

Submissions regarding:

1. Review of Cost Recovery By Commonwealth Agencies

Australian Productivity Commission

2. Review of Sovereignty Issues relating to International Treaties

New Zealand Parliament's Regulations Review Committee Inquiry

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Executive Summary

It is noted that people are named and strong statements are made regarding officials and their advisors.

- Every statement can be substantiated either through direct written evidence on record or by several witnesses being party to conversations. We will only be too willing to provide copies of documents if required.
- In short, the New Zealand dietary supplement industry requests that trans-Tasman Harmonisation means exactly that, not trans-Tasman Australianisation.
- We also show unequivocal evidence that TGA is an inappropriate body to regulate exceedingly safe complementary healthcare products.
- We provide unequivocal evidence that TGA's existing regime is an unnecessary financial burden on industry.
- We provide unequivocal evidence that officials cannot be trusted.

Australian Therapeutic Goods Administration

1. This submission provides an industry perspective of the expensive and inappropriate system used to regulate complementary healthcare products in Australia.¹
2. The New Zealand complementary healthcare industry has declared its total opposition to the Australian Therapeutic Goods Administration model being imposed on New Zealand as part of the Trans-Tasman Australianisation process. We have formally conveyed that rejection of the Australian system to officials in both Australia and New Zealand.
3. Documents received under the Official Information Act from the Deputy Prime Minister of New Zealand give industry further reasons

¹ For the purposes of this submission, complementary healthcare products, dietary supplements and complementary medicines are synonyms.

for grave concern. Papers submitted to a New Zealand Parliamentary Select Committee titled, 'Sally Mansell, Select Committee Estimates: Selected notes on output class D1' state,

- a. "A trans-Tasman officials group met first in August 1999 to identify and evaluate options for partial or full harmonisation. Subsequent work identified the Australian TGA as the preferred model for the achievement of full harmonisation."
 - b. "Summary, Officials have proposed to New Zealand and Australian Health Minister the adoption of the Australian Therapeutic Goods Administration as a cost effective model for the achievement of trans-Tasman harmonisation of pharmaceuticals and related therapeutic products."
 - At least six officials have continually denied to industry representatives that TGA was the preferred model. These officials are, Susan Martindale, Bob Boyd, Geoff Sanderson, Stewart Jessamine, (NZ) and Graham Peachey and Susan Adler (Aus).
 - At a TTH meeting of industry and government officials in Sydney in July every one was assured that the model proposed (and rejected by industry) was not a TGA takeover but a new entity.
 - Graham Peachey and Susan Adler stated vigorously that the new model would be a new model and that industry had no reason to be concerned.
4. Industry on both sides of the Tasman has and will continue to vigorously oppose a TGA takeover. As detailed in this submission, a pharmaceutical/poisons paradigm, whilst appropriate for unsafe drugs and poisons, is totally inappropriate for safe dietary supplements.
 5. In the past decade more than 100,000 Australasians have been killed by properly researched, properly regulated, properly prescribed and properly used drugs.

- a. There is one disputed death on record regarding dietary supplement use in Australasia over the past decade.
6. This means that dietary supplements have a proven safety profile approximately 100,000 times safer than drugs providing irrefutable proof that a different paradigm is required for regulating them.
7. For comparison, there have been more than 200 deaths from horse riding, 800 deaths from farm accidents, 4,000 deaths from eating food during the past decade.
 - a. Dietary supplements are considerably safer than food.
8. To give a scale of the difference in safety profile, there have been more than 240,000 deaths from preventable medical error and properly researched, properly regulated, properly prescribed and properly used drugs in Australasia during the past decade.
 - a. Based on economic models used by all government departments, that equates to an economic impact of more than \$100 billion dollars.
 - b. Officials never include such figures in their briefing papers to ministers.
 - c. It has been calculated that economic savings in New Zealand alone, made by reducing that fatality rate by 50% over a decade and continuing it for another decade would pay for the New Zealand government's proposed superannuation fund. It equates to \$25 billion in savings in New Zealand alone.
9. 240,000 citizens are equivalent to a city the size of Christchurch being killed by preventable medical error and properly researched, properly regulated, properly prescribed and properly used drugs in Australasia during the past decade.
10. A further 600,000 citizens of Australasia have been permanently maimed by preventable medical error and properly researched, properly regulated, properly prescribed and properly used drugs in Australasia during the past decade.

11. All told, that's a city the size of Auckland either killed or permanently maimed by preventable medical error and properly researched, properly regulated, properly prescribed and properly used drugs in Australasia during the past decade.
12. Official records only acknowledge 0.3 of 1% of these deaths in New Zealand and 0.6 of 1% in Australia.
13. In comparison, there has been one disputed death in Australasia due to complementary healthcare products.
14. Despite the 100,000 times riskier profile of drugs, TGA spends between 10% and 20% (Senator Tambling's estimate) of its resources regulating complementary healthcare products.
15. A Good Regulatory Practice warrant of fitness was undertaken on TGA; it failed on 20 out of 28 checks, passing only on three (on five points the jury is still out.)
16. It is industries contention that TGA is nothing more than an attempt by narrow-minded officials and their medical advisers to try and restrict the public's access to and to reduce their confidence in complementary healthcare products.
17. If the TGA system were imposed on New Zealand, many very small businesses would simply be forced off the market due to exorbitant compliance costs.
18. We beg the Australian Productivity Commission to help free industry from the clutches of the Australian Therapeutic Goods Administration. The present system has nothing to do with regulating a billion dollar industry based on good regulatory practice.
19. We beg the New Zealand Parliamentary Regulations Review Committee to ensure that trans-Tasman Harmonisation is simply that, not trans-Tasman Australianisation.

Australia New Zealand Foods Administration

20. ANZFA has become another millstone around the neck of the complementary healthcare industry.
21. The folic acid health claim pilot trial is a cruel hoax on the citizens of Australasia and a deliberate attempt to prevent the dietary supplement industry in New Zealand from making legitimate health claims.
22. Papers obtained under the Official Information Act reveal that the Ministry of Health, uses the excuse that dietary supplements are not made under GMP to establish policy regarding folic acid use in the prevention of spina bifida. In fact most product is made under GMP! Voluntarily, in New Zealand.
 - a. ANZFA has confirmed that foods making health claims regarding folic acid do not have to be made under GMP (Email on file.)
 - b. Breakfast cereal such as cornflakes are able to make health claims with as little as 10% of the folic acid content known to significantly reduce the risk of spina bifida – nearly all of the scientific research has been done using dietary supplements, yet they are prevented, by law, from making legitimate and scientifically proven health claims.
23. The when looking at regulatory costs, the Productivity Commission is asked to look at the costs to society of unfair and scientifically indefensible government policy.
24. When looking at regulatory process, the NZ Parliamentary Select Committee is asked to consider means to enforce good regulatory practice.
 - a. Industry proposes a Good Regulatory Practice Warrant of Fitness, a comprehensive checklist that bureaucrats have to sign off before promoting regulatory changes.
25. The successful complaint against Amendment no 11, Foods Regulations, 1996, provides ample evidence of the bullying by

ANZFA on the New Zealand Ministry of Health to impose unfair and scientifically indefensible regulations on bee products.

- a. Industry brings to the attention of the Regulations Review Select Committee that despite its recommendations 17 months ago that the regulations be revoked, and despite the minister of Health's independent scientific review being completed 12 months ago, ANZFA still has not made the fair and scientifically defensible changes.
 - b. Neither has the New Zealand Ministry of Health.
 - c. The NZ MOH says that it has to wait for ANZFA to move.
 - d. This provides further chilling evidence of the bullying and inappropriate behaviour of the Australian body, ANZFA to a sovereign nation, New Zealand.
26. Officials have told NNFA that the clause in the ANZFA act to allow New Zealand to opt out of any Trans-Tasman decision will never be invoked as no official will want to create the precedent.
- This makes an absolute mockery of any sense of good regulatory practice.
 - Terry Slater (General Manager of TGA) was told in writing in August 1997 (on file along with written acknowledgement and response) that scientific misconduct surrounded evidence used to discredit royal jelly.
 - In May 1999 the President of NNFA and its Executive Director spent 2½ hours with Senator Tambling, Terry Slater and Ian Lindenmayer (GM of ANZFA) in Wellington (at their request). Nearly all of the discussion revolved around the scientific misconduct and false evidence used by TGA and ANZFA to discredit royal jelly.
 - In August 1999, the President and Executive Director of NNFA presented copies of before and after documents to Graham Peachey and Fiona Cumming (TGA) proving that TGA had altered official records to make them fit a fraudulent scientific paper.

- In October 1999 Fiona Cumming wrote that it was normal practice to update files in light of new evidence.
- In June 2000 TGA wrote denying any knowledge of the scientific misconduct.
- ANZFA's expert committee on food allergies presented ANZFA with a report that contained grossly false science and zero scientific evidence to support its position on royal jelly and bee pollen.
- It can be seen as nothing more than a vindictive attempt by one member of the panel to discredit the complementary healthcare industry.
- This same member of the expert panel went on to give false evidence to a coroner's inquest and legitimise evidence from a witness that the coroner went to some length to declare a most unreliable witness.

Royal Jellygate

27. The royal jellygate debacle has cost industry on both sides of the Tasman immeasurably.
 - a. It has been conservatively estimated that Australian industry lost **\$30 million in sales in the two years following the public outrage** fuelled by ill-informed advisors and officials keen to get this 'dangerous product' off the market.
 - b. Lost opportunity would account for much more.
 - c. One New Zealand company, despite already having voluntary warning labels on their products, was forced to spend more than \$100,000 in relabelling and duplication of product line in warehouse to comply with different markets.
 - d. Within days of the June 1997 coroner's report being released, TGA disseminated a damning report on royal jelly world wide resulting in royal jelly being banned as a food in Germany.
 - e. Within weeks TGA had a report stating that the coroner's findings were wrong in fact.

f. It was some eight months before that report was released to industry, by which time the damage had been done.

- Given the circumstances surrounding the whole royal jelly affair, industry insists on a formal independent inquiry to ascertain the truth about not only the science, but also the political agenda used by the scientific and medical communities, ably supported and abetted by TGA and ANZFA officials, to discredit the complementary healthcare industry.
- Such an inquiry will find that two coroners were lead to wrong conclusions regarding cause of death.
- Such an inquiry will expose the woeful quality of evidence, much of which was false, falsified and even fabricated, used to impugn the good name of royal jelly.
- Such an inquiry will reveal that fabricated data still sits in altered official reports in TGA's files.

Introduction

This submission provides first hand experience regarding issues being examined by both the New Zealand Parliament's Regulations Review Select Committee and the Australian Productivity Commission.

Due to resource constraints, not all issues raised in the executive summary are included in the body of the report.

The New Zealand and Australian economies are increasingly being harmonised through the Australia New Zealand Closer Economic Trade Agreement and more recently the Trans-Tasman Harmonisation Agreement. In theory, therapeutic goods and dietary supplements are two of very few areas exempt from the provisions of TTH. We say in theory, because despite express exemptions, bureaucrats have proceeded with the harmonisation process and continually ignored not only the many concerns of Industry on both sides of the Tasman, but they have also blatantly ignored viable options presented by industry at formal liaison meetings. These issues will be addressed further.

Australia prides itself on being the initiator of the Asia Pacific Economic Co-operation (APEC) and rightly so. This initiative, which now involves 21 Asia Pacific economies, has achieved a great deal in providing a forum to facilitate the reduction of tariffs, the opening up of markets and reducing the costs of doing business under individual actions plans (IAPs) and APEC's collective action plan (CAP).

This submission focuses around the concept of Good Regulatory Practice espoused by both Australian and New Zealand governments. Indeed, both governments have taken a lead role in APEC developing a Collective Action Plan (CAP) upon which Individual nations develop their own Individual Action Plans (IAP) relating to good regulatory practice

It's worth quoting from a paper presented to the 2nd APEC conference on Standards and Conformance in 1998;²

"Good Regulatory Practice

The *Guidelines* provide a foundation for member economies to develop a common understanding of the principles of Good Regulatory Practice. However, they go only so far.

The draft *Guide for Good Regulatory Practice*³ developed for the consideration of SCSC by Australia provides a practical application of the principles contained in the *Guidelines*. Promoting similar approaches to regulatory management within APEC would be another step towards reducing technical and/or regulatory barriers to trade within the region....

However, the application to MRAs is only one aspect of the benefits from good regulatory practice. Its underlying objective within SCSC is to reduce regulatory impediments in all areas of conformity assessment through the development of common practices between member economies. This, perhaps, is the key challenge for SCSC.

...

Going Forward

The performance of economies is shaped by the quality of their regulatory environments. Economies that foster competition, create certainty in the business environment, and impose low regulatory costs on business will prosper. Successful businesses are increasingly operating on a global basis, looking to source inputs, attract investments, and service markets in different parts of the globe. Globalisation means that the economic performance of any one economy will be increasingly affected by the quality of the regulatory environment of those with which that economy has economic links. Co-ordination is critical."

² http://www.med.govt.nz/buslt/reg_man/apec_regulatory.html

³ <http://www.isr.gov.au/industry/tbt/apec/grpguide4.pdf>

- The complementary healthcare industry on both sides of the Tasman is proactively supporting the above concept.
- It is clearly evident from industry's experience over the past several years that Australia's Therapeutic Goods Administration is out of step with official government policy.
- TGA simply does not apply good regulatory practice.

The Australian department of industry, sciences, and resources operates under the slogan of "Competitive Australia."⁴ Under the heading, "Technical and Regulatory Barriers to Trade" it exclaims its vision and objectives as...

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"Our Vision

Improving the prosperity of Australia through optimising the trading environment. We do this by removing technical barriers to trade thus making markets bigger, reducing costs and reducing complexity. This should increase the competitiveness of Australian industries and encourage innovation.

Objectives

To contribute to the long-term competitiveness of Australian industry through helping to ensure that the domestic standards and conformance infrastructure is efficient and effective, able to respond to the changing needs of industry and the community, and able to meet the challenges of the changing international environment.

To improve market access for Australian industry through the breaking down of technical barriers to trade and facilitation of international trade. For example, through the promotion, development and implementation of mutual recognition agreements, alignment of standards and good regulatory practices."

⁴ <http://www.isr.gov.au/>

⁵ <http://www.isr.gov.au/industry/tbt/index.html>

- It is industry's view that TGA perpetrates an extremely effective technical and regulatory barrier to trade; not only from an international perspective such as relating to trans-Tasman trade, but also internally.

The vision is to improve the prosperity of Australia through optimising the trading environment. The means to achieve this is through removing technical barriers to trade thus making markets bigger, reducing costs and reducing complexity.

Fact: Medium sized New Zealand companies are only able to afford to market about 20% of their product range due to TGA direct cost and related costs.

For example: It costs approximately \$450 to list a product with TGA, even if there are a hundred identical products already on the market. Consultancy costs required to prepare documentation cost a minimum of \$500 and can easily be \$2-3,000 if there are any questions raised by TGA officials. Even allowing for these costs (say \$1,000 per product) it would cost a New Zealand company with a modest product range of, say, 200 products, would be required to spend \$200,000 every year as an entry fee to the Australian market. No such costs apply in New Zealand.

Fact: Many small suppliers in New Zealand are importers with several product ranges. New Hope Nutrition has over 1,000 individual products. If the TGA system was to be imposed on New Zealand as has been recommended to the New Zealand government⁶ they would be required to pay the absurd amount of nearly \$1,000,000 per year. TGA will say that they very graciously only apply a 'minimal' fee of \$75 for low volume products – that would still be a \$75,000 entrance fee to the market place every year. If, as TGA say, such a reduced fee is reduced to 'facilitate entry to the Australian market' and TGA is nearly fully funded through compulsory industry fees then TGA is enforcing a cross subsidisation through charging larger companies more than cost.

⁶ NZ Parliamentary Select Committee briefing papers obtained under the official information act from the NZ Ministry of Economic Development

Fact: Large complementary healthcare companies that operate internationally are only able to afford to market a small portion of their product range due to TGA direct costs and related expenses. Solgar has only just (October 2000) launched a very limited product range into Australia. It took them two years of preparation and Solgar has only been able to commence business with twenty products from an extensive range. Solgar has a full range of extremely high quality product on the New Zealand market due no technical barriers to trade.

- If free trade has been established as a strategic goal for improving the prosperity of Australia through increasing competitiveness and optimising the trading environment then TGA has clearly failed to support such initiatives.

Fact: The new 'improved' advertising code has created a very expensive distortion in the market place. For example, TGA approves the use of the term 'cough' regarding the labelling of propolis. The new advertising code prohibits the use of the term 'cough' in the label unless there is scientific evidence to support such a claim. The scientific literature proves that propolis is very effective at reducing 'the symptoms' of upper respiratory infections, yet, because it does not specifically mention the most common symptom of upper respiratory infections, 'cough,' it is illegal to market a product as 'cough elixir' even though TGA approves of the name. How absurd. Cough is not a disease; it is a common symptom. At least one company has been forced to spend tens of thousands of dollars repackaging product to meet TGA's Neanderthal advertising paradigm.

Fact: It is a scientific fact that cranberry juice reduces the ability of bacteria to adhere to the lining of the urinary tract thus reducing the risk of urinary tract infection. TGA has deemed altering the physiology of a bacteria (and we are talking about a fruit juice here) as being a 'high level claim.' This means that if a company wants to state the truth about cranberry juice in Australia it must register a fruit juice with an incredibly long history of safe use as a pharmaceutical medicine at a cost of thousands of dollars. How absurd.

Fact: Industry in the Australian market spends at least 15% of profit on TGA fees and compliance – for what benefit?

Paradox: Given the technical barriers to trade that TGA imposes on the complementary healthcare industry in Australia, one would think that Australian industry would be delighted – not so. Australian industry is united in its voice against the expensive and restrictive TGA regime.

This opposition to the current TGA regime has been so strong that it has evoked a puzzling response from the Under Secretary for Health, Senator Tambling. Senator Tambling has written strong criticisms of Australian industry for daring to challenge his failed December 1998 reforms. The letter was sent to every supplier of complementary healthcare products in the Australian market.

In this letter, and an accompanying article written by Senator Tambling and to be published in the Natural Health Review, a trade magazine, Tambling states that industry should be pleased that we don't have to pay more, as TGA could have harvested more from industry if it had moved to full cost recovery. This will be discussed in another section.

The APEC Guide to Good Regulatory Practice “provides member economies with guidance for the adoption of efficient regulatory arrangements which should lead to reductions in technical barriers to trade and will assist member economies in meeting their international obligations under the WTO TBT Agreement and their commitment under the APEC Bogor Declaration.”⁷

- TGA's current regulatory practices inhibit both international trade and internal trade. It is estimated that more than three hundred small businesses have been forced out of business through TGA inappropriate regulatory regime.
- It would clearly decimate New Zealand's very small-business industry if imposed on New Zealand.

⁷ Page 3

Regulation commensurate with risk

The guide to Good Regulatory Practice notes that regulation should be commensurate with risk. Industry agrees with this. TGA would argue that their regulatory environment is risk based as it has two levels of regulation, one being a 'simple listing system' (AUST-L) and the other being a more detailed 'registering system' (AUST-R). Both of these are approval systems. Individual ingredients need to get onto the list in the first place, and then individual products using these 'approved' ingredients then have to get over the listing hurdle. New Zealand has two systems as well; one being a negative listing system, whereby restrictions are placed on deemed unsafe ingredients under food law, and a medicines classifications system.

- It is worth noting here that a fundamental and incompatible difference exists in the way that Australia and New Zealand view complementary healthcare products.
- In New Zealand they are deemed to be foods and are considered safe unless proven otherwise.
- In Australia they are deemed medicines and are considered unsafe unless proven otherwise.

Before we discuss the merits or otherwise of these two different systems we firstly need to quantify the risks that we are talking about.

Safety of complementary healthcare products.

There have been no deaths confirmed to be due to complementary healthcare products in either Australia or New Zealand, ever. In Australia there have been three deaths attributed to royal jelly by both the medical fraternity and TGA and ANZFA officials and advisors. An independent 5-person scientific review established by the New Zealand Minister of Health in 1999 discounted two of these deaths and the third death they found a 'strong association' between the use of royal jelly and the death but could not establish causality.

Despite TGA internal documents obtained under the official information act in New Zealand stating that it would be unfair and scientifically indefensible to pin the death on royal jelly, TGA officials still do! As recently as October

6th, 2000 at a meeting in Canberra between TGA and trans-Tasman industry officials, Dr John McEwen and Graham Peachey said that it would remain on official records as being linked to royal jelly – in other words, despite being found not guilty by their own internal inquiry, TGA officials still refuse to accept the verdict. The circumstances surrounding each of the deaths and the subsequent actions of officials and their advisors leaves industry with a heavy heart – each could be subject to a substantial report in their own right.

The third death, in Sydney at Xmas in 1995 provides a very chilling case study of the rabid attempts by both officials and advisers to discredit complementary healthcare products.

Clear evidence of false, falsified and even fabricated data has been known about for more than three years. Officials have been told of this on numerous occasions; correspondence with Terry Slater (on record) goes back to at least August 1997.

- Officials, including the general managers of TGA (Terry Slater) ANZFA (Ian Lindenmayer) and Senator Tambling were personally made aware of this at a meeting in Wellington in May 1999 by the Executive Director of NNFA (Ron Law) and the then President of NNFA (Warren Sanderson).

They and many of their officials had also been made aware via extensive correspondence (on file) as far back as August 1997, yet as of June 2000 senior officials at TGA were denying any knowledge of the concerns raised by industry. In fact, in a 9 page report dated June 2000 (on file) TGA justified the altering of adverse reaction reports to fit published data; unfortunately they reconciled 7 reports to a paper that has been formally discredited due to scientific misconduct, including fabrication of data and false declarations of authorship.

- This fabricated data still sits in TGA's records, despite Graham Peachey and Fiona Cumming having been handed, in person, copies of before and after documents in Auckland in August 1999.

In October, Fiona Cumming wrote to the NNFA (letter on file) justifying TGA's actions by saying, "it was normal practice to update files in light of new evidence."

- The paradox is that when incontrovertible evidence is presented that TGA records are wrong, they refuse to 'update the records in light of new evidence.'
- TGA have zero confirmed deaths relating to complementary healthcare products on record.

At the October 6th 2000 meeting in Canberra, Dr John McEwen said that TGA gets just over 100 adverse reaction reports to complementary healthcare products each year and about 13,000 adverse reaction reports to medicinal drugs. He acknowledged that most of the reports regarding complementary healthcare products were nebulous, but that the Adverse Drug Reactions Committee reviewed all of the complementary healthcare reports and 'very few of the 13,000 drug reports.' When asked why, he said, "We are very much on a steep learning curve regarding these products.' TGA believes that less than 1% of adverse drug reactions are actually reported.⁸ In 1995 TGA set a goal of 'near 100% reporting – they have clearly failed miserably.

- Based on TGA's own records, less than one percent of all adverse reaction reports are due to complementary healthcare products and most of those are of a nebulous nature such as a 'rash.'

TGA regulates an industry with a safety record second to none based on advice of officials who admit that they know very little about these

The Australian government has set nine specific outcomes for the Health and Aged Care Portfolio including, "Protection and promotion of the health of all Australians and minimisation of the incidence of preventable mortality, illness, injury and disability."⁹

⁸ <http://www.health.gov.au/tga/docs/html/atdb/num27/news.htm#fees>

⁹ http://www.health.gov.au/pubs/budget2000/part_b.htm#b2

- Preventable medical error and properly used drugs are well proven causes of morbidity and mortality.
- In Australia 14,000 people are killed each year by preventable medical error.
- As many as 50,000 Australian's suffer permanent disabilities.¹⁰

Simply being a patient in an acute care hospital in Australia carries, on average, a 200-fold greater risk of dying from the care process than being in traffic, and a 2000-fold greater risk than working in the chemical industry. These statistics do not include those killed in private practice, nor those deaths due to properly used drugs – these alone are estimated to account for a further 10,000 deaths.¹¹

In other words, 24,000 Australians are killed every year from preventable medical error, and properly researched, properly registered, properly prescribed and properly used drugs each year. That's 240,000 deaths during the past decade. The 100,000 deaths related to properly researched, properly registered, properly prescribed and properly used drugs that TGA overseas compares to zero deaths due to complementary healthcare products.

Even if there was one (royal jelly was regulated as a food at the time of the death associated with its use) that means that properly researched, properly registered, properly prescribed and properly used drugs administered by TGA are more than 100,000 times more dangerous than complementary healthcare products.

By comparison, during the past decade, there have been 85 farm injury deaths per year, 20 horse-riding deaths per year and 400 food related deaths per year.^{12,13}

¹⁰ <http://www.health.wa.gov.au/warm/Symposium/abstracts/runciman.htm>

¹¹ The author is a member of the New Zealand Ministry of Health's working group advising the Director General of Health on reporting of medical error.

¹² <http://www.worksafe.gov.au/publications/factsheets/farm.htm#1>

Iatrogenic injury is also very costly; at least 10% of admissions to acute-care hospitals in Australia are associated with a potentially preventable adverse event.

- Official estimates are that the total direct medical costs of these events exceeds \$2 billion per year and that the total life-time cost of such preventable injury exceeds \$6 billion per year;¹⁴
- There is also a heavy toll in human costs on both those who are harmed and those who care for them.
- Furthermore, medical misadventure consumes over half the amount spent on compensation and insurance by State Treasury Departments.¹⁵

In Australia, there were 126,692 deaths in 1994.¹⁶

- This means that 11% of deaths in Australia are due to preventable medical error (14,000/126,000).
- This doesn't take into account the 10,000 deaths calculated (from US data) due to properly used drugs nor does it include deaths due to preventable medical error in private hospitals and general practitioners.
- This means that approximately 19% of all deaths in Australia (1 in 5) are due to preventable medical error or properly used drugs.
- The humble 'safe' low-dose Aspirin is acknowledged as killing 1:1,200 consumers after 2 months use. It is accountable for approximately 50,000 deaths per year worldwide!¹⁷ That's nearly

¹³ <http://www.nisu.flinders.edu.au/pubs/bulletin24/bulletin24-Mortalit.html>

¹⁴ <http://www.health.wa.gov.au/warm/Symposium/abstracts/runciman.htm>

¹⁵ <http://www.health.wa.gov.au/warm/Symposium/abstracts/runciman.htm>

¹⁶ <http://www.abs.gov.au/Ausstats/ABS%40.nsf/94713ad445ff1425ca25682000192af2/21e6a46021338765ca2568a900154b00?OpenDocument>, Source: Australian Demographic Statistics (3101.0).

¹⁷ <http://www.bmj.com/cgi/content/full/321/7270/1183>

500,000 deaths from properly used Aspirin in the past decade alone
– and it's been on the market for 100 years as a 'low risk' drug!¹⁸

TGA, on the other hand, regulates the complementary healthcare industry to the point where it spends more than 10% of its total expenditure on an industry that simply does not register on any sort of risk Richter scale other than advisors and regulators trying to generate a perception of a problem.

- Proven risks associated with complementary healthcare products are orders of magnitude less than pharmaceutical drugs.
- This disparity between established risk and regulatory response is clear demonstration of iniquitous abuse of regulatory power.

To give some idea of the difference between perception and reality, a survey in the USA found that most citizens rated the relative safety of healthcare somewhere between food handling and the workplace. The reality is that preventable medical error and TGA's properly regulated and used drugs kill more citizens than all of the other categories combined!¹⁹

Perceived Safety of Various Environments

Environment	Mean Scores
Airline travel	5.2
Workplace	5.2
Health care	4.9
Food handling	4.4
Nuclear power	4.2

Scores: 7=Safe, 1=Unsafe.

There are an estimated 3,176,700 people or 18% of the Australian population with one or more disabilities.²⁰

- None of these are defined as being iatrogenic in nature, and yet we know that at least 500,000 Australians or 2.5% of all Australians have been permanently maimed by iatrogenic disease in the past decade – none of these appear in official statistics!

¹⁸ Bayer Pharmaceuticals. *Facts about aspirin*.

www.wonderdrug.com/press/factsheets/aspirin_fact_sheet.pdf

¹⁹ http://research.aarp.org/health/ib35_medical_prn.html Source: National Patient Safety Foundation at the AMA, "Public Opinion of Patient Safety Issues." Survey conducted by Louis Harris & Associates, September 1997.

- In fact, in New Zealand, only 0.3 of 1% of all iatrogenic caused deaths are classified as such.
- Official databases even place a caveat on their statistical tables saying that, “Adverse affects due to drugs or medical care were excluded.”²¹

Senator Tambling has said that more than four million Australians get food poisoning every year, representing an annual bill to the nation of about \$2.6 billion.²² He compares the Australian statistics to those of the USA, in which case there are nearly 400 food related deaths per year or 4,000 deaths in the past decade in Australia.

Usage of Complementary Healthcare Products

Sixty percent of New Zealanders used complementary healthcare products in 1997.²³ Similar figures apply to Australia.

It is estimated from industry sales that 200 million doses of Echinacea are consumed in Australia each year.

We can therefore assume that complementary healthcare products are extremely widely used and that if there were public healthcare problems they would be surfacing.

- Interestingly, in none of the medical research projects undertaken in Australia, USA New Zealand has complementary healthcare products surfaced as a safety issue – over 40,000 case records have been examined in those studies.
- This has been confirmed via personal communication with several authors, including Professor Lucean Leappe from Harvard University.²⁴

²⁰ <http://www.aihw.gov.au/publications/welfare/aw95/aw95-c06.html>

²¹ http://www.otago.ac.nz/Web_menus/Dept_Homepages/IPRU/Stats/MM8.html

²² <http://www.health.gov.au/mediarel/yr2000/gt/gt20026.htm>

²³ NZ Ministry of Health Food and Nutrition Survey

Hundreds of millions of doses of St John's wort are consumed around the world each year. Despite all of the rhetoric about safety issues surrounding St John's wort, there have been zero deaths recorded anywhere in the world related to its use. Dr Stewart Jessamine, Senior Medical adviser of Medsafe, New Zealand, conducted a search of the WHO adverse reaction database – he concluded, *"There have, however, been no reported deaths associated with use of St John's wort."* Dr Jessamine's objective analysis of the data involved industry in a joint effort to determine both the extent of the problem and a responsible risk management strategy. He co-wrote an article to over twenty thousand healthcare professionals that was also posted on Medsafe's website.

- The unique factor of Dr Jessamine's article was that he qualified the risk. For example, he stated that the risk was hypothetical, weak, moderate, etc.²⁵

Table 1: Medsafe's advice to healthcare professionals regarding oral contraceptives

Oral contraceptives	Weak	Small numbers of case reports of breakthrough bleeding, contraceptive failure theoretically possible but no case reports of contraceptive failure have been reported.	Weigh the benefits of continuing SJW against theoretical possibility of reduced contraceptive efficacy. Review management of depression.
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Table 2: TGA's advice to healthcare professionals regarding oral contraceptives²⁶

Oral contraceptives	Reduced blood levels with risk of breakthrough bleeding. Possible contraceptive failure (see TGA Alert).	Weigh the benefits of continuing SJW against possible reduced contraceptive
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All risks were deemed, unscientifically and therefore unfairly, by TGA to be high.

- Furthermore, TGA even went to the absurd extreme of requiring homeopathic medicines to carry warning labels.

²⁴ Email on file.

²⁵ <http://www.medsafe.govt.nz/Profs/Safety/sjw.htm>

²⁶ <http://www.health.gov.au/tga/docs/html/info.htm>

Despite the fact that the proven risks associated with some St John's wort preparation being confined to two distinct groups of patients, organ transplants and AIDS patients, TGA, acting under urgency some five months AFTER New Zealand had implemented its measured risk management response, refused to adopt NZ's response or warning statement at considerable cost to some members of New Zealand industry who operate on both sides of the Tasman.

Further more, TGA required warning labels to be placed on all products with a matter of several weeks at considerable cost for a mostly hypothetical risk.

Compare that to the known, though hotly denied by TGA officials, link between suicides and Prozac use. Using figures on Prozac both from Lilly and independent research, however, Dr. David Healy, an expert on the brain's serotonin system and director of the North Wales Department of Psychological Medicine at the University of Wales, estimated that ``probably 50,000 people have committed suicide on Prozac since its launch, over and above the number who would have done so if left untreated."²⁷ Despite St John's wort being prescribed twenty more times than Prozac for treating depression in Germany,²⁸ there have been no suicides associated with its use. The debate doesn't exist.

From January 1992 to December 1999, New Zealand's Centre of Adverse Reaction Monitoring has received 122 reports of adverse reactions occurring in association with complementary therapies.²⁹ Such reports are unvetted and include reactions to baby formula and reports of reactions to an actual company! This is a world first.

²⁷ http://199.97.97.16/contWriter/yhd7/2000/05/09/medic/9895-0004-pat_nytimes.html
Go to any reputable web search engine, put in the words PROZAC and SUICIDE and read the claims and counter claims. A good article can be found at
http://www.guardianunlimited.co.uk/uk_news/story/0,3604,271006,00.html

²⁸ <http://nccam.nih.gov/nccam/fcp/factsheets/stjohnswort/stjohnswort.htm>

²⁹ <http://www.medsafe.govt.nz/Profs/Safety/cc.htm#Updates>

- The New Zealand Parliament's Regulations Review Select Committee deemed CARM report to be nothing more than an unscientific notification system.³⁰

An analysis of adverse reaction reports to vitamins revealed that 75% of them were falsely classified.³¹ Official government reports revealed that there were 141 cases of serious anaphylaxis to foods in New Zealand over a two year period during a time when there were zero such cases regarding complementary healthcare products.³²

Conclusion regarding relative risks

Therefore, we can see that despite a great deal of official rhetoric, there is simply no scientific evidence of complementary healthcare being a significant public health concern; there is, at most, one disputed death over the past decade in Australasia through complementary healthcare product use, compared to more than 100,000 deaths due to properly researched, properly regulated (by TGA) properly prescribed and properly used drugs over the past decade. (See figure 1)

³⁰ Complaint relating to the New Zealand Food Standard 1996, Amendment No. 11 Report of the Regulations Review Committee Forty-Fifth Parliament (Rt Hon Jonathan Hunt, Chairperson) July 1999 Presented to the House of Representatives

³¹ Reports on file.

³² Complaint relating to the New Zealand Food Standard 1996, Amendment No. 11 Report of the Regulations Review Committee Forty-Fifth Parliament (Rt Hon Jonathan Hunt, Chairperson) July 1999 Presented to the House of Representatives

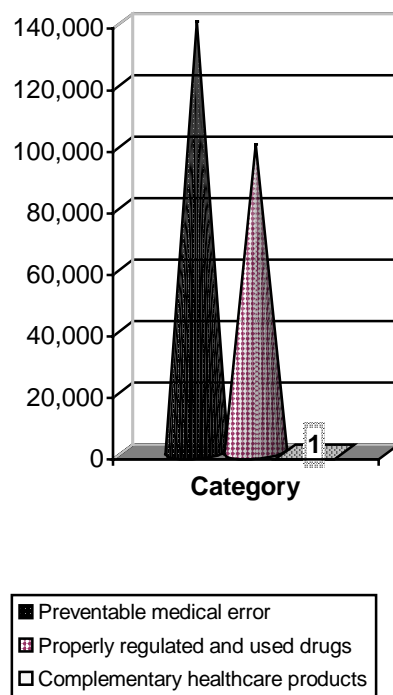


Figure 1: Relative risks over past decade

Costs associated with regulating complementary healthcare products

So what are the costs associated with regulating complementary healthcare products and how do these compare with the risks?

The total budget for the Department of Health and Aged Care is \$653 million of which 46.9 millions funds TGA and more than 4.75 millions (based on Senator Tambling's comments) is devoted to regulating complementary healthcare products.³³

	Revenue from Government (Appropriations) \$1,000's	Revenue from other sources	Price of Outputs
Therapeutic Goods Administration ²	4,661	42,267	46,928
Revenue from complementary healthcare industry		\$4,750 Included in above figure	

Data extracted from Budget 2000-2001 figures on government website and TGA's stated extortion from industry..

Income derived from fees charged to the complementary healthcare industry equals \$4.75 million, which is 10.1% of TGA budget. In a scathing attack on

³³ http://www.health.gov.au/pubs/budget2000/part_b.htm#b2

industry's criticisms of the current TGA regime, Senator Tambling said, "These new fee schedules are still well below what they would have been if TGA had simply doubled the fees and charges following the government's decision to move from 50% funding to 100 percent cost recovery in 1998."³⁴

Given that statement, then we can assume that TGA budgets nearer 20% of all its activities at the expense of an industry that imposes less than 1/100,000th of the proven risk.

How unjust. This is clear, unequivocal evidence of the financial shackles that TGA has imposed on an extremely safe industry through systematic abuse of its regulatory powers.

- Is there a safer industry? Is there an industry in Australasia where less than 1 (disputed) death has occurred per 144 million person years (240 times 0.6 representing the fact that 60% of the population consume dietary supplements.)

-
- ZEAL VERSUS SAFETY?³⁵

The above is the title of an article on TGA's own website. The heading is absolutely relevant to their myopic view of extremely safe complementary healthcare products. It is especially relevant regarding their infamous ELF-IV which is light years behind schedule even having been told in August that it would be ready in September!

So you've finally made it! After seemingly endless nights you've discovered that elusive "final" bug and re-coded just in the nick of time.

All those extra features that your boss talked to you about were difficult to implement and significant code had to be rewritten to accommodate them but that is all behind you now. Your boss is demanding results and the silent partner is wondering why he should fund the next stage of the project.

He is asking what is it about the device you just finished prototyping that is better than what the multinational on the other side of the city has just produced in its final form?

³⁴ Letter from Senator Tambling to complementary medicines sponsor dated 27th October 2000, on file.

³⁵ Excerpt from TGA's own website at <http://www.health.gov.au/tga/docs/html/atdb/num31/news.htm#6>

Uh oh, now that you've got the prototype working it's time to think about preparing the business plan and documenting the specifications of the device. You start to wonder whether you should have written something down about that tricky bit of code to overcome the design problem with the hardware. You wish you could go onto the next project. Why do you have to generate all this paper anyway, it works, doesn't it?

Many software applications developed by zealous software programmers seem to be developed in this fashion leading to unexpected defects in actual use.

Watts Humphrey of the Software Engineering Institute of Carnegie Mellon University in Pittsburgh, USA recently described software defects as being likened to landmines.*

"They are hard to find," he said. "They don't cause problems until you stumble across them and you could be in serious trouble."

- **Industry's experience with TGA is likened to walking a minefield; we are in serious trouble!**

In a speech to the Complementary Healthcare Council,³⁶ Senator Grant Tambling, Parliamentary Secretary for The Minister for Health and Aged Care said,

"NEW ZEALAND - The New Zealand industry and New Zealand government are understandably paying close attention to where the reforms have taken us and I have been doing my best to ensure that I keep them up to speed on where we are up to - and I know the CHC has been doing likewise. This is of course increasingly important as we continue on a path which will see even closer and more co-operative trans Tasman relationships in the future."

It is with regret that New Zealand industry reports that Senator Tambling doesn't even answer his mail these days – neither does TGA. In fact, TGA even get the New Zealand Ministry of Health to hassle both the President of NNFA and its immediate past President to stop 'annoying' TGA.

We also report that there has been zero "co-operative trans Tasman relationship."

- New Zealand industry simply rejects the idea that Trans Tasman Harmonisation means Trans-Tasman Australianisation.

³⁶ <http://www.health.gov.au/mediareel/yr2000/gt/gtsp200301.htm>

So what does New Zealand want?

The complementary healthcare industry on both sides of the Tasman wants good regulation commensurate with the established extremely low risk profile that our industry has established.

Is that too much to ask?

Despite the rhetoric to the contrary, neither officials nor their advisors can establish any risk profile approaching that of pharmaceutical medicines.

- The following is a list of questions that we believe need to be asked when considering an appropriate regulatory model for extremely safe complementary healthcare products;

Guidelines for the Preparation, Adoption, and Review of Technical Regulations

1. Has the problem been clearly identified?
2. What are the Government's objectives?
3. What is the problem?
4. What is the source of the problem?
5. How big is the problem?
6. Who is affected?
7. Why does the market fail to achieve the desired outcome?
8. Why is government intervention required?
9. Have all the options to address the problem been considered?
10. What are the alternatives to the imposition of a technical regulation to deal with the problem?
11. Are there any constraints which may make some alternatives undesirable or unattainable?
12. Does the imposition of a technical regulation involve either the least net cost or the maximum net benefits to society, compared to the other options?
13. Has the design and implementation of technical regulations been considered?
14. Is the technical regulation designed in such a way that it minimises the constraints on the ability of firms to enter and exit the market?
15. Have performance-based standards been considered?
16. Does the technical regulation focus on the outcome to be achieved rather than the means to achieve it?
17. Have international standards and obligations been considered?
18. Is the technical regulation consistent with international standards? If not, why not?
19. Is the technical regulation consistent with international obligations?
20. Is the technical regulation formulated in such a way that it minimises the constraints on the ability of firms to enter and exit the market?
21. Have compliance mechanisms been considered?
22. What are the alternative mechanisms to ensure compliance?
23. Does the risk of harm justify the cost burden of imposing mandatory third party conformity assessment?
24. Does the technical regulation recognise the conformity assessment procedures of other member countries?
25. Have provisions for review and monitoring of the technical regulation been considered?
26. Have the circumstances or objectives giving rise to the regulation changed, such that a different response may be required?
27. Are the objectives of the technical regulation being met?
28. What has been the impact of the technical regulation? Have there been any unanticipated effects?
29. Is the technical regulation still required, or is there a more appropriate option for addressing the problem?
30. Has consultation taken place?
31. Have all interested parties' opinions been taken into account?

Coincidentally, these are questions that are commensurate with good regulatory practice espoused by the Australian and New Zealand governments.

We believe that if such an objective and impartial review were undertaken then it would be seen that industry's cries for relief from the parasitic clutches of TGA would be heard. TGA is commercially heavy-handed, does not understand the nuances of the complementary healthcare industry and has failed to deliver the promised 1998 reforms proposed Senator Tambling. The exercise of the past two years would appear to have been nothing more than a smoke and mirror exercise.

We conclude by quoting from, and commenting on, the APEC Initiatives on Good Regulatory Practice document;

- "APEC aims to fulfil its trade facilitation mandate by promoting policies which reduce costs (administrative and technical barriers) and stimulate competition, thereby leading to efficiency gains. It is increasingly recognised that domestic regulation can have a positive or negative impact on competition at and behind the border. APEC has therefore recently promoted the need to address good regulatory practice as part of its integrated approach to facilitating trade."

Industry agrees with this statement and has demonstrated that the Australian Therapeutic Goods Administration has excessively burdened the complementary healthcare industry with enormous regulatory costs bearing no relationship to proven extremely low risks associated with such products.

TGA is a very effective barrier to trade, both internal trade and external trade.

TGA's stifling regulatory regime does not stimulate competition, in fact it stifles it.

TGA has a very negative impact on competition at and behind the border.

- “Regulation should therefore be approached with caution, and with a clear understanding of its potential benefits, and equally, its potential costs. Proposals to regulate need to be subject to proper analysis and scrutiny as to their necessity, efficiency, and net impact on public welfare.”

TGA has a rapacious appetite for regulating.

Its whole culture is one of command and compliance.

TGA does not approach regulation with caution.

TGA has no idea of either its potential benefits or costs.

There is very little opportunity to properly analyse or scrutinise TGA’s activities.

TGA has no idea of the necessity, efficiency or net impact of its regime on public welfare.

- “Bias to Regulate

Modern political systems encourage regulatory growth because, politically, regulation can be extraordinarily convenient. Regulatory costs are difficult to specify, are often unseen, and those who bear the costs are often diffuse (and in many cases those who benefit are concentrated). The impact of regulatory expenditures is therefore not as transparent compared with the impact of fiscal expenditures. Pressure for excessive regulation also arises because those who will bear the costs (for example, consumers) are under-represented in the political process.”

TGA is a worst-case scenario regarding the bias to regulate.

This is highlighted by the stupid decision to impose mandatory warning labels on homeopathic products.

- “Increasing Demands on Decision-Makers

Governments are being increasingly challenged to maintain a regulatory environment which is fair, efficient, and effective in achieving economic, social, and environmental goals. There is also

increasing recognition of the complexity of the challenge. Many factors contribute to this complexity.”

Industry on both sides of the Tasman believes that a regulatory body that requires approximately 15% of the profit of an industry through direct and indirect regulatory compliance costs to regulate an insignificant risk within the healthcare and therapeutic product industries is grossly unfair, and ineffective in achieving economic, social, and environmental goals.

It is not only grossly unfair, it is scientifically indefensible.

- “An ever present and increasing demand for more regulation. A key driver of regulatory inflation is the growing complexity of modern society. The pace of change in technology, economic opportunity, globalisation, and social conditions fuel the pressure for more regulation. In the New Zealand context, for example, since 1987 the Government has enacted 1,609 new or amended statutes and 3,699 new or amended regulations. This illustrates the demands on both decision-makers and those affected by regulation.”

Industry firmly believes that the sole reason for ever present and increasing demand for more regulation in the complementary healthcare industry is not a growing complexity of modern society, but a Neanderthal bureaucratic and medical industry response to a growing simplification of post-modern society who are returning to their roots and applying modern knowledge to old problems; they are garnishing healthy lifestyle choices with a great deal of commonsense.

It doesn't make sense to use drugs such as Prozac when an equally effective natural product is available and it has none of the nasty side effects.

It is not a paradox that those who can most afford modern medicine are the most significant users of complementary healthcare products; it is evidence that society is making informed choices regarding focussing on wellness, rather than illness.

- “The total regulatory burden on business is high, “

This statement is oh, so, true.

- “International obligations applying to domestic regulatory systems are more significant than in the past, and are likely to increase. For example, New Zealand has become party to 65 multi-lateral agreements (including amendments) in the last 5 years. This requires effective systems in place to ensure compliance with its international obligations.”

Given that TGA is relentlessly bullying New Zealand officials to adopt it as the Trans-Tasman regulator for healthcare and therapeutic products, this takes on even more significance.

New Zealand has a regulatory model that is not burdensome on industry, and which can be demonstrated to be just as safe as TGA's. There is zero evidence that New Zealand is any the worse for its hands off approach to regulation of the complementary healthcare industry.

New Zealand industry has already agreed with New Zealand officials that the existing system would be adjusted to include appropriate GMP (at industry's insistence), a simple notification system (so that regulators know what's on the market should a problem arise) and classification of products be based on the existing negative listing system using an evidence based risk analysis commensurate with international good regulatory practice espoused by Australia.

- “Alternatives to traditional regulation offer an increasing range of policy tools to government in meeting regulatory objectives at least cost.”

Here, here!

- “The Modern Regulatory Challenge

Good regulation is a product of good policy advice and good decision-making. The modern regulatory challenge is to develop a regulatory system which can effectively deal with the increasing demand for regulation, inherent bias to regulate, and complex nature of regulatory interventions. This requires that the right incentives, principles, procedures, and institutions of government are in place and working effectively to ensure that regulation is necessary, cost effective, and in the best interest of society.”

Here, here.

The current Therapeutic Goods Administration does not deliver good policy advice, it does not use good decision-making, and therefore it is incapable of delivering good regulations.

The Complementary Healthcare industry on both sides of the Tasman has developed a regulatory model that we believe will protect society and offer highest quality product in a manner that permits consumers to make informed choices based on honest product information.

- We simply reject the current regime as being inappropriate for extremely safe products marketed to discerning and educated society in the 21st century.
- We want the right incentives, principles, procedures, and institutions of government in place and working effectively to ensure that regulation is necessary, cost effective, and in the best interest of society. TGA is not that institution – they even fail to protect society from the ravages of properly regulated drugs.
- We insist that the Australian and New Zealand governments 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, *AKA: Good Regulatory Practice* which is mandated by both governments.

Therefore Australian and New Zealand industries objectives are clearly in line with the Australian and New Zealand governments' stated objectives.

We call on both the government of Australia and the government of New Zealand to ensure that a trans-Tasman regulatory regime is developed that is in line with good regulatory practice and is commensurate with the proven extremely low risks and high benefits associated with the complementary healthcare industry, and is administered by personnel who actually have an understanding of the products that they are dealing with.

2nd APEC Conference on Standards and Conformance
Kuantan, Malaysia, 4-5 September 1998

APEC Initiatives on Good Regulatory Practice

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Going Forward

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• Introduction

APEC aims to fulfil its trade facilitation mandate by promoting policies which reduce costs (administrative and technical barriers) and stimulate competition, thereby leading to efficiency gains. It is increasingly recognised that domestic regulation can have a positive or negative impact on competition at and behind the border. APEC has therefore recently promoted the need to address good regulatory practice as part of its integrated approach to facilitating trade.

This paper examines APEC, and in particular Standards and Conformance Sub-Committee (SCSC), initiatives which promote good regulatory practice. In doing so, it seeks to develop an understanding of the wider regulatory context and the key influences and pressures placed on governments for regulatory reform. APEC initiatives will be considered as part of this framework. The paper concludes by posing some challenges open to member economies.

• Regulatory Environment

Broadly, governments throughout the world engage in three main activities. They tax, they spend, and they regulate. Regulation is probably the least understood of these policy instruments, but has a broader and more far reaching impact on economic growth than do tax or fiscal policies.

Regulation is defined for the purposes of this paper as incorporating the full range of legal instruments and decisions through which governments establish conditions on the behaviour of citizens and enterprise. This includes parliamentary laws, subordinate legislation, decrees, licences, codes, and informal instruments. Regulatory systems encompass not only national and provincial rules, but also rules developed through international processes.¹

There is no doubt that there is a community demand for government regulation, particularly to achieve social and environmental goals. Regulatory interventions are necessary for sustaining the environment, saving lives, protecting consumers and vulnerable social and economic groups, and promoting better economic performance by, for example, safe-

guarding competition in the market place. There is, of course, a set of costs associated with any regulatory intervention. These will vary depending on how well the regulatory regime is designed, implemented, and administered. It is the impact of regulation which I will now turn to.

- **Impact of Regulation**

Regulatory costs are made up of the following three main components:

fiscal costs to government: the cost of administering the regulatory regime itself, including compliance and adjudication;

compliance costs to business and consumers: including both the capital and administrative (paperwork) costs to businesses and citizens; and

dynamic costs to economic performance: resulting from regulation which indirectly impacts on competition, innovation, and investment. This includes regulation which diverts resources from highest value use (allocative costs), and regulation which detracts from least cost production (productive costs)

These costs are often hidden and ultimately passed on to consumers in the form of higher prices for regulated goods and services, lower quality, and reduced variety.

In the United States context, for example, studies have estimated the direct costs of government regulation alone are between 4 percent and 10 percent of GDP.² Costs are added if regulation is poorly conceived, designed, or implemented.

Regulation should therefore be approached with caution, and with a clear understanding of its potential benefits, and equally, its potential costs. Proposals to regulate need to be subject to proper analysis and scrutiny as to their necessity, efficiency, and net impact on public welfare.

- **Bias to Regulate**

Modern political systems encourage regulatory growth because, politically, regulation can be extraordinarily convenient. Regulatory costs are difficult to specify, are often unseen, and those who bear the costs are often diffuse (and in many cases those who benefit are concentrated). The impact of regulatory expenditures is therefore not as transparent compared with the impact of fiscal expenditures. Pressure for excessive regulation also arises because those who will bear the costs (for example, consumers) are under-represented in the political process.

The nature of the government intervention is also important when considering pressures to regulate. The traditional command-and-control regulatory style continues to be the dominant regulatory approach in most developed countries. In part, this is driven by the need for governments to demonstrate to their constituents that they are taking action to solve problems. Therefore, regulation represents a visible sign of action that may be as much symbolic as real.

It is only relatively recently that we have observed an increasing use of alternative approaches to traditional command-and-control regulation (such as self-regulation, voluntary agreements, private standards setting, and economic instruments such as tradable permits). It is increasingly recognised that such approaches can provide more cost-effective ways of dealing with regulatory problems. A cultural shift away from traditional command-and-control approaches will only occur over time as experience and confidence grows.

- **Increasing Demands on Decision-Makers**

Governments are being increasingly challenged to maintain a regulatory environment which is fair, efficient, and effective in achieving economic, social, and environmental goals. There is also increasing recognition of the complexity of the challenge. Many factors contribute to this complexity:

An ever present and increasing demand for more regulation. A key driver of regulatory inflation is the growing complexity of modern society. The pace of change in technology, economic opportunity, globalisation, and social conditions fuel the pressure for more regulation. In the New Zealand context, for example, since 1987 the Government has enacted 1,609 new or amended statutes and 3,699 new or amended regulations. This illustrates the demands on both decision-makers and those affected by regulation.

The total regulatory burden on business is high, requiring effective linkages to be designed into legislation or dealt with between agencies after they are enacted. Good processes and

principles are therefore required to deal with the interactive and cumulative effects of regulation. For example, the New Zealand Employers and Manufacturers Association advise that they provide advice to businesses on 24 separate statutes on employment issues alone. In aggregate, the regulatory burden is substantial.

International obligations applying to domestic regulatory systems are more significant than in the past, and are likely to increase. For example, New Zealand has become party to 65 multi-lateral agreements (including amendments) in the last 5 years. This requires effective systems in place to ensure compliance with its international obligations.

Alternatives to traditional regulation offer an increasing range of policy tools to government in meeting regulatory objectives at least cost.

- **The Modern Regulatory Challenge**

Good regulation is a product of good policy advice and good decision-making. The modern regulatory challenge is to develop a regulatory system which can effectively deal with the increasing demand for regulation, inherent bias to regulate, and complex nature of regulatory interventions. This requires that the right incentives, principles, procedures, and institutions of government are in place and working effectively to ensure that regulation is necessary, cost effective, and in the best interest of society.

- **OECD Regulatory Reform Initiatives**

Improving economies' regulatory capability and quality is also a key focus for the OECD. It is recognised that regulatory reform which enhances competition and reduces regulatory costs can boost efficiency, bring down prices, stimulate innovation, and help improve the ability of economies to adapt to change and remain competitive.³ Recently, OECD Ministers welcomed and endorsed policy recommendations which aim to help governments assess and improve the quality of their regulatory regimes. Ministers agreed to work to implement these recommendations in their respective countries. Examples include:⁴

adopting at the political level broad programmes of regulatory reform that establish clear objectives and frameworks for implementation. This includes establishing principles of good regulation to guide reform which draw on the 1995 OECD Recommendations on Improving the Quality of Government Regulation;

review and strengthen where necessary the scope, effectiveness, and enforcement of competition policy;

reform economic regulations in all sectors to stimulate competition, and eliminate them except where clear evidence demonstrates that they are the best way to serve the public interest; and

eliminate unnecessary regulatory barriers to trade and investment by enhancing implementation of international agreements and strengthening international principles.

These recommendations constitute an action plan. The OECD has responded by conducting reviews of regulatory reform effort in Member countries, beginning this year. The reviews are based on a combination of self-assessment and peer review.

- **World Trade Organisation (WTO)**

The WTO is the legal and institutional foundation of the multilateral trading system. It provides the principal contractual obligations determining how governments frame and implement domestic trade legislation and regulation. It is, essentially, a trade policy forum which develops rules of engagement in trade for its members. The WTO is increasingly broadening its activities to look at the convergence of trade and competition policies.

The Trade Related Aspects of Intellectual Property Rights (TRIPS), Trade Related Investment Measures (TRIM), and the General Agreement on Trade in Services (GATS) agreements are examples of the WTO's broadened role. All these agreements have competition provisions in them to some greater or lesser degree. They recognise the intrinsic link between domestic regulatory environments and efficient trade outcomes. For example, the way governments regulate intellectual property, investments policies and services markets are inseparable from trade policy.

The Agreement on Basic Telecommunications negotiated as an annex to GATS came into force in February 1998. It covers trade in nearly 95% of the world telecommunications services, currently valued at 2% of global GDP. The interesting issue to note is that WTO negotiators focused much of their time on establishing a regulatory environment conducive

to market entry. A set of principles was agreed and members agreed to use these as a basis in deciding on regulatory disciplines.

- **Is APEC Meeting the Modern Regulatory Challenge?**

APEC is concerned with facilitating trade through reducing barriers. Poorly conceived regulation restricts the free flow of goods, services, investment, and technology, all of which disadvantages consumers and firms. This also distorts the efficient allocation of resources and constrains economic growth. The member economies of APEC have recognised that, in order to minimise the distorting effects of regulation for international trade and investment, it is necessary to ensure adherence to efficient regulation principles.

The APEC approach was foreshadowed in the Osaka Action Agenda. APEC leaders recognised that with trade barriers being rapidly dismantled, and the increasing globalisation of business, attention would swing, inevitably, to behind the border issues connected with regulatory reform.

More recently, the need for further APEC work on regulatory reform has been highlighted by the difficulties faced by a number of Asian economies. Commentators have stressed that reforms are required in a wide range of sectors, including the financial sector. These difficulties have highlighted the capacity and institutional constraints in many economies which affect the formulation and implementation of sound regulatory policies.

There has been activity by APEC in identifying and promoting best-practice principles for regulatory reform. For example:

as part of the Bogor Declaration, Leaders adopted the *APEC Non-Binding Investment Principles* which focused attention on ways to minimise the regulatory and institutional barriers to the outflow of investment;

the Experts Group on Government Procurement is currently developing a compendium of *Non Binding Principles* which incorporate a number of Transparency and best practice principles;

the Telecommunications Working Group and Energy Working Group have developed principles based on minimising barriers to market entry and exit through quality of regulation practice.

the Pacific Economic Co-operation Council (PECC) is developing principles that will guide the development of an international competition framework for business. These principles are about regulatory design and regulatory quality.

- **Regulatory Reform Symposium**

The Government of Malaysia is currently hosting an APEC Regulatory Reform Symposium on behalf of the APEC Committee on Trade and Investment (CTI). This is addressing broad policy issues associated with regulatory reform. These include:

Interrelationships between competition policy and regulation;

Ensuring high quality regulation;

Role of regulatory reform/deregulation;

Case study: occupational regulation; and

Globalisation and the regulatory environment.

The Symposium will provide an opportunity to consider how to further develop the APEC Collective Action Plan (CAP) for deregulation.

- **Standards and Conformance Sub-Committee (SCSC)**

SCSC has also recognised the links between standards and conformance and regulatory reform. Its approach is predicated by a recognition that standards and conformance requirements can have a significant impact on trade flows and investment in the region.

Standards, conformity assessment, and regulation can be necessary to safeguard consumer health and safety, to protect against deceptive practices and to protect the environment. The existence of such requirements adds certainty and security to trade in the region. However, misused or excessive requirements will harm international trade, increasing the cost of doing business and limiting competition in the importing economy.

- **SCSC Work: Guidelines for the Preparation, Adoption, and Review of Technical Regulations**

As part of its work programme SCSC has begun to examine the nature of the effects of technical regulations on trade and economic activity, and the need to consider alternative approaches to achieving regulatory outcomes. In 1997 SCSC developed and adopted *Guidelines for the Preparation, Adoption and Review of Technical Regulations*. These Guidelines are based on WTO principles that recognise the legitimate objectives of regulation.

The purpose of these *Guidelines* is to provide a common framework and set of principles for APEC members for the preparation, adoption and review of technical regulations. It is intended that promoting similar approaches to regulatory management within APEC can improve the consistency and transparency of technical regulations, thereby reducing unnecessary obstacles to trade.

The following *Guidelines* (checklist) have been adopted by APEC.

<p>Guidelines for the Preparation, Adoption, and Review of Technical Regulations</p> <p>Has the problem been clearly identified? What are the Government's objectives? What is the problem? What is the source of the problem? How big is the problem? Who is affected? Why does the market fail to achieve the desired outcome? Why is government intervention required?</p> <p>Have all the options to address the problem been considered? What are the alternatives to the imposition of a technical regulation to deal with the problem? Are there any constraints which may make some alternatives undesirable or unattainable? Does the imposition of a technical regulation involve either the least net cost or the maximum net benefits to society, compared to the other options?</p> <p>Has the design and implementation of technical regulations been considered? Is the technical regulation designed in such a way that it minimises the constraints on the ability of firms to enter and exit the market?</p> <p>Have performance-based standards been considered? Does the technical regulation focus on the outcome to be achieved rather than the means to achieve it?</p> <p>Have international standards and obligations been considered? Is the technical regulation consistent with international standards? If not, why not? Is the technical regulation consistent with international obligations? Is the technical regulation formulated in such a way that it minimises the constraints on the ability of firms to enter and exit the market?</p> <p>Have compliance mechanisms been considered? What are the alternative mechanisms to ensure compliance? Does the risk of harm justify the cost burden of imposing mandatory third party conformity assessment? Does the technical regulation recognise the conformity assessment procedures of other member countries?</p> <p>Have provisions for review and monitoring of the technical regulation been considered? Have the circumstances or objectives giving rise to the regulation changed, such that a different response may be required? Are the objectives of the technical regulation being met? What has been the impact of the technical regulation? Have there been any unanticipated effects? Is the technical regulation still required, or is there a more appropriate option for addressing the problem?</p> <p>Has consultation taken place? Have all interested parties' opinions been taken into account? Have the TBT Agreement's notification requirements been followed?</p>

- **Good Regulatory Practice**

The *Guidelines* provide a foundation for member economies to develop a common understanding of the principles of Good Regulatory Practice. However, they go only so far.

The draft *Guide for Good Regulatory Practice* developed for the consideration of SCSC by Australia provides a practical application of the principles contained in the *Guidelines*. Promoting similar approaches to regulatory management within APEC would be another step towards reducing technical and/or regulatory barriers to trade within the region.

The draft *Guide* contains a number of Practices (consolidated below) that set goals for future regulatory environments. These Practices would, if implemented, result in a regulatory environment characterised by:

- regulatory requirements specified in terms of performance based outcomes, wherever possible, and supported by deemed to comply standards;
- a member economy's own standards referenced in this manner being aligned with the relevant international standard wherever possible;
- the provision of conformity assessment activities (such as test reports and/or certificates of conformity) being subject to competition by duly accredited conformity assessment bodies, such as laboratories and/or certification bodies;
- such conformity assessment bodies being accredited in accordance with international standards and guides by accreditation bodies that operate accreditation programs also in accordance with relevant international standards and guides;
- assurance of conformity being provided by way of "suppliers' declarations", together with appropriate post-market surveillance systems, rather than by way of pre-market conformity assessment systems such as product approvals and licensing;
- participation in mutual recognition agreements in both the regulated and voluntary sectors, where appropriate.

conformance marks, where mandated, indicating that the good and/or service has been declared by the supplier/manufacturer as complying with the mandatory requirements of the economy in which it is traded.

The development of the draft *Guide* stemmed from SCSC debate on whether Mutual Recognition Arrangements (MRAs) on conformity assessment would benefit from the application of good regulatory practices. Clearly, any MRA will benefit if the regulatory and administrative practices of member economies reflect best practice, or where the regulatory systems across borders have similarities.

However, the application to MRAs is only one aspect of the benefits from good regulatory practice. Its underlying objective within SCSC is to reduce regulatory impediments in all areas of conformity assessment through the development of common practices between member economies. This, perhaps, is the key challenge for SCSC.

- **Going Forward**

The performance of economies is shaped by the quality of their regulatory environments. Economies that foster competition, create certainty in the business environment, and impose low regulatory costs on business will prosper. Successful businesses are increasingly operating on a global basis, looking to source inputs, attract investments, and service markets in different parts of the globe. Globalisation means that the economic performance of any one economy will be increasingly affected by the quality of the regulatory environment of those with which that economy has economic links. Co-ordination is critical.

A growing number of economies - APEC and non-APEC alike - have embarked in recent years on programmes to reduce regulatory burdens and improve the quality and cost-effectiveness of regulatory interventions. This task requires skilful strategies to deal effectively with the increasing demand for regulation, an inherent bias to regulate, and the complex nature of regulatory interventions.

An important first step is the establishment of international quality standards or principles for regulatory intervention by individual economies. These are derived from best practices which experience tells us lead to good regulatory outcomes. The *Guidelines for the Adoption, Preparation and Review of Technical Regulations* adopted by APEC and the draft *Guide for Good Regulatory Practice* currently under discussion in SCSC are important in this regard. This paper has identified others both within and outside APEC. Common themes run through them all.

These documents provide an explicit policy statement on when and how government should exert its regulatory powers. They also act as avenues of communication between governments, officials (bureaucracy), and the public. The pay-off from regulatory reform which is consistent with best-practice regulatory principles is improvements in public welfare.

It is important, therefore, that APEC continues the momentum of regulatory reform and member economies remain committed to progressing this area. Some possible actions include:

further developing explicit standards for regulatory quality and principles of regulatory decision-making, along with a means by which decision-makers and stakeholders are able to assess compliance with such standards;

systematically reviewing domestic regulation with a view to minimising unnecessary costs; strengthening the measurement of regulatory costs and benefits. Concrete information on the costs and benefits of regulation is crucial to maintaining the momentum of regulatory reform;

encouraging those APEC and non APEC members that are actively engaged in promoting regulatory reform programmes to share experiences with other members; and committing to Individual Action Plans for regulatory reform which can be subject to positive scrutiny and peer review.

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NZ's Code of Good Regulatory Practice³⁷

Quality of Regulation Team
 Competition and Enterprise Branch
 November 1997

- Contents

Efficiency

Effectiveness

Transparency

Clarity

Equity

- 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.

³⁷ http://www.med.govt.nz/buslt/reg_man/regprac.html

- 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 met.

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 be 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.

TGA's Good Regulatory Practice Scorecard

Efficiency Guidelines: 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.	
<i>Consideration of alternatives to regulation</i>	FAIL
<i>Minimum necessary regulation</i>	FAIL
<i>Regulatory benefits outweigh costs</i>	FAIL
<i>Reasonable compliance cost</i>	FAIL
<i>Minimal fiscal impact</i>	PASS
<i>Minimal adverse impact on competition</i>	FAIL
<i>International compatibility</i>	FAIL
Effectiveness Guidelines Regulation should be designed to achieve the desired policy outcome	
<i>Reasonable compliance rate</i>	PASS
<i>Reasonable compliance rate...</i> Regulatory measures should contain compliance strategies which ensure the greatest degree of compliance at the lowest possible cost to all parties.	FAIL
<i>Compatibility with the general body of law</i>	???
<i>Compliance with basic principles</i>	???
<i>Flexibility of regulation and standards</i>	FAIL
<i>Performance-based requirements that specify outcomes</i>	FAIL
<i>Review regulations systematically</i>	FAIL
Transparency Guidelines The regulation making process should be transparent to both the decision-makers and those affected by regulation.	
<i>Problem adequately defined</i>	FAIL
<i>Clear identification of the objective of regulation</i>	FAIL
<i>Cost benefit analysis</i>	FAIL
<i>Risk assessment</i>	FAIL
<i>Public consultation</i>	FAIL
<i>Direct approaches to problem:</i> 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.	FAIL
Clarity Regulatory processes and requirements should be as understandable and accessible as practicable.	
make things as simple as possible, but not simpler, in achieving the regulatory objective.	FAIL
Plain language drafting	???
Discretion should be kept to a minimum	PASS
Educating the public	???
Equity Guidelines Regulation should be fair and treat those affected equitably	
<i>Obligations, standards, and sanctions</i> should be designed in such a way that they can be imposed impartially and consistently	FAIL
<i>Regulation should be consistent with the principles</i> 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 met.	???
<i>People in like situations should be treated in a similar manner</i> , similarly, people in disparate positions may be treated differently.	FAIL
<i>Reliance should be able to be placed on processes and procedures of the regulatory system:</i> 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.	FAIL
In total. Pass, 3. Fail, 21, No comment, 5	FAIL

NZ Parliament's Regulations Review Committee Inquiry Terms of reference

The Regulations Review Committee invites public submissions on an inquiry into regulation-making powers that authorise international treaties to override any provisions of New Zealand enactments.

The closing date for submissions is 17 November 2000. The terms of reference of the inquiry are, to examine:

- The circumstances in which regulation-making powers that authorise international treaties to override any provisions of New Zealand enactments have been used.
- Alternative means of implementing international treaties into New Zealand law by regulations that do not authorise the provisions of a treaty to override any provisions of New Zealand enactments.
- Whether it is appropriate to enact regulation-making powers to implement international treaties into New Zealand law, notwithstanding the provisions of any other enactment.
- General principles for identifying if and when it is appropriate to enact regulation-making powers that authorise international treaties to override any provisions of New Zealand enactments.
- What limits should be imposed on prescribing regulations to implement international treaties by overriding any provisions of New Zealand enactments?

Australian Productivity Commission Inquiry terms of reference

1. COST RECOVERY

Terms of reference

PRODUCTIVITY COMMISSION ACT 1998

I, ROD KEMP, Assistant Treasurer, pursuant to Parts 2 and 3 of the *Productivity Commission Act 1998*, hereby refer the cost recovery arrangements of Commonwealth Government regulatory, administrative and information agencies — including fees charged under the *Trade Practices Act 1974* (TPA) — to the Commission for inquiry and report within twelve months of receipt of this reference. The Commission is to hold hearings for the purpose of the inquiry.

Background

2. This inquiry is principally a general review of cost recovery arrangements across Commonwealth regulatory, administrative and information agencies. In addition, the inquiry will incorporate the review of fees charged under the TPA, which is required under the *Commonwealth Legislation Review Schedule*. The inquiry will take into account the analytical requirements for regulation assessment by the Commonwealth, including those set out in the *Competition Principles Agreement*, where relevant.

Scope of Inquiry

3. The Commission is to report on:

the nature and extent of cost recovery arrangements across Commonwealth Government regulatory, administrative and information agencies, including identification of the activities of those agencies for which cost recovery is undertaken;

factors underlying cost recovery arrangements across Commonwealth Government regulatory, administrative and information agencies;

who benefits from the regulations, administrative activity and information to which cost recovery arrangements are applied;

the impact on business, particularly small business, consumers and the community of existing cost recovery arrangements, including any anti-competitive effects and incentive effects;

the impact of cost recovery arrangements on regulatory, administrative and information agencies, including incentive effects;

the consistency of cost recovery arrangements with regulatory best practice;

appropriate guidelines for:

(i) where cost recovery arrangements should be applied;

(ii) whether cost recovery should be full, partial or nil;

(iii) ensuring that cost-recovered activities are necessary and are provided in the most cost-effective manner;

(iv) the design and operation of cost recovery arrangements, including the treatment of small business;

(v) the review of cost recovery arrangements; and

(vi) where necessary, implementation strategies to improve current arrangements.

4. In reporting on matters in 3 above, the Commission should, where relevant, have regard to:
implications of recent and emerging technologies; and.

legal constraints on the design and operation of cost recovery arrangements.

5. With respect to fees charged under the TPA, the Commission should have particular regard to:
those fees charged that restrict competition, or which impose costs or confer benefits on
business; and

whether cost recovery arrangements that restrict competition should be retained in whole or part,
taking into account whether the benefits to the community as a whole outweigh the costs, and
whether the objectives of those arrangements can be achieved only by restricting competition.

6. In making its assessment of fees charged under the TPA:

the Commission is to have regard to environmental, welfare and equity considerations; economic
and regional development; occupational health and safety; consistency between regulatory
regimes and efficient regulatory administration; the interests of consumers generally; the
competitiveness of business including small business; compliance costs and the paperwork
burden on small business; and the efficient allocation of resources; and

the Commission should:

(i) identify the rationale for fees charged under the TPA;

(ii) clarify and assess the objectives of the fee arrangements;

(iii) identify whether, and to what extent, the fee arrangements impose costs or confer benefits on
business or restrict competition;

(iv) identify any relevant alternatives to these fee arrangements;

(v) analyse and, as far as reasonably practical, quantify the benefits, costs and overall effects of
the arrangements and alternatives identified in (iv);

(vi) identify the different groups likely to be affected by these arrangements and alternatives;

(vii) list the individuals and groups consulted during the review and outline their views;

(viii) determine a preferred option for the fee arrangements, if any; and

(ix) examine mechanisms for increasing the overall efficiency, including minimizing the
compliance costs and paper burden on small business, of the arrangements and, where it differs,
the preferred option.

7. The Commission should take account of any recent substantive studies relevant to the above
issues.

8. In undertaking the review, the Commission is to advertise nationally, consult with key interest
groups and affected parties, and produce a report.

9. The Government will consider the Commission's recommendations, and the Government's
response will be announced as soon as possible after the receipt of the Commission's report.

RODKEMP