members. A main objective has been to establish close liaison with the regulators.

In earlier years the major thrust of the NNFA was industry and consumer education, but in the last decade much effort has been directed toward ensuring the proper establishment of a regulatory environment that sees complementary healthcare products regulated separately from pharmaceuticals, as is appropriate given their very low risk profile and their unique position in maintaining and restoring well-being.

New Zealand Charter of Natural Health Practioners, Inc
Chief Executive: Paddy Fahy (09) 415 5501

The Charter was incorporated in 1993 to represented the varied practitioner modalities in the natural health profession in New Zealand, to represent the natural health sector to the government, and to raise professional standards. It was formed under a contractual agreement among 55 Incorporated Societies who are Affiliate Signatories to the Charter. Today the Charter has 72 Affiliate Signatories, with affiliate membership of over 7000 members. The Charter has a comprehensive Code of Ethics in place, backed by a Practice and Ethics Committee.

International Nutritional Products Association
Chair: Gary Mabey N.D. (09) 415 8624

The International Nutritional Products Association (INPA) consists of eight New Zealand-owned dietary supplement companies, representing 30 to 35 international companies. Members import and distribute dietary supplements from the USA, Europe and other countries excluding Australia. Some of these New Zealand-owned family companies have been in business for as long as 30 years. Member companies distribute the majority of international supplements currently on the New Zealand market.

Direct Selling Association of New Zealand Inc
Bruce Murray (09) 415 7781

The Association consists of 37 member companies who market their products by direct selling methods. The nutritional supplement market in Direct Selling is worth around $36 million wholesale and approximately $60 million at retail per annum. Direct Selling Association members export around $100 million dollars of products, including dietary supplements and food-type dietary supplements.

New Zealand Health Trust
Director: David Sloan

The New Zealand Health Trust was established to represent the interests of the complementary healthcare community, which includes manufacturers, suppliers, practitioners and consumers. The Trust has been a significant contributor to the alternative regime for complementary healthcare and therapeutic products that is set out in this submission. Its charter establishes a number of health-related objectives including research, education and communication. It is a registered charitable trust.

Citizens for Health Choices
Secretary: Jan Mabey (09) 420 5800

Citizens for Health Choices is one of New Zealand's leading and most visible advocates for consumer choice in health care. It was founded in 1992 by a group of consumers, health practitioners and people from the dietary supplements industry. Since then it has been working to make sure New Zealanders have continued access to the natural health products they know and trust. Today, Citizens for Health Choices comprises more than 1000 consumer members, an Advisory Board of industry representatives, and support from New Zealand companies and individuals from across the dietary supplement sector – manufacturers, distributors, importers and practitioners.

1. Introduction

1.1 The Discussion Paper

The Select Committee's inquiry was begun while the governments of New Zealand and Australia were considering submissions on the Discussion Paper *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products.*[1]

The Discussion Paper was produced and released under a mandate from the Ministers of Health of Australia and New Zealand. It is the latest iteration in a protracted review exercise that dates back to 1992.

The Discussion Paper proposes that complementary healthcare and therapeutic products (CHTPs) be regulated by a new trans-Tasman agency that would also regulate medicines (such as pharmaceutical drugs) and a wide range of medical devices (such as heart valves and breast implants). The framework proposed is identical to the current regime for these products in Australia, although a few of the details differ.

The Discussion Paper lacks a number of key elements that are expected in good policy-making, namely:

- a clear problem definition, including identification of the matters that require regulatory intervention
- risk analysis on the status quo of the problem – both in terms of its scope and magnitude, and including quantitative data to support the conclusions
- the development of an intervention logic or policy framework, against which various options identified can be evaluated and compared, and
- an evaluation and analysis of the degree to which each of the options would address the problem identified, and the relative costs of each.

The proposal in the Discussion Paper accordingly fails to provide an adequate policy framework for the government to make decisions on the regulation of CHTPs. It fails to present evidence that the proposed regulatory framework meets the public interest in the most effective and least-cost manner as required by the government's Code of Good Regulatory Practice.

It is, in our view, difficult to avoid the conclusion that the preference for a trans-Tasman agency as the regulatory outcome has been pre-determined, rather than arrived at through sound policy development processes.

We reflect our own perspective on the policy framework and the associated analysis in the sections that follow.

In Section 2.1 of this submission, we present our analysis of the appropriate problem definition. We support that with a risk assessment in Section 2.2. We outline an appropriate intervention logic in Section 2.4. Sections 3, 4, 5 and 6 of this submission constitute our options analysis.

[1] Peachey, Graham (Director, Trans Tasman Group, Therapeutic Goods Administration) and Susan Martindale (Project Leader, JTA Project Team, Medsafe), *A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products*, Discussion Paper, June 2002.

1.2 Trans-Tasman harmonisation and "mutual recognition"

The push for harmonising the rules for therapeutic products between Australia and New Zealand is driven primarily by trade, not by pre-existing concerns about health or safety issues.

An important part of the context for the Discussion Paper is the Closer Economic Relationship (CER) between Australia and New Zealand, and the Trans-Tasman Mutual Recognition Agreement (TTMRA) that flows from it.

The TTMRA is an arrangement between the Commonwealth, State and Territory governments of Australia and the government of New Zealand, the benefits of which are said to be: [2]

> "particularly significant where regulatory differences mainly reflect national historical or institutional arrangements, rather than the objective assessment of risks to public health, safety and the environment… The benefits of trade liberalisation under CER cannot be fully realised until these impediments are reduced."

The DSCG's objective in this exercise is good regulation for New Zealand. This is eminently achievable within a harmonised regime, but not if Australia insists on the joint application of regulations that do not suit the needs of the New Zealand CHTP industry and New Zealand consumers of CHTPs.

New Zealand should not accept bad rules in the name of harmonuisation. Harmonisation should not be pursued for harmonisation's sake.

[2] Department of Foreign Affairs and Trade (Australia) – http://www.dfat.gov.au/geo/new_zealand/ttmra_users_guide.pdf

2. Problem definition, risk analysis and intervention logic

2.1 Problem definition

Identifying the nature and extent of the problem is a key step in the process of evaluating the need for government action…

Code of Good Regulatory Practice
Ministry of Economic Development
http://www.med.govt.nz/buslt/compliance/regprac.html

A striking feature of the Discussion Paper is the absence of a problem definition, and the absence of a first-principles approach that identifies the relevant problem, the need for intervention and the most effective and efficient option for addressing the problem.

Indeed, little has changed since 1998, when the Treasury commented on a previous Ministry of Health proposal to regulate dietary supplements: [3]

> *"… we do not think that the case for regulating dietary products is well supported at all. Moreover, we are not clear why current legislation (for example, the Consumer Guarantees Act and the Fair Trading Act) doesn't already provide effective levels of consumer protection.*
>
> *… we consider that the key problem a regulatory regime for medical devices and dietary products ought to be addressing is safety, rather than efficacy and quality. As long as products are safe, issues of efficacy and quality are essentially purchasing, rather than regulatory decision."*

The DSCG has applied a first-principles approach in developing the proposed regulatory framework herein. The problems affecting our sector that need to be resolved are:

- **Australian trade barriers**: The current Australian regime for regulating this sector establishes non-tariff trade barriers that are contrary to the spirit of Closer Economic Relations and the Trans Tasman Mutual Recognition Arrangement (TTMRA). The Discussion Paper notes[4] that "therapeutic goods is one of six areas in which mutual recognition under the TTMRA has not yet been achieved".

  It is an essential point that insofar as CHTPs are concerned, nearly all impediments to trade are imposed by Australia. These include:

  - a unique list of allowable ingredients, and allowable dosages, that effectively ban many CHTPs that are freely traded among other countries

[3] The Treasury, memo from Peter Fraser to Kay Smith (Ministry of Health), "Therapeutics Bill", 21 May 1998.
[4] *Ibid*., page xviii

- expensive and complex procedures for approval of "new" ingredients, even where those ingredients have been approved through the regulatory regimes of reputable countries or have a long history of safe use
- registration fees and annual renewal fees that increase prices and in effect keep many low-volume products off the market for compliance-cost reasons only
- unique labelling requirements (including, but by no means limited to, an antiquated product numbering system) that impose compliance costs on exports of CHTPs to Australia and which, in practice, exclude many products available internationally.

By contrast, New Zealand imposes no significant barriers to imports from Australia.

- **Claims:** It is illogical that New Zealand consumers are denied accurate information about dietary supplements because together the Medicines Act 1981 and the Dietary Supplement Regulations 1985 (both of which preceded the Fair Trading Act 1986) prohibit claims being made about their purpose and effect.

  We concur with the Discussion Paper's assessment that the prohibition on claims is "inappropriate for two reasons. Firstly, it does not meet the needs of the sponsor to be able to promote a product for its intended purpose. Secondly, it does not meet the needs of the consumer to be provided with adequate and appropriate information about the product".[5]

- **Inconsistency between current restrictions on ingredients in both countries and best international regulatory practice:** In Australia and New Zealand some ingredients are currently either not allowed or have dosage restrictions applied in a manner that is not related to risk and that is not consistent with achieving their potential healthcare or therapeutic benefit. Examples include:

  - *Folic acid*

    Extensive scientific studies show that at least 400 ug of folic acid per day reduces considerably the risk of a number of diseases. The most well known benefit is folic acid supplementation in women just before and after becoming pregnant, which reduces by approximately 75% the risk of a baby with neural tube defects such as the crippling spina bifida.

    Other credible studies show that folic acid can reduce by nearly 75% the risk of cancer of the colon, from which 800 New Zealanders die each year. An increasing number of studies suggest that folic acid and vitamin B12 supplementation could reduce heart disease by 10% to 30%.

    Nearly all of the science is based on the use of dietary supplementation at between 400 ug and 5,000 ug per day. Most public health benefits are observed when at least 400 ug of supplement is utilised.

[5] *Ibid*., p. 100.

Despite approving health claims regarding neural tube risk reduction for selected breakfast cereals with only 40 ug of folic acid added, for which there are no scientific studies demonstrating efficacy, the Ministry of Health has declined to remove the 300 ug upper permitted levels for folic acid in dietary supplements. To the best of our knowledge, it is the only health authority in a comparable economy known to have taken such a stand after fully assessing the facts.

- *Some bee products*

  In 1999, the Ministry of Health introduced food standards requiring new warning labels on bee products. Following strong evidence-based submissions, the Regulatory Review Select Committee found that the Ministry had failed to follow due process and had abused its powers. The Chair, Jonathan Hunt, moved in the House that the food standard be revoked. The election intervened and the motion lapsed.

  Meanwhile, the Minister of Health commissioned a scientific review of the evidnce. The five-person scientific review found against the Ministry of Health on all five terms of reference. Despite promises to redress the Australian initiated warnings, the Ministry has not yet revoked the requirements.

- *Boron*

  Boron is freely sold in New Zealand, and has been for a long time. As a result of it being banned in Australia (even as a restricted medicine) Australia tried to get it banned in New Zealand via harmonisation of the medicines classifications.

  Industry responded with sound evidence-based risk analysis and Medsafe concurred with that evidence. Australia has meanwhile taken nearly two years to approve boron use in complementary medicines at levels no higher than present in foods, and at considerably lower levels than at least five internationally recognised risk assessments have deemed below *de minimis* levels of risk.

- *Vitamin B12*

  There has never been an adverse reaction or serious harm reported in over 30 years of extensive use of vitamin B12. However, the Ministry of Health has declined to remove the very low levels allowable in dietary supplements. Despite our concerns about Australia's restrictive regulatory regime, this is one ingredient where there are, quite correctly, no restrictions on upper levels in Australia.

- *Ephedra*

  Recently, Medsafe has moved to align New Zealand practice with Australia's by reclassifying Ephedra from a pharmacy-only to a prescription medicine.

  Extensive independent risk analyses have shown that when limited to 90 mg of the Ephedra alkaloid per day, split over three doses, there are no public health concerns.

Medsafe gazetted Ephedra as prescription medicine, but after being challenged "ungazetted" the change on 1 August 2002. If Medsafe's final decision is evidence-based, it will remove Ephedra from the "banned" list in quantities below 90 mg split over three doses per day.

In New Zealand, these matters can be addressed in the short term through better application of current law and in the medium to long term through new industry-specific legislation. We make specific proposals for regulatory and statutory changes in this area in Section 5 and at Appendix 4 of this submission.

- **Inappropriate categorisation and legislative framework:** In both Australia and New Zealand, the current regulatory approach classifies CHTPs as either "medicines" or "foods", and then subjects them to one regulatory regime or the other. In truth, however, these products generally have characteristics of both medicines and food, and it is anomalous to classify them as strictly one or the other. (This is acknowledged in part by the Medicines Act, which in certain circumstances enables therapeutic claims to be made about foods, not as medicines.)

  A new product category for CHTP is arguably required to provide for consistent treatment of CHTPs. In Section 5.2 of this submission we present a framework for legislation that would address the current anomalies through stand-alone legislation for the CHTP sector.

- **Risks:** We concur with the Discussion Paper's assessment that potential risks from using CHTPs may in theory arise from the use of certain ingredients, inferior product quality, inadequate consumer information, or misleading claims.[6] However, the Discussion Paper does not attempt to quantify these risks, nor does it attempt to relate the level of the proposed regulation to the quantum of risk. *Without a risk assessment, it is impossible to claim that the proposals are risk-based.* We address this issue in more depth in Section 2.2 below.

- **Regulator has poor information in case of genuine problems:** In New Zealand, the regulator (the Food Safety Authority) has little or no information on the products that are in the market, the ingredients they contain, and the relevant distributors. The DSCG concurs that the regulator should have that information to assist with reasonable regulatory requirements (for example, to allow for the recall of dangerous products). The DSCG believes that the necessary information can be achieved through a simple and inexpensive notification system as proposed below in Section 5.2.

[6] *Ibid*., pp. 99-101.

2.2 Risk assessment

> **Regulatory proposals should be subject to a risk assessment which should be as detailed as is appropriate in the circumstances.**
>
> NZ Code of Good Regulatory Practice

It is notable that while the Discussion Paper estimates that 95% of CHTPs should be classified as "low risk"[7], the authors do not provide any data on the quantum or costs of the supposed risk posed by this large group of products. In the absence of such data, it is impossible to assess the size of the regulatory "problem" (including whether it exists at all), and therefore to determine whether the costs of the proposed regime would outweigh the benefits.

Furthermore, the Discussion Paper makes a flawed assumption when, for the purposes of risk comparison, it places CHTPs on a scale that includes only medicines (including the most dangerous pharmaceuticals) and medical devices. This is false analogy. The Discussion Paper does not attempt to compare the risk of CHTPs with other activities or products in order to ensure that the proposed regulation is proportional to risk. An assessment of the proportionality of risk is a key component of the government's Code Of Good Regulatory Practice.

2.2.1 How safe is safe enough?

Two terms two terms – "*de minimis*" and "as low as reasonably practicable" – are used widely in international law to establish the threshold at which further effort to regulate trade or reduce risk are either pointless or unnecessary.

The ***de minimis*** threshold embraces the point at which risk would normally be determined negligible.[8] Examples of its legal application globally include, international trade law[9] [,10,11], takeover law[12], food law[13], exemptions from requirements to label genetically modified content of food[14], tax law[15,16,17], resource management law[18], telecommunications regulations[19], and computer sales[20].

---

[7] Peachey and Martindale, *op.cit.*, p. 101.
[8] http://www.executive.govt.nz/minister/sutton/singapore/analysis.pdf
[9] NAFTA Rules of Origin: The De Minimis Provision, http://infoserv2.ita.doc.gov/ticwebsite/naftaweb.nsf/3c5a68c244d2af1a85256691006d7add/197b7bc5e58aef65852566fe0070be24!OpenDocument
[10] http://www.maf.govt.nz/mafnet/issues/sustain/owg-report.pdf
[11] http://www.ejil.org/journal/curdevs/sr17.rtf
[12] http://www.takeovers.gov.au/Content/Resources/CASAC/CorporateGroupsMay2000.asp
[13] http://www.moh.govt.nz/moh.nsf/bbedab58c53332744c2566740013148d/4bfbc7660fe2d8d44c25695f007efbda/$FILE/cagmff99jan00.pdf
[14] http://www.nfpa-food.org/members/international/Biotechchart9_6.pdf
[15] http://www.inlandrevenue.gov.uk/budget2001/revbn17.htm
[16] http://www.taxreform.ato.gov.au/general/expla_statement.htm
[17] http://www.deloitte.co.nz/default.cfm?pageID=1026
[18] *Bayley* v *Manukau City Council*; *Barrett* v *Wellington City Council* [2000] NZRMA 481
[19] http://www.fplc.edu/risk/vol9/spring/Claycamp.pdf

The regulation of safety in many countries (including the United Kingdom, Australia, the USA and New Zealand) is based upon the principle that risks must be reduced to a level that is "**as low as reasonably practicable"** (ALARP).

The meaning of "reasonably practicable" is well established in case law: [21]

> "Reasonably practicable" is a narrower term than "physically possible" and 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.
>
> Judge Asquith
> *Edwards v. National Coal Board*
> All England Law Reports Vol. 1, p. 747 (1949)

It is best international practice that *de minimis* and ALARP principles are taken into account when evaluating proposed risk-reduction measures.

The Discussion Paper provides no analysis of whether its proposed regulatory requirements are appropriate when judged against these principles.

The DSCG presents its own analysis below.

2.2.2 Fatality data show that dietary supplements are extremely low-risk

New Zealand data[22] (see chart on next page) clearly demonstrate that in terms of deaths caused, consumption of legal dietary supplements is one of the lowest-risk activities that one can undertake in this country.

(In the chart, the number of deaths from dietary supplements has been set arbitrarily at "1" in order to make it possible to calculate a ratio. But in fact there are no proven cases of deaths from legal dietary supplements in New Zealand, so the chart exaggerates the actual known risk.)

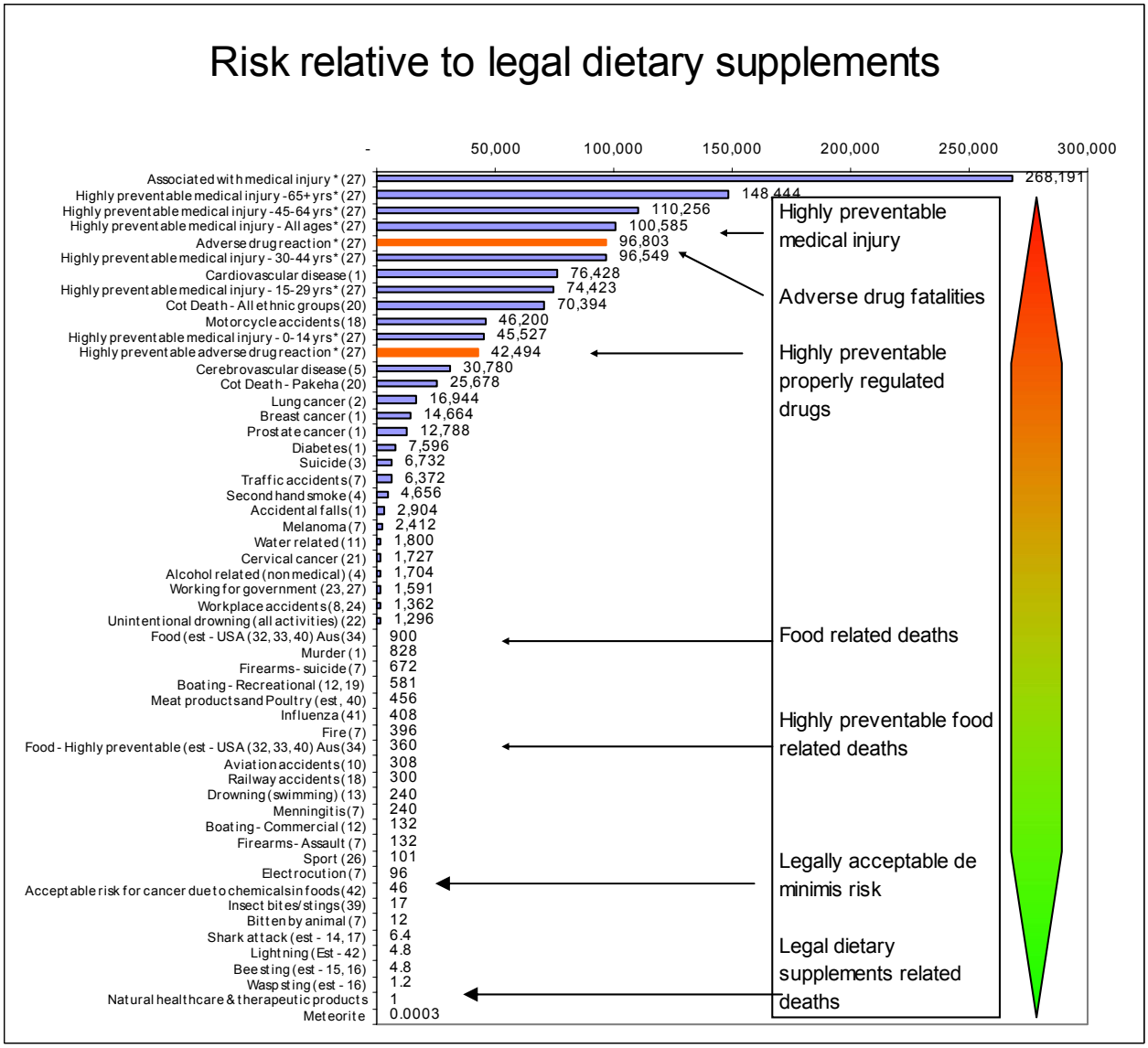
The data show that the risk of death from legal dietary supplements is in the same range as the risk of being killed by a lightning strike. Eating food is 900 times more likely to cause death than consuming legal dietary supplements, and officially regulated pharmaceutical drugs some 42,000 times more likely to cause a highly preventable death.

---

[20] http://www.bxa.doc.gov/factsheets/ExportGuidance.html

[21] as quoted in Geyer, T.A.W. ,Chapman, C.P. and Morris, M.I. *Improving Passenger Safety at Platforms*, Paper presented at The 1996 Annual Meeting of the Society for Risk Analysis-Europe accessed from http://www.riskworld.com/Abstract/1996/sraeurop/ab6ad054.htm

[22] Law, Ron, unpublished paper presented at conference of New Zealand Society for Risk Management, Wellington, October 2002. Data compiled from 44 official and NGO sources**.** Full list of references available on request.



The risk of death from legal dietary supplements is a tiny fraction of the legally acceptable *de minimis* risk – that is, the point at which the risk is considered trivial.

2.2.3 Other potential sources of harm

As noted above, the Discussion Paper states that ingredients, product quality, inadequate consumer information and the claims made can give rise to the risk of harm from the use of CHTPs. The regulatory proposals contained in the Discussion Paper are not, however, built on any quantification of these risks. The Discussion Paper does not attempt to demonstrate a positive cost-benefit ratio in advocating regulatory intervention, as would normally be expected.

In Section 5 and Appendix 4 of this submission, the DSCG provides a number of proposals that would effectively manage these potential hazards in a way that is significantly less costly than the Discussion Paper's proposals. Our proposals also provide for greater consistency with international best practice.

2.2.4 Anecdotes of harm don't stack up

In the absence of a comprehensive risk assessment, Medsafe officials have frequently provided anecdotes of alleged actual harm caused by dietary supplements[23].

It is notable that, even accepting the Medsafe anecdotes at face value, the alleged extent of risk and actual harm is extremely small compared with the number of New Zealanders who consume dietary supplements (estimated at 70% of the population[24]) and the size of the domestic market (estimated at $220 million retail per year – see Appendix 3).

The anecdotal "evidence" cannot, however, be taken at face value. The anecdotes do not constitute credible evidence of risk or harm, let alone of a need for tighter regulation. Without exception, the anecdotes demonstrate no more than the **potential** for harm when existing regulations are not enforced. They relate to:

- products or practices that are currently illegal in New Zealand, which suggests that enforcement of the current law is required, not more law
- cases where the alleged harm is not proven and are based on assertion rather than scientific evidence),
- cases that have been misclassified, such as referring to cosmetics as dietary supplements, and/or
- cases that the proposed new regime would not prevent.

In some cases, relatively minor adjustment to the current regime (for example, requiring distributors to certify that products are made under an appropriate, risk-based and internationally recognized (not trans-Tasman-only) standard of Good Manufacturing Practice (GMP)) would add another level of confidence.

A full summary and analysis of Medsafe's anecdotal evidence is provided in Appendix 2.

[23] Joint Therapeutic Agency Project, "Fact Sheet: What would What would a joint therapeutic products agency mean for dietary supplements in New Zealand?", July 2002. Available at: http://www.jtaproject.com/Downloads/Project%20Documents/pdf/Comms%20strategy-DS%20factsheet%20July%2002.pdf

[24] Minisitry of Health, National Nutritional Survey 1998, plus industry assessment of growth in market since.

2.2.5 Medsafe's own practices reveal the relative safety of CHTPs

Medsafe has recently stated somewhat candidly that the current Dietary Supplement Regulations 1985, made under the Food Act 1981, "have not been enforced for many years"[25]. These regulations[26]

> require dietary supplements to be properly labelled, [and] to have maximums for daily doses for vitamins and minerals. The regulations also set out what additives are permitted (preservatives, colouring, etc)… [and] also prohibit sponsors from making therapeutic claims.

Indeed, non-enforcement can be viewed as a sensible and rational choice by the regulators, given the very low level of risk imposed by CHTPs. Given a limited budget and the consequent need to set priorities, it is sensible for the authorities to put their effort where real risks arise.

Two questions arise:

- If harm is resulting from the use of products currently on the market, why are the regulators not enforcing the law?
- If in fact non-enforcement has not led to demonstrable harm, then what is the case for new and more onerous regulation?

2.3 Should exports of CHTPs require licences?

The export market for CHTPs is worth tens of millions of dollars to New Zealand (see Appendix 3), and is growing.

Under the Discussion Paper's proposals, exports would undergo similar regulation as products intended for local consumption. For example, products intended for export only would require an export licence (p. 69 of the Discussion Paper).

But the quality of products exported from New Zealand is already assured, because importing countries or firms typically ensure that goods are manufactured to appropriate GMP standards. Where evidence is required, this is supplied by way of a certified copy of the New Zealand Food Licence or its equivalent. This can be supported by a Free Sale Certificate issued by the local Public Health service, which inspects premises.

In our experience, such procedures are acceptable for all export markets except Australia, which has its own specific and expensive requirements for imports of CHTPs.

The only change that is required or warranted to the existing system is for Australia to recognise New Zealand certification of manufacture to GMP standards.

[25] Trans-Tasman Therapeutic Goods Agency Project, "About the Project", 29 April 2002, http://www.jtaproject.org/about.htm
[26] *Ibid.*

2.4 Intervention logic

In light of the analysis above, the Discussion Paper fails to present any – let alone compelling – logic for intervention on the scale proposed.

In the DSCG's view, there is nonetheless a case for regulatory change to address the problems we identify in Section 2.1 above, in a way that is consistent with international best practice. In light of the very low risk of harm and the lack of quantifiable evidence that harm has occurred to date, the ideal regime would be light-handed and very low in cost, so as to accord with the *de minimis* concept and the "as low as reasonably practicable" principle of risk management.

We propose such a regime below in Section 5 and in more detail in Appendix 4**.**

3. The process followed in developing the proposal for a Joint Trans-Tasman Agency

3.1 Consultation or pre-determination?

Members of the DSCG have been contributing to consultation processes on the future regulation of complementary healthcare and therapeutic products (CHTPs) more or less continuously since 1992.

Collectively we have devoted many thousands of hours to these consultations at the request of successive governments and their officials.

It is a matter of frustration that few if any of our concerns are acknowledged in the Discussion Paper and that, 10 years on, the industry remains under the control of 1992 regulations that are inadequate and outdated.

As the timetable below shows, in 1998 agreement was reached among the then-government, officials and stakeholders over a proposed Healthcare and Therapeutic Products Bill that would have introduced sensible, fair, affordable and effective regulations for the sector. *This proposed Bill was a constructive outcome from genuine consultation, and went a long way to resolving industry concerns about risk management and affordability.*

The proposed Healthcare and Therapeutic Products Bill was promoted as government policy and was on the government's legislative programme as late as February 2001. The government then announced that it was being put aside in favour of the proposal that was later outlined in more detail in the Discussion Paper.

It has never been explained to our satisfaction why the proposed Healthcare and Therapeutic Products Bill was withdrawn, and why the regime it proposed (which had been publicly endorsed by the new Minister of Health in August 2000 – see Section 3.2 below) had become so unacceptable.

We find it difficult to avoid the conclusion that what now appears to be the government's preferred regulatory outcome – namely, joint regulation by a trans-Tasman agency -- had been pre-determined outside the previous consultation processes. Given the contents of the Discussion Paper it appears that the government remains committed to the idea of a trans-Tasman agency.

3.2 A timeline of key events

Since the mid-1980s, dietary supplements in New Zealand have been treated not as medicines, but as foods – a status confirmed in the Dietary Supplements Regulations 1985, made under the Food Act 1981.

The United States followed New Zealand's lead in 1994 with the passage of the Dietary Supplement Health and Education Act, which also treats supplements as foods.

In New Zealand since 1992, successive governments have been working towards a new Act to replace the Medicines Act 1981 and the Dietary Supplements Regulations 1985. For example:

- In August 1992, industry received a letter from the Department of Health giving four weeks to make submissions on the Department's intention to introduce "urgent" legislative reforms and to re-regulate dietary supplements as "therapeutic goods".[27] The letter stated that "the new legislation aims to remove unnecessary regulatory requirements and to harmonise, wherever practicable, with the requirements or our major trading partners, particularly Australia."
- In 1995, the Cabinet rejected a proposal to essentially align New Zealand's medicines law with Australia's in order to facilitate the harmonisation process.
- In November 1998, major stakeholders reached a consensus with the Ministry of Health on how a new Healthcare and Therapeutic Products Bill would cover dietary supplements.

Following the election in November 1999, the proposed Healthcare and Therapeutic Products Bill was adopted in principle by the new government, with the current Minister of Health providing the following outline of it in a letter to a journalist in August 2000[28]:

- "The Healthcare and Therapeutic Products Bill is on this year's legislative programme."
- "The Bill will introduce new legislation to regulate medicines, medical devices and complementary healthcare products using a risk based approach."
- "Separate regulations for complementary healthcare products will sit under the proposed Act."
- "Work on the detail to be contained in the regulations will commence once the Bill is introduced."
- "As part of the implementation of the new legislation, a unit with expertise in complementary products will be established."
- "Under the proposed legislation, the regulatory authority could publish a list of prohibited ingredients [i.e. a 'negative' list of items that cannot be sold]."
- "An expert committee would make recommendations about the substances to be placed on the restricted [negative] list."
- "The main impact of the new legislation on the natural health industry will be a new requirement for registration (that is a listing, not an approval process) and audited good manufacturing practice programmes."
- "It is anticipated that additional costs to the industry will be minimal."
- "The Ministry of Health has consulted widely on the proposals. There has been general support for the current proposals."
- "Commencement date for the legislation will be set by Order in Council once the required regulations and rules are prepared. The earliest this is likely to be is July 2001."

[27] Martindale, S., "Revision of Medicines Act," August 1992,. Letter addressed to named industry members.
[28] King, Hon Annette, Minister of Health, letter to *Pharmacy Today*, 15 August 2000.

All of those statements concurred with what had been agreed with officials in November 1998, and subsequently discussed with the Minister in her office in April 2000.

Yet in July 2000 the New Zealand Institute for Economic Research (NZIER) had already been commissioned to undertake an economic impact report on a possible single joint agency (SJA) joint trans-Tasman agency to regulate therapeutic products. It prepared its report on "on the assumption that the SJA will operate along similar lines to the [Australian Therapeutic Goods Administration] TGA" and "that the range of interventions made by the SJA, and the rules and procedures applied, will not differ greatly from the TGA regime as at present."[29]

In February 2001, the government announced that it was putting aside the previous plans for the Healthcare and Therapeutic Products Bill in favour of pursuing a SJA with Australia.

It is worthy of note that information on a subsequent NZIER report on the costs and benefits of the proposal in the Discussion Paper has been persistently withheld in terms of the Official Information Act. The information in that analysis was not available to those who made submissions on the Discussion Paper.

[29] NZIER, *Regulatory Impact Analysis: A single joint Australia and New Zealand therapeutics goods agency*, October 2000, p. 39.

4. The legislative and regulatory regimes governing dietary supplements and traditional remedies in other countries

> **Where appropriate, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade.**
>
> NZ Code of Good Regulatory Practice

4.1 The significance of international best practice

The Code of Good Regulatory Practice emphasises that it is important to ensure compatibility with international standards wherever possible. It is well recognised that non-tariff barriers can arise from country-specific rules.

The Code also means that New Zealand should look beyond Australia when assessing international regulatory models. It is not defensible to assume without analysis that any one country is where best international practice will be found.

The Discussion Paper proposes that Australia and New Zealand "go it alone" in creating a unique standard for CHTPs that is inconsistent with the rest of the developed world.

Previous work by New Zealand officials was more open-minded in its approach to international standards. For example, the Treasury noted in 1998 that[30]:

> The paper [from the Ministry of Health] mentions that the regulatory arrangements of other countries (e.g. the USA) can be used by the NZ regulator to assess product entry criteria. If safety is the concern, we don't see why a NZ regulator can't 'piggy-back' on the regulatory regime of accepted countries.

In that vein, the DSCG herewith presents summaries of relevant regimes from what we believe should be 'accepted countries'. Our draft regulations at Appendix 4 propose that New Zealand adopt the best features of the high standards established in such countries

4.2 Examples of international best practice

4.2.1 Canada

A 1998 Select Committee review of the regulatory environment concluded that neither the food nor medicine models were appropriate for regulating CHTPs, especially given their finding of a lack of expertise, training and understanding in relation to CHTPs among regulators.

[30] The Treasury, *op. cit.*

The committee made 53 recommendations to establish the CHTP industry as an industry in its own right with equal legal status to foods and pharmaceuticals, separate regulations, and a separate regulatory directorate. Canada is in the process of implementing those reforms.

The transition is being fully funded by government and is being managed in co-operation with an industry-led transition team. Industry was involved as an equal partner in the appointment of the director.

Canada intends to start with a pre-market notification system, but has signalled that given the low risks associated with CHTPs it will consider a post-market notification system to reduce regulatory burden. Canada is introducing industry-appropriate Good Manufacturing Practice (GMP), an independent advisory task force, a simple dispute resolution mechanism, and has already introduced a GMP auditor guide which instructs assessors that CHTPs are low-risk products and therefore non-compliance issues should be dealt with on a risk-proportionate basis.

All of the above elements are embraced by our proposed model in Section 5 and Appendix 4.

Perhaps the best aspect of the emerging Canadian system is the co-operative approach being adopted by the new director who has training, qualifications and experience in the industry as a practitioner.

4.2.2 USA

In 1994, the USA government passed the Dietary Supplement Health and Education Act, which established dietary supplements as a subset of foods (similar to the existing legislation in New Zealand). Suppliers have to notify their intention to place new ingredients on the market along with a statutory declaration that they hold sufficient evidence to support their contention that the new ingredient is "generally regarded as safe". These notifications and decisions are on public record.

The difficulty with the USA system is that there is no public record of what ingredients are on the market, so it is difficult for suppliers and regulators alike to know if something is a new ingredient. The database in our proposal would address that weakness.

The USA is about to mandate CHTP-appropriate and risk-based GMP codes of practice, which are in line with our proposal and would be recognised as appropriate GMP.

4.2.3 European Union

The European Union is in the process of introducing several directives relevant to the regulation of CHTPs, including a recently passed Food Supplement Directive. Under that directive:

- Most vitamins and minerals will be regulated as a subset of foods with no mandated GMP. Food supplements will not have to be licensed or notified, but ingredients would need to be approved for general use, not unlike in New Zealand at present.

- Pharmacologically active herbals will be regulated as low-risk medicines. Manufacturers will have to be licensed and conform to GMP. In effect, many traditional herbal products will be banned due to less than 10 years' documented use in the EU.

This dividing of the industry will disenfranchise small business. Some markets such as England, Scotland, Wales, and the Netherlands will be especially disadvantaged – in particular their small, innovative businesses.

Features worthy of consideration are the fact that most vitamins and minerals are considered safe, and will be sold under food law with few regulatory constraints. Most products are already manufactured under industry-initiated voluntary GMP codes. Traditional medicines are defined as herbal remedies being in use for more than 30 years.

Features that need to be avoided are dividing the industry via different regulatory categories, and applying regulatory restraints that are not proportionate to established risk

4.2.4 South Africa

South Africa has to a large degree followed Europe, although its levels of vitamins and minerals permitted under food law are more in line with reputable scientific evidence. The South African approach is essentially to define what is a medicine and what is a food without making significant administrative changes (such as a third category). The views of the medical and pharmaceutical authorities dominate, with only one of 15 members of the Medicines Control Council having CHTP experience.

The head of the Nutrition Department has taken a very strong evidence-based, risk-proportionate approach to regulation, but is somewhat subservient to the MCC on interface issues.

The good features of the South African model are the use of evidence-based risk assessment to the regulating of vitamins and minerals. The downside is the subservient role that traditional remedies and herbal have compared with pharmaceutical medicines, and the dividing of the industry via regulation due to products being assigned to the food or medicine category – not to a third category.

4.2.5 United Kingdom

The United Kingdom currently operates a system similar to New Zealand, but without the dietary supplement regulations. They are being forced to comply with the EU directives, and the new regulations for the Food Supplements clearly state that the UK will be implementing as unrestrictive a regulatory regime as is possible. There will be no listing or notification of food supplements and no fees.

4.2.6 Australia

Australia regulates all CHTPs as medicines, and is the only country in the world identified as taking this regulatory approach. As in some other countries, all

ingredients need to be approved before sale in Australia -- but unlike no other, all CHTPs must be *notified* before sale as well.

In addition, the prescriptive nature of labelling and ingredient conditions of sale makes preparing products for entering onto the database very expensive. Australia is the only country identified that imposes a fee for the privilege of entering every product onto the market.

Australia operates a pharmaceutical GMP code which is audited by auditors with, by and large, pharmaceutical experience. This causes unwarranted auditing and non-compliance disputes at times.

Australia is purported to operate a risk-based system, but it is not evidence-based or proportionate to risk. It also involves burdensome bureaucracy and high compliance costs.

Worthy of adopting is a database of all suppliers, ingredients and products on the market. Our proposals embrace that concept.

The table at the end of this section demonstrates the unique nature of Australia's regulatory approach.

4.2.7 New Zealand

New Zealand leads the world by being the first country to regulate dietary supplements as a distinct class of product (although under food law).

New Zealand has operated a relatively liberal regulatory system that has not been enforced for some time.

In terms of best practice, the current New Zealand regulatory environment offers an appropriately light level of regulation with no burdensome compliance costs. This has resulted in product of quality that equals any country, including Australian product made under more onerous regulatory conditions.

Features to be avoided from the New Zealand regime are the inflexibility that does not update regulations in light of new evidence, knowledge and circumstances. Regulators need to work with industry and consumers to ensure that safe and effective product is not excluded from the market through technical breaches of poorly maintained regulation.

4.3 Lessons from international best practice

Based on the above and more extensive analysis, the DSCG proposes to adopt and adapt the following key points from other countries, and develop an industry specific best-practice co-regulatory model that is fair, affordable, evidence based risk proportionate and fully conforms to the code of good regulatory practice.

This proposal is set out in Section 5 of this submission and in draft regulations in Appendix 4.

The following list is not exclusive, but provides an indication of the use of a first-principles and best-practice approach to deriving our propose model.

Canada

- Separate regulations with regulators having industry related understanding, qualifications and training, including a good understanding of evidence-base risk analysis
- Industry-appropriate GMP
- Equitable and affordable risk proportionate dispute resolution mechanism
- Risk proportionate guidelines regarding management of non-compliance issues
- A co-regulatory/no surprises approach to regulation

European Union

- A risk-proportionate approach to subclasses of CHTPs, bearing in mind that the industry has a safety record second to none.

USA

- Notification of new ingredients system
- Ability of the regulator to challenge new or existing ingredients for evidence-based and risk assessed safety reasons.

United Kingdom

- Recognition that the CHTP industry is very low risk and that unreasonable compliance costs such as the payment of fees is an unwarranted and inefficient regulatory approach

Australia

- A modified database that is used for the management of the regulatory system, identifying who and what are in the marketplace.

New Zealand

- Light, permissive regulatory model
- Low compliance costs

How CHTPs are classified around the world

	Food law	Specific regulations under food law	Separate regulation under Food & Medicines umbrella	Specific regulations under medicines law	Medicines law	Fees
Australia					✓	✓
New Zealand		✓				×
USA		✓				×
Canada			✓			×
Germany	✓				✓	×
France	✓				✓	×
Italy	✓				✓	×
England	✓				✓	×
Scotland	✓				✓	×
Wales	✓				✓	×
Ireland	✓				✓	×
Sth Africa		✓		✓		×
Japan		✓			✓	×
Sth Korea		✓				×
New Zealand (proposed by Medsafe)					✓	×
New Zealand (proposed by Industry short term)		✓				×

5. The Consultative Group's proposal: a two-stage reform

The DSCG proposal outlined below draws on international best practice, as documented in the Section 5.1 immediately above. It also constitutes a regime that is compatible with trans-Tasman harmonisation or "mutual recognition" within the requirements of the government's Code of Good Regulatory Practice (reproduced at Appendix 1).

5.1 Stage One: a 'quick fix' of regulations under existing legislation

We attach as Appendix 4 two sets of draft regulations that address some of the problems identified in Section 2.1 above while relying on international best practice as identified in Section 4. These form Stage One of our proposal.

The draft regulations and their main features are described below.

5.1.1 New regulations for nutritional supplements under the Food Act 1981

Our proposed first set of regulations would:

- replace the Dietary Supplement Regulations 1985 promulgated under the Food Act 1981
- define "nutritional supplements" as products designed to maintain and improve health, but that are not promoted as food and drink
- adjust the maximum allowable daily dosages of certain ingredients to accord with best international practice and the best scientific evidence
- add boron, silver and vanadium to the table of permitted minerals, again in accordance with best international practice and the best scientific evidence.

5.1.2 New regulations exempting nutritional supplements from the Medicines Act 1981

The second proposed set of regulations would be under the Medicines Act 1981, and would state that nutritional supplements are not "related products" in terms of that Act. In effect, this allows nutritional supplements to make truthful claims, subject to the provisions of the Fair Trading Act 1986.

These regulations go part of the way to achieving the new category for CHTPs that the DSCG believes is necessary. More importantly:

- They immediately bring New Zealand into line with best international practice in terms of allowable ingredients and dosages, with consequent benefits to consumers and to international trade.
- They immediately enable New Zealand consumers to be provided with accurate information as to the purpose and effect of CHTPs.

We stress that the above benefits can be achieved immediately through new regulations under existing law.

5.2 Stage Two: a 'permanent fix' under separate legislation

Stage Two of our proposal is to introduce associated industry-specific legislation. This would create CHTPs formally as a separate (third) category of products – in

addition to food and medicines – under dedicated legislation. This would recognise the reality that, despite sharing some of the attributes of each, CHTPs are strictly speaking neither foods nor medicines.

The new legislation would:

- state as its *purpose* that it is to promote the safety of the relevant products
- state as an *underlying principle* that the industry and the regulator are to work in partnership
- include unilateral recognition of specified international standards for satisfactory, risk-based Good Manufacturing Practice (GMP), allowable ingredients, recognised pharmacopoeia, proper labelling and therapeutic claims
- a statutory advisory body
- include a simple electronic database through which distributors of products can register themselves and their products, ingredients and claims
- provide an objective risk-classification system providing, say, five categories of risk
- include an electronic notification system for new ingredients, allowing the regulator a statutory period (60 days, for example) in which to challenge an ingredient
- provide a simple disputes resolution procedure
- include enforcement mechanisms and penalties
- allow a transitional period of, say, three years.

Industry-specific legislation would cement in place the above improvements to ensure that only Parliament can change the substance of the regime, rather than allowing it to be substantially affected by regulation.

More detail on some of the key features and benefits of the proposed Act are set out below.

5.2.1 Reliance on international standards

Under our proposal, schedules would nominate countries with acceptable standards for GMP, labelling, determining allowable ingredients and dosages, and the making of therapeutic claims. In some instances, the schedules would include satisfactory industry Codes of Practice, the standards of bodies such as those of the United Nations or the European Union, and reputable sources such as internationally recognized pharmacopoeia. New Zealand would unilaterally recognise these standards.

More specifically our proposal:

- would require the distributors of products on the New Zealand market to certify compliance with such a GMP standard before marketing the product
- would accept labelling that conforms with the standards specified in the schedules as acceptable in New Zealand

- would accept such international standards as *prima facie* evidence that an ingredient is safe, although under the proposed multi-level risk management system the regulator would still have a period of time in which to argue that an ingredient should be in a higher risk category and thus be subject to greater scrutiny
- would permit any truthful claims, and provide that listings in sources nominated in the relevant schedule is satisfactory evidence of the truth of a claim. Claims made outside those sources would be allowable, but if challenged would have to be proven to the standard required under the Fair Trading Act.

5.2.2 Benefits of reliance on international standards

The system outlined in Section 5.2 would draw on international best practice and provide the following benefits:

- *Improved consumer confidence:* Products that do not comply with acceptable GMP would have to be removed from the market. (We note, however, that a significant increase in consumer safety should not be expected, given that the vast majority of products on the New Zealand market are already safe and are manufactured under international GMP standards, and that most of the actual problems relate to products that are not currently legal.)
- *Improved consumer information:* Truthful claims about a product's benefits would be allowed, and quality, independent sources would be specified to assist with establishing the truth of claims.
- *Minimal increase in compliance costs for suppliers of products that are already safe:* Existing products that meet international standards for GMP, ingredients, labelling and claims could stay on the market without additional compliance costs. No non-tariff barriers would be set up through establishing Australasia-only rules that limit competition from quality overseas products (as has occurred in Australia).

5.2.3 Risk classification system

A risk classification system, based on defined gradations of risk, is proposed. We believe this would provide a great deal of flexibility in terms of targeted risk management, bearing in mind the excellent safety record of the CHTP industry. This could also accommodate gradations of risk, which might, for example, require additional warnings on labels and packaging for higher dosages.

5.3 Cost recovery

A worrying aspect of the Agency proposed in the Discussion Paper is that it would not be subject to limits on its fee-setting and collection powers. The Discussion Paper states that the Agency's *operating costs would be fully funded by fees and charges recovered from industry*[31]. Because the Agency would not be government-funded, it would be free to determine its own budget and then set fees at the level required to meet its freely self-determined operations.

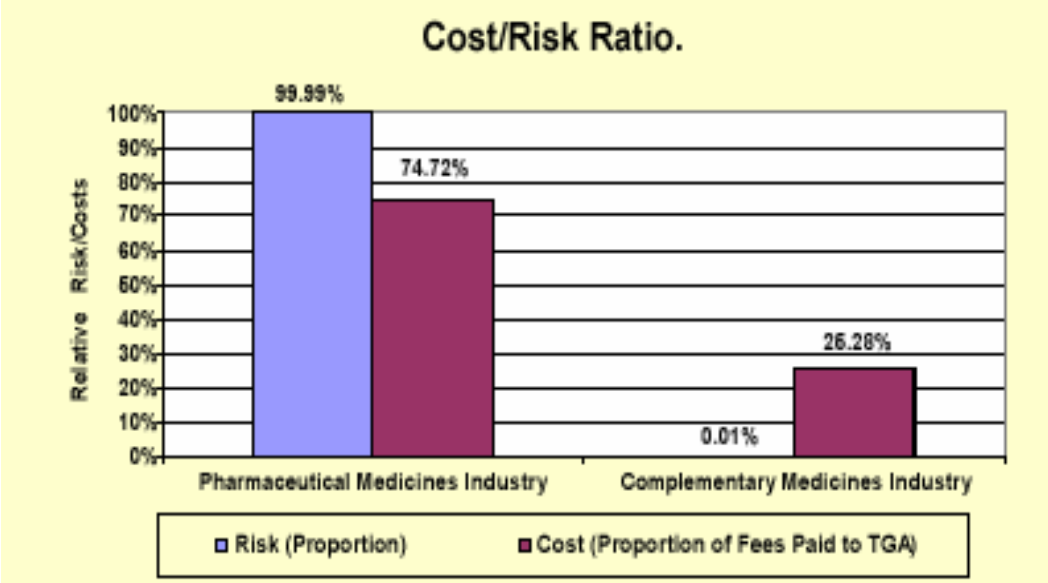
[31] *Ibid.*, p.20.

The proposed Agency would therefore have unfettered power to levy fees in order to meet priorities that it alone identifies, concerning rules that it alone sets. There is no other trans-Tasman authority with such powers.

There must be prior restraint on the costs incurred by any regulator of CHTPs – whether that regulator is the proposed Agency or otherwise. Since costs would be driven directly by the level of enforcement, the onus of proof must be on the regulator to show that enforcement is proportionate to risk. Further, cost minimisation should be an explicit goal of the regulator, in order to restrain its otherwise unlimited powers to decide enforcement levels paid for by others.

For example, it would be unacceptable to adopt the Australian situation, where complementary healthcare products incur 25% of the therapeutic-product fee income of the Australian Therapeutic Goods Administration, despite causing less than 1% of the risk in terms of deaths caused.

Illustration 2:
Who pays for the Australian TGA?



(Source: Blanchard, J., unpublished paper presented at conference of Complementary Healthcare Council (Australia), March 2001. Data sourced from Therapeutic Goods Administration documents.)

The method of paying for food regulation is instructive as a comparison. The costs of the new food regulations coming into force in New Zealand in 2002 are to be paid out of general taxation. *Given that the food industry causes more risk and more actual harm, there can be no justification for paying the cost of any regulation of dietary supplements through industry fees while food regulation is paid from general taxation.*

Using general taxation to pay for any increased regulation of dietary supplements has another advantage, in that it provides an external and democratic check on the powers of the regulator. It must seek an appropriation through the Parliaments of

the two countries, thus ensuring *ex ante* scrutiny of its budget and enforcement plans.

In summary, the DSCG proposes that the costs of regulating CHTPs should be paid from general taxation to ensure that the relevant agency is subject to parliamentary scrutiny. Quite apart from horizontal equity in relation to food, the cost of the appropriate level of regulation should be so small that cost recovery from the industry would be economically inefficient.

5.4 The regulator

We propose that in Stage One the Food Safety Authority would remain as the regulator of CHTPs (as at present). Consideration of the proposed industry-specific legislation would necessarily include an industry review that would consider the most appropriate agency to be regulator for the long term.

6. The compliance costs that would be imposed and any added cost to consumers

6.1 The current Australian system

We present below a number of case studies based on imposing the Discussion Paper's proposals on typical New Zealand firms.

Of course, the assumptions one makes are critical to any estimates – but the Discussion Paper provides very little to go on in this area. For that reason, our case studies are based on:

- the existing Australian rules and fees
- typical practice among Australian firms to comply with those rules
- each company's best guess as to how the rules would affect them.

The latter point means that some of the costings are compiled on a different basis from each other, reflecting different firms' operating practices.

None of the cost estimates attempt to quantify losses from lost opportunity due to market-entry delays, stifled innovation. Nor do they allow for the possibility that some businesses may become unviable due to compliance costs and fees.

Detail on the assumptions behind the cost estimates are included at Appendix 5.

6.2 Case Study 1

This is a medium-to-large New Zealand manufacturer with moderate number of product in the Australian market, and 200 products in total.

Cost Item	Assumptions	Number	Cost $NZ	Total cost
Initial listing costs				
Product listing	Listed medicine application fee	200	515	103,000
Consultant	Based on current practice.	200	500	100,000
In house costs	1 day per product based on actual time currently spent	200	250	50,000
Relabelling	$500 for consultant/drafting/design, $500 for new plate, $500 for new printing/ redundant labels	200	1,500	300,000
			Total Initial listing costs	**$553,000**
Ongoing annual costs				
Consultant retainer	Per month	12	500	6,000
Annual product listing fee		200	438	87,600
Formulation changes	10% of products	20	245 (fee only)	4,900
Salary of regulatory officer	Required to manage compliance issues	1	50,000	50,000
Overheads for regulatory officer		1	50,000	50,000
TGA/GMP Audit	Includes annual fee, audit and internal costs	1	40,000	40,000
			Total Ongoing Costs	**$238,500**
			Total Costs of Compliance for Australian market	**$791,500**

6.3 Case Study 2

This is a medium-to-large New Zealand manufacturer with 10% of its product on the Australian market, and 70 products in total.

Cost Item	Assumptions based as far as possible on actual invoices from this firm	Number	Cost $NZ	Total cost
Initial listing costs				
Product listing		70	515	36,050
Consultant		70	425	29,750
In-house costs	1 day per product	70	575	40,250
Advertising approval	Only initial advertisement approval – all others require assessing	70	145	10,150
Relabelling	$500 for consultant/drafting/design, $500 for new plate, $500 for new printing/ redundant labels	70	1,500	105,000
Non-invoiced costs as assessed by three senior operational managers based on experience to date	Such as: dealing with minor listing discrepancies, disputes in the wording of advertisements, minor GMP deviations requiring major operational retrofits.	70	2,000	140,000
			Total Initial listing costs	**$361,200**
Ongoing annual costs				
Annual product listing fee		70	435	30,450
Formulation changes	15% of products. Costs based on actual examples. $3,000 consultancy and $10,000 reformulation.	10	13,000	130,000
TGA/GMP Audit	Includes annual licence, audit, internal costs	1	40,000	40,000
			Total Ongoing Costs	**$200,450**
			Total Costs of Compliance for Australian market	**$561,200**

6.4 Case Study 3

This is a medium-sized New Zealand manufacturer who is not in Australian market, and makes 80 products.

Cost Item	Assumptions	Number	Cost $NZ	Total cost
Initial listing costs				
Product listing		80	515	41,200
Consultant	Based on other companies' experience	80	500	40,000
In house costs	1 day per product	80	250	20,000
Relabelling	$500 for consultant/drafting/design, $500 for new plate, $500 for new printing/ redundant labels	80	1,500	120,000
Upgrade to TGA/GMP Audit standard and initial audit	Cost estimates provided by GMP consulting company and include upgrades, operational changes, new laboratory and like.	1	160,000	160,000
			Total Initial listing costs	**$380,000**
Ongoing annual costs				
Additional operational costs		1	40,000	40,000
Annual product listing fee		80	435	34,800
Formulation changes	15% of products based on consultants report	12.5	5,000	62,500
Salary of regulatory and quality managers	Required to manage compliance issues.	1	50,000	50,000
Extra overheads		1	40,000	40,000
			Total Ongoing Costs	**$227,300**
			Total Costs of Compliance for Australian market	**$607,300**

6.5 Case Study 4

This is a medium-sized, New Zealand-only multi-sourced importer (not in Australian market) which offers 350 products.

Cost Item	Assumptions	Number	Cost $NZ	Total cost
Initial listing costs				
Product listing	Full fee	50	515	25,750
Low value declaration fee	For products with turnover of less than $10,000	300	80	24,000
Consultant		350	500	175,000
Relabelling	$500 for consultant/drafting/design, $500 for new plate, $500 for over labelling	350	1,500	300,000
Overseas manufacturing plants GMP inspected	Audit at business class travel, $940 per hour, plus annual licence fee of $4,460	12	12,500	150,000
			Total Initial listing costs	**$674,750**
Ongoing annual costs				
Consultant retainer	Per month	12	500	6,000
Product listing	Full fee	50	450	22,500
Low value declaration fee		300	80	24,000
Formulation changes/relabelling costs	10% of products relabelling costs	35	1,500	52,500
Salary of regulatory officer	Required to manage compliance issues	1	45,000	45,000
Overseas manufacturing plants GMP inspected	12 x every 1.5 years = 8 per year	8	12,500	100,000
			Total Ongoing Costs	**$250,000**
			Total Costs of Compliance for Australian market	**$924,750**

6.6 Case Study 5

This is a small New Zealand importer with 1000 products, and who is not involved in the Australian market.

Cost Item	Assumptions	Number	Cost $NZ	Total cost	Total Cost – No Fees
Initial listing costs					
Product listing	Full fee	100	515	51,500	0
	Low value fee	900	80	72,000	0
Consultant		1,000	100	100,000	100,000
Reformulation of products	10% (likely to be much higher in practice)	100	$5,000	500,000	500,000
In house costs	0.5 days per product	1,000	100	100,000	100,000
Relabelling	$500 for consultant/drafting/design, $500 for new plate, $500 for new printing/ redundant labels	1,000	1,000	1,000,000	1,000,000
			Total Initial listing costs	**$1,823,500**	**$1,700,000**
Ongoing annual costs					
Annual product listing fee	Full fee	100	450	45,000	
Low value fee		900	80	72,000	
Formulation changes	10% of products per year	100	1,500	15,000	15,000
Regulatory affairs officer		1	40,000	40,000	40,000
Overheads		1	40,000	40,000	40,000
Overseas manufacturing plants GMP inspected	9 x every 1.5 years = 6 per year	6	12,500	75,000	75,000
			Total Ongoing Costs	**$287,000**	**$170,000**
			Total Costs of Compliance for Australian market	**$,2110,500**	**$1,870,000**

Notes on this case study:

- 89% of compliance costs would be non-fee related
- This company would not be viable in its present form. The proprietors estimate that they would have to discontinue approx 95% of their product range and

make 75% of their existing staff redundant to give the business a chance of being viable. Their customers would lose choice of product range.

6.7 Case study 6

This is a large overseas supplier with significant market penetration in New Zealand, but very limited involvement in Australia.

Initial listing costs	
Company has over 200 of its own products made to pharmaceutical GMP standards, and freely available in over 30 countries.	It took nearly two years to prepare for and get the first 20 products onto the Australian market in September 2000. Subsequently, over the past two years it has been able to get less than 20 further products onto the Australian market. The company estimates that the total extra administrative, relabelling, reformulating and regulatory costs to date to get 15% of its existing products onto the Australian market are approximately $15,000 per product. This involves no new ingredients, and involves only products that are already freely and safely available in many countries, including New Zealand.

7. Whether indigenous complementary medicinal/rongoa products and extracts used for alternative therapy would be protected

The DSCG as a whole does not have a mandate to represent the commercial interests of associations that market extracts of indigenous plants, although some members of constituent bodies practice traditional therapies and/or use products with traditional ingredients.

As a matter of principle, however, the DSCG believes that, subject to the Treaty of Waitangi, tangata whenua should enter into the CHTP industry on the same basis as everyone else. There should be neither favouritism towards, nor disadvantage to, a supplier simply because they are Maori or because they are using traditional ingredients or remedies.

To the best of our knowledge there has been only the most superficial consultation with Maori in the development of the Discussion Paper. The Select Committee may wish to seek additional information on this point.

Finally, we note the WAI 262 claim on flora and fauna that is currently before the Waitangi Tribunal may have implications for any proposal to regulate CHTPs. The Select Committee may wish to investigate how the Crown wishes to address the protection and regulation of Maori remedies under any new regime that may result from this claim.

8. Pharmaceuticals, over-the-counter medicines and medical devices

We note that the Select Committee's inquiry does not extend to medical devices.

We note, however, that in some cases the Discussion Paper's proposed restrictions on medical devices may inhibit existing practices by natural health practitioners.

The Select Committee may wish to give this further consideration at the point it considers any eventual legislation that arises from the Discussion Paper.

Some of these matters could alternatively be dealt with in the legislation contemplated in Stage Two of our proposed new regime.

Appendix 1:
New Zealand's Code of Good Regulatory Practice

Source:
Ministry of Economic Development
http://www.med.govt.nz/buslt/compliance/regprac.html

Efficiency

Adopt and maintain only regulations for which the costs on society are justified by the benefits to society, and that achieve objectives at lowest cost, taking into account alternative approaches to regulation.

Efficiency Guidelines

- Consideration of alternatives to regulation: regulatory design should include an identification and assessment of the most feasible regulatory and non-regulatory alternative(s) to addressing the problem.
- Minimum necessary regulation: when government intervention is desirable, regulatory measures should be the minimum required, and least distorting, in achieving desired outcomes.
- Regulatory benefits outweigh costs: in general, proposals with the greatest net benefit to society should be selected and implemented.
- Reasonable compliance cost: the compliance burden imposed on society by regulation should be reasonable and fair compared to the expected regulatory benefit.
- Minimal fiscal impact: regulators should develop regulatory measures in a way that minimises the financial impact of administration and enforcement.
- Minimal adverse impact on competition: regulation should be designed to have a minimal negative impact on competition.
- International compatibility: where appropriate, regulatory measures or standards should be compatible with relevant international or internationally accepted standards or practices, in order to maximise the benefits of trade.

Effectiveness

Regulation should be designed to achieve the desired policy outcome.

Effectiveness Guidelines

- Reasonable compliance rate: A regulation is neither efficient nor effective if it is not complied with or cannot be effectively enforced.
- Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest possible cost to all parties. Incentive effects should be made explicit in any regulatory proposal.

- Compatibility with the general body of law, including the statute which it amends, statutes which apply to it, and the general body of the law of statutory interpretation.
- Compliance with basic principles of our legal and constitutional system, including the Treaty of Waitangi, and with New Zealand's international obligations.
- Flexibility of regulation and standards: regulatory measures should be capable of revision to enable them to be adjusted and updated as circumstances change.
- Performance-based requirements that specify outcomes rather than inputs should be used, unless prescriptive requirements are unavoidable. This will help ensure predictability of regulatory outcomes and facilitate innovation.
- Review regulations systematically to ensure they continue to meet their intended objectives efficiently and effectively.

Transparency

The regulation making process should be transparent to both the decision-makers and those affected by regulation.

Transparency Guidelines

- Problem adequately defined: identifying the nature and extent of the problem is a key step in the process of evaluating the need for government action. Properly done, problem definition will itself suggest potential solutions and eliminate others clearly not suitable.
- Clear identification of the objective of regulation: the policy goal should be clearly specified against the problem and have a clear link to government policy.
- Cost benefit analysis: regulatory proposals should be subject to a systematic review of the costs and benefit. Resources invested in cost benefit estimation should increase as the potential impact of the regulation increases.
- Risk assessment: regulatory proposals should be subject to a risk assessment which should be as detailed as is appropriate in the circumstances.
- Public consultation should occur as widely as possible, given the circumstances, in the policy development process. A well-designed and implemented consultation programme can contribute to better quality regulations, identification of the more effective alternatives, lower costs to business and administration, ensure better compliance, and promote faster regulatory responses to changing conditions.
- Direct approaches to problem: In general, adopting a direct approach aimed at the root cause of an identified problem will ensure that a more effective and efficient outcome is achieved, compared to an indirect response.

Clarity

Regulatory processes and requirements should be as understandable and accessible as practicable.

Clarity Guidelines

- Make things as simple as possible, but not simpler, in achieving the regulatory objective.
- Plain language drafting: where possible, regulatory instruments should be drafted in plain language to improve clarity and simplicity, reduce uncertainty, and to enable those affected to better understand the implications of regulatory measures.
- Discretion should be kept to a minimum, but be consistent with the need for the system to be fair. Good regulation should attempt to both minimise and standardise the exercise of bureaucratic discretion, in order to reduce discrepancies between government regulators, reduce uncertainty, and lower compliance costs.
- Educating the public as to their regulatory obligations is fundamental in ensuring compliance.

Equity

Regulation should be fair and treat those affected equitably.

Equity Guidelines

- Obligations, standards, and sanctions should be designed in such a way that they can be imposed impartially and consistently.
- Regulation should be consistent with the principles of the New Zealand Bill of Rights Act 1990, and the Human Rights Act 1993, and the expectations of those affected by regulation, as to their legal rights, should be meet.
- People in like situations should be treated in a similar manner, similarly, people in disparate positions may be treated differently.
- Reliance should be able to placed on processes and procedures of the regulatory system: a regulatory system is regarded as fair or equitable when individuals agree on the rules of that system, and any outcome of the system is considered just.

Appendix 2:
Analysis of alleged harm from complementary healthcare and therapeutic products in New Zealand

Product	Alleged problem/Issue	Comment
K4 (Indian herbal)	Alleged liver toxicity. Causality is assumed on the basis of anecdote, but is not proven. A coroner found that there was no evidence establishing causality in the alleged death.	These products are illegal now under the Medicines Act and/or the Food Act and/or the Dietary Supplement Regulations. No law change is required on the legal status of these products. The proposals of the Dietary Supplements Consultative Group in this submission to the Select Committee would improve the prevention of these incidents, and improve enforcement where necessary. The DSCG proposals would do so with less cost (financial and compliance) than the proposal in the Discussion Paper.
Tentex Forte	Presence of strychnine	
Metaliv (Ayuverdic)	Contained black nightshade. Also contained a pesticide with known toxic effects.	
Several Indian herbal medicines	Excessive levels of heavy metals	
Collodial Silver products	Marketed illegally as an dietary supplement (i.e. without pre-market regulatory assessment) despite containing sufficient levels of silver to be classified as a medicine, and despite making therapeutic claims.	
Weilong (Chinese herbal)	Found to contain sildenafil (Viagra) – not stated on label	Inaccurate labelling and/or spiking with pharmaceuticals are illegal now under the Medicines Act, Food Act and/or Dietary Supplement Regulations. No law change is required on the legal status of these practices. The proposals of the Dietary Supplements Consultative Group in this submission to the Select Committee would improve the prevention of these incidents, and improve enforcement where necessary. The DSCG proposals would do so with less cost (financial and compliance) than the proposal in the Discussion Paper.
Cheung Kum capsule (Chinese herbal)	Found to contain chlorpheniramine and betamethasone (prescription medicines) – not stated on the label	
Rejuvenesse Cream with Fematin	Found to contain progesterone (prescription medicine) – not stated on the label	
PC SPES & SPES	Found to contain warfarin and alprazolam (prescription medicine) – not stated on the label. This product is not known to have been been marketed in New Zealand. The case relates to advise received from authorities in Canada and the USA.	
Pi Yan Ping Cream	Found to contain betamethasone – not stated on the label	
Wild Yam Cream	Found to contain progesterone – not stated on the label	
Boron with Phytase	Found to contain selenium at toxic levels – not stated on the label	

Product	Alleged problem/Issue	Comment
Lyprinol	Claims for cancer The pharmaceutical company (not dietary supplement company) was convicted and fined.	False claims are illegal now under the Medicines Act and Dietary Supplement Regulations, so these anecdotes do not provide evidence of a need for change. Under the DSCG's proposals, false claims would continue to be illegal under the Fair Trading Act. Accurate claims would be allowed where they are illegal now.
Natural OPC (antioxidant)	Claims for a variety of ailments, including cancer, asthma, Alzheimers, bacterial infections, diabetes, stroke	
St John's Wort	Life-threatening interactions with some prescription medicines were alleged. These interactions have been proven to be largely hypothetical – despite millions of doses being consumers every year, there has never been a death associated with St John's wort.	With industry co-operation under existing New Zealand regulations, the issues were addressed through a joint approach that resulted in voluntary warning labels, over 10,000 mailings of educational material from Medsafe, and unprecedented co-operation between regulator and industry. In a media statement at the time, Medsafe stated: "The complementary healthcare industry has been responsive to our concerns and endorse the information provided in our leaflets. The industry bodies have also acted very responsibly and have proposed to add cautionary labelling statements to their products to ensure that consumers are informed about the risk of interaction with some medicines." This provides an example of international best practice and is consistent with the regulatory reform being proposed. **The above was achieved in New Zealand five months before the issues were resolved in Australia.**
Thyroid extracts	Suppression of thyroid-stimulating hormone was alleged. Causality is assumed, not proven. (For example, soy affects thyroid, as does excessive iodised salt.)	Problem not proven. No apparent breach of existing law. If the changes proposed in the Discussion Paper were to ban these products, that would be an over-reaction based on poor science and would therefore be inconsistent with Good Regulatory Practice.
Chapparal	Liver toxicity was alleged to have occurred overseas, but was not proven.	

Appendix 3:
Size of New Zealand market for CTHPs

New Zealand Retail: 2001

Point of Sale	$ Turnover	% of Ret
Grocery/supermarkets [1]	76,000,000	
Health Food Stores [2]	45,000,000	
Pharmacy [3]	41,000,000	
Direct Selling [4]	30,000,000	
Direct Marketing [5]	20,000,000	
Internet [6]	5,000,000	
Practitioners [7]	5,000,000	
		%
Total Retail	**$222,000,000**	
Export [8]	**$100,000,000**	
Total Sales	**$322,000,000**	

Sources:
[1] A C Neilsen (Grocery)
[3] Aztec (Pharmacy)
[4] Otago University (Direct Sellers)
[2, 5, 7, 8] Industry market research from numerous informal sources including actual sales in selected outlets and representative suppliers (health food stores, direct marketing, practitioners, export) and estimates of Internet sales.

Exports are estimated based on information from a variety of unofficial sources. The NZIER Regulatory Impact Analysis (2000) found that official export figures are impossible to correlate due to large discrepancies. For example, New Zealand's official figures said that New Zealand had exported $6 million worth of product to Australia, but Australian figures said that Australia had imported $22 million from New Zealand. Export figures from three NZ manufacturers alone equate to more than $30 million in exports to Australia.

It is estimated from a number of industry sources that total exports of dietary supplements and dietary supplement ingredients is more than $100 million including processed bee products, deer velvet and colostrum.

Appendix 4:
Proposed amendments to current regulatory system

Nutritional Supplements Regulations 2003

Governor-General

Order in Council

At Wellington this day of 2003

Present:
Her Excellency the Governor-General in Council

Pursuant to Section 42 of the Food Act 1981, Her Excellency the Governor-General, acting on the advice and with the consent of the Executive Council, makes the following regulations.

Contents

Regulations

1 Title

These regulations are the Nutritional Supplements Regulations 2003.

2 Commencement

These regulations come into force on [*date*].

3 Interpretation

(1) In these regulations, unless the context otherwise requires,—**amino acid—**

(a) means alanine, arginine, asparagine, aspartic acid, carnitine, citrulline, cysteine, cystine, glutamic acid, glutamine, glycine, histidine, isoleucine, leucine, lysine, methionine, ornithine, phenylalanine, proline, selenomethionine, serine, taurine, threonine, tryptophan, tyrosine, or valine; and

(b) includes salts or derivatives of any of the amino acids referred to in paragraph (a)

antioxidant means any substance that has the property of arresting or retarding oxidation

artificial sweetener means any substance that, when added to a nutritional supplement, is capable of imparting sweetness to that nutritional supplement, and that is not a natural sweetener such as a saccharide, polyhydric alcohol, botanical, or honey

batch or lot means a quantity of nutritional supplement produced under the same conditions during a particular period, and usually from a particular line or other identifiable processing unit

biotherapeutic means nutritional supplements that—

(a) use micro-organisms with therapeutic properties; and

(b) are administered for the prevention or treatment of a condition.

botanical means a whole plant or part of a plant, algae, macroscopic fungi, and combinations of those things

botanical, animal or micro-organism derived substance includes—

(a) a whole organism; or

(b) an extract; or

(c) an isolate that is obtained in such a manner that its primary molecular structure is unaltered from that found in the original material.

brand name, in relation to a nutritional supplement, means the name, whether or not including the name of any manufacturer, corporation, partnership or individual, in English—

(a) that is assigned to the nutritional supplement by its manufacturer, distributor or supplier; and

(b) under which the nutritional supplement is sold or advertised, and

(c) that is used to distinguish the nutritional supplement

colouring substance means any substance that, when added or applied to a nutritional supplement, is capable of imparting colour to that nutritional supplement

common name means the name in English by which the nutritional supplement is generally known

container means any box, packet, or other receptacle in which 1 or more packages of nutritional supplements are, or are to be, enclosed

daily dosage in relation to a nutritional supplement, means the mass, volume or number, as the case may be, that is recommended by the manufacturer, distributor or supplier as the amount usually to be taken during one single day, and the mass, volume, or number must be stated as the case may be

dietary phytoprotectants mean non-nutrient botanical chemicals that—
(a) contain protective, disease-preventing compounds; and
(b) are useful for the maintenance of optimum health

expiry date means the earlier of—
(a) the date, expressed at minimum as a year and month, up to and including which a nutritional supplement maintains its labelled potency, purity and physical characteristics; and
(b) the date, expressed at minimum as a year and month, after which the manufacturer recommends that the nutritional supplement should not be used

flavouring substance means any substance that, when added or applied to a nutritional supplement, is capable of imparting flavours to, or enhancing flavours in, that nutritional supplement

incidental constituent—
(a) means any extraneous substance, toxic substance, or pesticide that is contained or present in or on any nutritional supplement; but
(b) does not include any preservative, antioxidant, colouring substance, artificial sweetener, flavouring substance, food conditioner, anticaking agent, gaseous packing agent, propellant, vitamin, any mineral or any botanical

ingredient means any substance, including a food additive (other than an incidental constituent), that is—
(a) used in the manufacture or preparation of a nutritional supplement; and
(b) present, whether in a modified form or not, in the final product

label means any, brand, mark, pictorial or other descriptive matter, written, printed, stencilled, marked, embossed or impressed on a container of a nutritional supplement

lot or batch number means any combination of letters, figures, or both, by which any particular batch or lot of nutritional supplement can be traced in manufacture and identified in distribution

mineral means a mineral specified in regulation 20 or any salt or derivative of the mineral

nutrient means any natural or synthetic substance consumed as a constituent of food or nutritional supplement that provides energy or which is needed for optimal growth, development and maintenance of life or of which a deficit may cause biochemical or physiological changes to occur

nutritional supplement has the meaning set out in regulation 4.

permitted class names means antioxidants, artificial sweeteners, colouring or colour, encapsulating aids, flavouring or flavour, minerals, preservatives, processing or tabletting aids, vitamins

preservative means any substance that, when added to a nutritional supplement, has the property of arresting or impeding fermentation, putrefaction, oxidation, decomposition or microbial growth.

principal display panel means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale

printed includes written, typewritten, engraved, lithographed, or otherwise traced or copied

probiotic means micro-organisms which improve the microbial balance and positively affect the health and functioning of the body

tabletting or processing aid—

(a) means a food grade substance that is added to a nutritional supplement to constitute the form in which that nutritional supplement is sold; and

(b) includes an encapsulating or processing aid

vitamin means a vitamin specified in regulation 19 or any salt or derivative of the vitamin

(1) In these regulations, the symbols specified in the first column of the following table have the meanings specified in relation to those symbols in the second column of the table:

Symbol	Meaning
g or gm	grams
IU	international unit
mcg or ug	micrograms
Mg	milligrams

ML	millilitres
Mm	millimetres
Ppm	parts per million

(2) In these regulations, unless the context otherwise requires, all references to proportions (whether as percentages, parts per million, or otherwise) are references to proportions by weight in a nutritional supplement as sold.

(3) Nothing in these regulations prohibits the use of any symbol the style of which conforms with a specimen in the table to subclause (1), or with the conventional usage of metric measurements.

4 Meaning of nutritional supplement

(1) In these regulations, unless the context otherwise requires, **nutritional supplement**—

(a) means a substance that is—

(i) intended to be consumed for its nutritional value in the maintenance and improvement of normal physiology and the promotion of optimal human health, and

(ii) sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders, or tablets; but

(b) does not include anything that is presented in a form for use as food or drink for human beings to satisfy hunger or thirst.

(2) The following substances are examples of ingredients used in nutritional supplements:

a. amino acids
b. animal or botanical extracts and derivatives
c. antioxidants
d. biotherapeutics
e. co-factors
f. dietary phytoprotectants
g. edible substances
h. enzymes and co-enzymes
i. fatty acids
j. foodstuffs,
k. herbs or other botanicals
l. minerals
m. probiotics,
n. synthetic nutrients and vitamins
o. vitamins
p. any ingredient permitted in the current New Zealand Food Standards.

(3) Nutritional supplements are also commonly referred to as dietary supplements or food supplements.

General requirements

5 Maximum daily doses

Every nutritional supplement described as or containing minerals or vitamins specified in the first column of the following table must be manufactured so that each daily dosage (for an adult) does not contain more than the maximum specified in the second column of the table:

Nutritional supplement	Maximum daily dose (for adult)
Minerals:	
Copper	5 mg
Iron	24 mg
Selenium	200 mcg
Zinc	15 mg
Vitamins:	
Vitamin A or retinol	3000 mcg
Niacin (and salts) or nicotinic acid (and salts)	100mg
Vitamin D	25 mcg
Folic acid	1000 mcg

6 Nutritional supplements not to be sold unless properly labelled

A person must not sell any package or container containing a nutritional supplement, or a nutritional supplement contained in a package or container, if the package or container—

(a) does not bear a label containing all the details required by these regulations to be contained on a label relating to the package or container; or

(b) bears a label containing anything that is prohibited by these regulations from appearing on a label relating to the package or container; or

(c) bears a label containing any particulars that are not in the position, manner, and style required by these regulations in respect of a label relating to the package or container.

7 Labelling of nutritional supplements: general requirements

(1) Every package and container containing a nutritional supplement must, unless otherwise provided in these regulations, bear a label that includes the following:

(a) a bar code

(b) the common name of the nutritional supplement, or a description (other than the brand name of the nutritional supplement) sufficient to indicate the true nature of the nutritional supplement, or a description of the nutritional supplement including the common names of its principal ingredients

(c) 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 nutritional supplement concerned

(d) the trading name and business address of the manufacturer or seller or packer of the nutritional supplement, or of the owner of the rights of manufacture, or of the principal or the agent of any of them
(e) a consumer information panel that complies with regulation 13:
(f) a batch number
(g) an expiry date, being an expression in one of the following forms
(i) use by (followed by a date); or
(ii) not to be consumed after (followed by a date); or
(iii) words of similar meaning (followed by a date);—
(h) a statement of the daily dosage (for an adult and or child if applicable) both as to quantity and frequency.
(i) a warning or advisory statement in any case if a danger exists if an overdose is taken or product is misused:
(j) the method of preparation before use (if necessary).

(2) For the purposes of subclause (1)(d),—
(a) an address not being a telegraphic or code address or an address at a Post Office, must be given.
(b) the name and address of a business that is not ordinarily resident in New Zealand is not enough unless the nutritional supplement is wholly manufactured and packed outside New Zealand:
(c) if 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 nutritional supplement is actually manufactured or packed by the body corporate must be given as the address.

8 Nutritional supplements packed in blister or strip packaging

Despite regulation 6(a), if nutritional supplements are packed in blister or strip packaging, the packaging must be labelled with a minimum of—
(a) the product name; and
(b) a batch number.

9 When transparent coverings exempt from labelling requirements

If a package or container of a nutritional supplement is enclosed or wrapped in a transparent covering and the details with which that package or container is required to be labelled are clearly visible through that covering, that covering is exempt from the labelling requirements under these regulations.

10 Nutritional supplement labels not to be removed or altered

A person who has in that person's possession any package or container of a nutritional supplement intended for sale by retail must not—
(a) remove any label required by these regulations to be on the package or container; or
(b) alter, erase, obliterate, or obscure any word or statement borne on such a label in accordance with any of the requirements of these regulations.

11 Form and manner of labelling

(1) Every word or statement that is required by these regulations to be borne on a label must—

(a) 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

(b) be conspicuously printed and, for each statement separately required, be in uniform colour contrasting strongly with a uniform background; and

(c) be presented with continuity.

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

12 Principal display panel

(1) The details that are required by regulation 6(1)(a), and (b), to appear on a label must appear in the principal display panel.

(2) Every word or statement that is required by these regulations to appear in the principal display panel of a label must be in lines that are generally parallel to the base on which the package or container rests as it is designed to be displayed.

(3) In the case of a cylindrical package or container, the width of the principal display panel on the cylindrical surface should not exceed one-third of the circumference of the package or container.

13 Consumer information panel

(1) The following information, when required by these regulations must be on the label:

(a) the statement of ingredients, which must show—

(i) the quantities or proportions of the claimed active ingredients in the package or container or in each dosage unit, or, if the nutritional supplement is divided into a number of units, the quantity or proportion of the claimed active ingredients in each unit; and

(ii) the inactive ingredients in the package or container, which must be described either by their specific names or by any of their permitted class names or numbers:

(b) the storage instructions.

(2) The consumer information panel may be any part of the label, but must—

(a) be conspicuously placed in relation to other information included on the label; and

(b) be clearly differentiated from all other promotional material or illustrations.

Specific requirements

14 Tabletting aids

The following tabletting aids or encapsulating or processing aids, and any other food conditioners specified in the Food Regulations 1984 or the New Zealand Food Standards, may be added to nutritional supplements:

(a) alginic acid and its derivatives
(b) beeswax
(c) bone meal (sterilised); calcium phosphate
(d) carbohydrate sweeteners
(e) carnauba wax
(f) cellulose and its derivatives
(g) coating pigments
(h) enteric coatings
(i) gelatin
(j) gelatin capsule shells
(k) lactose
(l) lecithin
(m) light mineral oils
(n) monoglycerides, diglycerides, and triglycerides from edible oils and fats:
(o) montan ester wax
(p) pectins
(q) polyethylene glycols
(r) polyvinylpyrrolidone and its derivatives
(s) shellac
(t) silicic acid and its salts
(u) starch
(v) starches (modified)
(w) stearic acid and its salts
(x) talc (sterilised)
(y) vegetable gums
(z) vegetable oils, and hydrogenated vegetable oils
(za) xanthan gum
(zb) zein corn protein.

15 Preservatives

Nutritional supplements may, in addition to any preservatives permitted by the Food Regulations 1984 or the New Zealand Food Standards, contain any of the following preservatives:

(a) benzoic acid or sodium benzoate:
(b) parahydroxybenzoic acid and its esters:
(c) sorbic acid, or its sodium, calcium, or potassium salts:
(d) sulphur dioxide, or sulphites calculated as sulphur dioxide.

16 Antioxidants

Nutritional supplements may, in addition to any antioxidants permitted by the Foods Regulations 1984 or the New Zealand Food Standards, contain any of the following antioxidants:

(a) propyl gallate, dodecyl gallate, octyl gallate, butylated hydroxyanisole (BHA), butylated hydroxytoluene (BHT), and tertiary butylhydroquinone

(TBHQ), where the proportion of those antioxidants, singly or in combination, does not exceed 100ppm:

(b) ascorbyl palmitate, and ascorbyl stearate, where the proportion of those antioxidants, singly or in combination, does not exceed 500ppm:

(c) natural tocopherols, synthetic tocopherols, citric acid, and sodium citrate:

(d) isopropyl citrate mixture, monoglyceride citrate, and phosphoric acid, where the proportion of those antioxidants, whether singly or in combination, does not exceed 100ppm.

17 Colouring substances

Nutritional supplements may, in addition to any colouring substances permitted by the Food Regulations 1984 or the New Zealand Food Standards, contain any of the colouring substances (and, if appropriate, their aluminium lakes) specified in the following table:

Common Name	Index Name	Index Number
Allura Red AC	CI Food Red 17	16035
Aluminium		77000
Amaranth	CI Food Red 9	16185
Annatto extracts (bixin, norbixin)	CI Natural Orange 4	75120 40800
Anthocyanins		
Beet red (betanin)	CI Food Orange 5	
B-carotene	CI Food Orange 6	40820
B-apo-8'-carotenol		40825
B-apo-8'-carotenoic acid,	CI Food Orange 7	
and its ethyl	CI Food Black 1	28440
And methyl esters	CI Food Blue 2	42090
Brilliant Black PN	CI Food Brown 3	20285
Brilliant Blue FCF	CI Food Orange 8	40850
Brown HT		14720
Canthaxanthin	CI Food Red 3	
Caramel	CI Natural Green 3	75810
Carmoisine (azorubine)		75470
Chlorophyll		
Chlorophyll copper complex		
Chlorophyllin copper	CI Natural Red 4	
complex,	CI Food Red 14	45430
potassium and sodium salts	CI Food Green 3	42053
Cochineal (carminic acid)		77480
Erythrosine		44090
Fast Green FCF	CI Food Green 4	
Gold	CI Food Blue 1	73015
Grape skin extracts	CI Pigment Red 101&102	77491
Green S	CI Pigment Yellow 42&43	77495
Indigotine (indigo carmine)	CI Pigment Black 11	77499
Iron oxides and hydrated iron oxides		16255

	CI Food Red 7	75100
Paprika (paprika oleoresin) (capsanthin and capsorubin)	CI Natural Yellow 6 & 19	77820
Ponceau 4R	CI Food Yellow 3	15985
Riboflavin (lactoflavin)	CI Food Yellow 4	19140
Riboflavin-5-phosphate		77891
Saffron (crocin, crocetin)	CI Natural Yellow 3	75300
Silver	CI Natural Yellow 27	75135
Sunset Yellow FCF		
Tartrazine		
Titanium dioxide		
Turmeric (curcumin)		
Xanthophylls		

Note - The index numbers specified in the third column of this table are the numbers allotted in the current edition of the Colour Index published jointly by the Society of Dyers and Colourists of the United Kingdom and the Association of Textile Chemists and Colorists of the United States of America.

18 Artificial sweeteners and flavouring substances

Nutritional supplements may contain any artificial sweeteners and flavouring substances permitted by the Food Regulations 1984 or the New Zealand Food Standards.

19 Vitamins

(1) The vitamin specified in the first column of the following table must be calculated in accordance with the second column of that table:

Vitamins	Calculated as
Vitamin A or retinol	retinol in mcg or IU
Vitamin B1 or thiamine	thiamine in mg
Vitamin B2 or riboflavin	riboflavine in mg
Niacin or nicotinic acid	niacin equivalents in mg
Pantothenic acid	pantothenic acid in mg
Vitamin B6 or pyridoxine	pyridoxine in mg
Vitamin B12 or cyanocobalamin, or hydroxycobalamin	vitamin B12 in mcg
Vitamin C or ascorbic acid	ascorbic acid in mg
Vitamin D or calciferol	calciferol in mcg
Vitamin D or cholecalciferol	cholecalciferol in mcg
Vitamin E	vitamin E in mg or IU
Biotin	biotin in mcg
Vitamin K	vitamin K in mcg
Vitamin K1 or phytomenadione	vitamin K1 in mcg
Vitamin K or menaphthone	vitamin K in mcg
Folic acid	folic acid in mcg

(2) There may be marked on any package or container containing a nutritional supplement, described as or containing a vitamin, a statement indicating—

(a) the presence of vitamins; and

(b) the quantity, calculated in accordance with the table to subclause (1) that vitamin in each dosage unit, or daily dosage, if the nutritional supplement is divided into a number of units, the quantity of that vitamin in each unit.

20 Minerals

(1) Nutritional supplements may, in addition to any mineral substances permitted by the Food Regulations 1984 or the New Zealand Food Standards, contain any of the following minerals:

(a) boron
(b) calcium
(c) chlorine
(d) chromium
(e) copper
(f) fluorine
(g) iodine
(h) iron
(i) magnesium
(j) manganese
(k) molybdenum
(l) phosphorus
(m) potassium
(n) selenium
(o) silver
(p) sodium
(q) vanadium
(r) zinc.

(2) There may be marked on any package or container containing a nutritional supplement described as or containing a mineral, a statement indicating—

(a) the presence of minerals; and

(b) the quantity of that mineral in that package or container or in each dosage unit, or, where the nutritional supplement is divided into a number of units, the quantity of that mineral in each unit and expressed as the element.

21 Enzymes

The following enzymes and any enzymes permitted by the Food Regulations 1984 or the New Zealand Food Standards may be added to nutritional supplements:

(a) amylase and protease derived from Aspergillus flavus oryzae or Aspergillus niger
(b) bromelin
(c) ficin
(d) invertase
(e) papain
(f) pectinase
(g) pepsin

(h) rennet and protein—coagulating enzymes
(i) lactase
(j) lipase.

22 Advisory statement

(1) Nutritional supplements containing the bee product royal jelly shall contain an advisory statement with the following or similar wording:

"Royal jelly may cause serious allergic reactions. Most reports have been in asthma sufferers."

Miscellaneous

23 Offences and penalties

(1) Every person who fails to comply with any of regulations 5, 6, 10, 15 to, 18, and 19(1) commits an offence against these regulations.

(2) Every person who commits an offence against these regulations is liable to a fine not exceeding $500, and, in the case of a continuing offence, to a further fine not exceeding $50 for every day on which the offence has continued.

24 Revocation of Dietary Supplements Regulations 1985

The Dietary Supplements Regulations 1985 (SR 1985/208) are revoked.

Clerk of the Executive Council.

Explanatory note

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations, which come into force on [*date*], replace the Dietary Supplements Regulations 1985 ("former regulations").

These regulations, in a sense, fill the gap between the Food Regulations 1984 and the Medicines Regulations 1984, in that nutritional supplements are not "food" or "medicine" in the ordinary sense of those words.

The new definition of nutritional supplement, which takes account of new technologies and knowledge since the former regulations, makes it clear that nutritional supplements—

- Are intended to be consumed for their nutritional value in the maintenance and improvement of optimal human health; but
- are not intended to be used or represented for use as food or drink for human beings in the sense that they satisfy hunger or thirst.

Nutritional supplements will be "related products" within the meaning of the Medicines Act 1981 if therapeutic claims are made for them. However, in a companion measure to these regulations such nutritional supplements will be exempted from being classified as related products.

These regulations carry over and update from the former regulations many of the general requirements relating to—

- the manufacture, labelling, and advertising of nutritional supplements, and follow broadly the equivalent provisions of Part 1 of the Food Regulations 1984; and
- food additive standards in respect of certain classes of nutritional supplements.

Medicines (Related Products (Exempted Nutritional Supplements)) Regulations 2003

Governor-General

Order in Council

At Wellington this day of 2003

Present:
Her Excellency the Governor-General in Council

Pursuant to sections 94(1)(b) and 105 of the Medicines Act 1981, Her Excellency the Governor-General, acting on the advice of the Minister of Health tendered after consultation with the organisations and bodies that appeared to the Minister to be representative of persons likely to be substantially affected, and on the advice and with the consent of the Executive Council, makes the following regulations.

Contents

Regulations

1 Title
These regulations are the Medicines (Related Products (Exempted Nutritional Supplements)) Regulations 2003.

2 Commencement
These regulations come into force on [*date*].

3 Expiry
These regulations expire with the close of [*date*].

4 Nutritional supplements not related products
Every nutritional supplement within the meaning of regulation 4 of the Nutritional Supplements Regulations 2003 is not a related product for the purposes of the Medicines Act 1981.

Clerk of the Executive Council.

Explanatory note

023310250

This note is not part of the regulations, but is intended to indicate their general effect.

These regulations come into force on [*date*] and expire with the close of [*date*].

Regulation 4 provides that every nutritional supplement within the meaning of regulation 4 of the Nutritional Supplements Regulations 2003 is not a related product for the purposes of the Medicines Act 1981. Under section 94(1) of that Act, food in respect of which a claim is made that the food is effective for a therapeutic purpose would, unless it is declared by regulations not to be a related product, normally be caught by that definition.

In the interim, these regulations, along with their companion measure the Nutritional Supplements Regulations 2003 are intended to help fill the gap between the food and medicines regimes, in that nutritional supplements are not "food" or "medicine" in the ordinary sense of those words.

Issued under the authority of the Acts and Regulations Publication Act 1989.
Date of notification in *Gazette*: [*date*].
These regulations are administered in the Ministry of Health.

Appendix 5:
Assumptions underlying case studies in section 6

The costs estimated in section 6 above are based on the following assumptions.

- The cost estimates are based on the procedures proposed in the 2002 Discussion Paper on the proposed JTGA.
- In the absence of evidence to the contrary in the Discussion Paper, compliance costs are based on the existing Australian Regulatory System.
- In the absence of evidence to the contrary in the Discussion Paper, it is assumed that the current Australian fees would continue for the relevant processes as per http://www.health.gov.au/tga/docs/pdf/fees02.pdf.
- It is assumed that the current low-volume discount available in Australia will continue. In fact, however, it is not mentioned in the Discussion Document and we are aware of moves to end this discount.
- The exchange rate is assumed to be 0.89c (as per November 21, 2002).
- As for labelling, it is assumed that:
    - Based on the Discussion Paper, specific Australasian Product Licence numbers will be required to be printed on each product.
    - Based on existing TGA requirements, more extensive relabelling will be required such prescriptive names of botanicals and plant parts.
- The cost of relabelling is assumed to be $1500 per label. This is supported by UK estimates on the order of £300 - £500 per product, and industry estimates of $2500 per product to meet the relabelling requirements of the new FSANZ Food Code
- As for reformulations, it is assumed that:
    - the cost of reformulation is $10,000 per product, based on a UK government estimate of £3000 per product.
    - A 10% to 15% rate for required reformulations. Actual experience in Australia suggests that an average of 10% to 15% of all products requiring reformulation is a conservative estimate.
- It is assumed that most firms will retain a regulatory consultant, as is typical practice in equivalent Australian firms. Consultants commonly cost in the order of $250 per hour plus an annual retainer of approximately $6,000.
- It is assumed that most firms will hire an in-house regulatory affairs/compliance officer. This is typical in Australia. As per normal business practice, w assume that overhead costs for an in-house regulatory affairs/compliance officer are approximately equal to salary.

- The following standardised costs have been used in this assessment (based on existing Australian fees, converted to New Zealand dollars.

Listed medicine application fee	$NZ515
Listed medicine annual charge	435
GMP – Annual licence charge	4,460
Overseas GMP audit per hour	940
Low volume Application for Declaration	80
Advertising approval	145
New ingredient applications	Initial new ingredient TGA application fees start at $NZ5,470 for an application up to 50 pages and ranges up to $34,000 for applications > 3,000 pages (which would be rare.) This does not include assessment of clinical or toxicological data which are the same again. Nor does it include tome, and consultant costs in preparing the submission. UK figures are provided as a UK government estimate of total industry costs.

Appendix 6:
Acts and Regulations covering CHTPs in New Zealand

The Acts, regulations and codes of practice relevant to Complementary Healthcare Products in New Zealand include:

(1) Advertising Standards Association Advertising Codes of Practice/TAAS

(2) Agricultural Compounds and Veterinary Medicines Act 1997

(3) Animal Products Act 1999

(4) Bill of Rights

(5) Code of Good Manufacturing Practice

(6) Commerce Act 1986

(7) Companies Act 1993

(8) Consumer Guarantees Act 1993

(9) Dairy Industry Act 1952

(10) Dietary Supplement Regulations 1985

(11) Fair Trading Act 1986

(12) Food Act 1981

(13) Food Hygiene Regulations 1974

(14) Food Regulations 1984

(15) Hazardous Substances and New Organisms Act 1996

(16) Health and Safety in Employment Act 1992

(17) Meat Act 1981

(18) Medicines (Related Products (Exempted Foods)) Regulations 2002

(19) Medicines Act 1981

(20) Medicines Regulations 1984

(21) New Zealand Food Standard 2001

(22) NZ/AS Standards / Codes of Practice

(23) Sale of Goods Act 1908

(24) Weights and Measures Act 1987

(25) Weights and Measures Regulations 1999