Attachment one – Table of Changes by SOP

Natural Health and Supplementary Products Bill Commentary on SOP

Exports

The significant change is the removal of the exemption whereby export-only products did not have to be notified.

In the initial Bill, any product intended only for export did not have to be notified, unless an export certificate was sought. This was intended to allow different standards for different markets, in particular for ingredients, where the importing country's maximum amounts for particular vitamins might be higher than New Zealand's.

The exemption did give rise to a concern about New Zealand's wider export reputation, if potentially unregulated products were exported. We raised the possibility of removing the exemption with exporters. We were advised that export certificates were invariably sought, so it was not expected to be an issue, and in fact the more detailed certificates likely to be issued under the natural health products scheme would make exporting easier.

The previous exemption allowed for products to have ingredients that would not be permitted domestically, but were allowed in the importing country. This issue will now be managed through conditions on the ingredients list, for example we might have a condition on vitamin q to the effect of "no more than 40mg, except in export-only products".

Definition of natural health product

The intent of the definition has been to capture all things reasonably viewed as natural health products, including things described as complementary medicines, dietary supplements, and the like. It has gone through many revisions, as we attempted to ensure the definition covered everything it should, including things it shouldn't.

The proposed definition is:

a) Made for humans, for a health benefit

b) Made of natural substances, as defined in Schedule One of the Bill

Not

c) A food

d) A prescription or pharmacy medicine

e) A psychoactive substance

There is then an additional definition of ‘permitted natural health product’, which describes a natural health product that contains only permitted ingredients. This is necessary to properly apply regulatory controls. For example, the offence of altering a label required in regulations only applies to permitted natural health products, as they are the only ones to which labelling requirements can reasonably apply. The SOP sets out the similar changes on pages 4-5.

The Bill will add similar exclusions to the definition of food, medicine and psychoactive substance, in the appropriate legislation, so that something that is a natural health product cannot be a food, or a medicine, or a psychoactive substance, in regulatory terms. Essentially, everything is regulated once, with minimal confusion about what regulatory scheme is applicable.

Advertising

We propose a minor change to the advertising rules. The Bill prohibits advertising a product with reference to a named health condition, unless it is an allowable claim (the condition is on the Authority’s list). We had earlier agreed with stakeholders to include a provision allowing advertising that was not restricted to allowable claims if it was in a publication circulated only to practitioners, which is similar to an exception in the Medicines Act. Part of that agreement was including provisions prohibiting certain claims, including testimonials.

When we discussed claims and advertising in the workshops, there were mixed views on the value of testimonials. However, it was clear that a general prohibition on testimonials was a very blunt instrument, and probably an inappropriate one. In that light, we propose to remove the blanket prohibition on testimonials. The discussion about advertising centred on the need for certainty about what could and couldn’t be said, with most people, including the Ministry, saying the TAPS process was reasonable, and they were used to working within it. With that in mind, we propose adding regulation-making powers so that the Minister can make rules about claims on labels and in advertising, following consultation with affected parties, in case clarity is needed.

Attachment one – Table of Changes by SOP

Clause	***What***	***Why***
2	Commencement change to 30 November 2016, or earlier by Order in Council.	Passage of time. Intention is to commence in mid-2016.
5	Remove definition of dietary supplement	Not required with definitional change to clause 6
5	Add definition of permitted natural health product	Necessary with definitional change
6	Replace b) " contains only permitted ingredients unless— (i) section 22(2)(b)(i) applies; or (ii) the product is a dietary supplement" With words to the effect of: "contains only natural health product ingredients; ie substances of a kind listed in Schedule One (derived from nature, with minimal processing, and no chemical transformation) Remove reference to dietary supplements.	Prevents non-compliant natural health products being automatically regulated as medicines or food. Prior to the change, any health product with a non-permitted ingredient would likely fall into medicines or food regulation. Also allows removal of references to dietary supplements, which was confusing and only necessary because the definition included permitted ingredients. Requires a category of 'permitted natural health products', which are products containing only permitted ingredients, in order to properly apply regulatory controls.
6 (1) new d (replaces 6 (2))	**Delete** 6(2) any medicines that the Minister has given consent for distribution [registered medicines] **Add** 6(d) Does not contain: • a medicine listed in the first schedule to the Medicines Regulations 1984 • a psychoactive substance	Clarifies that products may not contain prescription or pharmacy medicines or psychoactive substances – definitionally excludes, to ensure enforcement sits in proper place. 6(d) replaces provision in 6(2) that excluded registered medicines. This is because the previous provision would prevent products being reclassified as natural health products.
6B	Change "a health benefit claim" to "health benefit claims"	Clarifies that there can be more than one claim – the control is on what conditions can be claimed about, not the wording of individual claims
8 (old 28 (2) (a))	Delete clause exempting manufacturers of	Controls all manufacture in New Zealand so that all exports

Attachment one – Table of Changes by SOP

	export-only products from manufacturing licenses. Also amendments to 16, 18 (b), 32, 34 (old 25), 39	have been manufactured safely. Prevents reputational risk of poor quality exports to countries that don't require an export certificate.
18	c) change 20ppm to 10 ppm	Intended to match Medicines Act, which says 10
20 (5)	new (c) the product notifier has paid the applicable fee	This is a standard provision to ensure that fees must be paid. Compare section 36 of the Plumbers, Gasfitters and Drainlayers Act 2006, or section 26 of the Health Practitioners Competence Assurance Act 2003
20	Change "the health benefit claims" to "any health benefit claims"	Clarifies that notifiers don't *have* to make a claim
24	Flexibility in period of suspension – "up to 90 days", rather than "21 days"	Allows different periods of suspension under different circumstances.
25	Insert "take all reasonable steps to" between 'must' and 'ensure'	Clarifies we don't expect miracles
27	Change "an allergic reaction" to "a serious allergic reaction"	Clarifies intent – very minor reactions not concerning (hives or rashes)
34 (5) (a)	Change "consumer" to "customer"	Commercial requirements are for customers, rather than consumers – matches other
42	Add new 2 (b) exemption for practitioners, similar to Medicines Act section 60 (c) Allows information about conditions to be distributed to practitioners, even if not an allowable claim. Adds 'label' to the definition of 'advertisement' for the purpose of this section, prohibits claims of infallibility or use or recommendation by a registered health practitioner.	Agreement with stakeholders - allows distribution of accurate information to practitioners, with reasonable controls. Did include prohibition on testimonials, now removed, following workshops.
48	Advisory Committee rules – the Authority may appoint a Chair, and dismiss members, etc. Modelled on section 11 of the New Zealand	These are standard provisions for advisory committees.

Attachment one – Table of Changes by SOP

	Public Health and Disability Act 2000	
49 (and other consultation clauses)	Delete “representative of the interests of persons” so that the consultation obligation is to consult “persons likely to be affected”.	Requires wider consultation on significant issues. Can be given effect via publication on website.
51 Form of applications	Product notification form. Form of applications for new allowable claim, manufacturing license, ingredient, declaration that product is a natural health product. Were to be in regulations, but reasonable for Authority to determine. Must be published so everyone knows what is required.	No need for detail in regulations, promotes flexibility.
57 regulation-making	Health claims on labels and advertising	Goes with 42. Concerns raised by industry about clarity of advertising rules in workshops. Regulation-making power will allow rules to be made if needed. Any regulations explicitly require consultation, and are subject to parliamentary review.
57	May make regulations about procedure of advisory committee.	There is a provision in 48 (8) that advisory committee may regulate its own procedure, subject to any requirement in the regulations. However there was no corresponding regulation-making power for the Minister. This is now rectified.
58	Change “Minister” to “Ministry”	Requires Minister to review the Act within 5 years, rather than Ministry
NEW	Consequential amendment to Psychoactive Substances Act s9 delete (d) and (e). New subsection “a natural health and supplementary product (within the meaning of section 6 of the Natural Health and Supplementary Products Act 2015)	Provisions referring to herbal remedies and dietary supplements now superfluous.
Schedule		
	Remove amino acid list and just say “amino acid”	Simpler, leaves option open. No safety risk, as still constrained by permitted ingredients list

Attachment one – Table of Changes by SOP

Provisions removed entirely

Clause	What	Why
Old 18	Remove requirement for new notification if manufacturer changes	Multiple manufacturers used by industry as a matter of routine. Records kept by notifier, tied to batch numbers, so no safety or traceability concern.
18 (1) Provision removed entirely. To be managed administratively.	Delete (a). Add new (c) “must withdraw the previous notification as soon as practicable, following depletion of stocks	Clarifies that old product may still be sold legally
24A	Delete	No longer need to distinguish dietary supplement after change to clause 6
old 51(2)	Delete	Refers to a non-existent section – not needed since commencement of relevant bits of Medicines Amendment Act 2013