

**The Natural Health and Supplementary
Products Bill:
A National Cost-Benefit Analysis**

May 2014

A report prepared for the New Zealand Health Trust

TDB Advisory Ltd
L5, Wakefield House
90 The Terrace
P.O. Box 93
Wellington
New Zealand

Principal contact for this report:

Philip Barry, Director

Mob: 021 478 426

Email: phil.barry@tdb.co.nz

Disclaimer

This report has been prepared by TDB Advisory Limited (TDB) with care and diligence. The statements and opinions given by TDB in this report are given in good faith and in the belief on reasonable grounds that such statements and opinions are correct and not misleading. However, no responsibility is accepted by TDB or any of its officers, employees or agents for errors or omissions arising in the preparation of this report, or for any consequences of reliance on its content, conclusions or any material, correspondence of any form or discussions arising out of or associated with its preparation.

Table of contents

1	Executive summary.....	4
2	Introduction.....	7
2.1	Current regulatory requirements.....	7
2.2	The bill’s proposals.....	8
3	An assessment of the approach proposed in the bill.....	10
3.1	The framework for analysis.....	10
3.2	What is the problem?.....	11
3.3	What are the feasible options.....	13
3.4	The costs and benefits of the bill.....	14
3.5	Do the overall benefits outweigh the costs?.....	20
4	Conclusions.....	22
	Bibliography.....	24
	Appendix: Indicative estimates of the compliance costs arising from the bill.....	26

1 Executive summary

This paper provides a national cost-benefit analysis of the proposed legislation for natural health and supplementary products (NHSPs), the Natural Health and Supplementary Products Bill (the bill). In undertaking this assessment we adopt a conventional national economic welfare perspective. In particular, we assess whether the benefits to the economy as a whole of the bill are likely to exceed the costs.

It is important to note when evaluating the costs and benefits of the proposed legislation that the alternative against which the bill is assessed is not zero regulation of NHSPs. NHSPs are already subject to a wide range of existing legislation aimed at protecting consumers including the Food Act (including the Dietary Supplements Regulations and the Food Hygiene Regulations), the Medicines Act, the Fair Trading Act and the Consumer Guarantees Act. The question then is not whether NHSPs should be regulated but whether additional sector-specific regulation is desirable for NHSPs.

The table below summarises our overall assessment of the costs and benefits of the proposed sector-specific legislation for NHSPs.

Overall assessment of the costs and benefits of the bill

Benefits	Costs
May avoid premature deaths or pain and suffering	Administrative costs of the government (~ \$4m p.a. initially)
Better information for consumers and regulators	Compliance costs to firms (~ \$3m to \$14m p.a. on a conservative basis)
	Loss of products from the market
	Loss of physical and human capital as firms withdraw from the market
	Reduced incentives to innovate

The primary potential benefit of the Bill is the avoidance of premature deaths and pain and suffering that may be occurring under the current regulatory environment for NHSPs. However, while such benefits are possible, there appears to be little or no evidence that adverse health consequences from NHSPs are a major problem in New Zealand under the current regulatory regime. Other benefits may arise from better information for consumers

and regulators. As is discussed in the main body of the report, these latter benefits could be achieved by updating and better enforcing existing regulations and do not appear to require a special regulatory regime for NHSPs.

The costs the bill imposes are likely to include:

- the administrative costs the government incurs in implementing the legislation. These costs include the costs of designing, monitoring and enforcing the legislation. The Ministry of Health (the ministry) estimate these costs are likely to be around \$4m p.a. and we adopt the ministry's estimate as our base case assumption. However we consider this assumption to be conservative given the degree of discretion in the bill granted to the government to develop new regulations (e.g., around manufacturing standards) and the widely observed tendency for regulatory powers to increase over time (a tendency referred to as "regulatory creep"). In large part these administrative costs are likely to be borne by the industry through increased user charges;
- the costs that suppliers of NHSPs face in complying with the new regime. These costs include the costs companies face in relabeling and reformulating their products to comply with the new regime and the set up and ongoing costs of complying with regulatory reviews and audits.¹ We estimate these costs, on a conservative basis, to be in the range of around \$3m to \$14m p.a. (see Appendix for details). The costs could be considerably higher if the regime evolves over time towards the heavy-handed Australian regulatory regime. Given the fixed nature of many of the compliance and administration costs, their burden will fall disproportionately on smaller and medium sized enterprises, especially those with many products;²
- the deadweight costs to the economy arising from the new regulatory regime including beneficial products being withdrawn from sale, to the detriment of consumers and suppliers (with the loss of employment opportunities and investor capital resulting from company scale-downs and closures), reduced incentives to innovate and other distortions to economic behaviour. It is difficult to quantify these deadweight costs but they can be much larger than the more obvious direct administrative and compliance costs of regulation.

¹ It should be noted that our estimates of the compliance costs exclude the charges the government will impose to recover the costs it incurs in administering the new regime. The government has stated it will look to recoup its administration costs in large part from companies supplying NHSPs but as these costs have already been included under our category "administration costs" we do not include them under compliance costs as to do so would be double counting.

² We estimate the compliance costs for relatively small (\$1m p.a. turnover) companies with between 50 and 500 products could be between 6% and 11% of revenue while for larger companies (\$20m p.a. revenue) with a similar range of products the costs may account for less than 1% of annual revenue (refer the Appendix).

Overall it is not obvious that passage of the bill is likely to enhance national welfare. The administrative and compliance costs of the bill alone are, on conservative assumptions, likely to cost the economy around \$7m to \$18m p.a. Based on official estimates of the value of life saved of around \$3.8m,³ around two to five premature deaths each year – or an equivalent value of suffering – would have to be avoided as a result of the regulatory regime for these benefits to outweigh the administrative and compliance costs alone. Greater benefits would likely be needed to outweigh the deadweight costs of the bill. As noted above, there does not appear to be compelling evidence that such health benefits are likely. A review of coroners' reports found no deaths in New Zealand had been attributed to the use of NHSPs and the available data indicates few serious adverse events associated with the use of NHSPs.⁴ Estimates from Australia suggest a New-Zealand equivalent rate of deaths associated with the use of NHSPs of the order of 0.3 lives p.a.⁵ If we adopt the Australian estimates, the costs that can be quantified (on a conservative basis) exceed the benefits in terms of premature deaths avoided by a factor of around 6 to 15 times.⁶

As noted above, over time the costs of the bill are likely to increase rather than decrease. The bill will allow the NHSP Regulatory Authority (a new office to be administered by the Ministry of Health) considerable discretion in implementing the regime. Experience from other regulatory regimes, both in New Zealand and overseas, is that the extent and costs of the regulations is likely to increase rather than decrease over time.

The above analysis does not necessarily mean the bill will reduce overall economic welfare. Not all the benefits and costs of the bill can be quantified in monetary terms and there is inevitably a range of uncertainty around those factors that can be quantified. Nevertheless, the analysis indicates that better evidence of the problems with the status quo is warranted before imposing substantial costs on a small but growing sector of the economy.

In conclusion, there does not appear to be a compelling case for moving from the current general regulatory regime for NHSPs. It appears that a significant problem with the current regulatory regime is that the existing regulations are outdated and are not being adequately enforced.⁷ If that is the case, the best solution would normally be to revise and enforce the

³ Official estimates of the value of life saved in New Zealand are sourced from the Ministry of Transport (2013).

⁴ Data from the Centre for Adverse Reactions at Otago University indicates around two suspected serious adverse events p.a. associated with the use of NHSPs in New Zealand (refer section 3.2).

⁵ As is discussed in section 3.2 of this report, the estimates of possible deaths in Australia associated with the use of NHSPs appear to have been misreported and significantly overestimated in the RIS accompanying the bill.

⁶ As noted above the costs that can be quantified total around \$7m to \$18m while the benefits in terms of premature deaths avoided each year using the Australian data equate in monetary terms to benefits of around \$1.2m p.a.

⁷ Ministry of Health (2011), p.5.

existing regulations on a basis proportionate with the risk and benefits, rather than to pass more regulations and establish a new subsector-specific regulatory regime.

2 Introduction

This paper provides an economic analysis of the Natural Health and Supplementary Products Bill (“the bill”), as reported back from the Select Committee in October, 2012. In particular, this paper addresses the proposals in the bill that natural health and supplementary products (NHSPs) be subject to new sector-specific regulatory regime.

In assessing the proposals for additional sector-specific regulations for NHSPs we take a national interest perspective, applying the tools of conventional welfare economics to assess whether it is likely to be in the national economic interest to introduce special regulations for the NHSP sector. Our analysis draws in particular on the insights from institutional economics, transactions costs economics, public economics, public choice theory and the relevant empirical literature.

This report begins by describing briefly the current regulatory requirements for supplying NHSPs in New Zealand and the changes to the regulatory regime proposed in the bill. We then assess the new regulatory regime proposed in the bill. In particular we focus on the nature of the problem that the proposals seek to address, the costs and benefits of the proposed policies (relative to the status quo and feasible alternatives) and whether the costs of the proposals are likely to outweigh the benefits. The final section of the paper provides our overall conclusions.

2.1 Current regulatory requirements

NHSPs are subject to a wide range of existing legislation aimed at protecting consumers. The existing legislation includes:

- the Food Act, 1981 and the Dietary Supplements Regulations 1985 issued under the Act. The regulations describe a number of requirements including, but not limited to, labelling and maximum permitted daily doses for several vitamins and minerals. As with food-related products in general, there are no pre-approval or pre-evaluation processes for dietary supplements.⁸ It remains the responsibility of the supplier to ensure the product is made to an acceptable quality, is safe to use and complies with the law. The New Zealand Medicines and Medical Devices Safety Authority (Medsafe), a unit within the Ministry of Health, is responsible for

⁸ In general, dietary supplements are substance(s) for oral use that are packed in a controlled dosage form and are intended to supplement the intake of that substance(s) normally derived from food.

administering the dietary supplement regulations although the Minister responsible for the administration of the Food Act is the Minister for Food Safety;⁹

- the Medicines Act, 1981 which regulates as medicines or related products all products claiming a therapeutic purpose. For example, dietary supplements cannot be sold with a stated or implied therapeutic purpose unless they are registered as medicines. Nor can dietary supplements contain ingredients listed in the First Schedule to the Medicines Regulations 1984 – i.e., substances that are scheduled as prescription medicines, restricted (pharmacist-only) medicines or pharmacy-only medicines;
- the Misuse of Drugs Act 1975. In particular, dietary supplements cannot contain ingredients scheduled as controlled drugs under the Misuse of Drugs Act;
- the Food Hygiene Regulations, 1974. Dietary supplements must be manufactured and packed in a manner that complies with the Food Hygiene Regulations 1974 and Food Act 1981. This may involve, for instance, registration with a local council under the Food Hygiene Regulations 1974 or registration with the Ministry for Primary Industries through a Food Safety Programme;
- the Fair Trading Act, 1986. Under the Fair Trading Act misleading and deceptive conduct, false representations and unfair practices are prohibited. The Act also provides for regulations creating consumer information and product safety standards for goods and services. As of June this year, the FTA also prohibits unsubstantiated representations (i.e. making claims without evidence to support those claims). The FTA is enforced by the Commerce Commission and individuals and corporations can take action under the general provisions of Act prohibiting misleading conduct. Breaches of the prohibition on unsubstantiated representations will only be able to be prosecuted by the Commerce Commission; and
- the Consumer Guarantees Act, 1993. The Consumer Guarantees Act provides certain protections to consumers and provides consumers with a right of redress where certain standards (such as acceptable quality) are not met. The legislation relies on consumers taking action for themselves.

2.2 The bill's proposals

The bill, if passed in its current form, would establish a sector-specific system for the regulation of NHSPs in New Zealand. Key features of the bill, as reported back to the House by the Health Select Committee, are it would:

⁹ It is unusual for regulation to be administered by an agency that sits within a different Ministry.

- define a NHSP according to how the product is consumed, the form it is presented in, its ingredients and the type of claim of health benefit made;
- establish a NHSP Regulatory Authority (“the Authority”) within the Ministry of Health;
- establish an approval process for NHSPs in relation to health benefit claims and ingredients:
 - an initial black-list for claims relating to approximately 14,000 conditions recorded in the World Health Organisation’s International Classification of Diseases database;
 - a whitelist of approved conditions (about which health benefit claims may be made) is to be established by the Authority. Only NHSPs making general health benefit claims or health benefit claims about approved conditions would be permitted to be marketed in New Zealand. If a NHSP wishes to make claims relating to a condition not on the approved list, approval must be obtained from the Authority; and
 - a whitelist of approved ingredients and a blacklist of prohibited ingredients are also to be developed. If a NHSP includes an ingredient not on the approved list, approval must be obtained from the Authority;
- permit the Authority to audit, suspend or cancel notifications, prohibit ingredients, undertake safety assessment and prescribe fees; and
- permit the Authority to establish standards and a code of manufacturing practice for NHSPs.¹⁰

Much of the details of how the bill would work in practice are to be prescribed by regulations and operating procedures that would be established after the bill is passed. There is therefore considerable uncertainty about how the regime will work in practice. The bill provides considerable discretion for the Authority to amend and extend its activities (and charges) over time.

¹⁰ This power already exists under the Food Act, 1981.

3 An assessment of the approach proposed in the bill

3.1 The framework for analysis

The standard framework for public policy analysis and design is outlined well in the Treasury's "Regulatory Impact Analysis Handbook".¹¹ In brief, the Handbook notes that the key steps in Regulatory Impact Analysis (RIA) are to:

- a) describe the status quo;
- b) define the nature and magnitude of the problem and the need for government action;
- c) define the public policy objective(s);
- d) identify the full range of feasible options (regulatory and/or non regulatory) that may constitute viable means for achieving the desired objectives(s); and
- e) analyse the options and assess the net benefits of the proposal, including the total regulatory costs (administrative, compliance, and broader economic costs) and benefits (including non-quantifiable benefits) of the proposal, and other feasible options.

The above approach is reinforced by the Government's 2009 Statement on Regulation¹² and the Process & Content of Legislation Guidelines provided by the Legislative Advisory Committee (LAC).¹³

The Government's Statement on Regulation requires advisors on public-policy issues to ask whether:

- the problem cannot be adequately addressed through private arrangements and if a regulatory solution is required in the public interest;
- all practical options for addressing the problem have been considered;
- the benefits of the preferred option not only exceed the costs (taking account of all relevant considerations) but will deliver the highest level of net benefit of the practical regulatory options available;
- the proposed obligations or entitlements are clear, easily understood and conform as far as possible to established legislative principles and best-practice formulations; and

¹¹ The Treasury (2013).

¹² <http://www.beehive.govt.nz/release/cutting+red+tape+create+better+smarter+economy>

¹³ Legislative Advisory Committee (2001).

- implementation issues, costs and risks have been fully assessed and addressed.

The LAC similarly recommends in its guidelines that an informed consideration of the options available to deal with an identified problem be carried out. The options available to the Government might include (but not be limited to): no government intervention; the status quo; the use of existing law; increasing enforcement; information and education campaigns; economic instruments (taxes, subsidies, and tradable property rights); voluntary standards/codes of practice; self regulation; and co-regulation. The LAC notes that these options are likely to have very different implications for results, the magnitude of costs and benefits, their distribution, and administrative requirements.

We have, therefore, approached our task by asking the following three questions:

- what is the problem to be addressed? This issue is addressed in section 3.2 of our report;
- what are the feasible options (including both government and/or non-government) for achieving the desired objectives? This issue is addressed in section 3.3 of our report; and
- what are pros and cons of the different options and are the benefits of the bill likely to outweigh the costs? This issue is addressed in section 3.4 of our report.

3.2 What is the problem?

As noted in the Treasury's RIA guidelines, a key step in public policy analysis is identifying clearly the problem that needs to be addressed and assessing how significant the problem is. Without this critical early step being undertaken carefully and rigorously, the subsequent policy analysis can go off the rails: we can be left, at the end of the process with "a solution in search of a problem."

In the case of the bill and the accompanying RIS, it is not clear what the fundamental problem is that the proposed legislation is seeking to address.

The bill outlines general principles (s4), one of which (s4(b)) is that "the regulation of NHSPs should be proportionate to the risks associated with their use."

The commentary on the bill from the Health Committee (p.324-2) indicates that NHSPs are considered by the Committee to be low risk. The commentary states (p. 324-2): "The bill seeks to regulate low-risk natural health products."

The RIS notes (p. 4): "There is little information on the adverse events resulting from the use of natural health products in New Zealand."

In their accompanying report for the NZHT, Castalia review the available evidence and conclude that there is “little evidence of major problems with the safety or consumer protection in the NHSP market. We find that there is very little that a regulatory intervention might hope to achieve.”¹⁴

There is some evidence from Australia of adverse events and deaths associated with NHSPs. If the Australian estimates of around 1.6 deaths per year are applied to New Zealand, and taking into account New Zealand’s population is around 1/5th of Australia’s, this would imply around one death in a little over every three years in New Zealand associated with the use of NHSPs. It should be noted that the Australian regime is considerably more heavily regulated than New Zealand, that the Australian estimates do not purport to show causation (i.e., no claim is made that the NHSPs caused the adverse events or deaths) and that the estimates from Australia appear to have been significantly overstated in the RIS.¹⁵

We are not aware of any evidence (e.g., from coroners’ reports) to conclude there have been any deaths in New Zealand caused by NHSPs.¹⁶ However, to err on the side of caution, in our assessment of the costs and benefits of the bill (section 3.4 below) we use the Australian figures, modified for New Zealand’s population, as one indicative benchmark to test the net benefits of the bill.

Official data indicates few adverse events associated with the use of NHSPs in New Zealand.¹⁷ The Centre for Adverse Reactions (CARM) at the University of Otago received a total of 4,138 reports of suspected adverse reactions from all sources in New Zealand in 2013.¹⁸ Regulated medicines (64.2%) accounted for the majority of adverse events. Vaccines accounted for 35.6% and NHSPs only 0.2%.^{19, 20} 37% of the medicine reports, 3% of the vaccine reports and 29% of the NHSP reports were considered serious. This equates to around seven reported cases of adverse events associated with NHSPs in New Zealand in 2013, of which around two were serious. It is likely that not all cases of adverse events to NHSPs in New Zealand are

¹⁴ Castalia Ltd (2014).

¹⁵ The RIS reported that a 2005 Australian study (unreferenced) found Australia as having had 62 deaths over the preceding decade associated with natural health products. The Australian Therapeutic Goods Administration (TGA) however advises that the numbers reported in the RIS are an incorrect interpretation of the Australian study and that the correct numbers are 15 deaths over the preceding decade (emails of TGA to Ron Law of 29 March 2012 and 9 September 2013). The Australian study referred to is a report from the TGA’s Office of Medicines Safety Monitoring generated on 3 July 2008 from the adverse drug reaction database.

¹⁶ The Castalia report notes that a 2006 report from the then Chair of the Coroners’ Council found no deaths in New Zealand had been attributed to NHSPs in coroners’ reports.

¹⁷ Medsafe (2014).

¹⁸ Medsafe notes that the number of reports submitted annually in New Zealand has remained consistent over the last five years.

¹⁹ The category used in the CARM reports that is closest to NHSPs is described as “complementary and alternative medicines”.

²⁰ The comparative figures for 2012 were 67.8%, 31.8% and 0.3% respectively.

reported to CARM, especially if the events are minor and cease when the person stops taking the NHSP. Nevertheless we would expect that most serious adverse events would be reported and captured by the data.

The case provided in the RIS (p. 6) for sector-specific regulation for NHSPs also rests on perceived “market failures” arising from consumers “inability to detect safety or quality deficiencies in a product” ... and their ... “inability to distinguish between valid claims made by reputable distributors and the sorts of extravagant claims made by some products.” Such problems (that economists refer to as information asymmetry)²¹ are not unique to NHSPs. They are common to many goods and services throughout the economy. Further, there exist a range of market mechanisms which deal to varying extents with such problems including the use of brands, repeat purchase, social media and 3rd party experts or agents to assess the quality of a good or service. To the extent there is a residual problem there may be a case for government intervention but, as is discussed below, government agencies also have difficulty in determining and enforcing safety and other quality standards and any intervention should be commensurate with the risks to individuals and the community involved.

Many of the problems with the current regulatory regime identified in the RIS appear to be based largely on government failure rather than market failure. For example the RIS notes that the interface between the Medicines Act and Dietary Supplements Regulations is not clearly stated; offenders are rarely prosecuted; and the penalties for non-compliance are extremely low. Many of these problems would seem to be addressable by amendments to the existing regulations (e.g., by increasing the penalties for breaches) and by more strictly enforcing the existing regulations rather than introducing a new regulatory regime.

3.3 What are the feasible options

There is a broad range of feasible options for regulating NHSPs in New Zealand. In principle there is a continuum of options from do nothing (i.e., rely on the existing generic legislation) to heavy-handed regulation of the products by, for example, requiring any product that makes a health claim to be subject to the medicines regime. In between are options such as mandating disclosure of ingredients, having blacklists of prohibited ingredients and conditions for which health claims cannot be made and having whitelists of approved ingredients and conditions for which health claims can be made.

²¹ One of the principal anomalies that has been documented in the risk-perception and choice-under-uncertainty literature is that individuals tend to overreact to increases in the risk level. Viscusi (1995) has termed this a “reference risk” whereby changes in the risk level from the accustomed risk (e.g., as a result of a highly publicised or dramatic failure) lead to an exaggerated response. Another impact that is observed is a “lulling” effect where regulations do not have the expected impact because people alter their behaviour in response to the regulation: see e.g., Viscusi, Vernon and Harrington (1995).

In our report we focus on the costs and benefits of the bill (relative to the status quo). We also note two key alternative options to the bill that seem most practical for dealing with many of the problems identified in the RIS:

- i. a notification or disclosure regime whereby suppliers of NHSPs must advise the Authority of the contents and therapeutic claims of their products. Such information would then be made available to the public, presumably via the Authority's website. This information would permit consumers and the Authority to know "who and what is in the market". This information would, for example, facilitate a product recall if one was required; and
- ii. updating and more extensive enforcement of the existing regulations. We understand the current regulations have not been updated for many years. Further, we understand the existing regulations are often not being enforced, the penalties for noncompliance are very low (\$500) and there are numerous (unprosecuted) breaches of the prohibition on therapeutic claims by dietary supplements. This does not seem satisfactory.

The above options could be introduced in isolation or together. Either way, they would supplement the extensive systems of consumer protection and food safety laws that already exist in New Zealand (as discussed in section 2.1 above).

3.4 The costs and benefits of the bill

This section of the report provides our assessment of the costs and benefits of the bill. The counterfactual against which we assess the costs and benefits is the current regulatory environment (i.e., we assess the costs and benefits of the bill relative to the status quo). Where possible we provide quantitative estimates of the additional costs and benefits of the proposed regulatory environment relative to the status quo. Given the uncertainties around the scale of the NHSP industry and the uncertainties around the details of how the proposed regulatory regime would work, our quantitative estimates of the costs and benefits should be regarded as indicative only.

As is often the case with regulatory proposals, many of the costs of the proposed new regime for NHSPs can be quantified more readily than the benefits. In these circumstances, when weighing up the overall net benefits of the proposed regime, judgements must inevitably be made, either explicitly or implicitly, about the likely order of magnitude of the non-quantifiable benefits (and costs). One technique used by economists to make the assumptions underlying a regulatory proposal or other intervention more explicit is to "reverse engineer" an estimate of the key assumptions implicit in the proposal. That is, to ask the question, how many lives would have to be saved or other adverse health events avoided as a result of the

bill for the likely benefits of the bill to outweigh the projected costs. We consider this question in section 3.5 below.

3.4.1 The costs of the bill

The costs the bill imposes on the economy include the costs to the government of administering the new regime (administrative costs); the direct costs to industry of complying with the regime (compliance costs) and the broader economic costs imposed on the economy (deadweight costs) by the regime. We discuss each of these costs in turn below.

Administrative costs

The costs the government incurs in implementing the legislation include the costs of designing, monitoring and enforcing the legislation. We refer to these costs as “administrative costs”. The RIS highlights a number of outputs that would need to be funded. These include:

- regulatory policy advice;
- notification of products and new ingredients;
- standards setting;
- export certificates;
- compliance, audit, licensing manufacturers and monitoring; and
- enforcement.

The Ministry of Health estimates in the RIS that it would cost around \$1.1m in capital expenditure and \$1.8m in operating costs to set up the regulatory authority, with ongoing costs of around \$3.64m p.a.

The set-up costs can be annuitised into an equivalent annual cost (using the Treasury-approved public sector discount rate of 8% real)²² of around \$0.23m p.a. Combining the annuitised set-up costs with the ongoing costs provides an estimate of total administrative costs of around \$3.87m p.a.

These costs of administering the regime are likely to be passed on in large part to the industry by way of user-charges. The RIS proposes that all costs (including set-up costs) be paid for by the industry except for regulatory policy advice and enforcement costs.

²² The Treasury (2010).

For the purposes of our national cost-benefit analysis we focus on the real resources used in the economy. We therefore exclude the user charges from our estimate of compliance costs below. This avoids any risk of double-counting the administrative costs of the proposal.

Compliance costs

Compliance costs are the costs businesses incur when meeting a regulatory obligation. In the case of the NHSP Bill, compliance costs would arise due to the time it would take to understand the new requirements, implement the systems required to meet the requirements of the manufacturing code and gather the information necessary to complete the web-based notification process.

Cost would be incurred by manufacturers if they need to upgrade their systems, equipment or buildings, re-label or reformulate products or introduce new tests in order to meet new regulatory standards. Given many of the costs are fixed and given also that many large enterprises already have good manufacturing practice (GMP) status, the compliance costs will fall disproportionately on small and medium sized enterprises (SMEs).

Given the uncertainties about the scale of the NHSP sector and the lack of detail at this stage about the regulations and the nature of the manufacturing standards, it is difficult to estimate with accuracy the total industry-wide compliance costs likely to arise from the bill. We estimate the compliance costs using a “bottom-up” approach, looking at the likely range of individual costs per compliance activity in the NHSP sector. More details on our estimates of the compliance costs are provided in the Appendix to this report.

Our bottom-up estimate suggests a possible range for the total compliance costs of the bill, on a conservative basis, to be in the range of \$3m to \$14m p.a. The actual compliance costs could however be considerably higher, depending on the approach adopted by the Authority, especially with regard to setting and auditing manufacturing standards. We understand that in Australia, where the regulations administered by the Therapeutic Goods Administration (TGA) are more onerous than is proposed initially in New Zealand, the compliance costs can exceed \$1m p.a. for large companies.

It should be noted that our estimate of compliance costs exclude the costs of licensing, auditing and monitoring of firms by the government as these costs are included in the regulator’s administration costs above.

Compliance costs – a case study

This section provides a case study of how one company, a small Christchurch-based manufacturer, could be affected by the NHSP Bill. The company has annual turnover of around \$2m and 10 staff. The company encapsulates products on contract for around 12 clients, with around 50 different products encapsulated in a typical year. The company also freeze-dries products. The company achieves an average margin of around 15% of sales.

The company already complies with Ministry of Primary Industry (MPI) regulations as a food producer, including the appropriate Hazard Analysis Critical Control Point (HACCP) standards.²³ The company currently employs 1.5 full-time equivalent staff on quality assurance (QA). The company's annual MPI audit costs are approximately \$30,000 p.a.

Only the encapsulation side of the company's business would be affected by the NHSP Bill. Encapsulation accounts for around 30% of the company's revenue and a similar percentage of its staff. The extent to which the encapsulation business would be impacted by the legislation will depend on the nature of the regulations that are passed and the way in which the regulations evolve over time. As the regulations have yet been promulgated, there is inevitably considerable uncertainty about the nature of the regulations and how the company would be impacted.

If the company had to comply with pharma-equivalent GMP standards, the company estimates it would have to spend around \$50,000 to \$100,000 upgrading its physical facilities (e.g., its floor coverings and air filtration systems). The company also advises it would have to employ additional staff (at a cost of around \$50,000 p.a., excluding overheads) and pay the government for extra audits at an estimated cost of around \$12k p.a. These additional costs would have to be either passed on to consumers or, if that was not possible, the company would probably have to withdraw from that side of its business.

²³ HACCP is a science-based control system for assuring food safety and is widely-used in New Zealand. Food safety is achieved by systematically assessing hazards, developing control systems and focusing on preventative measures. The Codex Alimentarius Commission's Committee on Food Hygiene has developed a guideline document that covers the principles and application of HACCP to all sectors of the food chain from producer to consumer (refer Codex, 1996 and van Schothorst, 2003).

Deadweight costs

In addition to the administrative and compliance costs of regulation there are the broader costs to the economy arising from the distortions to economic behaviour resulting from government regulations. These costs include transitional costs associated with the loss of employment opportunities and loss of capital investment and ongoing costs from safe or low-risk products being withdrawn from sale (to the detriment of consumers and producers), reduced incentives to innovate, and other distortions to economic behaviour as a result of the regulatory impositions. These costs are referred to as the “deadweight costs” of regulation.

Given the structure of the NHSP sector, with a large number of SMEs and only a comparatively few large-scale enterprises, these deadweight costs are likely to be borne disproportionately by the SME sector.

A significant concern that we have in this regard relates to the costs the new proposed regulatory regime could impose on innovation in the NHSP sector. The NHSP sector in New Zealand has a long tradition of successful start-ups, often from cottage-based industries. Examples include businesses harnessing the antibacterial properties of manuka honey, mussel extract powder, marine oils, natural honey products, deer velvet, skincare, botanical and dairy products and research and development that has identified a non-calorific natural sweetener.

The NHSP sector in New Zealand is a relatively fast growing and dynamic sector under the current regime. Export markets have been established in Asia and North America, and there is a developing presence in Europe. Asian markets in particular, with their growing middle class, aging populations, and increasing health consciousness are experiencing strong growth.²⁴ Bay of Plenty-based Comvita, for example, which markets products including manuka honey, lozenges and bee pollen capsules, sells in more than 450 retail sites across Asia. Eco-tourism is also growing, with sales of NHSPs to visiting Chinese and other tourists reported to be growing strongly.

Larger, established companies like Integria Healthcare, Lifestream International, Manuka Health and Vitaco Health Ltd and NZX-listed companies Comvita NZ, Promisia Integrative and SeaDragon may have relatively little difficulty absorbing the costs of the proposed regime. Start-up and smaller companies, however, may struggle. Under the bill, a new product that contains an ingredient or makes a health claim relating to a condition that is not on the Authority’s approved lists will have to apply for approval. As well as the delays associated with

²⁴ The natural health products market in China is reported to be growing by 15% to 20% p.a.
http://www.nzherald.co.nz/health-wellbeing/news/article.cfm?c_id=1501238&objectid=11220767

the process, the company will have to incur the fees associated with approval and incur the costs in complying with the new regime. Such costs and uncertainties may well reduce incentives to bring new products to the market.

In addition, as is noted in the RIS, consumers are likely to lose access to some existing NHSPs as a result of the cost increases or rationalisation of product lines resulting from the bill.

It is difficult to quantify these deadweight costs of regulation but they can be much larger than the more obvious direct administrative and compliance costs of regulation noted above.

25

3.4.2 The benefits of the bill

The key benefit or outcome sought from the bill is the avoidance of premature deaths and pain and suffering that may be occurring under the current regulatory environment for NHSPs.

While such benefits are possible, there appears to be little or no evidence that adverse health consequences from NHSPs are a major problem in New Zealand under the current regulatory regime. This issue is discussed in section 3.2 and is not repeated here.

One related risk with the current regime identified in the RIS is where consumers put off going to a doctor and attempt to treat serious conditions by using NHSPs, in the belief that the claimed benefits from the products are true, where there is no basis for such claims. However, people defer going to the doctor for a variety of reasons. To the extent this is a problem, it is a general problem and not unique to NHSPs. Further, to the extent that going to the doctor is subsidised the government provides a financial incentive to visit medical professionals.

Another potential benefit from the bill is it could result in better information for consumers and regulators of NHSPs. As noted in the RIS, the bill is designed to give consumers confidence that NHSPs are “true to claim and true to label.” While this goal is laudable it should be recognised firstly that suppliers who provide misleading or inaccurate information are at risk of damaging their reputation and losing market share. While such market disciplines are by no means perfect, the advent of the internet, social media and other aspects of the information revolution have helped shifted the balance of power towards consumers. Nevertheless some suppliers will still inevitably seek to mislead customers. That is a problem the Fair Trading Act is designed to address. As noted above, under the Fair Trading Act

²⁵ A study for the Small Business Administration put the cost to Americans of all regulations at \$843 billion in 2000, 10 percent of America’s gross domestic product, more than half the output of the US manufacturing sector and over US\$8,000 per household. These costs are probably underestimated – it is impossible to measure the cost of innovations that didn’t happen. See Gattuso (2004) and World Bank (2004).

misleading and deceptive conduct, false representations and unfair practices for all goods and services are prohibited. To the extent this generic legislation does not suffice and there is evidence of a problem particular to NHSPs, there may be a case for an information disclosure regime specifically designed for NHSPs. Under such a disclosure regime suppliers of NHSPs could be required to advise the Authority of the contents and therapeutic claims of their products. Such information would then be made available to the public, presumably via the Authority’s website. This information would permit consumers and the Authority to know “who and what is in the market”. Such a disclosure regime could be implemented at relatively little cost to the government and industry and would not require extensive NHSP sector-specific regulations.

However, as noted above the bill goes well beyond being an information disclosure regime. The bill establishes an approvals regime: the regime establishes an initial black-list for claims relating to around 14,000 conditions; a whitelist of approved conditions (about which health benefit claims may be made) is to be established; and a whitelist of approved ingredients and a blacklist of prohibited ingredients are also to be developed.

Finally we note that a problem identified in the RIS with the current regime is the widespread breaches of the current prohibition on therapeutic claims by suppliers of NHSPs. A Ministry of Health review found 107 of 355 NHSP websites it surveyed were in breach.²⁶ It is not clear to us however that passing additional regulations will necessarily overcome a problem of compliance with the existing regulations. A lower cost option may be to better enforce the existing regulations.

3.5 Do the overall benefits outweigh the costs?

The table below summarises our assessment of the overall key likely costs and benefits of the bill.

Overall assessment of the costs and benefits of the bill

Benefits	Costs
May avoid premature deaths or pain and suffering	Administrative costs of the government (~ \$4m p.a. initially)
Better information for consumers and regulators	Compliance costs to firms (~ \$3m to \$14m p.a. on a conservative basis)

²⁶ Ministry of Health (2011), p.6.

	Loss of products from the market
	Loss of physical and human capital as firms withdraw from the market
	Reduced incentives to innovate

It is possible to provide indicative monetary estimates of some of the costs but inevitably a number of benefits and costs are unable to be readily quantified. Weighing up the overall costs and benefits therefore requires judgement and an overall assessment of the balance of risks.

We can obtain some insights into how large some of the non-quantified benefits and costs would have to be to assist with this overall risk assessment by “reverse engineering” some of the key unquantified parameters. In particular, we can address the question: “how many lives would have to be saved as a result of the bill for this potential benefit to outweigh the quantified costs”.

Official estimates of the value of a life saved in New Zealand are currently around \$3.8m.²⁷ Using this estimate of the value of a life saved, and comparing it to the costs that have been quantified, around two to five deaths each year would have to be avoided as a result of the regulatory regime for this benefit to outweigh the administrative and compliance costs of the bill (these costs are estimated to total around \$7m to \$18m p.a.). As noted in section 3.2 above, there is little evidence of the likely health costs of the current regime but applying estimates from Australia suggests that the number of deaths might be of the order of 0.3 possible lives p.a.

Considerably greater benefits in terms of lives saved or pain and suffering avoided would likely be needed to outweigh the deadweight costs of the bill such as the reduced incentives to innovate and the loss of products from the market. As noted above, these deadweight costs are typically significantly greater than the more visible administrative and compliance cost of regulation.

The above analysis does not necessarily mean the bill will reduce overall economic welfare. Not all the benefits and costs of the bill can be quantified in monetary terms and there is inevitably a range of uncertainty around those factors that can be quantified. Nevertheless,

²⁷ Official estimates of the value of life saved in New Zealand are sourced from the Ministry of Transport (2013).

the analysis indicates that better evidence of the problems with the status quo is warranted before imposing substantial costs on a small but growing sector of the economy.

We note that over time the costs of the bill are likely to increase rather than decrease. The bill allows the Authority considerable discretion in implementing the regime. Experience from other regulatory regimes, both in New Zealand and overseas, is that the extent and costs of the regulations tend to increase rather than decrease over time.

There has been some discussion about harmonising New Zealand's regulatory regime for NHSPs with that administered by the TGA in Australia.²⁸ If Australia's regime for regulating NHSPs was assessed to be international best practice, then alignment with Australia may be appropriate. However, there is little evidence that the Australian regime is considered best practice. Indeed, as noted above, the Australian regime for regulating NHSPs imposes high compliance costs on Australian suppliers. The regime also is likely to impose high deadweight costs on the Australian economy through the delays in approvals,²⁹ the products that have been withdrawn and through losses in international competitiveness.

The dangers of harmonising New Zealand's general regulatory environment with Australia's for "harmonisation's sake" have been pointed out by Neil Quigley, Professor of Economics at Victoria University. As Quigley notes, "The harmonisation of laws may provide benefits to those firms who operate in more than one jurisdiction. But it may impose higher transaction and compliance costs on the vast majority of firms who operate only in the domestic market."³⁰ Further, Quigley notes that there can be substantial benefits to New Zealand maintaining independence in its regulatory regime. Maintaining independent regulations permits New Zealand to achieve a competitive advantage by putting in place regulations that have lower compliance and transaction costs than those in other countries.

4 Conclusions

Issues involving human safety and risk require careful judgement and a careful evaluation and balancing of the risks and benefits of alternative regimes.

The bill as reported back from the Select Committee, in our assessment is likely to impose administrative, compliance and deadweight costs on NHSP suppliers and consumers that do not appear to be outweighed by evidence of comparable offsetting benefits. The proposed

²⁸ A joint Australia New Zealand Therapeutic Products Agency (ANZTPA) is currently under development. The ANZTPA is to be responsible for medical devices and pharmaceuticals only, with NHSPs explicitly carved out.

²⁹ For example, an application by the Complementary Healthcare Council of Australia (CHC) for the approval of a widely used traditional ingredient took five years. http://www.pc.gov.au/_data/assets/pdf_file/0008/82547/subdr68.pdf

³⁰ Quigley N (2003).

regime goes well beyond being a light-handed disclosure regime and does not appear commensurate with the risks arising from NHSPs in New Zealand.

We do not consider a convincing case has been made for establishing a new sector-specific regulatory regime for NHSPs. Updating and better enforcing the existing regulations would appear to be a logical step if material breaches of the current regulations are occurring. In addition, the government could require all NHSP suppliers to provide information on their ingredients and therapeutic claims on the Authority's website. When combined with existing general consumer protection and food safety regulations, these steps would seem more commensurate with the risk-profile of the NHSP industry.

Finally we note that there is a question about the appropriate location of responsibility for regulating NHSPs. As noted above, the Bill proposes establishing a separate unit with the Ministry of Health responsible for administering the NHSP regulations. However, given the relatively low risks associated with NHSPs and the export focus of many in the industry, it is questionable whether allocating responsibility to the Ministry of Health is the best fit. The Ministry of Health is responsible for regulating medicines and medical devices and has developed a relatively risk-averse culture more appropriate for high-risk activities. Further, the Ministry of Health has little experience and expertise in monitoring and authorising export products. A better fit for the NHSP sector may be the Ministry of Primary Industries (MPI) given the NHSP sector is primary-industry based, is export-oriented and is relatively low risk. Most suppliers of NHSPs already have to interact with MPI as the agency responsible for regulating food safety and biosecurity and compliance costs for the sector would be lowered, without any obvious losses in consumer safety, if MPI was the "one-stop shop" for NHSPs.

Bibliography

ARNOLD T, BOLES DE BOER D and EVANS L (2003), “The Structure of New Zealand Industry”, in *Competition Law at the Turn of the Century: a New Zealand Perspective*, edited by Mark N Berry and Lewis T Evans (Wellington).

BENSTON G (1977), “An appraisal of the costs and benefits of government-required disclosure: SEC and FTC requirements”, *Journal of Law and Contemporary Problems*, Vol. 41 No.3 pp 30 – 62.

BUSINESS NEW ZEALAND- KPMG, *Compliance Cost Survey, October 2008*,
<http://www.businessnz.org.nz/resources/surveys-and-statistics/compliance-cost-survey>

CABINET OFFICE, *CabGuide, Guide to Cabinet and Cabinet Committee Processes*,
<http://cabguide.cabinetoffice.govt.nz/procedures/regulatory-impact-analysis>

CASTALIA LTD (2014), *Natural Health and Supplementary Products Bill: Regulatory Assessment, a report to the New Zealand Health Trust, March 2014*.

CODEX (1996): “Hazard analysis and critical control point (HACCP) system and guidelines for its application.” *Report of the Twenty Ninth Session of the Codex Committee on Food Hygiene*. Alinorm 97/13A, Appendix II. Codex Alimentarius Commission, Food and Agriculture Organisation, Rome.

COMPLEMENTARY HEALTH COUNCIL OF AUSTRALIA (2008), *Submission to the Australian Productivity Commission*, 4 August 2008.
http://www.pc.gov.au/data/assets/pdf_file/0008/82547/subdr68.pdf

CREDIT SUISSE FIRST BOSTON (1998), *Regulation of the Food and Beverage Industry*, Wellington, July 1998.

DEMSETZ H (1968), “The costs of contracting”, *Quarterly Journal of Economics*, 82, 33-53.

ENGLISH W, HIDE R (2009), Cutting red tape to create a better, smarter, economy.
<http://www.beehive.govt.nz/release/cutting+red+tape+create+better+smarter+economy> (17 August 2009).

EPSTEIN R (1995), *Simple Rules for a Complex World*, Harvard University Press, Cambridge.

GATUSSO J (2004), *Reforming Regulation to Keep America’s Small Businesses Competitive*, Testimony to the Subcommittee on Regulatory Reform and Oversight Committee on Small Business, United States House of Representatives, <http://www.heritage.org/Research/Regulation/tst052104a.cfm>

LEGISLATIVE ADVISORY COMMITTEE (2001), Guidelines on Process and Content of Legislation 2001 edition and amendments. Available at: <http://www2.justice.govt.nz/lac/> (28 October 2009).

MEDSAFE (2014), *Adverse Reaction Reporting in New Zealand - 2013*,
<http://www.medsafe.govt.nz/profs/PUArticles/March2014AdverseReactionReporting2013.htm#Updated%2021%20March%202014>

MINISTRY OF HEALTH (2011), *Regulatory Impact Statement: The Development of a Natural Health Products Bill Agency Disclosure Statement*, June 2011, <http://www.health.govt.nz/about-ministry/legislation-and-regulation/regulatory-impact-statements/development-natural-health-products-bill>

MINISTRY OF TRANSPORT (2013), *The Social Costs of Road Crashes and Injuries, 2013 Update*, <http://www.transport.govt.nz/assets/Uploads/Research/Documents/Social-Cost-of-Road-Crashes-and-Injuries-June-2013-update.pdf>

MYERS S and N MAJLUF (1984), “Corporate Financing and Investment Decisions when Firms have Information the Investors Do Not Have”, *Journal of Financial Economics* 13, 187-221.

NORTH D (1990), *Institutions, Institutional Change and Economic Performance*, Cambridge University Press, Cambridge.

QUIGLEY N (2003), “Commercial Law and Regulation: Harmonisation vs Competition” in *Competition and Regulation Times*, New Zealand Institute for the Study of Competition and Regulation, Wellington.

THE TREASURY (2010), *Cost Benefit Analysis including Public Sector Discount Rates*, October 2010, <http://www.treasury.govt.nz/publications/guidance/planning/costbenefitanalysis>

THE TREASURY (2013), *Regulatory Impact Analysis Handbook*, July 2013, <http://www.treasury.govt.nz/publications/guidance/regulatory/impactanalysis/ria-handbk-jul13.pdf>

van Schothorst M (2003): HACCP. *A simple guide to understanding and applying the hazard analysis critical control point concept*, International Life Sciences Institute, Europe.

VISCUSI WK (1995), “Carcinogen Regulation: Risk Characteristics and the Synthetic Risk Bias”, *The American Economic Review*, 85, 2, pp51-52.

VISCUSI WK, VERNON JM and HARRINGTON JE (1995), *The Economics of Regulation and Antitrust*, The MIT Press, Cambridge, Massachusetts, pp 662-663.

WILKINSON B (2001), *Constraining Government Regulation*, Wellington, 2001 http://nzinitiative.org.nz/site/nzbr/files/publications/publications-2001/constraining_govt.pdf

WORLD BANK (2004), *Doing Business in 2004: Understanding Regulation*, World Bank, International Finance Corporation, Oxford University Press.

Appendix: Indicative estimates of the compliance costs arising from the bill

This appendix provides high-level estimates of the likely compliance costs to the natural health and supplementary products industry from the Natural Health and Supplementary Products Bill.

There is inevitably a wide range of uncertainty about the likely order of magnitude of the total industry-wide compliance costs likely to arise from the bill given the uncertainties about the scale of the NHSP sector and the lack of detail at this stage about the regulations and the nature of the manufacturing standards.

As noted in the Regulatory Impact Statement there is relatively little information about the number and turnover of NHSPs in the market. However, the work the Ministry of Health undertook (drawing on the New Zealand Bioactives Report 2008) estimated there were around 450 companies supplying natural health products on the New Zealand market and they sold around 6,600 products. The number of products on the market could be significantly higher. The Ministry of Health noted that a small industry group submitted that the number could be as high as 20,000. The report also indicated that 75% of the companies had revenues of less than \$5m per annum.

We have calculated an indicative cost of compliance for the industry based on a range of what we believe are conservative inputs. The key inputs in the model and the ranges we have applied are:

- Number of companies in the industry: 400 to 500
- Number of products sold: 7,000 to 20,000
- Re-labelling cost (per product): \$1,000 to \$2,000
- Formulation change/re-labelling p.a.: 5% to 10% of total products
- Consultant retainer p.a. (per company): \$3,000 to \$7,000
- Salary of regulatory officer p.a.: \$45,000 to \$65,000
- % companies who will need a regulatory officer: 10% to 20%

Table 1 below provides a summary of the results. Based on the input ranges the total ongoing cost could be between \$3.3m and \$14m p.a.

Table 1: High level compliance cost estimate – ‘bottom-up’ approach

High-Level Compliance Cost Estimate Bottom-Up Approach	Low	High
Total Ongoing Cost Estimate:	\$3,350,000	\$14,000,000

It should be noted that the above estimates of the compliance costs exclude the user charges that are likely to be imposed on the industry to recover the government’s administration costs

(e.g. standard setting, compliance, audit, licensing manufacturers and monitoring). This avoids any double-counting of the administrative costs in our national cost-benefit analysis.

Industry demographics and relative costs

As discussed above, there are uncertainties about the scale of the NHSP sector within New Zealand as no database exists that provides robust information about the market. The Ministry of Health’s RIS stated that many of the companies in the industry are young and small with around 75% of companies generating less than \$5 million in annual revenue. This suggests that the NHSP sector is heavily weighted toward small to medium companies.

We provide below some examples that demonstrate how compliance costs will fall relatively more heavily on small to medium sized business with many products. The key assumptions we have made include:

- company 1 has a turnover of \$1m and sells 50 products;
- company 2 has a turnover of \$1m and sells 500 products;
- company 3 has a turnover of \$5m and sells 50 products;
- company 4 has a turnover of \$5m and sells 500 products;
- company 5 has a turnover of \$20m and sells 50 products;
- company 6 has a turnover of \$20m and sells 500 products;
- each company pays a consultants retainer of \$5,000 per year;
- each year 7.5% of products will require relabeling at a cost of \$1,500 per product; and
- each company will require a new staff member to complete the compliance requirements at a cost \$55,000.

Table 2 below provides a summary of our working example.

Table 2: Working example – compliance cost as % of company revenue

Compliance costs	Company 1	Company 2	Company 3	Company 4	Company 5	Company 6
Turnover	\$1,000,000	\$1,000,000	\$5,000,000	\$5,000,000	\$20,000,000	\$20,000,000
Number of Products	50	500	50	500	50	500
- Consultant Retainer	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000	\$5,000
- Formulation Change/Re-labeling	\$5,625	\$56,250	\$5,625	\$56,250	\$5,625	\$56,250
- Assume New Staff Member	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000	\$55,000
<i>Estimated Ongoing Compliance Cost</i>	<i>\$65,625</i>	<i>\$116,250</i>	<i>\$65,625</i>	<i>\$116,250</i>	<i>\$65,625</i>	<i>\$116,250</i>
% of Company Turnover	6.6%	11.6%	1.3%	2.3%	0.3%	0.6%

The key point from this working example is that the smaller companies, and especially those with many products, will be faced with far greater costs relative to revenues. In the above example, company 1, a \$1m turnover company with 50 products will be faced with around \$66k of compliance costs which are around 6.6% of revenues, while company 6, a \$20m turnover company with 500 products, will be faced with around \$116k of compliance costs which are around 0.6% of revenues. As the number of products increases the burden of the proposed regulation increases. For example, Company 2 with 500 products and \$1m turnover will face costs of around 11.6% of annual turnover.

If we assume companies 1 and 2 only require a 0.25 FTE staff member to assist with meeting compliance requirements then the compliance costs as a percentage of revenue fall to 2.4% and 7.5% respectively. This ratio is still significantly higher than the ratios of 0.3% and 0.6% for companies 5 and 6.

The burden of compliance costs will fall most heavily on smaller companies with larger product lines. We have assumed that as turnover increases the number of products does not change. However, in practice smaller companies may have very large product lines while larger companies may have very few products. As such, the variance in the cost to revenue ratios between small and large companies could be greater than our worked example above.