CONSULTATION DRAFT

House of Representatives

Supplementary Order Paper

Tuesday, 18 August 2015

Natural Health Products Bill

Proposed amendments for the consideration of the Committee of the whole House

Key:

- **<u>this is inserted text</u>**
- **~~this is deleted text~~**

Note: This Supplementary Order Paper shows amendments to the Bill that are being proposed by the Minister for the purposes of consideration in Committee of the whole House. This document does—

- **NOT have official status in terms of unamended text**
- **NOT have the status of an as-reported version of the Bill.**

Explanatory note

This Supplementary Order Paper amends the Natural Health Products Bill.

The Bill currently aims to regulate natural health and supplementary products, which by definition contain only permitted ingredients (which are *Schedule 1* substances declared to be permitted ingredients by the Authority). It is proposed that the Bill also regulate natural health products, which is similar in meaning, except that the *Schedule 1* ingredients that constitute the product need not be permitted ingredients. A new term, permitted natural health product, is proposed in place of natural health and supplementary product. The following table illustrates the proposed changes:

Current definitions	Proposed definitions
natural health and supplementary product means any product, subject to *subclause (2) of clause 6*, that— (a) is or appears to be manufactured for human use and for the primary purpose of bringing about a health benefit to users; and (b) contains only permitted ingredients unless it is a new approved ingredient or a dietary supplement; and (c) is not, or is not presented as, a food. *Subclause (2) of clause 6* excludes certain medicines, related products, and medical devices under the Medicines Act 1981 from the definition of natural health and supplementary products	**natural health product** means any product that— (a) is or is represented as having been manufactured for human use and for the primary purpose of bringing about a health benefit to users; and (b) contains, or is represented as containing, only natural substances; and (c) is not, or is not presented as, a food; and (d) is not or does not contain a medicine listed in Schedule 1 of the Medicines Regulations 1984 or a psychoactive substance
permitted ingredient means any substance that is or belongs to a class of substance listed in *Schedule 1* and declared by the Authority to be a permitted substance.	**natural substance** means any substance or class of substance listed in *Schedule 1* **permitted substance** means any natural substance declared by the Authority to be a permitted substance **permitted natural health product** means a natural health product that contains only permitted substances.

The effect of these changes is that dietary supplements will be regulated as natural health products. Accordingly, the word supplementary in the term natural health and supplementary product is no longer necessary and is removed.

The Bill would now regulate—

- the manufacture of natural health products:

- the sale, offering for sale, and export of permitted natural health products.

This Supplementary Order Paper proposes that *Part 2* of the Bill be comprehensively restructured to reflect the different levels of regulation being proposed and to enable key regulatory provisions to appear first and provisions relating to administrative matters to appear at the end. *New Part 2* carries over most of the provisions currently in *Part 2* of the Bill with consequential changes as well as substantive changes being made to those provisions. Minor drafting and editorial changes are also proposed.

Manufacture of natural health products

The most significant change proposed to provisions relating to the manufacture of natural health products (*clauses 8 to 15*) is that the obligation to obtain a licence to manufacture now extends to manufacturers of natural health products (instead of the narrower range of natural health and supplementary products). The significance of this change is reinforced by incorporating the relevant offence provision into *clause 8*.

Under the current Bill, manufacturers of natural health and supplementary products for export who do not require an export certificate are exempt from the requirement to obtain a licence to manufacture. That exemption is not carried forward.

Natural health products for sale or export

Clause 16(1) prohibits the sale and offering for sale in New Zealand and the export of any natural health product unless—

- it is a permitted natural health product (containing only permitted substances); and
- it has a valid product notification or is a product to which *clause 18* applies (for example, an exempted product).

New clause 18, which lists natural health products that do not require product notification, contains the following changes (*see previous clause 13A*):

- export-only natural health and supplementary products are no longer exempt:
- the reference to natural health products in which the active ingredient is in a concentration of not more than 20 parts per million is amended to 10 parts per million.

Clauses 21(4) and (6) are offence provisions relating to certain permitted natural health products that do not require product notification. It is an offence for a person to make, on the label or in any advertisement for such products, any health benefit claim that relates to a named condition except as provided in regulations.

Clause 27, which requires product notifiers to notify the Authority of any serious adverse reaction to the product, is amended. *Paragraph (e)* of the definition of serious adverse reaction is amended by replacing allergic reaction with serious allergic reaction.

Clause 28, which carries forward *previous clause 18*, sets out when a new product notification is required for a product. Unlike under *previous clause 18*, a new product

notification will not be required where there is a change of premises in the case of products manufactured overseas.

Clause 32 regulates the use of new substances (which are natural substances that are not permitted substances) in the manufacture of a natural health product for sale or export. *Previous clause 23*, which relates to safety assessments of new ingredients, is not carried forward. However, the processes and criteria for the declaration of new ingredients in *previous clause 22* will continue to apply to new substances.

Previous clause 21, which relates to prohibited ingredients, is not carried forward.

Previous clause 24A, which sets out requirements for natural health products that are dietary supplements, is not carried forward.

Offences

New offence provisions are introduced. A person commits an offence who—

- sells or offers for sale in New Zealand or exports any natural health product knowing that the product does not comply with *clause 16(1)* (must be a permitted natural health product with a valid product notification):
- knowingly manufactures a notified natural health product that contains a substance other than a permitted substance:
- knowingly sells or offers for sale in New Zealand or exports any natural health product that is different from its description in the product notification.

Clause 43 sets out offences for deceptive behaviour and contains a new offence provision relating to false representation of natural health products, permitted natural health products, and notified natural products.

The following offence provisions apply to all natural health products:

- *clause 39* (prohibited methods of administration):
- *clause 41* (endangerment of human health):
- *clause 42* (publishing of certain advertisements relating to natural health products).

Other changes

Clause 51 is new, and allows the Authority to set out the manner in which a product notification is to be completed, and the manner in which certain applications must be made (*clauses 9, 20, 22, 32, and 56*).

Clause 56 allows the Authority to declare, in certain circumstances, a product or class of product to be a natural health product or permitted natural health product.

Clause 57 includes a new power to make regulations prescribing requirements relating to advertisements of natural health products.

Schedule 1 contains the following changes:

- *item 2(b)* is amended to remove the words “for preparation of the substance or mixture of substances in an active medicinal form”:

- *item 3* is amended by replacing "folic acid" with "folate":
- *item 8* is replaced with "An amino acid".

Departmental disclosure statement

The Ministry of Health considers that a departmental disclosure statement is not required to be prepared for this Supplementary Order Paper.

Regulatory impact statement

The Ministry of Health produced [a regulatory impact statement/regulatory impact statements] on [date] to help inform the new policy decisions taken by the Government relating to the contents of this SOP.

[A copy of this regulatory impact statement/Copies of these regulatory impact statements] can be found at—

- [Insert URL link(s) to the RIS on the agency's/agencies' Internet site(s)]
- http://www.treasury.govt.nz/publications/informationreleases/ris

The Honourable Minister, in Committee, to propose the amendments shown in the following document.

Hon Jonathan Coleman

Natural Health ~~and Supplementary~~ Products Bill

Government Bill

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The Parliament of New Zealand enacts as follows:

1 Title

This Act is the Natural Health ~~and Supplementary~~ Products Act **2011**.

2 Commencement

This Act comes into force on ~~3 January 2014~~ 30 November 2016, unless it is earlier brought into force on a date appointed by the Governor-General by Order in Council.

Part 1
Preliminary matters

Preliminary provisions

3 Purpose

The purpose of this Act is to establish a system for the regulation of natural health ~~and supplementary~~ products in New Zealand.

3A Scheme of Act

(1) This Act aims to achieve its purpose by—

(a) establishing a licensing regime for manufacturers of natural health products; and

(b) requiring that a natural health product must not be sold or offered for sale in New Zealand, or exported, unless it contains only permitted substances and has a valid product notification (made to the Authority); and

(c) specifying who is responsible for completing a product notification (the **product notifier**); and

(d) regulating the health benefit claims that may be made for a permitted natural health product by—

(i) requiring the product notifier to provide, for each health benefit claim made for the product, a summary of evidence relied on to support the claim; and

(ii) restricting the health benefit claims that may relate to a named condition; and

(e) enabling the Authority to audit product notifications and to suspend or cancel a product notification in accordance with specified criteria; and

(f) providing for the enforcement of this Act, including the imposition of offences and penalties, and providing for appeals against decisions of the Authority; and

(g) providing for the powers of the Authority and requiring the establishment of an advisory committee.

(2) This section is only a guide to the general scheme and effect of this Act.

4 ~~Principles~~

~~1~~ ~~This Act is based on the following principles:~~

~~(a)~~ ~~that natural health and supplementary products should be fit for human use:~~

~~(b)~~ ~~that the regulation of natural health and supplementary products should be proportionate to the risks associated with their use:~~

~~(c)~~ ~~that natural health and supplementary products should be accompanied by information that —~~

~~(i)~~ ~~is accurate; and~~

~~(ii)~~ ~~tells consumers about any risks, side-effects, or benefits of using the product:~~

~~(d)~~ ~~that health benefit claims made for natural health and supplementary products should be supported by scientific or traditional evidence.~~

5 Interpretation

In this Act, unless the context otherwise requires,—

additive means any preservative, antioxidant, colouring, flavouring, or sweetener

advisory committee means the Natural Health ~~and Supplementary~~ Products Advisory Committee established under ~~**section 10**~~ **section 48**

allowable claim means any health benefit claim that the authority has, under ~~**section 12B(1)**~~ **22**, determined may relate to a named condition

~~**approved pharmacopeia** means a pharmacopeia listed in **Schedule 2**~~

appeals committee means the Natural Health ~~and Supplementary~~ Products Appeals Committee established under ~~**section 41**~~ **44**

approved pharmacopoeia means a pharmacopoeia listed in **Schedule 2**

authorised person means—

(a) a person authorised by the Authority for the purpose of ~~**section 31A**~~ **12**; or

(b) a person to whom the Authority has delegated any powers, functions, or duties under ~~**section 45**~~ **55**

Authority means the Natural Health ~~and Supplementary~~ Products Regulatory Authority established under ~~**section 8**~~ **46**

code means the code of practice for ~~manufacturing~~ the manufacture of natural health ~~and supplementary~~ products established under ~~**section 27**~~ **49**

database means the natural health ~~and supplementary~~ products database established under ~~**section 11**~~ **52**

~~**dietary supplement** means a product that is—~~

~~(a) sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet); and~~

~~(b) intended to be ingested orally; and~~

~~(c) intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food~~

food has the meaning given to it in **section 6(3)**

formulation aid means any thing that is added to a product to—

(a) provide a carrier for the product's active ingredients:

(b) modify the pH, viscosity, or handling properties of the product during its manufacture:

(c) provide a vehicle for its administration

health benefit means any 1 of the following benefits:

(a) the maintenance or promotion of health or wellness:

(b) nutritional support:

(c) vitamin or mineral supplementation:

(d) affecting or maintaining the structure or function of the body:

(e) relief of symptoms

health benefit claim means a claim of a health benefit

Internet site means an Internet site that is publicly accessible at all reasonable times

label includes any written, pictorial, or other descriptive matter that—

(a) relates to any natural health ~~and supplementary~~ product or any package containing that product; and

(b) appears on, is attached to, or is associated with that product

licence to manufacture means a licence granted under **section ~~29~~ 9** to manufacture natural health ~~and supplementary~~ products

manufacture, in relation to a product, means to make up, prepare, produce, or process the product for the purposes of sale, and includes the packaging of the product in a container for the purposes of sale

Minister means the Minister who, under the authority of any warrant or with the authority of the Prime Minister, is for the time being responsible for the administration of this Act

Ministry means the department of State that, with the authority of the Prime Minister, is responsible for the administration of this Act

named condition has the meaning given to it in **section ~~12C~~ 6B**

natural health ~~and supplementary~~ product has the meaning given to it in **section 6**

natural substance, for the purposes of this Act, means any substance or class of substance listed in **Schedule 1**

new substance means a natural substance that is not a permitted substance

notified natural health ~~and supplementary~~ product means a natural health ~~and supplementary~~ product for which a product notification has been completed

parenteral infusion means the gradual introduction of fluid into the human body by means other than the alimentary canal

permitted natural health product means a natural health product that contains only permitted substances

permitted ~~ingredient~~ substance means any ~~substance that is, or belongs to a class of substance, listed in **Schedule 1** and~~ natural substance declared by the Authority under **section ~~20~~ 31** to be a permitted ~~ingredient~~ substance

prescribed manner means the manner prescribed in regulations

product notification means the product notification required under **section ~~13~~ 20**

product notifier, in relation to a natural health ~~and supplementary~~ product, means the person identified as the product notifier under **section ~~11A~~ 6A**

~~**prohibited ingredient** means any substance declared by the Authority to be a prohibited ingredient under **section 21**~~

recognised authority means a person or body for the time being declared to be a recognised authority under **section ~~9~~ 47**

regulations means regulations made under this Act

regulatory principles means the principles relating to the regulation of permitted natural health products set out in **section 17**

scientific evidence means evidence derived from either or both of the following sources:

(a) empirical studies:

(b) repeatable experiments

traditional evidence means evidence of traditional use of a substance based on knowledge, beliefs, or practices passed down from generation to generation

use, in relation to a product, includes—

(a) consumption of the product; and

(b) being administered the product~~.~~

valid product notification, in relation to a natural health product, means a product notification that—

(a) has been completed in accordance with **section 20** and in the manner specified by the Authority (*see* **section 51**); and

(b) has not been cancelled or suspended.

6 Definition of natural health ~~and supplementary~~ product

(1) **Natural health ~~and supplementary~~ product** means~~, subject to **subsection (2)**~~, any product that—

(a) is, ~~or appears to be~~ or is represented as having been, manufactured—

(i) for human use; and

(ii) for the primary purpose of bringing about a health benefit to the person who uses the product; and

(b) contains, or is represented as containing, only natural substances; and

~~(b) contains only permitted ingredients unless—~~

~~(i) **section 22(2)(b)(i)** applies; or~~

~~(ii) the product is a dietary supplement; and~~

(c) is not, or is not presented as, a food~~.~~; and

(d) is not, or does not contain,—

(i) a medicine listed in Schedule 1 of the Medicines Regulations 1984; or

(ii) a psychoactive substance within the meaning of section 9 of the Psychoactive Substances Act 2013.

(2) ~~**Natural health and supplementary product** does not include—~~

~~(a) any medicine that—~~

~~(i) the Minister has, under section 20 or 23 of the Medicines Act 1981, given consent to its distribution; or~~

~~(ii) the Minister is, under section 20(7) of that Act, deemed to have given consent to its distribution; or~~

~~(iii) the Director-General, has under section 24 of that Act, given consent to its distribution:~~

~~(b) any related product that the Minister has, under section 20 and 96 of the Medicines Act 1981, given consent to its distribution:~~

~~(c) any medical device that is the subject of a declaration under regulation 6 of the Medicines (Database of Medical Devices) Regulations 2003.~~

(3) In **subsection (1)**, **food** means anything that is ordinarily used or represented for use as food or drink for human beings.

6A Product notifier

(1) In the case of a natural health product that is manufactured in New Zealand,—

(a) the product notifier is the manufacturer of the product; but

(b) if the manufacturer manufactures the product on behalf of another person, the product notifier is that other person.

(2) In the case of a natural health product that is manufactured in a country other than New Zealand,—

(a) the product notifier is the person who imports the product into New Zealand; but

(b) if the person imports the product on behalf of another person, the product notifier is that other person.

(3) A product notifier of a natural health product must be resident in New Zealand within the meaning of section YD 1 or YD 2(1)(a) of the Income Tax Act 2007.

6B Named conditions

(1) In this Act, **named condition** means any disease, disorder, condition, ailment, or defect that is listed or described in the *International Statistical Classification of Diseases and Related Health Problems* (the **ICD**) published by the World Health Organization, as amended from time to time by that organisation.

(2) The Authority must arrange for—

(a) a reasonable number of copies of the ICD to be made available for inspection free of charge at places in New Zealand specified by the Authority; and

(b) if the ICD has been amended, the most up-to-date version of it to be made available in accordance with **paragraph (a)**; and

(c) at any time that the most up-to-date version of the ICD is not available free of charge on the Internet, copies of the most up-to-date version of the ICD to be made available for purchase at a reasonable price.

(3) The ICD or any amendment to the ICD does not have effect until it is made available for inspection in accordance with **subsection (2)**.

(4) The ICD is a disallowable instrument, but not a legislative instrument, for the purposes of the Legislation Act 2012 and must be presented to the House of Representatives under section 41 of that Act.

7 Act binds the Crown

This Act binds the Crown.

~~Natural Health and Supplementary Products Regulatory Authority~~

8 ~~Natural Health and Supplementary Products Regulatory Authority~~

~~(1) This section establishes the Natural Health and Supplementary Products Regulatory Authority.~~

~~(2) The Authority is the Director-General of Health.~~

(3) The office of the Authority must be administered by the Ministry of Health.

9 Authority may declare recognised authorities

(1) The Authority may, by notice in the *Gazette*, declare a person or body to be a recognised authority—

(a) for a specified purpose under this Act or provision of this Act; and

(b) for a specified period or not.

(3) Before declaring a person or body to be a recognised authority for a specified purpose under this Act or provision of this Act, the Authority must be satisfied that the person or body (whether in New Zealand or any other country)—

(a) makes decisions in respect of similar products that require the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act; or

(b) is engaged in an area of work that requires the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act.

(4) In this section, **similar products** means products that (however described) are the same type of products as natural health and supplementary products.

Natural Health and Supplementary Products Advisory Committee

10 Natural Health and Supplementary Products Advisory Committee

(1) The Authority must establish an advisory committee to provide expert advice to the Authority on matters referred to it by the Authority.

(2) The advisory committee must consist of not more than 8 members.

(2A) The Authority must consult the Minister before making any appointment to the advisory committee.

(3) The members of the advisory committee may be appointed by the Authority on any terms and conditions that the Authority thinks fit.

(4) In appointing members of the advisory committee, the Authority must—

(a) take into account the need for members to have among them a breadth of experience and expertise in, and depth of knowledge in, areas of knowledge that relate to or are relevant to natural health and supplementary products:

(b) ensure that there is at least 1 member with experience, expertise, and depth of knowledge in manufacturing:

(c) ensure that there is at least 1 member with experience, expertise, and depth of knowledge in science.

(5) The Authority may give terms of reference—

(a) on the advice that the advisory committee provides to the Authority; and

(b) on the use of external experts to assist the advisory committee.

(6) The advisory committee may, subject to any provision in this Act, the regulations, and the terms of reference, determine its own procedures.

Natural health and supplementary products database

11 Natural health and supplementary products database

The Authority must establish and maintain a natural health and supplementary products database.

Product notifier

11A Product notifier

(1) In the case of a natural health and supplementary product that is manufactured in New Zealand,—

(a) the product notifier is the manufacturer of the product; but

(b) if the manufacturer manufactures the product on behalf of another person, the product notifier is that other person.

(2) In the case of a natural health and supplementary product that is manufactured in a country other than New Zealand,—

(a) the product notifier is the person who imports the product into New Zealand; but

(b) if the person imports the product on behalf of another person, the product notifier is that other person.

12 Product notifier must be resident in New Zealand

A product notifier of a natural health and supplementary product must be resident in New Zealand within the meaning of section YD 1 or YD 2(1)(a) of the Income Tax Act 2007.

Part 2
Regulation of natural health and supplementary products

Health benefit claims

12A Health benefit claims relating to named conditions

(1) A product notifier must not include in the product notification of a natural health and supplementary product any health benefit claim that relates to a named condition unless it is an allowable claim.

(2) A product notifier must not include in or attach to the summary of evidence required under **section 13(2A)** any health benefit claim that relates to a named condition unless it is an allowable claim.

(3) No person may make on the label of a natural health and supplementary product or in any advertisement for the product any health benefit claim that relates to a named condition unless it is an allowable claim.

(4) In **subsection (3)**, **advertisement** has the meaning given to it by **section 40C(4)**.

12B Authority may determine allowable claims

(1) The Authority may, on its own initiative or on application by any person,—

(a) determine, in accordance with **subsections (2) and (3)**, that a health benefit claim for a natural health and supplementary product or class of that product may relate to a named condition or class of named condition; or

(b) determine, in accordance with **subsection (4)**, that a health benefit claim may relate to a named condition or class of named condition.

(2) In determining whether a health benefit claim for a natural health and supplementary product or class of that product may relate to a named condition, the Authority must—

(a) be guided by the principles of this Act; and

(b) consider, subject to **subsection (3)**,—

(i) the nature and quality of the evidence provided in support of the claim; or

(ii) if the Authority is determining the matter on its own initiative, the nature and quality of the evidence before the Authority; and

(c) be satisfied that the level of risk associated with use of the product or class of product is low.

(3) If any traditional evidence provided to or before the Authority in support of a health benefit claim is a reference to information contained in an approved pharmacopeia—

(a) the Authority must accept the reference as evidence if satisfied that the information to which it refers is relevant to the health benefit claim; and

(b) **subsection (2)(b)** does not apply to the evidence.

(4) In determining whether a health benefit claim may relate to a named condition or class of named condition, the Authority must—

(a) be guided by the principles of this Act; and

(b) be satisfied that the level of risk associated with allowing the health benefit claim to be made is low.

(5) The Authority must publish on an Internet site maintained by or on behalf of the Ministry a list of allowable claims determined under **subsection (1)** and, where applicable, the natural health and supplementary product or class of that product for which those claims may be made.

(6) An application under this section must be made to the Authority in the prescribed manner.

12C Named conditions

(1) In this Act, **named condition** means any disease, disorder, condition, ailment, or defect that is listed or described in the *International Statistical Classification of Diseases and Related Health Problems* (the **ICD**) published by the World Health Organization, as amended from time to time by that organisation.

(2) The Authority must arrange for—

(a) a reasonable number of copies of the ICD to be made available for inspection free of charge at places in New Zealand specified by the Authority; and

(b) if the ICD has been amended, the most up-to-date version of it to be made available under **paragraph (a)**; and

(c) at any time that the most up-to-date version of the ICD is not available free of charge on the Internet, that copies of the most up-to-date version of the ICD be made available for purchase at a reasonable price.

(3) The ICD or any amendment to the ICD does not have effect until it is made available for inspection in accordance with **subsection (2)**.

(4) The ICD is a regulation for the purposes of the Regulations (Disallowance) Act 1989, but not for the purposes of the Acts and Regulations Publication Act 1989.

Product notification of natural health and supplementary products

13 Product notification of natural health and supplementary products

(1) A natural health and supplementary product must not, subject to **section 13A**, be sold in New Zealand without a product notification for the product having been completed.

(2) The product notification must be made to the Authority and must be completed by the product notifier in the prescribed manner.

(2A) Before completing the product notification, the product notifier must make available on an Internet site, in respect of each health benefit claim made for the product, a summary of the evidence that the product notifier relies on to support the claim.

(3) The product notification is complete when—

(a) the product notifier has provided—

(i) information as required by regulations relating to the name of the product, the product details, the product notifier, the manufacturer, and the health benefit claims made for the product; and

(ii) any other information required by regulations; and

(b) the product notifier has provided a declaration that—

(i) the information provided is complete and accurate; and

(ii) the product notifier is able to provide, at the Authority's request, evidence to support the health benefit claims made for the product.

(4) The product notifier must, if requested by the Authority, provide the Authority with the evidence described in **subsection (3)(b)(ii)**.

(5) If a manufacturer of a natural health and supplementary product is not in New Zealand and is not listed on the database, the product notifier must satisfy the Authority that the manufacturer complies with the code after providing any documentation or information required by the Authority.

(8) In this section, **evidence** means either of the following types of evidence, each of which must be consistent with any prescribed standard:

(a) scientific evidence:

(b) traditional evidence.

Natural health and supplementary products that do not require product notification

13A Natural health and supplementary products that do not require product notification

Section 13 does not apply to—

(a) any natural health and supplementary product that is made by a practitioner to be administered to a particular person after being requested by or on behalf of that person to use the practitioner's own judgement as to the treatment required; or

(b) any export-only natural health and supplementary product, unless it is a product for which export certification is sought under **section 25**; or

(c) natural health and supplementary products or categories of natural health and supplementary products that are exempted under **section 14**; or

(d) any natural health and supplementary product in which the active ingredient to be administered is in a concentration not more than 20 parts per million.

14 Authority may exempt natural health and supplementary products from product notification

(1) The Authority may, by notice in the *Gazette*, exempt a natural health and supplementary product or category of natural health and supplementary product from the requirements of **section 13**.

(2) The Authority must not exempt a natural health and supplementary product unless the Authority is satisfied that—

(a) compliance with **section 13** would be impractical or unreasonable in the circumstances; and

(b) exempting the product is consistent with **section 4(b)**.

(3) The Authority must not exempt a category of natural health and supplementary product unless—

(a) it has considered advice from the advisory committee on the exemption; and

(b) the Authority is satisfied that there is no risk to public health in exempting that category.

(4) A notice under **subsection (1)**—

(a) is a regulation for the purposes of the Regulations (Disallowance) Act 1989 but not for the purposes of the Acts and Regulations Publication Act 1989:

(b) must include the reasons of the Authority.

Audit of product notifications

15 Authority may audit product notifications

(1) The Authority may at any time audit any product notification or class of product notification.

(2) The audit may be conducted in any manner that the Authority considers appropriate and consistent with the principles of this Act.

Suspension and cancellation of product notification

16 Grounds for suspension of product notification

(1) The Authority may suspend a product notification of a natural health and supplementary product if—

(a) the Authority has reasonable grounds to believe that the product has caused, is causing, or is likely to cause any harm to any person; or

(b) the Authority has reasonable grounds to believe that the product notifier has provided false, misleading, or incomplete information in the product notification; or

(c) the Authority has reasonable grounds for concern because of new information about the safety, quality, health benefit claims, or manufacturing standards of the product.

(2) If the Authority decides to suspend a product notification, it must notify the product notifier in writing of—

(a) the date that the suspension takes effect, being the date of the notice or a date specified in the notice; and

(b) the period of suspension (being a period of 21 working days); and

(c) the reason for the suspension.

16A Effect of suspension of product notification

If a product notification for a natural health and supplementary product is suspended, the product notifier—

(a) must ensure that the product is not sold by any person on and from the date that the suspension takes effect; and

(b) must not complete another product notification for the product during the period of suspension.

16B Cancellation or reinstatement of product notification

(1) Before the period of suspension ends, the Authority must—

(a) decide whether to cancel or reinstate the product notification for the natural health and supplementary product; and

(b) give written notice of the decision to the product notifier.

(2) A cancellation or reinstatement takes effect immediately after the end of the period of suspension.

(3) If a product notification is cancelled under this section, the product notifier—

(a) must ensure that the product is not sold by any person on and from the date the cancellation takes effect; and

(b) must not complete another product notification for the product unless the Authority is satisfied, on application by the product notifier, that the grounds for cancellation no longer apply or any concerns of the Authority leading to the cancellation have been addressed appropriately.

17 Product notifier must notify Authority of any serious adverse reaction to natural health and supplementary product

(1) The product notifier of a notified natural health and supplementary product must notify the Authority as soon as the product notifier becomes aware of any serious adverse reaction to the product.

(2) In this section, **serious adverse reaction** means any reaction that—

(a) results in hospitalisation, or prolongs any existing hospitalisation:

(b) is life-threatening or fatal:

(c) results in disability or incapacity or requires intervention to prevent permanent disability or incapacity:

(d) results in any congenital abnormality:

(e) is an allergic reaction.

18 When new product notification needed

(1) If, in relation to a notified natural health and supplementary product, there is any change of a kind described in **subsection (1A)**, the product notifier must, as soon as practicable,—

(a) withdraw the product notification for the product; and

(b) complete a new product notification for the product that accurately reflects the change.

(1A) The changes referred to in **subsection (1)** are—

(a) the product is manufactured by a different manufacturer:

(b) in the case of a product that is manufactured overseas, the product is manufactured in different premises:

(c) there is a change to any of the health benefit claims made for the product:

(d) there is a change in any of the product's ingredients (including the amount of any ingredient) other than—

(i) an additive; or

(ii) a formulation aid.

(2) A product notifier is not required to complete a further product notification for a natural health and supplementary product if there is any variation in the weight, size, or packaging of the product.

(3) The product notifier may change the product notifier's contact details on a product notification without the need for a new product notification.

19 Product notifier may cancel product notification

A product notifier of a notified natural health and supplementary product may cancel the product notification for the product if the product is no longer sold.

19A Authority may cancel product notification if no longer necessary

(1) The Authority may cancel the product notification for a natural health and supplementary product if it is satisfied that the product notification is no longer necessary in the circumstances.

(2) Before cancelling a product notification under this section, the Authority must—

(a) give notice to the product notifier that it is considering cancelling the product notification and give reasons; and

(b) give the product notifier a reasonable opportunity to respond to the notice; and

(c) consider any submission made by the product notifier in response to the notice.

(3) The Authority does not have to comply with **subsection (2)** if, after reasonable inquiry, the product notifier cannot be found.

Prohibited methods of administration

19B Prohibited methods of administration

No natural health and supplementary product may be sold in New Zealand that is or appears to be manufactured for administration by:

(a) injection or parenteral infusion:

(b) application to the eye.

Ingredients of natural health and supplementary products

20 Permitted ingredients

(1) The Authority may, for the purpose of this Act, declare any substance that is, or belongs to any class of substance, listed in **Schedule 1** to be a permitted ingredient in a natural health and supplementary product.

(2) The Authority may impose restrictions on the use of any substance it has declared to be a permitted ingredient.

(3) In considering whether a substance should be declared a permitted ingredient, the Authority—

(a) may conduct a safety assessment of the substance; and

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) whether a recognised authority permits the use of the substance in a similar product and, if so, whether it imposes any restrictions on the use of the substance:

(ii) whether the substance is recognised in traditional medicine or pharmacopoeias:

(iii) any other matter that the Authority considers relevant in the circumstances.

(4) Every substance declared to be a permitted ingredient must be listed on the database along with any restrictions on the use of the substance.

(5) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(6) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

(7) In this section, **similar products** means products that (however described) are the same type of products as natural health and supplementary products.

21 Prohibited ingredients

(1) The Authority may, for the purpose of this Act, declare a substance to be a prohibited ingredient.

(2) In considering whether to declare a substance to be a prohibited ingredient, the Authority—

(a) must consider the risk of any harm arising from the use of the substance; and

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) any history of human therapeutic use of the substance:

(ii) whether a recognised authority prohibits or restricts use of the substance by human beings:

(iii) any other matter that the Authority considers relevant in the circumstances.

(3) Every substance declared to be a prohibited ingredient must be listed on the database.

(4) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(5) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

New ingredients

22 If new ingredient intended for use in natural health and supplementary product

(1) In this section and **section 23**, **new ingredient** means any substance that is, or belongs to a class of substance, listed in **Schedule 1** and that is not—

(a) a permitted ingredient; or

(b) a prohibited ingredient.

(2) If a product notifier intends to use a new ingredient in a natural health and supplementary product for sale in New Zealand,—

(a) the product notifier must apply to the Authority in the prescribed manner no later than 90 working days before the product notifier intends to complete a product notification for the product (the **90-day period**); and

(b) if, within the 90-day period, the Authority does not raise any concern or commence a safety assessment for the product,—

(i) the new ingredient may be used in the product after the 90-day period; and

(ii) the product notifier may, after receiving written confirmation from the Authority that the new ingredient may be used, complete a product notification for the product; but

(c) if, within the 90-day period, the Authority raises a concern and commences a safety assessment, the product must not be notified under **section 13**, or sold until or unless the Authority determines that the new ingredient may be used in the product.

(3) The Authority must, when determining whether the new ingredient may be used in the product, apply the criteria set out in **section 20(3)(b)(i) to (iii)**.

(4) If the Authority determines that the new ingredient may be used in the natural health and supplementary product, the Authority must, as soon as practicable,—

(a) declare the new ingredient to be a permitted ingredient in accordance with **section 20**; and

(b) list the new ingredient on the database in accordance with **section 20(4)**; and

(c) comply with **section 20(6)**.

23 Safety assessment of new ingredient

(1) If the Authority is notified of a new ingredient under **section 22**,—

(a) the Authority must, as soon as practicable, notify the applicant as to whether a safety assessment will be undertaken; and

(b) if a safety assessment is to be undertaken, the Authority must, within 30 working days of being notified of the new ingredient, notify the applicant of—

(i) the outcome of the assessment; or

(ii) whether further time is needed to complete the assessment.

(2) The Authority may request further evidence of the safety of the new ingredient from the applicant.

Dietary supplements

24A Natural health and supplementary products that are dietary supplements

A natural health and supplementary product that is a dietary supplement must contain only permitted ingredients.

Labelling

24 Labelling

A natural health and supplementary product that is sold in New Zealand must comply with the labelling requirements prescribed in regulations.

Exports

25 Export certificate

(1) A product notifier may, subject to **section 26**, apply to the Authority for an export certificate for a natural health and supplementary product.

(2) Any application under this section must be accompanied by the prescribed fee(if any) and the product notifier must comply with any requests for information made by the Authority for the purposes of the application.

(3) The Authority may grant an export certificate for a natural health and supplementary product if the product notifier has completed a product notification for the product.

(4) If the product notifier is seeking an export certificate for a natural health and supplementary product that is manufactured in New Zealand but not sold in New Zealand,—

(a) the product notifier must complete a product notification for the product; and

(b) the manufacturer of the product must hold a licence to manufacture.

(5) The Authority may determine the form and content of the export certificate.

(6) An export certificate is not a guarantee that the natural health and supplementary product—

(a) necessarily meets the commercial requirements of the consumer; or

(b) necessarily meets the specific requirements of overseas markets.

26 Natural health and supplementary products that are animal products

Despite **section 25**, if a natural health and supplementary product is also an animal product within the meaning of the Animal Products Act 1999, any application for an export certificate or a similar statement for that product must be made in accordance with that Act instead of this Act.

Code of practice for manufacture of natural health and supplementary products

27 Code of practice for manufacture of natural health and supplementary products

(1) The Authority must establish a code of practice for the manufacture of natural health and supplementary products.

(1A) The code must come into force no later than 1 year after the commencement of this section.

(2) In developing the code and any amendments to the code, the Authority must—

(aa) be guided by the principles of this Act:

(a) comply with any requirements relating to the content of the code that is prescribed in regulations:

(b) consult persons or organisations that the Authority considers to be representative of the interests of persons likely to be affected by the code.

(3) The Authority must ensure that the code, and every amendment to it,—

(a) specifies the date on which it takes effect:

(b) is published on an Internet site.

Manufacture of natural health and supplementary products

28 Licence to manufacture natural health and supplementary products

(1) A person must not manufacture a natural health and supplementary product without a licence to manufacture granted under **section 29**.

(2) **Subsection (1)** does not apply to—

(a) any natural health and supplementary product that is being manufactured for export and for which an export certificate is not sought by the exporter:

(b) any practitioner who makes a natural health and supplementary product to be administered to a particular person after being requested by or on behalf of that person to use the practitioner's own judgement as to the treatment required.

29 Application for licence to manufacture

(1) An application for a licence to manufacture natural health and supplementary products must be made to the Authority in the prescribed.

(2) The Authority may grant a person a licence to manufacture natural health and supplementary products if—

(a) the Authority is satisfied that the manufacturing facilities meet the requirements of the code; and

(b) the Authority is satisfied that the person is a fit and proper person to hold the licence.

(3) In determining whether a person is a fit and proper person to manufacture natural health and supplementary products, the Authority must take into account the following:

(a) any conviction of the person or any director or manager of the person for any offence involving or relating to the manufacture of any product for human consumption:

(b) whether there has in the past been a serious or repeated failure by the person to comply with any requirement under this Act:

(c) whether there are other grounds for considering that the person is likely in the future to fail to comply with those requirements:

(d) any other matters that the Authority considers relevant.

(4) A licence to manufacture remains in force for 5 years after the date that it is granted, unless—

(a) the Authority specifies a shorter period for the licence; or

(b) it is earlier revoked.

30 Conditions of licence

(1) It is a condition of a licence to manufacture that the licence holder must at all times comply with the code.

(2) The Authority may, when granting a licence to manufacture, impose other conditions on the licence as the Authority thinks fit.

31 Audits of manufacturing facilities

(1) This section applies to any manufacturing facility—

(a) in which a natural health and supplementary product is being manufactured under a licence to manufacture; or

(b) in respect of which an application for a licence to manufacture is made.

(1A) For the purpose of assessing whether the manufacturing facility complies with the code and, if applicable, any conditions of the licence to manufacture, the Authority may do one or both of the following:

(a) conduct audits of the manufacturing facility at any time:

(b) to the extent the Authority considers applicable, recognise any audit of the manufacturing facility conducted by another person under another enactment or for another purpose.

(2) The Authority may conduct an audit of the manufacturing facility in any manner that the Authority considers appropriate and consistent with the principles of this Act.

31A Authorised person may enter manufacturing facility and take samples in specified circumstances

(1) The Authority may authorise a person to enter a manufacturing facility during the normal business hours of that facility and exercise any power set out in this section for the purpose of—

(a) assessing an application for a licence to manufacture; or

(b) assessing whether the manufacturing facility is complying with the code or any conditions of the licence to manufacture.

(2) For the purpose of **subsection (1)(a) or (b)**, an authorised person may—

(a) open containers and packages and inspect the contents:

(b) request, gather, or secure evidence, take samples of natural health and supplementary products, their ingredients, water, air, or any substance,

and test or analyse or arrange for the testing and analysis of such samples:

(c) inspect, inquire about, or copy any documents or other records, including records in an electronic form, relating to the obligations imposed under this Act or regulations:

(d) remove any documents or other records, including records in an electronic form, from the place for the purposes of copying such documents or records.

(3) An authorised person must provide—

(a) evidence of his or her authorisation to the person in charge of the facility when the person first enters the facility, and at any later time at the request of the person in charge; and

(b) provide to the person in charge of the facility a list of any items that have been removed from the facility.

(4) The Authority must ensure that—

(a) any items (other than a sample) that have been removed from the facility under this section are retained only for as long as necessary to achieve the purpose for which they were removed; and

(b) any property (other than a sample) that has been removed is maintained, cared for, and secured during the period of its removal.

(5) An authorisation under **subsection (1)** must be in writing and contain—

(a) a reference to this section; and

(b) the full name of the person authorised; and

(c) a statement of the powers conferred on that person under this section; and

(d) the reasons for entering the manufacturing facility.

(6) For the purposes of **subsection (1)**, **enter the manufacturing facility** includes to go on, into, under, or over the manufacturing facility.

Compare: 1997 No 87 s 64

32 Authority may issue compliance notice

The Authority may issue a compliance notice to any person whose manufacturing facility has been audited under **section 31** requiring the person to do, or refrain from doing, within a specified time, a particular thing that affects the person's compliance with the code or any condition of the person's licence to manufacture.

33 Deemed compliance with code

A manufacturing facility in which natural health and supplementary products are manufactured under a licence granted by a recognised authority is deemed

to be compliant with the code unless the Authority has reasonable grounds to believe that the manufacturing facility does not comply with the code.

34 Authority may revoke or suspend licence or export certificate for non-compliance with code

(1) The Authority may revoke or suspend a licence to manufacture if, after conducting an audit of the manufacturing facility or considering any audit recognised under **section 31(1A)(b)**, it is satisfied that the holder of the licence has failed to maintain compliance with the code or any condition of the licence.

(2) The Authority may revoke or suspend an export certificate if, after conducting an audit of the manufacturing facility or considering any audit recognised under **section 31(1A)(b)**, it is satisfied that the holder of the certificate has failed to maintain compliance with the code.

Fees

35 Authority may prescribe fees

(1) The Authority may, by notice in the *Gazette*, prescribe fees payable in respect of any notification, application, notice, certification, or audit under this Act.

(1A) Before prescribing any fee under **subsection (1)**, the Authority must consult any person or organisation that it considers to be representative of the interests of persons likely to be substantially affected by the proposed fee.

(1B) The Authority must take all reasonable steps to ensure that the direct and indirect costs of the Authority in administering this Act that are not provided for by money that is funded by the Crown for the purpose are recovered under this section.

(1C) In determining the most appropriate method of cost recovery, the Authority must take into account, as far as is reasonably practicable, the following criteria:

(a) equity, in that funding for a particular function, power, or service, or a particular class of function, power, or service, should generally, and to the extent practicable, be sourced from the users or beneficiaries of the relevant functions, powers, or services at a level commensurate with their use or benefit from the function, power, or service:

(b) efficiency, in that costs should generally be allocated and recovered in order to ensure that maximum benefits are delivered at minimum cost:

(c) justifiability, in that costs should be collected only to meet the actual and reasonable costs (including indirect costs) of the provision or exercise of the relevant function, power, or service:

(d) transparency, in that costs should be identified and allocated as closely as practicable in relation to tangible service provision for the recovery period in which the service is provided.

(1D) This section does not require a strict apportionment of the costs to be recovered for a particular function or service based on usage.

(1E) Without limiting the way in which fees may be set under this section, a fee may be set at a level or in a way that—

(a) is determined by calculations that involve an averaging of costs or potential costs:

(b) takes into account costs or potential costs of services (that are not directly provided to the person who pays the fee but which are an indirect or potential cost) arising from the delivery of the service to a class of persons or all persons who use the service.

(1F) Any notice prescribing a fee or fees under **subsection (1)** is a regulation for the purposes of the Regulations (Disallowance) Act 1989, but is not a regulation for the purposes of the Acts and Regulations Publication Act 1989.

(2) For the purpose of ensuring that any fee prescribed under **subsection (1)** is proportionate to the cost of the activity to which it relates, the Authority must, no later than 3 years after the commencement of this Act,—

(a) conduct a review of the fees prescribed under **subsection (1)**; and

(b) publish the outcome of the review on an Internet site maintained by or on behalf of the Authority.

Sanctions and penalties

36 Deception

(1) A person commits an offence who, with intent to deceive and for the purpose of obtaining any material benefit or avoiding any material detriment,—

(a) makes any false or misleading statement or any material omission in any notification, application, record, or summary of evidence required under this Act; or

(ab) destroys, cancels, conceals, alters, obliterates, or fails to provide any document, record, or information required to be kept, published, or communicated under this Act; or

(b) falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any label of a natural health and supplementary product; or

(ba) alters a label of a natural health and supplementary product to cause it to no longer comply with any labelling requirement in regulations:

(c) misrepresents, substitutes in whole or in part, adulterates, or otherwise tampers with any natural health and supplementary product so that it no longer matches or complies with its description, label, notification, or health benefit claims; or

(d) falsifies, alters, or misapplies any notification, notice, licence, certificate, or declaration attached or relating to a natural health and supplementary

product, or tampers with a natural health and supplementary product that is subject to such notification, notice, certificate, licence, or declaration; or

(e) falsifies, removes, suppresses, or tampers with any samples, test procedures, test results, or evidence taken; or

(f) aids, abets, incites, counsels, procures, or conspires with any other person to commit an offence under this section.

(3) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $250,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $50,000.

37 Sale of natural health and supplementary products that have not been notified or do not meet standards

(1) A person commits an offence who sells or offers for sale—

(a) any natural health and supplementary product for which, to the person's knowledge,

(i) a product notification has not been completed; or

(ii) the product notification is suspended or cancelled:

(b) any natural health and supplementary product that, to the person's knowledge, does not meet—

(i) appropriate standards of evidence required for any health benefit claims for the product; or

(ii) applicable standards for labelling or manufacturing.

(2) A person commits an offence who knowingly sells or offers for sale any natural health and supplementary product that is different in any way from its description in its product notification (for example, the product label contains additional health benefit claims not included in the product notification).

(4) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

(5) In this section, **sale** includes—

(a) every method of disposition for valuable consideration, including barter; and

(b) disposal by way of gambling (as that term is defined in section 4(1) of the Gambling Act 2003); and

(c) to give or distribute, in the course of business, as a sample or otherwise, without charge.

38 Manufacturing without licence

(1) A person commits an offence who knowingly manufactures a natural health and supplementary product in contravention of **section 28(1)**.

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

39 Obstruction of authorised person

(1) A person commits an offence who threatens, assaults, or intentionally obstructs or hinders any authorised person who is acting in the performance or exercise of a function, power, or duty that the person is authorised to perform or exercise under **section 31A or 45**.

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

40 Endangerment of human health

(1) A person commits an offence who, being the manufacturer or product notifier of a natural health and supplementary product, contravenes or fails to comply with any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention or failure would or is likely to endanger the health of the public or the health of any individual.

(2) A person commits an offence who, being the manufacturer or product notifier of a natural health and supplementary product, contravenes or fails to comply with any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention or failure—

(a) may create, directly or indirectly, a risk to human health; or

(b) may, directly or indirectly, increase the likelihood of an existing risk to human health.

(4) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $500,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000.

(5) A person who commits an offence against **subsection (2)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $300,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 2 years and a fine not exceeding $75,000.

40A Specified offences relating to natural health and supplementary products

(1) A person commits an offence who knowingly manufactures or sells a notified natural health and supplementary product that contains a prohibited ingredient.

(2) A product notifier commits an offence who knowingly contravenes **section 12A(1) or (2)**.

(3) A person commits an offence who knowingly contravenes **section 12A(3)**.

(4) A person commits an offence who knowingly sells a natural health and supplementary product in New Zealand in contravention of **section 19B**.

(5) A person who commits an offence under this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

40B Offence relating to natural health and supplementary products that are dietary supplements

(1) A person commits an offence who knowingly manufactures or sells a natural health and supplementary product that is a dietary supplement in contravention of **section 24A**.

(2) A person who commits an offence under this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

40C Offence to publish certain advertisements relating to natural health and supplementary products

(1) A person must not publish or cause to be published (either on that person's own account or as the agent or employee of the person seeking to promote the sale) any advertisement that—

(a) directly or by implication states or suggests that a natural health and supplementary product for sale in New Zealand may be administered by—

(i) injection or parenteral infusion; or

(ii) application to the eye:

(b) includes any health benefit claim that directly or by implication states or suggests that a natural health and supplementary product for sale in New Zealand is able to treat or can assist in the treatment of a named condition.

(2) **Subsection (1)(b)** does not apply if the health benefit claim is an allowable claim.

(3) A person who contravenes **subsection (1)** commits an offence and is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

(4) In **subsection (1)**,—

advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design, used or appearing to be used to promote the sale of any natural health and supplementary product and includes any trade circular, any label, and any advertisement in a trade journal

publish means—

(a) insert in any newspaper or other periodical publication printed or published in New Zealand; or

(b) send to any person by post or otherwise; or

(c) deliver to any person or leave upon premises occupied by any person; or

(d) broadcast within the meaning of the Broadcasting Act 1989; or

(e) bring to the notice of the public in New Zealand in any other manner.

Disputes

41 Appeals committee

(1) This section establishes the Natural Health and Supplementary Products Appeals Committee.

(2) The appeals committee must consist of 3 members, each appointed by the Minister on any terms and conditions that the Minister thinks fit.

(3) The function of the appeals committee is to determine appeals against decisions of the Authority made by or under this Act.

(4) The appeals committee may, subject to **section 42** and any provision in the regulations relating to the conduct of its proceedings, regulate its own procedure.

42 Appeals

(1) A person who is a party to a decision of the Authority under this Act may appeal against that decision to the appeals committee.

(1A) The appeal—

(a) must be lodged with the appeals committee by way of notice of appeal in accordance with the procedure (if any) prescribed in regulations:

(b) must be lodged within 20 working days after notice of the decision is communicated to the appellant, or within any further time that the appeals committee allows on an application made before or after the period expires.

(1B) A decision of the Authority against which an appeal is lodged continues in force unless the appeals committee orders otherwise.

~~(1C) An appeal to the appeals committee must be heard as soon as is reasonably practicable after it is lodged.~~

~~(1D) An appeal under **subsection (1)** is by way of rehearing.~~

~~(1E) On hearing the appeal, the appeals committee may—~~

~~(a) confirm, reverse, or modify the decision appealed against; and~~

~~(b) make any other decision that the Authority could have made.~~

~~(1F) The appeals committee must not review—~~

~~(a) any part of a decision not appealed against; or~~

~~(b) any decision not appealed against at all.~~

~~(3) An appeal against a determination of the appeals committee on a question of law only may be made to the High Court in accordance with the rules of court.~~

~~*Other powers of Authority*~~

~~43 Statement by Authority~~

~~(1) The Authority may, for the purpose of protecting the public, publish statements relating to—~~

~~(a) natural health and supplementary products of any description; or~~

~~(b) any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisement relating to natural health and supplementary products of any description.~~

~~(2) Every statement published under this section is protected by qualified privilege.~~

~~44 Recall of natural health and supplementary products~~

~~(1) If the Authority has good reason to believe that a natural health and supplementary product is not fit for its intended purpose, or is mislabelled or incorrectly identified, the Authority may, by written notice, require the product notifier or manufacturer of the product to—~~

~~(a) arrange for the recall of the product (for example, by issuing recall notices to retailers and consumers); and~~

~~(b) arrange for the disposal of the product or, if appropriate, relabel the product.~~

~~(2) The notice may specify the time and manner by which the product notifier or manufacturer must comply with the notice.~~

~~(3) The product notifier or manufacturer, as the case may be, must advise the Authority as soon as practicable—~~

~~(a) of the manner and time in which the product notifier or manufacturer proposes to comply with the notice, unless those matters are already specified in the notice; and~~

(b) when the notice has been complied with.

45 Delegation

(1) The Authority may, as he or she thinks fit, delegate to any person any of his or her powers, functions, or duties under this Act.

(2) A delegation under **subsection (1)**—

(a) may be made subject to any conditions or restrictions that the Authority thinks appropriate:

(b) may be made generally or in any particular case:

(c) does not prevent the Authority from exercising any power, or carrying out any function or duty:

(d) does not affect the responsibility of the Authority for the actions of any person acting under delegation.

(3) A person who is delegated any powers, functions, or duties under **subsection (1)**—

(a) may, with the prior written approval of the Authority, delegate those powers, functions, or duties to any other person:

(b) may, subject to any conditions or restrictions, exercise those powers, functions, or duties in the same manner and with the same effect as if they had been conferred on that person directly by this Act and not by delegation.

(4) Every person purporting to act under any delegation under **subsection (1)** is, in the absence of proof to the contrary, presumed to be acting in accordance with the terms of the delegation.

Authority may declare product or class of product to be natural health and supplementary product in certain circumstances

45A Authority may declare product or class of product to be natural health and supplementary product in certain circumstances

(1) The Authority may, on application by any person, declare a product or class of product to be a natural health and supplementary product if—

(a) the Authority is satisfied that the product falls within the definition of natural health and supplementary product in **section 6**; and

(b) the Authority is satisfied, after considering the circumstances and any applicable regulatory regime, that a declaration is necessary to provide clarity to the applicant and any industry likely to be affected.

(2) The Authority may refuse to declare a product to be a natural health and supplementary product if it is not satisfied that the product falls within the definition of natural health and supplementary product or for any other reason.

(3) Before making any decision under this section, the Authority must refer the matter to the advisory committee and take into account any advice from the committee.

(4) An application for a declaration under this section must be made in the prescribed manner.

(5) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(6) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

Transitional provisions

46 Application of this Act to certain products sold before commencement of this Act

(1) This section applies to any product, other than an excluded product, that—

(a) was sold before the commencement of this section; and

(b) complies with **paragraphs (a) and (c)** of the definition of natural health and supplementary product in **section 6(1)**; and

(c) does not contain (as an ingredient) any substance that—

(i) is a prohibited ingredient; or

(ii) is not listed, or does not belong to a class of substance listed, in **Schedule 1**.

(2) A product to which this section applies may continue to be sold after the commencement of this section if the requirements of **subsection (3)** are met.

(3) The product notifier of a product to which this section applies must ensure that—

(a) the product notification for the product is completed no later than 1 year after the commencement of this section; and

(b) the product complies with labelling requirements set out in regulations no later than 2 years after the commencement of this section; and

(c) the manufacture of the product complies with the requirements of this Act (for example, licensing requirements if made in New Zealand) no later than 3 years after the commencement of this section.

(4) In **subsection (1)**, **excluded product** means any medicine, related product, or medical device referred to in **section 6(2)**.

Regulations

47 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) adding a substance or class of substance to **Schedule 1** if the Minister is satisfied that the substance or class of substance is safe for use in a natural health and supplementary product:

(ab) omitting a substance or class of substance from **Schedule 1**:

(ac) amending a description of any substance or class of substance listed in **Schedule 1**:

(ad) amending **Schedule 2** by—

(i) adding a pharmacopoeia to, or removing a pharmacopeia from, the schedule:

(ii) amending a description of any pharmacopoeia listed on the schedule:

(ae) prescribing, in relation to a natural health and supplementary product referred to in **section 13A(c) or (d)**, requirements or restrictions relating to health benefit claims that may be made on the label of the product or in any advertisement for the product:

(b) prescribing the manner in which a product notification for a natural health and supplementary product must be completed:

(c) prescribing standards for scientific evidence or traditional evidence:

(d) prescribing the information that must be provided by the product notifier or applicant for the purposes of any application or matter under this Act:

(e) prescribing the criteria by which new ingredients will be assessed:

(f) prescribing requirements for the labelling of natural health and supplementary products:

(h) prescribing the manner in which applications for a licence to manufacture natural health and supplementary products must be made:

(i) prescribing requirements relating to the manufacture of natural health and supplementary products, including requirements relating to the content of the code:

(j) prescribing the procedure and conduct of appeals to the appeals committee:

(k) prescribing requirements relating to access to the database, and any other requirements relating to the use of the database:

(l) providing for any other matters contemplated by this Act, necessary for its administration, or for giving effect to any provision of this Act.

~~(2) Before making any recommendation under any of **paragraphs (b) to (l)** of **subsection (1)**, the Minister must consult any person or organisation that the Minister considers to be representative of the interests of persons likely to be substantially affected by the regulations.~~

~~(2A) The Minister must carry out the consultation process set out in **subsection (2B)** before—~~

~~(a) recommending the addition of a substance or class of substance to, or the omission of a substance or class of substance from, **Schedule 1**:~~

~~(b) recommending the addition of a pharmacopeia to, or the removal of a pharmacopeia from, **Schedule 2**:~~

~~(c) recommending any regulations under **paragraph (ae)**:~~

~~(2B) The consultation process requires that the Minister—~~

~~(a) publish a notice in the *Gazette*—~~

~~(i) setting out the proposed recommendation and the reasons for it; and~~

~~(ii) inviting submissions on the recommendation to be made by a date no sooner than 21 days after the date of the notice; and~~

~~(iii) specifying a date by which submissions must be made (being a date no sooner than 21 days after the date of the *Gazette* notice); and~~

~~(b) consider the submissions (if any) on the proposed recommendation.~~

~~(2C) When recommending any regulations under **subsection (1)(ae)** the Minister must have particular regard to the principle that the regulation of natural health and supplementary products should be proportionate to the risks associated with their use.~~

~~*Review of Act*~~

~~48 Ministry of Health must review Act~~

~~(1) The Ministry of Health must, no later than 5 years after the commencement of this Act,—~~

~~(a) conduct a review of the policy and operation of this Act; and~~

~~(b) prepare for the Minister a report of the review.~~

~~(2) As soon as practicable after receiving the report, the Minister must present a copy to the House of Representatives.~~

~~*Amendments to Medicines Act 1981*~~

~~49 Amendments to Medicines Act 1981~~

~~**Sections 50 to 54** amend the Medicines Act 1981.~~

50 Interpretation

(1) The definition of **herbal remedy** in section 2(1) is repealed.

(2) Section 2(1) is amended by inserting the following definition in its appropriate alphabetical order:

natural health and supplementary producthas the meaning given to it by **section 6** of the Natural Health and Supplementary Products Act **2011**

51 Meaning of medicine, new medicine, prescription medicine, and restricted medicine

(1) Section 3(1) is amended by inserting "or natural health and supplementary product" after "medical device".

(2) Section 3(1)(b)(iii) is repealed.

52 Section 28 repealed

Section 28 is repealed.

53 Exemptions for agents and employees

Section 31(1)(c) is repealed.

54 Duty of importer and manufacturer to have and produce specifications of medicines

Section 42(1) is amended by omitting "other than a herbal remedy".

Amendment to Misuse of Drugs Amendment Act 2005

55 Amendment to Misuse of Drugs Amendment Act 2005

Section 56 amends the Misuse of Drugs Amendment Act 2005.

56 Interpretation

Paragraph (b) of the definition of **substance** in section 31 is amended by repealing subparagraphs (iii) and (vi) and substituting the following subparagraph as subparagraph (vi):

(vi) natural health and supplementary product (as defined in **section 6** of the Natural Health and Supplementary Products Act **2011**), medicine (as defined in section 3 of the Medicines Act 1981), or related product (as defined in section 94 of Medicines Act 1981):

Amendment to Trans-Tasman Mutual Recognition Act 1997

56A Amendment to Trans-Tasman Mutual Recognition Act 1997

Section 56B amends the Trans-Tasman Mutual Recognition Act 1997.

~~56B~~ ~~Schedule 2 amended~~

~~In Schedule 2, omit "Dietary Supplements Regulations 1985" and substitute "Natural Health and Supplementary Products Act **2011**".~~

~~Revocation~~

~~57~~ ~~Dietary Supplements Regulations 1985 revoked~~

~~The Dietary Supplements Regulations 1985 (SR 1985/208) are revoked.~~

Part 2
Regulation of natural health products

Subpart 1—Manufacture of natural health products

8 Licence to manufacture natural health products

(1) A person must not manufacture a natural health product without a licence to manufacture granted under **section 9**.

(2) **Subsection (1)** does not apply to a person who makes a natural health product in the circumstances described in **section 18**.

(3) A person who knowingly manufactures a natural health product in contravention of **subsection (1)** commits an offence and is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

9 Application for licence to manufacture

(1) An application for a licence to manufacture natural health products must be made to the Authority in the manner specified by the Authority (*see* **section 51**).

(2) The Authority may grant a person a licence to manufacture natural health products if—

(a) the Authority is satisfied that the manufacturing facilities meet the requirements of the code; and

(b) the Authority is satisfied that the person is a fit and proper person to hold the licence.

(3) In determining whether a person is a fit and proper person to hold a licence to manufacture, the Authority must take into account the following:

(a) any conviction of the person or any director or manager of the person for any offence involving or relating to the manufacture of any product for human consumption:

(b) whether there has in the past been a serious or repeated failure by the person to comply with any requirement under this Act:

(c) whether there are other grounds for considering that the person is likely in the future to fail to comply with those requirements:

(d) any other matters that the Authority considers relevant.

(4) A licence to manufacture remains in force for 5 years after the date that it is granted, unless—

(a) the Authority specifies a shorter period for the licence; or

(b) it is earlier revoked.

10 Conditions of licence

(1) It is a condition of a licence to manufacture that the licence holder must at all times comply with the code.

(2) The Authority may, when granting a licence to manufacture, impose other conditions on the licence as the Authority thinks fit.

11 Audits of manufacturing facilities

(1) This section applies to any manufacturing facility—

(a) in which a natural health product is being manufactured under a licence to manufacture; or

(b) in respect of which an application for a licence to manufacture is made.

(2) For the purpose of assessing whether the manufacturing facility complies with the code and, if applicable, any conditions of the licence to manufacture, the Authority may do 1 or both of the following:

(a) conduct audits of the manufacturing facility at any time:

(b) to the extent that the Authority considers applicable, recognise any audit of the manufacturing facility conducted by another person under another enactment or for another purpose.

(3) The Authority may conduct an audit of the manufacturing facility in any manner that the Authority considers appropriate and consistent with the regulatory principles.

12 Authorised person may enter manufacturing facility and take samples in specified circumstances

(1) The Authority may authorise a person to enter a manufacturing facility during the normal business hours of that facility and exercise any power set out in this section for the purpose of—

(a) assessing an application for a licence to manufacture; or

(b) assessing whether the manufacturing facility is complying with the code or any conditions of the licence to manufacture.

(2) For the purpose of **subsection (1)(a) or (b)**, an authorised person may—

(a) open containers and packages and inspect the contents:

(b) request, gather, or secure evidence, take samples of natural health products or their ingredients, water, air, or any substance, and test or analyse or arrange for the testing and analysis of such samples:

(c) inspect, inquire about, or copy any documents or other records, including records in an electronic form, relating to the obligations imposed under this Act or regulations:

(d) remove any documents or other records, including records in an electronic form, from the place for the purposes of copying such documents or records.

(3) An authorised person must provide to the person in charge of the facility—

(a) evidence of his or her authorisation when the authorised person first enters the facility, and at any later time at the request of the person in charge; and

(b) a list of any items that have been removed from the facility.

(4) The Authority must ensure that—

(a) any items (other than a sample) that have been removed from the facility under this section are retained only for as long as is necessary to achieve the purpose for which they were removed; and

(b) any property (other than a sample) that has been removed is maintained, cared for, and secured during the period of its removal.

(5) An authorisation under **subsection (1)** must be in writing and contain—

(a) a reference to this section; and

(b) the full name of the person authorised; and

(c) a statement of the powers conferred on that person under this section; and

(d) the reasons for entering the manufacturing facility.

(6) For the purposes of **subsection (1)**, **enter a manufacturing facility** includes to go on, into, under, or over the manufacturing facility.

Compare: 1997 No 87 s 64

13 Authority may issue compliance notice

The Authority may issue a compliance notice to any person whose manufacturing facility has been audited under **section 11** requiring the person to do, or refrain from doing, within a specified time, a particular thing that affects the person's compliance with the code or any condition of the person's licence to manufacture.

14 Deemed compliance with code

A manufacturing facility in which natural health products are manufactured under a licence granted by a recognised authority is deemed to be compliant with the code unless the Authority has reasonable grounds to believe that the manufacturing facility does not comply with the code.

15 Authority may revoke or suspend licence for non-compliance with code

(1) The Authority may revoke or suspend a licence to manufacture if, after conducting an audit of the manufacturing facility or considering any audit recognised under **section 11(2)(b)**, it is satisfied that the holder of the licence has failed to maintain compliance with the code or any condition of the licence.

(2) The maximum period of any suspension under this section is 90 days.

Subpart 2—Natural health products for sale or export

Requirements for natural health products for sale or export

16 Requirements for natural health products for sale or export

(1) A natural health product must not be sold or offered for sale in New Zealand or exported unless—

(a) it is a permitted natural health product (contains only permitted substances); and

(b) it has a valid product notification or is a product referred to in **section 18**.

(2) *See* **section 38** (which sets out offences relating to the sale or export of natural health products).

Regulatory principles for regulation of permitted natural health products

17 Regulatory principles

(1) The regulation of permitted natural health products is based on the following principles:

(a) that permitted natural health products should be fit for human use:

(b) that the regulation of permitted natural health products should be proportionate to the risks associated with their use:

(c) that permitted natural health products should be accompanied by information that—

(i) is accurate; and

(ii) tells consumers about any risk, side effects, or benefits of using the product:

(d) that health benefit claims made for permitted natural health products should be supported by scientific or traditional evidence.

(2) **Subsection (1)** does not confer any legal right that is enforceable in a court of law.

Permitted natural health products that do not require product notification

18 Permitted natural health products that do not require product notification

The following natural health products do not require product notification:

(a) any permitted natural health product that—

(i) is made by a person claiming to be available for consultation by other persons for therapeutic purposes (within the meaning of section 4 of the Medicines Act 1981); and

(ii) is made by the person to be administered to an individual after the person is requested by or on behalf of the individual to use his or her own judgment as to the treatment required; or

(b) any permitted natural health product or any category of that product that is exempted under **section 19**; or

(c) any permitted natural health product in which the active ingredient is in a concentration of not more than 10 parts per million.

19 Authority may exempt permitted natural health products from product notification

(1) The Authority may, by notice in the *Gazette*, exempt a permitted natural health product or category of that product from the requirements of **section 20**.

(2) The Authority must not exempt a permitted natural health product under this section unless the Authority is satisfied that—

(a) compliance with **section 20** would be impractical or unreasonable in the circumstances; and

(b) exempting the product is consistent with the principle in **section 17(1)(b)**.

(3) The Authority must not exempt a category of permitted natural health product under this section unless—

(a) it has considered advice from the advisory committee on the exemption; and

(b) the Authority is satisfied that there is no risk to public health in exempting that category.

(4) A notice under **subsection (1)**—

(a) is a disallowable instrument, but not a legislative instrument, for the purposes of the Legislation Act 2012 and must be presented to the House of Representatives under section 41 of that Act:

(b) must include the reasons of the Authority.

Product notification

20 Product notification

(1) A product notification is required for any permitted natural health product (other than a product to which **section 18** applies) that is for sale or to be offered for sale in New Zealand or exported.

(2) The product notification must be completed by the product notifier in accordance with this section and in the manner specified by the Authority (*see* **section 51**).

(3) For the purposes of this section, **evidence** means either of the following types of evidence, each of which must be consistent with any prescribed standard:

(a) scientific evidence:

(b) traditional evidence.

(4) Before completing the product notification, the product notifier must make available on an Internet site, in respect of each health benefit claim made for the product, a summary of the evidence that the product notifier relies on to support the claim.

(5) The product notification is complete when—

(a) the product notifier has provided—

(i) information, in the manner specified by the Authority (*see* **section 51**), relating to the name of the product, the product details, the product notifier, the manufacturer, and any health benefit claims made for the product; and

(ii) any information required by regulations; and

(b) the product notifier has provided a declaration that—

(i) the information provided is complete and accurate; and

(ii) the product notifier is able to provide, at the Authority's request, evidence to support the health benefit claims made for the product; and

(c) the product notifier has paid the applicable fee.

(6) The product notifier must,—

(a) if requested by the Authority, provide the Authority with the evidence referred to in **subsection (5)(b)(ii)**; and

(b) if the manufacturer of the product is not in New Zealand and is not listed on the database, satisfy the Authority that the manufacturer complies with the code after providing any documentation or information required by the Authority.

Health benefit claims that may be made for permitted natural health products

21 Restrictions on health benefit claims relating to named conditions

(1) A product notifier must not include in the product notification of a permitted natural health product any health benefit claim that relates to a named condition unless it is an allowable claim.

(2) A product notifier must not include in or attach to the summary of evidence required under **section 20** any health benefit claim that relates to a named condition unless it is an allowable claim.

(3) No person may make, on the label of a permitted natural health product or in any advertisement for the product, any health benefit claim that relates to a named condition unless it is an allowable claim.

(4) No person may make, on the label or in any advertisement for a permitted natural health product referred to in **section 18(b) or (c)**, any health benefit claim that relates to a named condition except as provided in regulations.

(5) A product notifier who knowingly contravenes **subsection (1) or (2)** commits an offence and is liable to a fine specified in **subsection (7).**

(6) A person who knowingly contravenes **subsection (3) or (4)** commits an offence and is liable to a fine specified in **subsection (7)**.

(7) The fine for the commission of an offence under this section is—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

(8) In **subsection (3)**, **advertisement** has the meaning given to it by **section 42(4)**.

(9) **Subsection (3)** does not apply to any permitted natural health product referred to in **section 18(b) or (c)**.

22 Authority may determine allowable claims

(1) The Authority may, on its own initiative or on application by any person,—

(a) determine, in accordance with **subsections (2) and (3)**, that a health benefit claim for a permitted natural health product or class of that product may relate to a named condition or class of named condition; or

(b) determine, in accordance with **subsection (4)**, that 1 or more health benefit claims may relate to a named condition or class of named condition.

(2) In determining whether a health benefit claim for a permitted natural health product or class of that product may relate to a named condition, the Authority must—

(a) be guided by the regulatory principles; and

(b) consider, subject to **subsection (3)**,—

(i) the nature and quality of the evidence provided in support of the claim; or

(ii) if the Authority is determining the matter on its own initiative, the nature and quality of the evidence before the Authority; and

(c) be satisfied that the level of risk associated with use of the product or class of product is low.

(3) If any traditional evidence provided to or before the Authority in support of a health benefit claim is a reference to information contained in an approved pharmacopeia,—

(a) the Authority must accept the reference as evidence if satisfied that the information to which it refers is relevant to the health benefit claim; and

(b) **subsection (2)(b)** does not apply to the evidence.

(4) In determining whether 1 or more health benefit claims may relate to a named condition or class of named condition, the Authority must—

(a) be guided by the regulatory principles; and

(b) be satisfied that the level of risk associated with allowing the health benefit claim or claims to be made is low.

(5) The Authority must publish on an Internet site maintained by or on behalf of the Ministry—

(a) a list of allowable claims determined under **subsection (1)(a)** and the permitted natural health product or class of that product for which each claim is made; and

(b) a list of allowable claims determined under **subsection (1)(b)** and the named condition or class of named condition to which the claim or claims may relate.

(6) An application under this section must be made in the manner specified by the Authority (*see* **section 51**).

Audit of product notifications

23 Authority may audit product notifications

(1) The Authority may at any time audit any product notification or class of product notification.

(2) The audit may be conducted in any manner that the Authority considers appropriate and consistent with the regulatory principles.

Suspension and cancellation of product notification

24 Grounds for suspension of product notification

(1) The Authority may suspend a product notification of a permitted natural health product if—

(a) the Authority has reasonable grounds to believe that the product has caused, is causing, or is likely to cause any harm to any person; or

(b) the Authority has reasonable grounds to believe that the product notifier has provided false, misleading, or incomplete information in the product notification; or

(c) the Authority has reasonable grounds for concern because of new information about the safety, quality, health benefit claims, or manufacturing standards of the product.

(2) If the Authority decides to suspend a product notification, it must notify the product notifier in writing of—

(a) the date that the suspension takes effect, being the date of the notice or a date specified in the notice; and

(b) the period of suspension (being a period of up to 90 days); and

(c) the reason for the suspension.

25 Effect of suspension of product notification

If a product notification for a permitted natural health product is suspended, the product notifier—

(a) must take all reasonable steps to ensure that the product is not sold by any person on and from the date that the suspension takes effect; and

(b) must not complete another product notification for the product during the period of suspension.

26 Cancellation or reinstatement of product notification

(1) Before the period of suspension ends, the Authority must—

(a) decide whether to cancel or reinstate the product notification for the permitted natural health product; and

(b) give written notice of the decision to the product notifier.

(2) A cancellation or reinstatement takes effect immediately after the end of the period of suspension.

(3) If a product notification is cancelled under this section, the product notifier—

(a) must ensure that the product is not sold by any person on and from the date the cancellation takes effect; and

(b) must not complete another product notification for the product unless the Authority is satisfied, on application by the product notifier, that the grounds for cancellation no longer apply or any concerns of the Authority leading to the cancellation have been addressed appropriately.

27 Product notifier must notify Authority of serious adverse reaction to product

(1) The product notifier of a permitted natural health product must notify the Authority as soon as the product notifier becomes aware of any serious adverse reaction to the product.

(2) In this section, **serious adverse reaction** means any reaction that—

(a) results in hospitalisation or prolongs any existing hospitalisation:

(b) is life-threatening or fatal:

(c) results in disability or incapacity or requires intervention to prevent permanent disability or incapacity:

(d) results in any congenital abnormality:

(e) is a serious allergic reaction.

28 When new product notification needed

(1) If, in relation to a notified natural health product, there is any change of a kind described in **subsection (2)**, the product notifier must, as soon as practicable, complete a new product notification for the product that accurately reflects the change.

(2) The changes referred to in **subsection (1)** are as follows:

(a) there is a change to any of the health benefit claims made for the product:

(b) there is a change in any of the product's ingredients (including the amount of any ingredient) other than—

(i) an additive; or

(ii) a formulation aid.

(3) A product notifier is not required to complete a further product notification for a notified natural health product if there is any variation in the weight, size, or packaging of the product.

(4) A product notifier may change the product notifier's contact details on a product notification without the need for a new product notification.

29 Product notifier may cancel product notification

A product notifier of a permitted natural health product may cancel the product notification for the product if the product is no longer sold.

30 Authority may cancel product notification if no longer necessary

(1) The Authority may cancel the product notification for a permitted natural health product if it is satisfied that the product notification is no longer necessary in the circumstances.

(2) Before cancelling a product notification under this section, the Authority must—

(a) give notice to the product notifier that it is considering cancelling the product notification and give reasons; and

(b) give the product notifier a reasonable opportunity to respond to the notice; and

(c) consider any submission made by the product notifier in response to the notice.

(3) The Authority does not have to comply with **subsection (2)** if, after reasonable inquiry, the product notifier cannot be found.

Subpart 3—General rules relating to permitted natural health products

Permitted substances

31 Permitted substances

(1) The Authority may, for the purpose of this Act, declare any natural substance to be a permitted substance.

(2) The Authority may impose restrictions on the use of a permitted substance.

(3) In considering whether a natural substance should be declared a permitted substance, the Authority—

(a) may conduct a safety assessment of the substance; and

(b) must have regard and give weight to, as it considers appropriate, the following:

(i) whether a recognised authority permits the use of the substance in a similar product and, if so, whether it imposes any restrictions on the use of the substance:

(ii) whether the substance is recognised in traditional medicine or pharmacopoeias:

(iii) any other matter that the Authority considers relevant in the circumstances.

(4) Every natural substance declared to be a permitted substance must be listed on the database along with any restrictions on the use of the substance.

(5) A declaration made under this section must be published on an Internet site maintained by or on behalf of the Authority.

(6) The Authority must, as soon as practicable after making any declaration under this section, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

(7) In this section, **similar products** means products that (however described) are the same type of products as permitted natural health products.

New substances

32 If new substance to be used in natural health product

(1) This section applies if a product notifier intends to use a new substance in the manufacture of a natural health product for sale in New Zealand or for export.

(2) The product notifier must apply to the Authority no later than 90 working days before the product notifier intends to complete a product notification for the product (the **90-day period**).

(3) After receiving the application, the Authority—

(a) must, as soon as practicable, notify the applicant as to whether it will undertake a safety assessment of the new substance; and

(b) may request further evidence of the safety of the new substance from the applicant.

(4) If, within the 90-day period, the Authority does not raise any concern or commence a safety assessment,—

(a) the new substance may be used in the product after the 90-day period; and

(b) the applicant may, after receiving written confirmation from the Authority that the substance may be used, complete a product notification for the product.

(5) However, if, within the 90-day period, the Authority raises a concern and commences a safety assessment, a product notification must not be completed for the product until or unless the Authority determines that the new substance may be used in the product.

(6) The Authority must, when determining whether the new substance may be used in the product, apply the criteria set out in **section 31(3)(b)**.

(7) If the Authority determines that the new substance may be used in the product, the Authority must, as soon as practicable,—

(a) declare the substance to be a permitted substance in accordance with **section 31** as if that determination had been made under **section 31**; and

(b) comply with **section 31(4) to (6)**.

(8) An application under this section must be made in the manner specified by the Authority (*see* **section 51**).

Labelling

33 Labelling

A permitted natural health product that is sold in New Zealand must comply with the labelling requirements prescribed in regulations.

Exports

34 Export certificate

(1) A product notifier may, subject to **section 35**, apply to the Authority for an export certificate for a permitted natural health product.

(2) The application must be accompanied by the fee prescribed under **section 50** (if any) and the product notifier must comply with any requests for information made by the Authority for the purposes of the application.

(3) The Authority may grant an export certificate for a permitted natural health product for which there is a valid product notification.

(4) The Authority may determine the form and content of the export certificate.

(5) An export certificate is not a guarantee that the permitted natural health product—

(a) necessarily meets the commercial requirements of the customer; or

(b) necessarily meets the specific requirements of overseas markets.

35 Permitted natural health products that are animal products

Despite **section 34**, if a permitted natural health product is also an animal product within the meaning of the Animal Products Act 1999, any application for an export certificate or a similar statement for that product must be made in accordance with that Act instead of this Act.

36 Authority may revoke or suspend export certificate for non-compliance with code

(1) The Authority may revoke or suspend an export certificate if, after conducting an audit of the manufacturing facility or considering any audit recognised under **section 11(2)(b)**, it is satisfied that the holder of the certificate has failed to maintain compliance with the code.

(2) The maximum period of any suspension under this section is 90 days.

Transitional provisions

37 Application of this Act to certain products sold before commencement of this Act

(1) This section applies to any product that—

(a) was sold before the commencement of this section; and

(b) conforms to the definition of permitted natural health product in **section 5**.

(2) The product may continue to be sold after the commencement of this section if the requirements of **subsection (3)** are met.

(3) The product notifier of the product must ensure that—

(a) the product notification for the product is completed no later than 1 year after the commencement of this section; and

(b) the product complies, no later than 2 years after the commencement of this section, with the labelling requirements prescribed in regulations; and

(c) the manufacture of the product complies with the requirements of this Act (for example, licensing requirements) no later than 3 years after the commencement of this section.

Subpart 4—Offences

38 Sale or export of natural health products that do not comply with section 16(1) or standards, or do not conform to product notification

(1) A person commits an offence who sells or offers for sale in New Zealand or exports—

(a) any natural health product that to the person's knowledge does not comply with the requirements of **section 16(1)**; or

(b) any notified natural health product that, to the person's knowledge, does not meet—

(i) the prescribed standards of evidence that apply to any health benefit claims for the product; or

(ii) applicable standards for labelling or manufacturing.

(2) A person commits an offence who knowingly sells or offers for sale in New Zealand or exports any notified natural health product that is different in any way from its description in its product notification (for example, the product label contains additional health benefit claims not included in the product notification).

(3) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

(4) In this section, **sale** includes—

(a) every method of disposition for valuable consideration, including barter; and

(b) disposal by way of gambling (as that term is defined in section 4(1) of the Gambling Act 2003); and

(c) to give or distribute, in the course of business, as a sample or otherwise, without charge.

39 Prohibited methods of administration

(1) A natural health product must not be sold or offered for sale in New Zealand or exported that is or appears to be manufactured for administration by—

(a) injection or parenteral infusion:

(b) application to the eye.

(2) A person who knowingly sells or offers for sale in New Zealand or exports a natural health product in contravention of **subsection (1)** commits an offence and is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

40 Obstruction of authorised person

(1) A person commits an offence who threatens, assaults, or intentionally obstructs or hinders any authorised person who is acting in the performance or exercise of a function, power, or duty that the person is authorised to perform or exercise under **section 12 or 55**.

(2) A person who commits an offence against this section is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

41 Endangerment of human health

(1) A person commits an offence who, being the manufacturer or product notifier of a natural health product, contravenes any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention would or is likely to endanger the health of the public or the health of any individual.

(2) A person commits an offence who, being the manufacturer or product notifier of a natural health product, contravenes any provision of this Act or of regulations made or any notice given under this Act, knowing that the contravention—

(a) may create, directly or indirectly, a risk to human health; or

(b) may, directly or indirectly, increase the likelihood of an existing risk to human health.

(3) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $500,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000.

(4) A person who commits an offence against **subsection (2)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $300,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 2 years and a fine not exceeding $75,000.

42 Offence to publish certain advertisements relating to natural health products

(1) A person must not publish or cause to be published (either on that person's own account or as the agent or employee of the person seeking to promote the sale) any advertisement that—

(a) directly or by implication states or suggests that a natural health product for sale in New Zealand may be administered by—

(i) injection or parenteral infusion; or

(ii) application to the eye:

(b) directly or by implication claims, indicates, or suggests that a natural health product for sale in New Zealand—

(i) is a panacea or infallible; or

(ii) is or has been used or recommended by a practitioner, nurse, or pharmacist, or by any other person qualified to provide therapeutic treatment in the course of a profession or occupation and registered under any enactment as a person so qualified, or by a person who is engaged in study or research in relation to any of those professions or occupations or the work performed by persons employed in those professions or occupations:

(c) includes any health benefit claim that directly or by implication states or suggests that a natural health product for sale in New Zealand is able to treat or can assist in the treatment of a named condition.

(2) **Subsection (1)(c)** does not apply if—

(a) the health benefit claim is an allowable claim; or

(b) the health benefit claim is authorised by regulations for products referred to in **section 18(b) or (c)**; or

(c) the advertisement is distributed solely to persons claiming to be available for consultation by other persons for therapeutic purposes (within the meaning of section 4 of the Medicines Act 1981) and to persons privately consulting them.

(3) A person who contravenes **subsection (1)** commits an offence and is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

(4) In **subsection (1)**,—

advertisement means any words, whether written, printed, or spoken, and any pictorial representation or design used or appearing to be used to promote the sale of any natural health product and includes any trade circular, any label, and any advertisement in a trade journal

publish means—

(a) insert in any newspaper or other periodical publication printed or published in New Zealand; or

(b) send to any person by post or otherwise; or

(c) deliver to any person or leave upon premises occupied by any person; or

(d) bring to the notice of the public in New Zealand by broadcasting within the meaning of the Broadcasting Act 1989; or

(e) bring to the notice of the public in New Zealand in any other manner.

43 Deception and false representation

(1) A person commits an offence who, with intent to deceive and for the purpose of obtaining any material benefit or avoiding any material detriment,—

(a) represents that a product is a natural health product, permitted natural health product, or notified natural health product when it is not; or

(b) makes any false or misleading statement or any material omission in any notification, application, record, or summary of evidence required under this Act; or

(c) falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any label of a permitted natural health product; or

(d) misrepresents, substitutes in whole or in part, adulterates, or otherwise tampers with any notified natural health product so that it no longer matches or complies with its description, label, product notification, or health benefit claims; or

(e) falsifies, alters, or misapplies any notification, notice, licence, certificate, or declaration attached or relating to a natural health product, or tampers with a natural health product that is subject to such notification, notice, licence, certificate or declaration; or

(f) destroys, cancels, conceals, alters, obliterates, or fails to provide any document, record, or information required to be kept, published, or communicated under this Act; or

(g) alters a label of a permitted natural health product to cause it to no longer comply with any labelling requirement in regulations; or

(h) falsifies, removes, suppresses, or tampers with any samples, test procedures, test results, or evidence taken under this Act; or

(i) aids, abets, incites, counsels, procures, or conspires with any other person to commit an offence under this section.

(2) A person who commits an offence against **subsection (1)** is liable,—

(a) in the case of a body corporate, to a fine not exceeding $250,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $50,000.

Subpart 5—Appeals

44 Appeals committee

(1) This section establishes the Natural Health Products Appeals Committee.

(2) The appeals committee must consist of 3 members, each appointed by the Minister on any terms and conditions that the Minister thinks fit.

(3) The function of the appeals committee is to determine appeals against decisions of the Authority made under this Act.

(4) The appeals committee may, subject to **section 45** and any provision in the regulations relating to the conduct of its proceedings, regulate its own procedure.

45 Appeals

(1) A person who is a party to a decision of the Authority under this Act may appeal against that decision to the appeals committee.

(2) The appeal—

(a) must be lodged with the appeals committee by way of notice of appeal in accordance with the procedure (if any) prescribed in regulations:

(b) must be lodged within 20 working days after notice of the decision is communicated to the appellant, or within any further time that the appeals committee allows on an application made before or after the period expires.

(3) A decision of the Authority against which an appeal is lodged continues in force unless the appeals committee orders otherwise.

(4) An appeal to the appeals committee must be heard as soon as is reasonably practicable after it is lodged.

(5) An appeal is by way of rehearing.

(6) On hearing the appeal, the appeals committee may—

(a) confirm, reverse, or modify the decision appealed against; and

(b) make any other decision that the Authority could have made.

(7) The appeals committee must not review—

(a) any part of a decision not appealed against; or

(b) any decision not appealed against at all.

(8) An appeal against a determination of the appeals committee on a question of law only may be made to the High Court in accordance with the rules of court.

Subpart 6—Natural Health Products Regulatory Authority

46 Natural Health Products Regulatory Authority

(1) This section establishes the Natural Health Products Regulatory Authority.

(2) The Authority is the Director-General of Health.

(3) The office of the Authority must be administered by the Ministry of Health.

47 Authority may declare recognised authorities

(1) The Authority may, by notice in the *Gazette*, declare a person or body to be a recognised authority—

(a) for a specified purpose under this Act or a provision of this Act; and

(b) for a specified period or not.

(2) Before declaring a person or body to be a recognised authority, the Authority must be satisfied that the person or body (whether in New Zealand or any other country)—

(a) makes decisions in respect of similar products that require the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act; or

(b) is engaged in an area of work that requires the person or body to assess conformity against, or compliance with, standards that are equivalent to or more robust than those under this Act.

(3) In this section, **similar products** means products that (however described) the Authority considers are the same type of products as natural health products or permitted natural health products.

48 Natural Health Products Advisory Committee

(1) The Authority must establish an advisory committee to provide expert advice to the Authority on matters referred to it by the Authority.

(2) The advisory committee must consist of not more than 8 members.

(3) The Authority may, in accordance with this section,—

(a) appoint a person to be a member or chairperson of the advisory committee; and

(b) terminate the advisory committee or the appointment of a member or chairperson of the committee.

(4) The Authority must consult the Minister before making any appointment to the advisory committee.

(5) Each member of the advisory committee may be appointed on any terms and conditions that the Authority thinks fit.

(6) In appointing members of the advisory committee, the Authority must—

(a) take into account the need for members to have among them a breadth of experience and expertise in, and depth of knowledge in, areas of knowledge that relate to or are relevant to natural health products:

(b) ensure that there is at least 1 member with experience, expertise, and depth of knowledge in manufacturing:

(c) ensure that there is at least 1 member with experience, expertise, and depth of knowledge in science.

(7) The Authority may give terms of reference—

(a) on the advice that the advisory committee is to provide to the Authority; and

(b) on the use of external experts to assist the advisory committee.

(8) The advisory committee may, subject to any provision in this Act, the regulations, and the terms of reference, determine its own procedures.

Code of practice

49 Code of practice for manufacture of natural health products

(1) The Authority must establish a code of practice for the manufacture of natural health products.

(2) The code must come into force no later than 1 year after the commencement of this section.

(3) In developing the code and any amendments to the code, the Authority must—

(a) be guided by the regulatory principles:

(b) comply with any prescribed requirements relating to the content of the code:

(c) consult persons or organisations that the Authority considers likely to be affected by the code.

(4) The Authority must ensure that the code, and every amendment to it,—

(a) specifies the date on which it takes effect:

(b) is published on an Internet site.

Fees

50 Authority may prescribe fees

(1) The Authority may, by notice in the *Gazette*, prescribe fees payable in respect of any notification, application, notice, certification, or audit under this Act.

(2) Before prescribing a fee under this section, the Authority must consult any person or organisation that it considers to be representative of the interests of persons likely to be substantially affected by the proposed fee.

(3) The Authority must take all reasonable steps to ensure that the direct and indirect costs of the Authority in administering this Act that are not provided for by money that is funded by the Crown for the purpose are recovered under this section.

(4) In determining the most appropriate method of cost recovery, the Authority must take into account, as far as is reasonably practicable, the following criteria:

(a) equity, in that funding for a particular function, power, or service, or a particular class of function, power, or service, should generally, and to the extent practicable, be sourced from the users or beneficiaries of the relevant functions, powers, or services at a level commensurate with their use of or benefit from the function, power, or service:

(b) efficiency, in that costs should generally be allocated and recovered in order to ensure that maximum benefits are delivered at minimum cost:

(c) justifiability, in that costs should be collected only to meet the actual and reasonable costs (including indirect costs) of the provision or exercise of the relevant function, power, or service:

(d) transparency, in that costs should be identified and allocated as closely as practicable in relation to tangible service provision for the recovery period in which the service is provided.

(5) This section does not require a strict apportionment of the costs to be recovered for a particular function or service based on usage.

(6) Without limiting the way in which fees may be set under this section, a fee may be set at a level or in a way that—

(a) is determined by calculations that involve an averaging of costs or potential costs:

(b) takes into account costs or potential costs of services (that are not directly provided to the person who pays the fee but that are an indirect or potential cost) arising from the delivery of the service to a class of persons or all persons who use the service.

(7) A notice prescribing a fee or fees under this section is a disallowable instrument, but not a legislative instrument, for the purposes of the Legislation Act

2012 and must be presented to the House of Representatives under section 41 of that Act.

(8) For the purpose of ensuring that any fee prescribed under this section is proportionate to the cost of the activity to which it relates, the Authority must, no later than 3 years after the commencement of this Act,—

(a) conduct a review of the fees prescribed; and

(b) publish the outcome of the review on an Internet site maintained by or on behalf of the Authority.

Manner in which product notification and certain applications to be made

51 Manner in which product notification and certain applications must be made

(1) The Authority must, by written notice, specify—

(a) the manner in which a product notification must be completed, including the manner in which information referred to in **section 20(5)(a)(i)** must be provided:

(b) the manner in which an application under **section 9, 22, 32, or 56** must be made.

(2) A notice under **subsection (1)** must—

(a) state the date on which it takes effect; and

(b) be published on an Internet site maintained by the Authority.

Natural health products database

52 Natural health products database

The Authority must establish and maintain a natural health products database.

Other powers of Authority

53 Statement by Authority

(1) The Authority may, for the purpose of protecting the public, publish statements relating to—

(a) natural health products of any description; or

(b) any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisement relating to natural health products of any description.

(2) Every statement published under this section is protected by qualified privilege.

54 Recall of natural health products

(1) If the Authority has good reason to believe that a natural health product is not fit for its intended purpose, or is mislabelled or incorrectly identified, the Authority may, by written notice, require the product notifier or manufacturer of the product to—

(a) arrange for the recall of the product (for example, by issuing recall notices to retailers and consumers); and

(b) arrange for the disposal of the product or, if appropriate, relabel the product.

(2) The notice may specify the time and manner by which the product notifier or manufacturer must comply with the notice.

(3) The product notifier or manufacturer, as the case may be, must advise the Authority as soon as practicable—

(a) of the manner and time in which the product notifier or manufacturer proposes to comply with the notice, unless those matters are already specified in the notice; and

(b) when the notice has been complied with.

(4) A person who fails to comply with the notice commits an offence and is liable to a fine not exceeding—

(a) $250,000, in the case of a body corporate:

(b) $50,000, in the case of an individual.

55 Delegation

(1) The Authority may, as he or she thinks fit, delegate to any person any of his or her powers, functions, or duties under this Act.

(2) A delegation under **subsection (1)**—

(a) may be made subject to any conditions or restrictions that the Authority thinks appropriate:

(b) may be made generally or in any particular case:

(c) does not prevent the Authority from exercising any power or carrying out any function or duty:

(d) does not affect the responsibility of the Authority for the actions of any person acting under delegation.

(3) A person who is delegated any powers, functions, or duties under **subsection (1)**—

(a) may, with the prior written approval of the Authority, delegate those powers, functions, or duties to any other person:

(b) may, subject to any conditions or restrictions, exercise those powers or carry out those functions or duties in the same manner and with the same

effect as if they had been conferred on that person directly by this Act and not by delegation.

(4) Every person purporting to act under any delegation under **subsection (1)** is, in the absence of proof to the contrary, presumed to be acting in accordance with the terms of the delegation.

56 Authority may declare product to be natural health product or permitted natural health product

(1) The Authority may, on application by any person, declare a product or class of product to be a natural health product if—

(a) the Authority is satisfied that the product falls within the definition of natural health product in **section 6**; and

(b) the Authority is satisfied, after considering the circumstances and any applicable regulatory regime, that a declaration is necessary to provide clarity to the applicant and any industry likely to be affected.

(2) The Authority may, on application by any person, declare a product or class of product to be a permitted natural health product if—

(a) the Authority is satisfied that the product falls within the definition of permitted natural health product in **section 5**; and

(b) the Authority is satisfied, after considering the circumstances and any applicable regulatory regime, that a declaration is necessary to provide clarity to the applicant and any industry likely to be affected.

(3) The Authority may refuse to make a declaration if it is not satisfied that the product falls within the definition of natural health product or, as the case may require, permitted natural health product or for any other reason.

(4) Before making any decision under this section, the Authority must refer the matter to the advisory committee and take into account any advice from the committee.

(5) An application for a declaration must be made in the manner specified by the Authority (*see* **section 51**).

(6) The declaration must be published on an Internet site maintained by or on behalf of the Authority.

(7) The Authority must, as soon as practicable after making the declaration, arrange for publication in the *Gazette* of a notice indicating that the declaration has been made and include in the notice details of the Internet site on which the declaration is published.

Subpart 7—Miscellaneous

Regulations

57 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) adding a substance or class of substance to **Schedule 1** if the Minister is satisfied that the substance or class of substance is safe for use in a natural health product:

(b) omitting a substance or class of substance from **Schedule 1**:

(c) amending a description of any substance or class of substance listed in **Schedule 1**:

(d) amending **Schedule 2** by—

(i) adding a pharmacopoeia to, or removing a pharmacopoeia from, the schedule:

(ii) amending a description of any pharmacopoeia listed in the schedule:

(e) prescribing, in relation to a natural health product referred to in **section 18(b) or (c)**, requirements or restrictions relating to health benefit claims that may be made on the label of the product:

(f) prescribing requirements or restrictions relating to health benefit claims that may be made on the label of any natural health product:

(g) prescribing requirements relating to advertisements for natural health products or different classes or types of natural health products:

(h) prescribing standards for scientific evidence or traditional evidence:

(i) prescribing the information that must be provided by the product notifier or applicant for the purposes of any application or matter under this Act:

(j) prescribing the criteria by which new substances will be assessed:

(k) prescribing requirements for the labelling of natural health products:

(l) prescribing requirements relating to the manufacture of natural health products, including requirements relating to the content of the code:

(m) prescribing the procedure and conduct of appeals to the appeals committee:

(n) prescribing requirements relating to access to the database, and any other requirements relating to the use of the database:

(o) prescribing any requirements relating to the procedure of the advisory committee:

(p) providing for any other matters contemplated by this Act, necessary for its administration, or necessary for giving effect to any provision of this Act.

(2) Before recommending that regulations under any of **paragraphs (f) to (p)** of **subsection (1)** be made, the Minister must consult any person or organisation that the Minister considers to be representative of the interests of persons likely to be substantially affected by the regulations.

(3) The Minister must carry out the consultation process set out in **subsection (4)** before—

(a) recommending the addition of a substance or class of substance to, or the omission of a substance or class of substance from, **Schedule 1**:

(b) recommending the addition of a pharmacopoeia to, or the removal of a pharmacopoeia from, **Schedule 2**:

(c) recommending that regulations under **subsection (1)(e)** be made.

(4) The consultation process requires that the Minister—

(a) publish a notice in the *Gazette*—

(i) setting out the proposed recommendation and the reasons for it; and

(ii) inviting submissions on the recommendation to be made by a date no sooner than 21 days after the date of the notice; and

(b) consider the submissions (if any) on the proposed recommendation.

(5) In deciding whether to recommend the making of any regulations under **subsection (1)(e)**, the Minister must have particular regard to the principle that the regulation of permitted natural health products should be proportionate to the risks associated with their use.

Review of Act

58 Minister must review Act

The Minister must, no later than 5 years after the commencement of this Act,—

(a) conduct a review of the policy and operation of this Act; and

(b) prepare a report of the review and present a copy of the report to the House of Representatives.

Amendment to Food Act 2014

59 Amendment to Food Act 2014

Section 60 amends the Food Act 2014.

60 Section 9 amended (Meaning of food)

In section 9(1)(c)(iii), after "within the meaning of the Misuse of Drugs Act 1975)," insert "any natural health product within the meaning of the Natural Health Products Act **2011**,".

Amendments to Medicines Act 1981

61 Amendments to Medicines Act 1981

Sections 62 to 66 amend the Medicines Act 1981.

62 Section 2 amended (Interpretation)

(1) In section 2(1), repeal the definition of **herbal remedy**.

(2) In section 2(1), insert in its appropriate alphabetical order:

natural health product has the meaning given to it by **section 6** of the Natural Health Products Act **2011**

63 Section 3 amended (Meaning of medicine, new medicine, prescription medicine, and restricted medicine)

In section 3(1)(c)(i), after "a medical device", insert "or natural health product".

64 Section 28 repealed (Exemptions in respect of herbal remedies)

Repeal section 28.

65 Section 31 amended (Exemptions for agents and employees)

Repeal section 31(1)(c).

66 Section 42 amended (Duty of importer and manufacturer to have and produce specifications of medicines)

In section 42(1), delete "other than a herbal remedy".

Amendment to Psychoactive Substances Act 2013

67 Amendment to Psychoactive Substances Act 2013

Section 68 amends the Psychoactive Substances Act 2013.

68 Section 9 amended (Meaning of psychoactive substance)

Replace section 9(3)(d) and (e) with:

(d) a natural health product within the meaning of **section 6** of the Natural Health Products Act **2011**:

Amendment to Trans-Tasman Mutual Recognition Act 1997

69 Amendment to Trans-Tasman Mutual Recognition Act 1997

Section 70 amends the Trans-Tasman Mutual Recognition Act 1997.

70 Schedule 2 amended

In Schedule 2, item relating to the Misuse of Drugs Act 1975, the Medicines Act 1981, and the Dietary Supplementary Regulations 1985, replace "Dietary Supplements Regulations 1985" with "Natural Health Products Act **2011**".

Revocation

71 Dietary Supplements Regulations 1985 revoked

The Dietary Supplements Regulations 1985 (SR 1985/208) are revoked.

Schedule 1
~~Suitable~~ Natural substances

~~ss 5, 20(1), 22(1), 46(1), 47(1), (2A)~~
57(1), (3)

Item	Substance or class of substance
1	A plant or a plant material, an alga, a fungus, a mineral, or a non-human animal material
2	A substance or mixture of substances— (a) obtained by expressions, extraction, distillation, purification, or a traditional preparation of a material described in **item 1**; and (b) not subject to any other process involving chemical transformation other than hydrolysis or electrolysis ~~for preparation of the substance or mixture of substances in an active medicinal form~~
3	A vitamin or provitamin, including salts and other compounds, of the following types: vitamin A vitamin B1 vitamin B2 vitamin B3 vitamin B5 vitamin B6 vitamin B12 vitamin C vitamin D vitamin E vitamin K biotin choline ~~folic acid~~ folate
4	A synthetic equivalent of any substance specified in **item 2, 3, or 8**
5	A mineral compound
6	A micro-organism, whole or extracted, except a vaccine
~~7~~	~~Prebiotics~~

Item	Substance or class of substance
8	~~Any of the following amino acids:~~
	An amino acid
	~~Alanine~~
	~~Arginine~~
	~~Asparagine~~
	~~Aspartic acid~~
	~~Cysteine~~
	~~Glutamic acid~~
	~~Glutamine~~
	~~Glycine~~
	~~Histidine~~
	~~Isoleucine~~
	~~Leucine~~
	~~Lysine~~
	~~Methionine~~
	~~Phenylalanine~~
	~~Proline~~
	~~Serine~~
	~~Threonine~~
	~~Tryptophan~~
	~~Tyrosine~~
	~~Valine~~
9	An additive
10	A formulation aid~~.~~

Schedule 2
Approved pharmacopoeia<u>s</u>

~~ss 5, 12B(3), 47(1)(a)(c)~~ <u>57(1), (3)</u>

American Herbal Pharmacopoeia
Ayurvedic Pharmacopoeia of India
British Pharmacopoeia
British Herbal Pharmacopoeia
European Pharmacopoeia
European Scientific Cooperative on Phytomedicines (ESCOP)
German Commission E Monographs
Indian Herbal Pharmacopoeia
Pharmacopoeia of the People's Republic of China
United States Pharmacopoeia and National Formulary
World Health Organisation Monographs on Selected Medicinal Plants