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Natural Health and Supplementary Products Bill: Regulatory Assessment

Report to NZHT

**March
2014**

Acronyms and Abbreviations

CHC	Complementary Healthcare Council of Australia
FTA	Fair Trading Act
MOH	Ministry of Health
NHSP	Natural Health and Supplementary Products
NZHT	New Zealand Health Trust
RIS	Regulatory Impact Statement
TGA	Therapeutic Goods Administration

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Figure 6.1: Health Benefit Claims Process in NHSP Bill

Executive Summary

Castalia has been engaged by the New Zealand Health Trust (The Trust) to evaluate regulatory regimes for the natural health and supplementary products (NHSP) industry. The Government intends to pass a Bill regulating the NHSP industry in 2014.

The Ministry of Health identified a problem that could be addressed by new legislation. It considered that the current regulatory framework does not ensure NHSP are safe, true to claim and true to label. By implication the legislation and regulatory regimes that currently address those factors are deficient.

Little evidence of a problem or gap in regulatory landscape

We do not find that there is a significant problem in the regulatory regime for NHSP. There is very little evidence of safety risks from NHSP consumption. No coroner reports have attributed any deaths in New Zealand with consumption of NHSP. The rate of adverse events is low with some evidence suggesting 20 per year (in an industry selling over \$500 million of products by some estimates).

NHSP are currently regulated under the Food Act. If they make a therapeutic claim, however, they are regulated as medicines. The medicines approvals system is costly and unsuitable for NHSP, undermining the ability for firms to make legal health benefit claims. Consumers are protected from inaccurate advertising and unsubstantiated claims under the Consumer Guarantees Act and the Fair Trading Act. Food safety requirements and the Medicines Act cover the safety of consumption.

There is no indication that the regulatory landscape is failing in any significant way to protect consumers from false and misleading claims. Complaints that have been made to the Commerce Commission regarding false or misleading claims, have gone through the processes in place to deal with these issues.

The regulatory principles do not ensure balance

The principles of the Bill seek consumer safety and protection from misrepresentation. There is no explicit principle or objective to limit the pursuit of safety other than a principle to seek risk proportionality. We recommend compliance cost minimisation and fostering competition as balancing objectives and principles in the Bill along with risk proportionality.

Many of the important regulatory decisions in the Bill are left to subsequent regulations which are not yet defined, including, fee structure, allowed and banned ingredient lists and manufacturing standards. This makes regulatory principles very important as it may be the only way to ensure that subsequent regulations are low cost and proportional to risk without unnecessarily hampering competition.

The regulatory options cover two areas: regulations that apply to ingredients used and claims made; and, the imposition of manufacturing standards. We find options for ingredients and claims range from, at one extreme, imposing the strict approval regime that applies to medicines and at the other extreme a light handed (information disclosure only) regime. In between there are options to require disclosure while maintaining a blacklist of banned ingredients and options to require disclosure and maintain an approved list of allowable claims and ingredients.

The costs of regulation are potentially large

A regulatory regime will impose administrative costs, compliance costs and efficiency losses on the NHSP industry. Operating costs of the new proposed regulator are

expected to be in the order of \$3-4 million. Compliance costs with any new regime would include relabeling, applying for approvals, delays and associated staff and management time. Efficiency losses would result from a reduction in product range, loss of competition as players exit the market, and higher prices in the long run.

The proposed fee structure is currently undetermined but a majority of administrative costs are expected to be recovered from industry via fees. The way that administrative costs of the regime are distributed could alter the structure of the NHSP industry and increase efficiency losses. Fees imposed per product notification or per application for an ingredient to be added to the approved list will fall more heavily on smaller, varied firms. These firms make up most of the NHSP industry. Compliance costs add to this burden, particularly time costs, systems changes and management costs.

A disclosure regime with blacklists would be appropriate for the NHSP industry

There is a case to shift from the status quo so NHSP producers can legally make health benefit claims without being regulated as medicines. There is no evidence, however, of a safety or any other risk sufficient to justify the costs of more stringent options analysed in this report.

From the options we have identified, the strongest form of legislation commensurate with the risks is a disclosures regime with blacklist features. Consumers can access information about NHSP in a standardised format and blacklists are relatively low cost for the regulator to produce. Producers must simply notify their products, claims and ingredients while avoiding banned ingredients.

The risk of 'regulatory creep' whereby the effective regulatory burden increases over time exists with any regulatory regime identified. A high degree of discretion for the regulator makes this outcome more likely as risk aversion can increase over time. Good regulatory principles can mitigate this risk to a small extent through being specific about balancing factors when making decisions.

The current Bill resembles an approval regime with blacklists and whitelists

The current Bill has a notification system and a combination of blacklists and whitelists for ingredients and specific health claims. There are no guarantees in the proposed regime to ensure the blacklist criteria is not set too low or that whitelists exclude legitimate ingredients or health benefit claims.

Critical aspects of the regime such as the fee structure and the manufacturing code of practice have been left to be developed in regulations. These factors determine the extent of the final costs of the Bill. An approvals regime will impose greater administrative and compliance costs on the industry compared with a disclosure only regime and it has a greater potential to impose most of the regulatory burden on small and innovative firms increasing the efficiency losses of the Bill.

The efficiency costs will be observable as firms reduce their product ranges, competition is weakened (particularly as smaller, varied firms are forced out of the market) and product innovation is reduced, subsequently raising prices. The current iteration of the Bill risks producing efficiency losses that will lower the growth of the NHSP industry without a commensurate increase in safety or consumer protection.

1 Introduction

Castalia has been engaged by the New Zealand Health Trust (The Trust) to evaluate appropriate regulatory regimes for the natural health and supplementary products (NHSP) industry. Regulating the NHSP industry has been an ongoing process for many years. It is currently at the stage of a Bill reported back from Select Committee. The Government has plans to introduce this Bill in 2014.

Industry had understood from early work and consultations that any regulation would be a low cost 'notification' regime in the form of a disclosure regime. A regulatory unit would be established to manage the regulatory processes, separate from Medsafe (the regulator of medicines). Fees to cover part of the costs would be imposed and a blacklist of banned ingredients would be produced.

The purpose of this report is to investigate optimal regulatory options and assess how the Bill performs against these. Decision makers will then be in a better position to make final decisions on the passage of the Bill.

This report will proceed by firstly assessing the problem that is being addressed with a regulatory intervention (Section 0). It will then identify regulatory principles in Section 0 and regulatory options in Section 4. Regulatory costs are examined in Section 0. Section 6 analyses the options against the principles to identify the best possible regulatory intervention. Section 0 concludes with recommendations for how the regulatory regime can best achieve the principles.

2 The Nature of the Problem

A regulatory intervention should aim to solve a problem. The problem needs to be defined in a credible fashion and the regulatory intervention needs to be targeted at, and shown to be effective at, solving the problem. This section will identify the problem that is being addressed by this regulatory intervention. We will consider the safety risks, the consumer protection landscape and the evidence that exists for the scale and nature of any problems identified.

NHSP are different to food and medicines

Natural Health and Supplementary Products are distinguished from food on the one hand and from medicines on the other. NHSPs are not used or represented as food and they may make a claim to a health benefit. Unlike medicines they are not approved under the medicines regime.

NHSP are distinguished from food if a claim to a health benefit is made. If no claim of a health benefit is made then the Dietary Supplements Regulations (1985), made under the Food Act (1981) apply.

If the product makes a therapeutic claim, it is considered a medicine, and Medsafe must approve the evidence provided on the product's claims, ingredients and manufacturing process. Some NHSP products have indeed applied for and have been sold under this medicines approval regime such as arnica cream. This procedure is not commonly used nor enforced, however, due to the costs and general unsuitability of the medicines regulations for NHSP (where firms have little intellectual property protection).

There are no obvious gaps in the regulatory landscape

All products sold in New Zealand are subject to the Fair Trading Act (FTA) and the Consumer Guarantee Act. The regulatory regimes that apply are comprehensive with no obvious gaps. A question therefore arises as to what a regulatory regime, specifically targeted at NHSP, might hope to achieve.

One possible source of a problem might be if the products are not safe to consume because they cause adverse reactions, up to and including death. Many products cause serious adverse reactions, however, including many foods. This does not obviously generate a need for specific regulation over and above, say, food regulations.

Consumer protection might be insufficient if it is very difficult to determine if the products contain the ingredients they say they do or if the claims made about the product are unable to be verified. This behaviour is already targeted by the consumer protection regime including the Commerce Commission oversight via the FTA and CGA. Specific gaps in the ability of the regime to be effective in the NHSP category would need to be identified for this to be a problem requiring an additional regulatory intervention.

One way to identify a problem that needs a regulatory intervention is to assess the evidence as to whether there are safety issues despite the regulatory landscape that applies. Alternatively we can examine whether there is a lack of enforcement in the consumer protection regulations, or any other identified evidence of a failure.

2.1 Evidence of Safety Risk

There is very little evidence of safety risks from consuming NHSP in New Zealand. Safety risk might be in two forms:

- Direct adverse reactions up to and including death from consumption

- Indirect risk from deferring a diagnosis from a doctor and delaying treatment for a dangerous disease

No studies conducted in NZ on safety risks from NHSP

According to the Ministry of Health, an Australian report from 2005 stated that natural health products were associated with nearly 400 adverse events per year and 62 deaths over the previous ten years. However, the Australian Therapeutic Goods Administration (TGA) has stated this incidence is a misinterpretation from one of its reports.¹ The TGA has only identified 15 deaths that NHSP have been 'associated' with but not necessarily responsible for. If that rate prevailed in New Zealand, at the same incidence within the population, it suggests 0.3 deaths per year would be linked with NHSP use.

Actual reporting of adverse events due to NHSP in New Zealand is low. Between 1992 and March 2009, only 344 reports of suspected adverse reactions from NHSP were made to the Centre for Adverse Reaction Monitoring.² In contrast, between 1995 and 1997, there were 221 reports of food-related anaphylaxis, a serious adverse event.³ In a 2006 report the then acting Chair of the Coroners' Council, Dr Wallace Bain, found no deaths in New Zealand have been attributed to NHSP in coroner reports.⁴

Often any adverse reaction stops when the consumption of the product stops. This is the case for most NHSP. The risk of adverse health effects from consuming the product is limited if this is the case.

NHSP as substitutes for qualified diagnosis

If consumption of a product defers a visit to a doctor, who would make a diagnosis, then the potential for harm comes from not identifying a dangerous disease. Health risks from deferring a diagnosis are a common and universal problem in medicine here and overseas. Cancer death rates, for example, are closely related to early detection. Screening programmes aim to overcome this problem in at risk populations.

There are many products and influences which contribute to this behaviour. For example food supplements, weight loss products, lifestyle changes, exercise or aspirin might all be regularly taken and a doctor's visit deferred. There is no evidence that NHSP are particularly responsible for this phenomenon in any specific way.

2.2 Current Legislation Addresses Consumer Protections

There are three regulatory frameworks that address aspects of the potential problem:

- Consumer protection laws
- Food safety laws
- Medicine regulations

¹ Email of TGA to Ron Law, 29 March 2012

² Medsafe. "Complementary Medicine Corner: Reporting adverse reactions." Prescriber Update, November 2009. Available online at <http://www.medsafe.govt.nz/profs/PUArticles/PDI/Prescriber%20Update%20Nov%202009.pdf>.

³ Mary Louise Hannah, "Peanut Allergy." Prescriber Update, November 2000. Available online at <http://www.medsafe.govt.nz/profs/PUArticles/peanut.htm>.

⁴ Report available online at <http://www.newmediaexplorer.org/scpp/BainReport2006.pdf>.

Consumers are well protected in New Zealand from misleading claims

Consumers are protected under the Fair Trading Act, the advertising code and the Consumers Guarantees Act. These make it illegal to make false or misleading claims and provide some penalties and opportunities for complaints to be made.

Additionally, the changes to the Fair Trading Act to come into effect this year directly target unsubstantiated claims. Firms are prohibited from making claims about their product that they do not have evidence or reasonable grounds to make and the Commerce Commission can prosecute offending companies.

Enforcement requires that a complaint be made via the Commerce Commission. It is possible that this might be less effective in some medical categories. People might be unlikely or unable to report a lack of symptom relief for example relative to other categories of complaint.

Consumers have, however, used the current framework to complain about misleading advertising claims on NHSP. For instance, Zenith Corporation was ordered to pay \$792,000 in fines, court and corrective advertising costs for false claims about its natural health product Body Enhancer.⁵ This indicates that current approaches to consumer protection in the NHSP market are having some effect.

Products sold for consumption must meet manufacturing standards

NHSP do not have to meet a set of specific manufacturing standards. Manufacturers must comply with the Food Hygiene Regulations 1974 and the safety requirements under the Food Act 1981. The Food Bill also intends to require manufacturers to follow food control plans, where the stringency depends on the product's risk level. NHSP containing animal products intended for export must also be produced under the Risk Management Programme under the Animal Products Act 1981.

The manufacturing standards regime is not specific to the NHSP industry. This may leave a gap in ensuring the quantity of active ingredients in a product. It is not clear why this might be the case however and the food labelling requirements already cover this as does the Fair Trading Act (FTA). This restricts government assurance of the quality of NHSP, however, there is no evidence of standards failure to date.

Medicines regulation covers claims about therapeutic benefit

Medicine regulations control the availability and standards of medicines. Consumers cannot access products claiming a therapeutic purpose (medicines and related products) until they have been approved by Medsafe. A therapeutic purpose includes diagnosing, treating or preventing disease, or interference with normal physiological functions. Medsafe evaluates the safety, quality and efficacy of medicines from product information and clinical trial results.

Consumers are also protected after a medicine has been marketed. Medsafe regularly inspects manufacturers, monitors adverse reactions, investigates unsafe products and can remove them from use.

The residual problem is small

We have identified 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. Given that risks are low and the majority of potential

⁵ Commerce Commission, 2006. Available online at <http://www.comcom.govt.nz/the-commission/media-centre/media-releases/detail/2006/792000payoutforfalseclaimsaboutbod>.

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issues are already addressed by existing legislation we find that any regulatory intervention should be light and not seek to duplicate existing regulations or impose significant costs.

3 Regulatory Objectives

In this section, we critically assess the principles used in the policy process and identify the objectives that a regulatory regime should seek to achieve. We find that the stated principles are broad and should be more targeted to insure the risk of costly or unnecessary regulations is limited.

3.1 Principles of the Bill

The proposed regulation in the Bill is based on the following principles:

- That natural health and supplementary products should be fit for human use
- That the regulation of natural health and supplementary products should be proportionate to the risks associated with their use
- That natural health and supplementary products should be accompanied by information that:
 - is accurate; and
 - tells consumers about any risks, side-effects, or benefits of using the product:
- That health benefit claims made for natural health and supplementary products should be supported by scientific or traditional evidence.

These principles are something that any reasonable regulator would want. However, they do not explicitly describe the trade-offs that must be made when creating regulations. It is inevitable that increasing safety and consumer protection will come at an increase in cost. This will create a trade-off including fewer products on the market, less innovation and a higher price to consumers. It is also unclear when a principle limits the pursuit of another and when it is a 'nice to have' that can be discarded if it limits the preferred option.

Regulation already deals with a number of the principles raised including that products are true to label and safe. Good policy should target problems not already solved to prevent duplicate regulations which add cost for no benefit. No problem was defined with the consumer protection laws that already exist.

The principles above do not target the problem well. It is not clear that they can, by themselves, identify the best option available to solve the problem. This leaves a future opportunity for regulations to increase in pursuit of the principles but divorced from any identified problem and with little regard for their increasing costs.

3.2 Good Regulatory Principles

Principles more tightly targeted at the problem could reduce regulatory risk. The regulatory risk in this case is that the regulations are too costly for the identified problem. Without any specific balancing principle a regulator may pursue safety and consumer protection without limit, either now or more likely, over a long period of time. This would lead to a range of possible welfare limiting outcomes. These might include:

- An increase in the price consumers must pay
- A lack of innovation in the market including new products coming to market
- A limited range of products offered.

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A principle of minimising compliance costs and/or not undermining competition is a key part of ensuring the regulation provides long-term benefits to consumers. A low cost industry and a low cost regulatory regime ensure products are low cost and a wide range is available. The only balancing principle that is present and that might provide this assurance is the principle of risk proportionality.

The principle of risk proportionality needs to be more specific and identify the need for regulatory costs commensurate with risks. Minimising costs is a worthy principle in its own right because if costs can be reduced without losing effectiveness then this is clearly superior. A principle of encouraging competition is an effective tool for ensuring that an industry is low cost and a wide range of product is available. A regulatory regime that undermined competition unnecessarily would be unlikely to be a low cost or risk proportionate regime.

As we have discussed in Section 0 above, the principle of commensurate risk and regulation would imply that there is little case for extensive regulation as the safety and consumer risk is not present.

4 Regulatory Options

Options for achieving the principles in terms of ingredients and claims range from doing nothing (the status quo) at one extreme through to including any product that makes a health claim in the medicines regime – the most restrictive regime that could apply in the circumstances. Neither extreme would meet the principles.

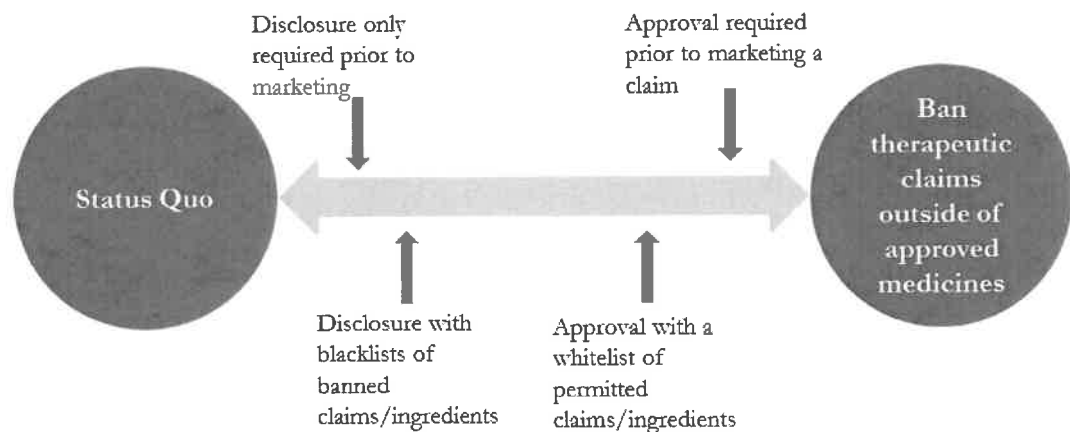
In between this range are options that are based on notification and disclosure by the producer only and options that require prior approval but at a lesser standard than that required by medicine regulation.

We firstly consider the range of options for regulating ingredients and claims. Manufacturing standards are considered separately in Section 4.2.

4.1 The Range of Options for Regulating Ingredients and Claims

Figure 4.1 below shows the range of options:

Figure 4.1: Range of Regulatory Options Available



These key features of the options are described in Table 4.1 below and the options are evaluated in Section 0 below:

Table 4.1: Features of the Regulatory Options for Claims and Ingredients

Option	Notification process	Application process	Evidence required	Regulator powers
A Disclosure Only Regime	Products, ingredients and claims notified	Notification only	Declaration of supportive evidence from traditional or approved sources	<ul style="list-style-type: none"> ▪ Penalises non-compliance under existing food safety and consumer protection legislation ▪ Medicines regulations may declare a product is regulated within that regime
A Disclosure Regime with Blacklist Features	Products, ingredients and claims notified	Notification only	Declaration of supportive evidence from traditional or approved sources	<ul style="list-style-type: none"> ▪ Determines a list of prohibited ingredients and health benefit claims ▪ Delay marketing by <ul style="list-style-type: none"> – Raising concerns – Start a safety assessment ▪ Add ingredients or claims to blacklist
An Approvals Regime with Whitelist	Only products with approved ingredients and claims notified	New, unapproved ingredients or claims seek addition to whitelist	Declaration of supportive evidence from traditional or approved sources	<ul style="list-style-type: none"> ▪ Determines list of permitted ingredients and claims (possibly derived from overseas approvals regimes) ▪ Blacklist also created ▪ Determine whether unapproved ingredients or claims are added to whitelist
Medicines Act Regime	All claims must seek approval	Each product applies for approval	Detailed product information (safety, manufacturing, labelling) and evidence (supported by clinical trials) of realising claims	<ul style="list-style-type: none"> ▪ Medsafe determines safety, efficacy and labelling standards (may also recognise international standards) ▪ Medsafe reviews information and evidence ▪ Advises whether product should proceed to market

For example, Australia's regime might fall between an approvals regime with whitelists and the medicines Act regime.

4.2 Manufacturing Standards

Additional manufacturing standards might contribute to achieving the regulatory principles. The Regulatory Impact Statement (RIS), for example, identifies manufacturing standards as a way of ensuring safe product formulation, such as the use of active ingredients, and a safe manufacturing process specific to the NHSP industry.

This section considers the available options in applying manufacturing standards to the NHSP industry. We identify two options, either the status quo is maintained, or a sector specific standard is developed.

Status quo

The status quo applies manufacturing standards under the Food Act to the NHSP industry. The Food Act is under review, however, and the current iteration of the Food Bill does not exclude NHSP from the definition of food. It would require that NHSP be subject to a food control plan based on NHSP's considered level of risk. Current and imminent consumer protection legislation would allow for misleading labelling claims to be exposed and penalised.

NHSP-specific manufacturing standards

This option requires NHSP to be produced under an industry-specific manufacturing code. This option has been suggested in the Bill and is intended to provide government assurance that NHSP products are true to label. The exposure of misleading labelling claims would still rely on consumer protection legislation although manufacturers who breach the code would be subject to specific fines.

5 Regulatory Costs

The costs incurred under any of the regulatory options are a critical factor to consider. This is especially the case here when the regulatory problem is small. Any significant level of cost will likely turn the balance of evaluation against the regulatory intervention.

We see three categories of costs that should be considered in this assessment. They are:

- Administrative costs
- Compliance costs
- Efficiency losses

In this section we discuss each of these in turn. We identify the likely types of costs imposed by the options and how these intend to be allocated to industry. We also explain the impact of costs and their distribution on the industry's structure and consumer welfare.

5.1 Administrative Costs

Administrative costs include the set-up and ongoing costs of the regulatory regime. The Ministry of Health estimates the costs from establishing the regulator to be \$1.8 million and ongoing costs to be \$3.64 million.⁶ Industry will meet the costs of all activities (except regulatory policy advice and enforcement) which are anticipated to be \$3.75 million on an annual basis.

The more stringent the regulatory regime, the greater the administrative costs will be. The maintenance of a whitelist or medicines approval regime will require greater resources than a disclosure regime, increasing the cost burden, because the regulator is required to maintain the whitelist and approve additions to the list.

The method of distributing administrative costs will shape the NHSP industry structure as it determines who takes on the cost burdens and ultimately who will remain in the market. The Ministry of Health has identified that regulatory costs will have the greatest impact on small to medium-sized businesses, especially importers and those with wide product ranges. Most of the industry will fall within these categories. A New Zealand Trade and Enterprise survey, which also included the bioactives industry, found 50 percent of respondents were small operations, employing up to 10 full time employees.⁷

The Bill enables the regulator to prescribe fees based on further consultation with industry. The final shape of fee structures will be determined in regulations and is at the time of writing unknown. The structure of the industry is skewed towards a large number of small turnover firms; often with a large product range which combined with the unknown structure of fees makes the incidence of costs largely unknown.

Table 5.1 below describes the range of cost distribution options suggested by industry stakeholders.

Table 5.1: Options for Regulatory Cost Distribution

Fee Option	Example Fee Type	Effects

⁶ Ministry of Health, June 2011. Regulatory Impact Statement: The Development of a Natural Health Products Bill.

⁷ New Zealand Trade and Enterprise, December 2011. "Natural Products Industry Survey"

Product Notification Fee	<ul style="list-style-type: none"> ▪ \$188-568 per product fee⁸ (based on estimated products in market) 	<ul style="list-style-type: none"> ▪ Increased cost per product line ▪ Firms rationalise their product range ▪ Greater impact on smaller firms with varied product ranges
New ingredient or claim application fees	<ul style="list-style-type: none"> ▪ \$X per application (successful or unsuccessful?) 	<ul style="list-style-type: none"> ▪ Increased costs per new product line ▪ Costs of new ingredient application fall only on first applicant ▪ Regulator has incentive to produce restricted whitelists to generate more applications and fees
Turnover-based fee	<ul style="list-style-type: none"> ▪ Y % of industry turnover p.a. 	<ul style="list-style-type: none"> ▪ Incumbents face a relatively higher cost on approved product ▪ New products and ingredients do not face the regulatory cost of application ▪ Neutral broad based tax leaves competition and product innovation relatively unaffected
Annual charge	<ul style="list-style-type: none"> ▪ \$Z per product/per year/per company in the market 	<ul style="list-style-type: none"> ▪ Effects vary depending on method of allocating cost across the industry

5.2 Compliance Costs

Compliance costs are the costs associated with meeting the regulatory requirements beyond any administrative costs imposed by the regulator. We see the range of options potentially creating four categories of compliance costs:

Table 5.2: Potential Compliance Costs

Source of Compliance cost	Reasons
Delay	<ul style="list-style-type: none"> ▪ Time taken to notify a product or have new ingredients approved delays products from reaching the market <ul style="list-style-type: none"> – Delays have been significant in other jurisdictions. An application by the Complementary Healthcare Council of Australia (CHC) for the approval of a widely used traditional ingredient took five years.⁹ ▪ Information gathering activities required for disclosure, researching new requirements, and particularly for applications to add to whitelists
Systems and process change	<ul style="list-style-type: none"> ▪ The costs involved in upgrading processes or capital to meet requirements e.g. computer systems ▪ Altering the manufacturing process ▪ Product relabeling ▪ New liability through the introduction of new manufacturing standard obligations

⁸ See footnote 7. Correspondence with the MOH has suggested a target of \$100 per product fee although this is yet to be stated in official documents.

⁹ Complementary Health Council of Australia submission to the Australian Productivity Commission at page 3. Available online at http://www.pc.gov.au/data/assets/pdf_file/0008/82547/subdr68.pdf.

Management Costs	<ul style="list-style-type: none"> ▪ The costs, including specialist services, to understand the new regulation ▪ Determining the interaction with other legislation which could impose additional costs ▪ Increasing administrative costs
Labour costs	<ul style="list-style-type: none"> ▪ Further recruitment may be required in order to manage compliance issues

Compliance costs can be significant to individual firms and therefore the industry. A report by TDB Advisory anticipated compliance costs from the proposed NHSP regime to range from \$3 million to \$14 million, based on conservative estimates.¹⁰

5.3 Efficiency Losses

Efficiency losses (costs) are welfare losses incurred through a reduction in market transactions that would otherwise occur. This might be a result of reduced competition, innovation, product ranges and access, or in increased prices. The choice of fee structure can influence the extent of these costs.

The following sources of efficiency losses are relevant for this situation:

Table 5.3: Potential Efficiency Losses

Impact	Why might this occur
Reduced competition	<ul style="list-style-type: none"> ▪ Product notification fees create a barrier to market entry ▪ Smaller and more varied suppliers may be forced out of the market if their total fees are high. This has been observed in Australia following the implementation of the TGA. ▪ Competition based on novel ingredients or claims is discouraged by new ingredient or claim application fees ▪ Imposing delays to product marketing or sales reduces competition based on product differentiation
Reduced Innovation	<ul style="list-style-type: none"> ▪ Suppliers face incentives to reduce existing product ranges and avoid future expansion ▪ Uncertainty is created about whether new ingredient or claims will be accepted on whitelist which increases the effective cost of applications ▪ Application fees for new ingredients or claims create a first mover disadvantage. The first applicant faces costs while competitors cannot be excluded from the benefits of an approved application due to the nature of intellectual property in the NHSP industry. This reduces the competitive advantage to product innovation.

These effects lead to efficiency losses in the NHSP market through:

- Increased prices—Reduced competition will impact consumers through higher prices. Consumption of NHSP is deterred
- Reduced range—Consumer choice is reduced as the incentive to innovate or widen product ranges is reduced in order to minimise the regulatory costs.

¹⁰ Natural Health and Supplementary Products Bill: A National Cost-Benefit Analysis, 2014.

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Consumer access to new products or ingredients is diminished. They will face a smaller range of NHSP that is only permitted to address a smaller range of needs

Allocative efficiency losses are also likely to occur. The impact of the introduction of the regulatory regime may reveal that investment in assets, products or markets has been misdirected. Firms may be forced to write off some investments and write down expected future revenue flows and market growth opportunities. This may lead to losses in employment and firm exit.

Costs are likely to escalate over time

There is potential for these costs to escalate over time in the unrestricted pursuit of product safety and consumer protection. The fee structure, manufacturing standards and criteria for the black and whitelists all directly affect costs to competition, innovation and product ranges. The regulator has extensive discretion in determining these crucial aspects of the regime, providing no assurance that costs will be minimised.

6 Regulatory Options Analysis

In this section the range of options are assessed against the objectives of the regulations. We find that the best option is a regulatory regime that relies on notification and also allows a regulator to assess issues and remove products, without placing an onus on the marketer to seek approval before going to market.

The primary reason for this finding is that there is no evidence of any benefit from further interference on the market trade. This interference would, however, impose costs on the industry and consumers through the regulatory compliance costs. On balance consumer welfare is reduced from the imposition of costs on the industry.

6.1 Options Assessed Against Good Regulatory Principles

Table 6.1: Options Compared Against Regulatory Principles

Options	Principles				
	Safety performance	Consumer protection	Risk proportionate	Compliance costs	Competition, innovation, consumer choice
A. Baseline: Status Quo	<ul style="list-style-type: none"> ▪ Poor information ▪ No hard evidence of unsafe products ▪ Little hard evidence of actual Adverse Events 	<ul style="list-style-type: none"> ▪ From other legislation only ▪ Enforcement limited to CC process 	<ul style="list-style-type: none"> ▪ Appropriate if products are low risk 	<ul style="list-style-type: none"> ▪ None 	<ul style="list-style-type: none"> ▪ No change
B. Disclosure only	<ul style="list-style-type: none"> ▪ Little improvement over (A) 	<ul style="list-style-type: none"> ▪ Some small improvement over the status quo as it requires a standardised and consolidated approach to ingredients and claims 	<ul style="list-style-type: none"> ▪ Appropriate if products are low risk 	<ul style="list-style-type: none"> ▪ Minimal Fees ▪ Few other compliance costs 	<ul style="list-style-type: none"> ▪ No change
C. Disclosure with blacklists	<ul style="list-style-type: none"> ▪ Increased safety over (B) as a cost effective mechanism to bring new products to light and prevent known unsafe ingredients inadvertently entering the market ▪ It provides an opportunity for removal by regulator if 	<ul style="list-style-type: none"> ▪ Some small improvement over the status quo as it requires a standardised and consolidated approach to ingredients and claims 	<ul style="list-style-type: none"> ▪ Appropriate if products are low risk. ▪ Increase over (B) as it allows occasional issues to be effectively addressed. 	<ul style="list-style-type: none"> ▪ Minimal fees ▪ Regulator faces a burden maintaining a blacklist which will increase fees over (B) ▪ Few other compliance costs 	<ul style="list-style-type: none"> ▪ No substantial change

<p>D. Approval (with whitelists and blacklists)</p>	<p>found to be unsafe</p> <ul style="list-style-type: none"> ▪ Little improvement over (C) – Whitelists may limit new products 	<ul style="list-style-type: none"> ▪ Little improvement over (C) 	<ul style="list-style-type: none"> ▪ Appropriate only if there is a real risk of unsafe new products emerging 	<ul style="list-style-type: none"> ▪ Increased fees over (C) ▪ New products not already on the whitelist face time and expense. 	<ul style="list-style-type: none"> ▪ Whitelists will limit new products ▪ Negative impacts on innovation, competition especially if fees are imposed on new ingredients, products or claims.
<p>E. Medicines approval</p>	<ul style="list-style-type: none"> ▪ Very little chance any unsafe products enter any market ▪ Likely that claims would be dropped from products and possible anecdotal claims being made 	<ul style="list-style-type: none"> ▪ Little improvement over (B-D) ▪ Little benefit to ensuring truthful claims by imposing clinical trials. Scientific method is suited to testing a single active ingredient not a group of complex, interacting ingredients as in NHSP 	<ul style="list-style-type: none"> ▪ Only if a high risk of unsafe products is present 	<ul style="list-style-type: none"> ▪ High fees 	<ul style="list-style-type: none"> ▪ Prohibitive time and application costs for many new products

6.2 Preferred Option

The preferred option is (Option C), a disclosure regime, built on notification, allowing sufficient time to investigate if necessary and collate known risks on a blacklist. The benefits over (Option B) are not great however and bad implementation of the option could undermine any improvement that is achieved.

There is no support for comprehensive approval regimes that prevent the market from functioning without pre-approval. There is no evidence that a safety or any other risk is sufficient to warrant the loss in welfare that the costs of regulation would impose including reductions in product range and increases in price.

Whitelists (Option D) are an approval regime. Any approval regime will unnecessarily limit product range and increase costs. There is insufficient evidence that there are any risks that warrant this loss in welfare. The use of an extensive and open whitelist will limit the extent of the cost and the negative consequences of the approval requirement but further regulatory risks emerge with this approach:

- There is no guarantee that this will not creep through a lack of expansion of the list or a limited initial list
- There is no guarantee that costs will not fall on the innovators and new entrants further restricting innovation and product range.

There is slight support from the options evaluation for moving from the status quo and facilitating a notification and disclosure repository. NHSP firms can make health benefit claims without having to face excessive costs and requirements under the Medicines Act. A comprehensive information repository would enable industry participants to ensure they did not inadvertently include ingredients or combinations that are known to be hazardous. We note that this is an outcome that could be achieved through non regulatory means. A regulatory requirement may have some co-ordination benefits if the industry is small, numerous and diverse (which it is claimed to be).

Blacklists are potentially a cost effective and convenient way to allow the regulator to ensure that significant known risks are eliminated prior to marketing. Blacklists are likely to be relatively low cost for the industry and will allow the industry to avoid known risks cost effectively if they are managed well and have defined risk based criteria that do not creep over time or become risk averse in their application. It is possible that blacklists may become a de facto approval regime if the approach to risk is not balanced or stable.

6.3 Current Natural Health and Supplementary Products Bill

This section outlines the features of the current iteration of the NHSP Bill and compares it to the preferred option in our regulatory analysis. The Bill requires NHSP firms to notify their products, ingredients and health benefit claims to the regulator. This must include a declaration they have evidence to support their health claims.

The Bill allows the regulator to create a blacklist and a whitelist for ingredients. The Bill does not guarantee that only high-risk ingredients will be prohibited, instead granting the regulator wide discretion. Blacklists with minimal criteria are susceptible to regulatory creep, imposing further compliance and deadweight costs on the NHSP market. The regulator can also impose restrictions on the use of permitted substances.

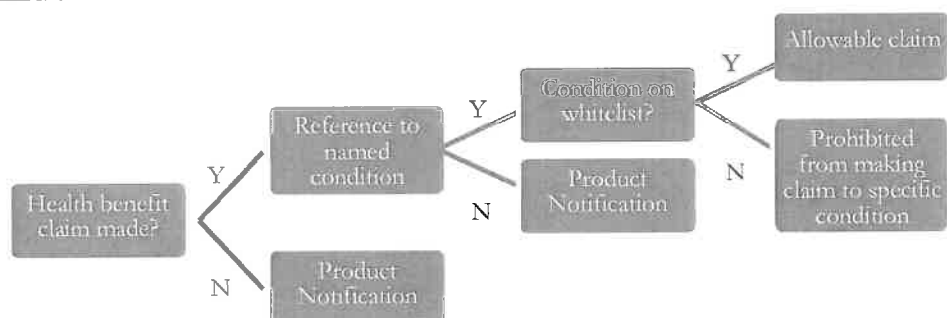
A new ingredient, that is those not listed on either the blacklists or whitelists, must be reported to the regulator at least 90 days before product notification. If the regulator does not raise concerns or start a safety assessment during the 90 days, and the applicant

receives written confirmation, the product using the new ingredient may proceed to the notification process.

The Bill regulates health benefit claims in two distinct ways depending on the nature of the claim:

- Non-specific claims: Health benefit claims that do not reference particular conditions are subject to a notification regime where they must be entered on the database with a declaration of supportable evidence.
- Claims to named conditions: Claims that refer to named conditions are subject to an approval regime. Named conditions are all those on the *International Statistical Classification of Diseases and Related Health Problems* (ICD-10). The regulator creates a whitelist of allowable claims from the over 14,500 listed conditions on the ICD-10. If a condition is listed on the whitelist it may be referred to in the health benefit claim. Otherwise the product may not make a reference to the specific condition.
- This process is illustrated below in Figure 6.1:

Figure 6.1: Health Benefit Claims Process in NHSP Bill



The Bill states that a code for the manufacture of NHSP must be developed by the regulator. The fee structure prohibited and permitted ingredients and claims lists and the manufacturing code of practice have all been left to be developed in regulations, entitling the regulator to a significant amount of discretion in determining crucial elements of the legislation.

The Bill most closely resembles an approval regime with blacklists and whitelists

The Bill most closely resembles our Option D above: ‘An approval regime with blacklists and whitelists’. The key divergence between the Bill and the preferred option is the requirement for a whitelist of approved ingredients and conditions and the requirement for approval for additions to the whitelist. The industry is left vulnerable to escalating regulatory costs over time as the regulator only faces minimal criteria to prohibit ingredients or health conditions.

Several aspects of the proposed regime in the current Bill are unspecified as they will be determined in subsequent regulations. This includes fees which will be an important determining factor in costs. How the fees are imposed affects the deadweight losses that can be expected. An approvals regime will necessarily impose a higher total administrative cost burden and higher compliance costs.

7 Conclusions and Recommendations

We conclude that there is no justification for the imposition of a costly regulatory regime. The problems we have identified that require a regulatory intervention are slight. There is very little evidence of serious harm ever occurring in New Zealand.

The regulatory options of disclosure and notification prior to marketing do not carry a high cost, however, provided they do not go beyond simple disclosure and notification. The costs imposed on the industry by approval regimes reduce consumer welfare through a reduction in product range, innovation, competition and a subsequent increase in prices. The identified problem does not justify these costs.

We note that the regulatory options of disclosure and notification are also improvements that could be achieved by industry itself, provided any co-ordination problems can be overcome. A regulatory intervention for these purposes should therefore be built on industry agreement and an identified industry co-ordination problem.

The point at which the costs outweigh the benefits comes when the option moves from a blacklist to a whitelist. This is an approval regime that inevitably increases cost and leads to a particular distribution of that cost (subject to the final outcome of fees and charges). The risk that this regime would subsequently lead to an imposition of costs on those who seek to expand the list, that the list might not expand, and that the costs will increase, is large.



T: +1 (202) 466-6790
F: +1 (202) 466-6797
1747 Pennsylvania Avenue
NW 12th Floor
WASHINGTON DC 20006
United States of America

T: +61 (2) 9231 6862
F: +61 (2) 9231 3847
36 – 38 Young Street
SYDNEY NSW 2000
Australia

T: +64 (4) 913 2800
F: +64 (4) 913 2808
Level 2, 88 The Terrace
PO Box 10-225
WELLINGTON 6143
New Zealand

T: +33 (1) 45 27 24 55
F: +33 (1) 45 20 17 69
7 Rue Claude Chahu
PARIS 75116
France

----- www.castalia-advisors.com