

# **The Natural Health Products Bill and Proposed Supplementary Order Paper: Assessment against Treasury Criteria**

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**A report prepared for the New Zealand Health Trust**

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## 1. Introduction

The Natural Health and Supplementary Products Bill (the Bill) was introduced to Parliament several years ago. More recently, a proposed Supplementary Order Paper (SOP) amending the Bill has been circulated for comment prior to tabling by the government. We refer to the Bill as amended by the proposed SOP as the “proposed legislation.”

This paper assesses the proposed legislation against the Treasury’s “Best Practice Regulation Model” as outlined in two Treasury reports.<sup>1</sup>

## 2. The proposed legislation

The bill, if passed in its current form, would establish a sector-specific system for the regulation of Natural Health Products (NHPs) in New Zealand. Key features of the bill, as reported back to the House by the Health Select Committee and as modified by the proposed SOP, are;

It would:

- define a NHP 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 NHP Regulatory Authority (“the Authority”) within the Ministry of Health;
- establish an approval process for NHPs in relation to health benefit claims and ingredients that would:
  - have the effect of prohibiting all acclaims relating to approximately 14,000 conditions recorded in the World Health Organisation’s International Classification of Diseases database unless they are permitted by the Authority;
  - enable the establishment of a list of permitted conditions (about which health benefit claims may be made) by the Authority. Only NHPs making general health benefit claims or health benefit claims about approved conditions would be permitted to be marketed in New Zealand. If a NHP wishes to make claims relating to a condition not on the approved list, approval must be obtained from the Authority; and
  - have the effect of prohibiting all ingredients in the first instance;
  - enable the establishment of a permitted list of approved ingredients. If a NHP 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
- require the Authority to establish standards and a code of manufacturing practice for NHPs.<sup>2</sup>

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<sup>1</sup> The Treasury, “The Best Practice Regulation Model: Principles and Assessments”, July 2012 and February 2015.

<sup>2</sup> This power already exists under the Food Act, 1981.

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.

### 3. The Treasury's criteria

The best-practice regulatory principles were originally developed in response to a request from the Minister of Finance and then Minister for Regulatory Reform in late 2010. The Minister of Finance challenged Treasury to answer three questions: (1) What is a best practice regulation? (2) How close are we to the frontier? (3) What can we do to get closer?

The Treasury notes that "The principles were distilled from a range of sources, including APEC and OECD documents, and guidelines and directives from many governments around the world, including New Zealand's Good Regulatory Practice guidelines developed in the 1990's. They are intended to help with overall assessments of the regulatory state of play, and with targeted reviews."<sup>3</sup> The Treasury also notes that "Agencies are encouraged to use the principles in internal and stakeholder discussions on regulatory design and implementation."<sup>4</sup>

The best-practice regulatory principles are:<sup>5</sup>

**1. Growth compatible:** economic objectives are given an appropriate weighting relative to other specified objectives. These other objectives could be related to health, safety or environmental protection, or consumer and investor protection. Economic objectives include impacts on competition, innovation, exports, compliance costs and trade and investment openness.

**2. Proportional:** the burden of rules and their enforcement should be proportional to the benefits that are expected to result. Another way to describe this principle is to place the emphasis on a risk-based, cost-benefit regulatory framework and risk-based decision-making by regulators. This would include that a regime is effective and that any change has benefits that outweighs the costs of disruption.

**3. Flexible, durable:** Regulated entities have scope to adopt least cost and innovative approaches to meeting legal obligations. The regulatory system has the capacity to evolve in response to changing circumstances. A regulatory regime is flexible if the underlying regulatory approach is principles or performance-based, and policies and procedures are in place to ensure that it is administered flexibly, and non-regulatory measures, including self-regulation, are used wherever possible.

**4. Certain, predictable:** the regulatory system should be predictable to provide certainty to regulated entities, and be consistent with other policies. There can be a tension between certainty and flexibility. A principles or performance based regime that provides for safe harbours such as deemed-to-comply standards tries to resolve this tension, but ensuring both attributes are optimally reflected is a challenge.

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<sup>3</sup> The Treasury, op cit. (2012), P. 2.

<sup>4</sup> Ibid, p.3.

<sup>5</sup> The 2012 principles were modified somewhat in 2015. We use the latest (2015) principles for our assessment.

**5. Transparent:** reflected in the principle that rules development, implementation and enforcement should be transparent. In essence, regulators must be able to justify decisions and be subject to public scrutiny. This principle also includes non-discrimination, provision for appeals and sound legal basis for decisions.

**6. Capable regulators:** means that the regulator has the people and systems necessary to operate an efficient and effective regulatory regime. A key indicator is that capability assessments occur at regular intervals, and subject to independent input or review.

The Treasury also provides a colour-coded rating systems for assessing regulatory regimes. The system is:

	<b>No significant concerns</b>
	<b>Possible areas of material concern</b>
	<b>Strong indications of material concern</b>
	<b>Not known</b>

## 4. Assessment of the proposed legislation against the criteria

In the sections below we assess the proposed legislation for Natural Health Products against each of the Treasury’s best-practice regulatory principles using the Treasury’s rating system.

### 4.1 Growth compatible

The primary objective of the legislation is to promote the health and safety of consumers. In theory, it is possible that the proposed legislation could promote health and safety by resulting in the avoidance of premature deaths and pain and suffering that may be occurring under the current regulatory environment for NHPs. However, while such benefits are possible in principle, there is little or no evidence that adverse health consequences from NHPs are a major problem in New Zealand under the current regulatory regime.<sup>6</sup>

At the same time, however, the proposed legislation imposes significant costs that are likely to undermine the government’s economic growth objectives through the bill’s adverse impacts on competition, innovation, exports, compliance costs and trade. Quantitative estimates of the costs the bill is likely to impose on the economy are provided in TDB Advisory’s national cost-benefit analysis of the NHP bill.<sup>7</sup> In summary the costs are likely to include:

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<sup>6</sup> Refer, for example, to Castalia Ltd, “Natural Health and Supplementary Products Bill: Regulatory Assessment”, a report to the New Zealand Health Trust, March 2014. Castalia notes (p.i) that “no coroner reports have attributed any deaths in New Zealand with consumption of NHSPs ... and ... that the rate of significant adverse events is low, with some evidence suggesting 20 per year (in an industry selling over \$500 million of products by some estimates).”

<sup>7</sup> TDB Advisory, “The NHSP Bill, A National Cost-Benefit Analysis”, a report prepared for the NZ Health Trust, May 2014.

- the administrative costs the government incurs in implementing the legislation. The Ministry of Health (the ministry) estimate these costs are likely to be around \$4m p.a. though they are likely to grow over time;
- the costs that suppliers of NHPs face in complying with the new regime. TDB estimates these costs, on a conservative basis, to be in the range of around \$3m to \$14m p.a. but they could be considerably higher if the regime evolves over time towards the heavy-handed Australian regulatory regime; and
- 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.

Overall, it is not obvious that the proposed legislation strikes an appropriate balance between the government's health and safety, economic and other objectives. The proposed regime will impose significant costs on the economy without appearing to provide material offsetting benefits in terms of better health and safety or other outcomes.

## **4.2 Proportional**

The proportionality principle means that the burden of the rules and their enforcement should be proportional to the benefits that are expected to result. However, as is noted above the costs of the bill are likely to outweigh the benefits by a significant margin. Both Castalia and TDB Advisory reach this conclusion. The administrative and compliance costs of the bill alone are, on conservative assumptions, likely to cost the economy around \$7m to \$18m p.a. TDB estimates that, based on official estimates of the value of life saved of around \$3.8m,<sup>8</sup> 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 any convincing evidence that such health benefits are likely.

## **4.3 Flexible/ durable**

The Treasury notes that “a regulatory regime is flexible if the underlying regulatory approach is principles or performance-based, and policies and procedures are in place to ensure that it is administered flexibly, and non-regulatory measures, including self-regulation, are used wherever possible.”<sup>9</sup>

The administration of the proposed regime may be flexible in that it is intended that the manufacturing standards are based on the assessed risk of a site or production process.

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<sup>8</sup> Official estimates of the value of life saved in New Zealand are sourced from the Ministry of Transport, “The Social Costs of Road Crashes and Injuries, 2013 Update”, 2013.

<sup>9</sup> The Treasury (2015). p. 80.

However, the regime fails to meet the test of using self-regulation wherever possible. In particular, one claimed benefit of the proposed regime is that it will promote exports due to the new regulatory authority's ability to provide certification for products sold in offshore markets. However there are numerous private commercial solutions to certification that do not require the government to get involved. Such private "self-regulatory" solutions include investing and developing brands, industry bodies establishing certification regimes and through companies reaching acceptable industry standards such as ISO 9000 certification. These private solutions are likely to be more durable and flexible than government administrative processes, especially in light of the Government's attempts to establish New Zealand as part of the TPPA.

#### **4.4 Certain, predictable**

A regulatory system should be predictable so as to provide certainty to the regulated entities. As noted above, the proposed legislation grants the NHP Regulatory Authority considerable discretion in implementing the regime. Such discretion inevitably results in uncertainty amongst industry participants. Investment in the industry is likely to suffer as a result. Moreover, experience from other regulatory regimes, both in New Zealand and overseas, suggests that the extent and costs of the regulations are likely to increase rather than decrease over time.

#### **4.5 Transparent**

The transparency of the process that will be followed by the regulator is uncertain and therefore must be an area of concern to the industry participants. It is possible that the development, implementation and enforcement of the new regulations will be transparent and subject to public scrutiny but we reserve judgement at this stage.

#### **4.6 Capable regulators**

As noted above, it is proposed under the bill that a NHP Regulatory Authority be established within the Ministry of Health to administer the new regime. The Ministry of Health has developed capabilities and a modus operandi that are suited to regulating high-risk products such as pharmaceuticals psychoactive products. Inevitably, given the risks associated with such medical products, the Ministry has developed quite risk-averse standards and a risk-averse culture. Such a culture, however is likely to be quite ill-suited to the low-risk NHP sector. Applying a risk-averse regulatory culture to the NHP sector risks stifling a relatively rapidly growing, innovative and increasingly export-oriented sector.

## 4.7 Overall Assessment

Our overall assessment of the proposed legislation for Natural Health and Supplementary Products against each of the Treasury's best-practice regulatory principles using the Treasury's colour-coded rating system is provided in the table below.

Principle	Growth compatible	Proportional	Flexible/durable	Certain/predictable	Transparent	Capable regulators
	Strong indications of material concern	Strong indications of material concern	Possible indications of material concern	Strong indications of material concern	Possible indications of material concern	Strong indications of material concern

## 5. Conclusions

There is inevitably a degree of subjectivity when ranking regulatory regimes against best-practice guidelines. However, the proposed legislation falls short of best practice by a wide margin. In fact the proposed legislation fails to meet the most fundamental test: that there is evidence of a problem that the government must address. Rather the proposed legislation appears to be a solution in search of a problem.

In our view there are likely to be better, smarter ways to achieve the government's objectives in the areas of NHPs. Given the absence of evidence of major harm from NHPs, a more balanced, proportionate approach would be to adopt a genuinely light-handed regime. Such a light-handed regime could automatically recognise international food standards like FSANZ and Codex Alimentarius; automatically permit an ingredient that is approved by a recognised authority; and would not require ingredients of which there is no evidence of harm to go through a costly pre-approval process. In addition, it would involve the government seeking to enforce the existing wide range of regulations that already apply to NHPs.<sup>10</sup> And it could involve placing responsibility for regulating NHPs under any new regime with the Ministry of Primary Industries, which is more familiar with regulating export-oriented industries rather than with the Ministry of Health.

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<sup>10</sup> NHPs are already subject to a wide range of existing legislation aimed at protecting consumers including the recently revised 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 recently amended Fair Trading Act already has severe penalties for making unsubstantiated claims, including unsubstantiated health claims.