Natural Health Products Bill

Government Bill

As reported from the Health Committee

Commentary

Recommendation

The Health Committee has examined the Natural Health Products Bill and recommends by majority that it be passed with the amendments shown.

Introduction

The bill seeks to regulate low-risk natural health products in New Zealand. Part 1 of the bill defines a natural health product according to how the product is consumed, its ingredients, and the type of claim of health benefit made. It also proposes the establishment of a regulatory authority within the Ministry of Health, which would recognise decisions made by other authorities, create an advisory committee to advise the authority, and maintain an online database of natural health products. Finally, part 1 requires the notifier of a natural health product to be resident in New Zealand.

Part 2 sets out the regulatory scheme. It proposes that before products can be marketed, they would have to be notified on an online database. This process would require the applicant to declare that the product met the scheme's requirements, and the product notifier to hold evidence supporting any claim of health benefit. It provides

for the authority to audit, suspend, or cancel notifications; prohibit ingredients; issue export certificates and compliance notices; undertake safety assessments of ingredients; and prescribe fees. Part 2 would establish penalties, a code of manufacturing practice, and mechanisms for appeal and the recall of products. It would also require product notifiers to inform the authority about any serious adverse reactions to products, and any ingredients which were not previously notified.

Natural health and supplementary products are widely consumed around the world. They are used and produced on a personal basis. They are also produced for mass use, in a global trade, by significantly sized businesses.

While some of these products have clear scientific evidence of efficacy, others do not. This caused an obvious divide between many submitters on this bill.

A large number of products rely on traditional evidence for their appeal and many consumers believe they are good for them. The committee had a difficult task to achieve a bill that balances the demand for consumer choice, protects public health safety, ensures regulations and compliance costs are light when there is low risk, and responds to the increasing need to have a sound scientific evidence base underpinning the use of natural health and complementary medicine.

We consider that over time there is a strong case to increase through research the scientific evidence that underpins the use of natural and complementary medicines, as this will assist consumers, health practitioners, and policy makers alike. We also consider it important for the outcomes of this legislation to be carefully monitored so that any appropriate adjustments can be made over time.

Our commentary covers the main amendments we recommend to the bill and some of the matters we discussed in our consideration of the bill. It does not cover minor or technical amendments.

Title

We recommend amending clause 1 to change the bill's title to read "Natural Health and Supplementary Products Bill". This reflects the fact that the range of products dealt with in this bill includes natural and synthetic, and that these products might also be encapsulated, and contain binding agents and other excipients. We recommend adding

"and supplementary" to every reference to natural health products throughout the bill.

Commencement

As introduced, the bill was to be brought into force by Order in Council. The Regulations Review Committee commented that an Order in Council should only be used in exceptional circumstances, and that a final date should be specified by which the Act must commence. We therefore recommend an amendment to clause 2 requiring the Act to come into force no later than 3 January 2014.

Principles

We recommend inserting new paragraph 4(d) to set out an underlying principle of the bill, that either scientific or traditional evidence should support health benefit claims made for natural health or supplementary products. As the distinction is set out in the interpretation section of the bill, scientific evidence is produced from empirical studies or repeatable experiments, whereas traditional evidence is evidence derived from use of a substance based on knowledge, beliefs, or practices passed down through generations.

We heard concern expressed that the bill would "allow untrue claims and prevent true claims". This was because some low-risk natural products with associated health claims for named conditions, for which there was scientific evidence, would be required to be registered as medicines. It would however be permissible to make a health claim for products based on traditional evidence, but without scientific evidence.

Interpretations and definitions

In the bill as introduced, the interpretation of "health benefit" excludes the relief of symptoms of a serious condition. We recommend amending part (e) of the interpretation of "health benefit" to read "relief of symptoms". This should prevent claims that could lead to delays in treating conditions that require clinical intervention. Claims of health benefit for named conditions are dealt with in clauses 12A, 12B, and 12C. While we acknowledge that people with serious conditions may find relief from natural health or supplementary products,

we consider it highly advisable that New Zealanders visit registered health practitioners in the first instance.

We recommend inserting an interpretation of "label". The proposed interpretation has been taken from the Food Bill, which is currently awaiting its second reading, and has been modified to reflect this bill.

We recommend amending clause 6 to modify the definition of a natural health or supplementary product. We recommend removing methods of administration from this clause and inserting them into new clause 19B. This would make the method of administration a matter of compliance rather than part of the definition of natural health or supplementary product.

It can be difficult to distinguish between a natural health or supplementary product and a food or medicine. For example, honey could be considered to be all three, depending upon the claims that were made for the particular product. We are very wary of making the bill so prescriptive that items such as herbal teas, claiming to offer qualities such as clarity or to be aids for sleeping or as a pick-me-up, should be unnecessarily burdened by compliance and regulatory requirements when their claims are not weighty and their consumption is common. We suggest referencing such products back to the Food Bill, as referred to above, and see such products as another example of the porosity between this bill and the Food Bill. To that end, we recommend amending clause 6 to define a natural health or supplementary product as a product which is not, or is not presented as, a food. Under the bill as amended, food is anything that is ordinarily used, or represented for use, as food or drink for human beings. We further recommend amending clause 6 to define a natural health or supplementary product as a product that is not any medicine, related product, or medical device for which the Minister of Health or the Director-General of Health has given consent for distribution under the Medicines Act 1981.

We were concerned that a product such as honey could be registered as a medicine, which would then remove it from coverage under the bill. If a particular honey product were approved for distribution as a medicine, it could not also be notified as a natural health or supplementary product. However, honey could continue to be used as an ingredient in natural health or supplementary products. A product approved for distribution as a medicine is not included in the definition of a natural health or supplementary product in the bill as amended.

The term "product" refers to the total product, including ingredients, packaging, and claims. There are many hundreds of products made from honey. It is likely that most of them would be classified as natural health products, but if significant health benefit claims were made and appropriate testing had been carried out, the notifier might wish to register the product as a medicine.

We were concerned that the term "manufacture" implies that a product undergoes a transformation before sale, and considered recommending an amendment to also include the term "presented" to cover products which had not been processed or tableted, such as raw Chinese herbs that have been dried and packaged for sale. However, the interpretation of "manufacture" for the purpose of this bill includes the concept of presentation, so we decided an amendment was unnecessary.

We recommend amending the interpretation of "serious adverse reaction" in clause 17 to include reactions which result in hospitalisation, are life-threatening or fatal, or require intervention to prevent permanent disability. We also recommend including allergic reactions. This amendment would align the bill with the World Health Organisation's definition of a serious adverse reaction, which is widely used by the Ministry of Health.

Natural Health and Supplementary Products Regulatory Authority

Establishment of the authority

The authority's office is to be administered by the Ministry, and we were concerned that it might not be sufficiently independent. We were assured that the authority will be separated from Medsafe. We heard that while the authority would be able to delegate powers to any person as he or she saw fit under clause 45(1), section 41 of the State Sector Act 1988 allows only public service chief executives, in this case the Director-General of Health who would delegate on behalf of the authority, to delegate powers to public service employees. In addition, the Government is committed to keeping the authority and Medsafe separate.

We recommend amending clause 10 in two ways. First, we recommend inserting new subclause 10(2A) to require the authority to consult the Minister of Health before making any appointment to the

committee. Second, we recommend replacing subclause 10(4) to require the advisory committee to have amongst its members significant experience regarding natural health or supplementary products, at least one member with experience in the manufacture of such products, and at least one with experience in the field of science. The bill as introduced would require the authority to ensure only that each advisory committee member had relevant expertise in at least one area related to natural health products. We believe that these amendments would strengthen and balance the membership of the Natural Health and Supplementary Products Advisory Committee, ensuring adequate representation of the sector.

Powers of the authority

Under the bill as introduced, the authority could declare a person or body a recognised authority for the purpose of the Act and for a specified purpose or provision of this Act. We were concerned about the risk involved in granting complete recognition to another authority. We therefore recommend amending paragraph 9(1)(a) and deleting subclause 9(2). Subclause 9(3) would allow the authority to declare a person or body to be a recognised authority for a specified purpose or provision of this Act, thereby covering the deleted provisions.

We recommend inserting new paragraph 31(1A)(b) to allow the Authority to recognise audits conducted by another person.

We recommend inserting new clause 31A to give the authority power to enter a manufacturing facility and take samples. We believe that specifying a threshold at which the authority could enter a facility is appropriate. The proposed amendment would allow the authority to enter a facility only for the purpose of assessing an application for a licence to manufacture or assessing compliance with the code or conditions of the licence. In addition, the amendment would provide for reasonable search powers, which are consistent with the New Zealand Bill of Rights Act 1990. This section has been modelled on section 64 of the Agricultural Compounds and Veterinary Medicines Act 1997.

We recommend inserting new clause 45A to allow the authority to declare products to be natural health or supplementary products. This clause also sets out the administrative processes for a declaration.

We also remain concerned about the significant regulatory powers of the authority and the role of the advisory committee. We consider it important that natural health and supplementary products be regulated in a way that reflects their generally low risk, ensures public health safety, allows appropriate health claims when supported by scientific evidence, and maintains New Zealand's credibility as an exporter and manufacturer.

We would expect the expert advisory committee and the authority to exercise informed professional discretion to ensure the principles of the bill are adhered to.

Products would be allowed as natural health and supplementary products proportionate to the risks associated with their use, the level of health benefit claims, and the level of scientific evidence supplied. Where there are high level health benefit claims, the product would be required to be classified as a medicine.

Regulation of natural health and supplementary products

Health benefit claims

We recommend inserting new clauses 12A, 12B, and 12C to guide procedure for allowable health claims. New clause 12A would prohibit the inclusion of claims relating to a named condition in product notifications, on natural health or supplementary product labels, or in the summary of evidence supporting a health benefit claim, other than allowable claims. New clause 12B would provide the authority with the power to determine whether allowable health benefit claims related to named conditions, taking into consideration the principles of the bill, the nature and quality of the supporting evidence, and related risk. Under new clause 12C, a named condition is any disease, disorder, condition, ailment, or defect that is recognised by the World Health Organisation.

The authority will assess the evidence available, and make a judgement on whether a health benefit claim is reasonable on the basis of the quality of the evidence. However, in the case of some claims for low-risk conditions, the authority is expected to be satisfied with the evidence of traditional use. For example, it is likely that a claim for milk thistle, which has traditionally been used for the treatment of mild digestive disorders, would be accepted. We recommend in-

serting new schedule 2 to specify the approved pharmacopoeias from which traditional evidence would be accepted. In addition, it is possible that inclusion in another recognised pharmacopoeia could be accepted as evidence for traditional use.

Product Notification

We recommend inserting new clause 11A setting out who would be required to notify a product to the authority in various situations.

We recommend inserting new clause 13A setting out which products would not require notification. This clause would replace and expand on subclause 13(6) of the bill as introduced. It would exempt natural health or supplementary products in which the active ingredient is in a concentration not more than 20 parts per million. We were concerned that homeopathic products would not be regulated by this bill. The dilutions of homeopathic products are such that the concentration of active ingredient is typically too small to be detected. Therefore, we believe that requiring a notification for such products would be impractical because it would be impossible to audit the product itself. However, we note that homeopathic products will still be subject to manufacturing requirements and audits. We understand that currently there is no accepted scientific evidence for the effectiveness of homeopathy and therefore that health benefit claims should not be made for homeopathic products on this basis.

We consider that exemptions should be made only where necessary, and in exceptional circumstances. We recommend an amendment to clause 14, specifying the appropriate reasons for and guiding the use of exemptions. We took advice from the Regulations Review Committee, and recommend that an appropriate reason for exemption be required: for example, that it was impractical to notify a particular product. We also recommend providing that the authority must not exempt a product unless it has received advice from the advisory committee and is satisfied that there is no risk to public health from doing so.

We recommend replacing clause 16 with a new clause 16 and new clauses 16A and 16B, to provide for immediate suspension of notifications and a more formal process preceding cancellation of notifications. The proposed amendments would require the authority to inform the product notifier of the details of and reason for a suspension,

and also whether it had decided to cancel or reinstate the product before the end of the suspension period. Upon cancellation, no person could sell the product or distribute it for sale, and the product notifier could not notify again the same product unless the authority was satisfied that the grounds for cancellation, and any other concerns it might have, had been addressed.

Under the bill as introduced, a new notification would be required for any change in a product's manufacturing arrangements. We recommend inserting new subclause 18(1A) to require a new notification only when there is a change in manufacturer or the location overseas in which the product is manufactured. We also recommend amending subclause 18(1) to require the product notifier to act on a change in circumstances "as soon as practicable". This amendment provides for these procedures to be carried out more quickly than the bill as introduced.

We recommend inserting new clause 19A to allow the authority to cancel a product notification if it is no longer necessary. In this situation, the authority must give the product notifier time to respond, and consider any submission from the product notifier.

We recommend inserting new clause 19B to prohibit the sale of natural health or supplementary products that are administered by injection, parenteral infusion, or application to the eye. While most products meet the sterility requirements of recognised manufacturing practice for therapeutic goods, we consider this clause a necessary safeguard against those which do not.

Code of practice for manufacture of natural health and supplementary products

We recommend amending paragraph 27(2)(b) to require the authority when developing the code to consult only persons or organisations representative of the interests of those likely to be affected by the code. The bill as introduced requires the authority to consult any person likely to be affected.

Fees

We recommend amending clause 35 to insert new subclauses 35(1A)–35(1F) to guide the authority's setting of fees. Some of

these subclauses were taken from the Food Bill which is currently awaiting its second reading, and have been modified to align with it.

Offences

We recommend inserting new paragraph 36(ba) to provide that it is an offence to alter a label so that it no longer complies with this legislation.

We recommend inserting a definition of "sale" in subclause 37(5) to clarify what would constitute a sale under the Act. Under this definition, a sale would include the commercial distribution of products, including distribution free of charge, for example at seminars. This definition has been modelled on similar definitions in the Maori Commercial Aquaculture Claims Settlement Act 2004 and the Agricultural Compounds and Veterinary Medicines Act 1997.

We recommend inserting new clauses 40A, 40B, and 40C to enhance the offence provisions of the bill. They would make it an offence to manufacture or sell a natural health or supplementary product that contains prohibited ingredients, or is a dietary supplement that does not contain permitted ingredients, and to advertise that any product may be administered illegally or used to treat a serious condition.

Appeal

We recommend amending clause 42 to set out the procedure to be followed when appeals are made. We also recommend clarifying that appeals could be made to the High Court only on a question of law.

Regulations

Having received advice from the Regulations Review Committee, we recommend several amendments.

As introduced, paragraph 47(1)(a) contains a Henry VIII power which would allow the primary legislation to be overridden by regulations. We recommend inserting new paragraphs 47(1)(a), 47(1)(ab), 47(1)(ac), and 47(2A) as safeguards to control the use of the Henry VIII power.

As introduced, paragraph 47(1)(g) provides for matters of policy to be determined by regulation. We recommend deleting this paragraph to prevent this happening.

We recommend amending paragraph 47(1)(i) to ensure that requirements relating to the code of practice for manufacture of natural health or supplementary products are included in regulations prescribing product manufacturing requirements.

We consider that the quality of the regulations setting the standards of evidence required in support of a health benefit claim to be fundamentally important. Subclause 47(3) requires different levels of evidence for specified kinds of claim. A product that claims to treat health conditions, for example, would require more evidence to support the claim than one which claims to be good for health. We recommend inserting new subclause 13(2A) to require product notifiers to publish a summary of evidence to support the claims they make for their products. We believe that New Zealand's reputation as an exporter of regulator-approved foods and natural health and supplementary products is at risk if this legislation is not adequately supported by regulation. This is crucial given the central role of food exports in New Zealand's economy. Natural health and supplementary products are currently estimated to be a billion-dollar export business.

Requirements for the labelling of natural health or supplementary products are prescribed by paragraph 47(1)(f). As a minimum, we believe that product labels should be consistent with overseas requirements; but we consider requirements in this area should not be overly prescriptive. The information provided should be required to be accurate, but style, such as font size for example, should not be prescribed. Under these circumstances, we heard that overseas labels would easily meet the New Zealand requirements.

Green Party minority view

The Green Party supports the overall objective of this bill, which is to bring in a simple low-cost system for protecting consumers of natural health and supplementary products. However, we have concerns about some sections of the bill and how it will be applied. The bill gives significant powers to the authority. This means that it is difficult to assess exactly what the impact of the bill will be on products currently on the market. We outline some of our specific concerns below.

Allowable claims

The new clauses 12A–12C set up a pre-approval system for allowable claims, so that all claims for any named condition are prohibited unless allowed. We have significant concerns about this section. We are worried that if applied rigorously it would have the effect of disallowing claims for a wide range of everyday minor named conditions for which many products currently make claims, including acute pharyngitis (sore throat), acute nasopharyngitis (common cold), and constipation.

An initial list of common conditions suitable for self-treatment, for which it is expected that claims will be permitted (with evidence), has gone some way to alleviating these concerns. Advice that further expansion of this draft list during the transition period until the bill comes into full effect should go some way to providing a system which protects consumers while not putting an overly onerous burden on the natural health sector.

We were also advised that a broad interpretation would be taken of "affecting or maintaining the structure or function of the body"; so that for example reference to "supporting cardiovascular health", "promoting circulation", "supporting healthy liver function" and so on are likely to be accepted if the authority was satisfied with the supporting evidence.

We consider that retaining the flexibility to add to and remove from this list without having to go through regulation will help encourage a more permissive list, resulting in better outcomes for consumers and the natural health sector.

We remain concerned that an unintended consequence of this section may mean that some producers will opt for more generalised claims about their product, which may make it harder for consumers to make accurate, informed decisions around which natural health product is most appropriate for them (for example vegans choosing B12 supplements).

While we fully understand that there is concern from the Ministry that some consumers of natural health or supplementary products may fail to seek appropriate medical treatment for conditions that are poten-

tially serious, we believe that this situation mainly arises not because of (true) claims being made on the products but because of

- misleading or wrong information and claims on the internet that are out of the control of the producer of the product
- misleading or wrong advice from unqualified, untrained, or unscrupulous self-styled health "experts"
- the cost of visiting the doctor, which is a significant barrier for many people.

We are mindful that the primary purpose of the bill is to ensure that natural health and supplementary products are true to claim, not to stop true claims from being made, and are keen for the authority to adopt a permissive approach in the interpretation of this section.

We strongly support the proposed addition of a schedule of approved pharmacopoeias and the proposed clauses 12B(3)(a) and 12B(3)(b) which allow the authority to accept theses as sources for traditional evidence in support of health benefit claims. This will help ensure that it is relatively simple for many products relying on traditional evidence to obtain approval for health benefit claims.

Permitted ingredients list

Currently only classes of permitted ingredients are listed in the bill. We had sought a list of permitted ingredients, to be included as a schedule in the bill. We feel that to have an initial list of permitted ingredients commonly used by the industry would allay industry and consumer fears and be helpful to the transition process. We suggested that this could be simply done through recognising comparable overseas jurisdiction ingredients lists.

We heard advice that while it was expected that most ingredients in the recognised pharmacopoeias were expected to be permitted, it was known that some pharmacopoeias also contained references to known toxic substances such as arsenic. We accepted that it is important that these substances are identified and placed on the prohibited ingredients list before publishing a permitted ingredients list. Our preferred position would have been to have had this work done prior to passing the bill and a list included in a schedule.

Cost recovery

The proposed fees-based system for cost recovery favours producers which produce a large volume of a small range of products over smaller operators with smaller turnover but a wide range of products. We heard from many submitters that they were concerned that their access to the current range of natural health products would be limited by the bill because some operators may find it too costly to maintain their current range. The Green Party has always held the position that provision for a levy should be included within the bill. Provision for turnover based fees would go some way to addressing our concerns.

Recognition of Te Tiriti

The Green Party is committed to legislation that honours Te Tiriti and ensures Māori participation in decision-making processes that affect them. Any system that will potentially regulate Māori taonga (such as the traditional use of plants) needs to be administered in a way that is consistent with the Treaty. While the bill exempts products made on a 1-1 basis, such as occurs with Rongoa, from notification, it still has the potential to affect the use of traditional plants. Our desired addition to the bill is to insert a clause that states, "In achieving the purpose of this Act, all persons exercising functions and powers under it shall honour the articles of Te Tiriti o Waitangi."

Appendix

Committee process

The Natural Health Products Bill was referred to the committee on 15 September 2011. The bill was reinstated in the 50th Parliament on 21 December 2011. The closing date for submissions was 24 February 2012. We received and considered 739 written submissions from organisations and individuals. The committee also received 108 form submissions. We heard 67 of the submissions orally, which included holding hearings in Auckland and Wellington.

We received advice from the Ministry of Health and the Parliamentary Counsel Office. The Regulations Review Committee reported to the committee on the powers contained in clauses 2, 14, and 47 of the bill.

Committee membership

Dr Paul Hutchison (Chairperson)
Shane Ardern
Dr Jackie Blue
Dr Cam Calder
Kevin Hague
Iain Lees-Galloway
Andrew Little
Barbara Stewart
Hon Maryan Street
Dr Jian Yang
Mojo Mathers replaced Kevin Hague for this item of business.

Key to symbols used in reprinted bill

As reported from a select committee

text inserted by a majority

text inserted unanimously

~~text deleted unanimously~~

Hon Tony Ryall

Natural Health and Supplementary Products Bill

Government Bill

Contents

The Parliament of New Zealand enacts as follows:

1 Title

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

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

2 Commencement

~~This Act comes into force on a date appointed by the Governor-General by Order in Council and 1 or more orders may be made bringing different provisions into force on different dates.~~

This Act comes into force on 3 January 2014, 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.

4 Principles

This Act is based on the following principles:

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

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

~~(c) that natural health products must be accompanied by information that is accurate and tells consumers about the risks and benefits of using the product.~~

(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**

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

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

appeals committee means the ~~Natural Health Product Appeals Committee~~ Natural Health and Supplementary Products Appeals Committee established under ~~**section 42**~~ **section 41**

~~**authorised person** means any person to whom the Authority has delegated any powers, functions, or duties under **section 45**~~

authorised person means—

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

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

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

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

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

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** means anything that is used or represented for use as food or drink for human beings; and includes—~~

~~(a) any ingredient or nutrient or other constituent of any food or drink, whether that ingredient or nutrient or other constituent is consumed or represented for consumption by human beings by itself or when used in the preparation of or mixed with or added to any food or drink; and~~

~~(b) anything that is or is intended to be mixed with or added to any food or drink; and~~

~~(c) chewing gum, and any ingredient of chewing gum, and anything that is or is intended to be mixed with or added to chewing gum~~

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 ~~of any condition that is not a serious condition~~

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** to manufacture ~~natural health products~~ natural health and supplementary products ~~granted under **section 29**~~

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

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

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

~~**natural health product database** means the database established under **section 11**~~

~~**natural health product ingredient** means any substance that—~~

~~(a) belongs to a class of substance that is listed in the **Schedule**; and~~

~~(b) is declared by the Authority to be a natural health product ingredient under **section 20**~~

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

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

prescribed manner means the manner prescribed in regulations

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

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

prohibited ingredient means any ~~ingredient~~ 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**

regulations means regulations made under this Act

~~**serious condition** means a disease, disorder, condition, ailment, or defect (or any symptom of the disease, disorder, condition, ailment, or defect) that is generally accepted as not suitable for at least 1 of the following:~~

~~(a) self-diagnosis:~~

~~(b) self-management~~

~~**sponsor** means, in relation to a natural health product, a person who imports or manufactures, or arranges the import or manufacture of, a natural health product.~~

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.

6 Definition of natural health and supplementary product

~~(1) In this Act, unless the context otherwise requires, a **natural health product** means a product—~~

~~(a) that is intended by the sponsor of the product—~~

~~(i) to be administered to a human being; and~~

~~(ii) to bring about a health benefit to the person to whom the product is administered; and~~

~~(iii) to be administered by any of the methods specified in **subsection (2)**; and~~

~~(iv) not to be administered by any of the methods specified in **subsection (3)**; and~~

~~(b) that, subject to **section 22(2)(b)(i)**, contains only natural health product ingredients; and~~

~~(c) that does not contain any prohibited ingredient; and~~

~~(d) that is not—~~

~~(i) a food; or~~

~~(ii) a prescription medicine or pharmacy-only medicine as those terms are defined in the Medicines Act 1981; or~~

~~(iii) a controlled drug within the meaning of the Misuse of Drugs Act 1975.~~

~~(2) The methods of administration referred to in **subsection (1)(a)(iii)** are the following:~~

~~(a) oral ingestion:~~
~~(b) application to the skin, scalp, or nails:~~
~~(c) application to the teeth, throat, anal canal, or vagina:~~
~~(d) application to the mucosa of the mouth or nose.~~

~~(3) The methods of administration referred to in **subsection (1)(a)(iv)** are the following:~~
~~(a) injection or parenteral infusion:~~
~~(b) application to the eye:~~
~~(c) application in the ear.~~

(1) **Natural health and supplementary product** means, subject to **subsection (2)**, any product that—
(a) is, or appears to be, 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 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.

(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.

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 the purpose of this Act, or~~ for a specified purpose under this Act or provision of this Act; and

(b) for a specified period or not.

~~(2) Before declaring a person or body to be a recognised authority for the purpose of this Act, the Authority must be satisfied that the person or body (whether in New Zealand or any other country) administers a system for the regulation of natural health products that is equivalent to or more robust than the system administered under this Act.~~

(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 ~~natural health~~ 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 products advisory committee~~
Natural Health and Supplementary Products Advisory Committee

10 ~~Natural health products advisory committee~~ 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 ~~must~~ may be appointed by the Authority on any terms and conditions that the Authority thinks fit.

~~(4) In appointing members of the committee, the Authority must ensure that each member has expertise in at least 1 area of knowledge that relates to or is relevant to natural health products.~~

(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 procedure.

Natural health and supplementary ~~product~~ products database

11 Natural health and supplementary ~~product~~ products database

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

~~*Sponsor*~~

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 ~~Sponsor~~ Product notifier must be resident in New Zealand

~~A sponsor of a natural health product~~ 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~~ YD 2(1)(a) ~~(excluding section YD 2(2))~~ 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 ~~required before distribution~~

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

(2) The product notification must be made to the Authority and must be completed by the ~~sponsor~~ 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 ~~sponsor~~ product notifier has provided—

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

(ii) any other information required by regulations; and

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

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

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

(4) The ~~sponsor~~ 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 ~~natural health product~~ database, the ~~sponsor of the product~~ product notifier must satisfy the Authority that the manufacturer complies with the code after providing any documentation or information required by the Authority.

~~(6) This section does not apply to—~~

~~(a) any natural health 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 product, unless it is a natural health product for which export certification is sought under **section 25**; or~~

~~(c) natural health products or categories of natural health products that are exempted under **section 14** from the requirements of this section.~~

~~(7) A sponsor is not required to complete a further product notification for a natural health product if there is any variation in the weight, size, or packaging (excluding the labelling) of the product.~~

(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 ~~based on traditional use of a substance or product~~.

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 ~~requirement to have a product notification under~~ 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.

~~**16 Authority may suspend or cancel product notifications**~~

~~(1) The Authority must, as soon as practicable, suspend the product notification of any natural health product that the Authority has reasonable grounds to believe has caused, is causing, or is likely to cause harm to any person.~~

~~(2) The Authority may suspend a product notification if—~~

~~(a) the Authority has reasonable grounds to believe that the sponsor of the product has provided false, misleading, or incomplete information in the product notification; or~~

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

~~(3) The Authority may—~~

~~(a) reinstate any product notification that has been suspended under **subsection (1)** if it is satisfied that there are no reasonable grounds to believe that the product has caused, is causing, or is likely to cause, harm to any person; or~~

~~(b) reinstate any product notification that has been suspended under **subsection (2)(a)** if it is satisfied that the sponsor did not provide false, misleading, or incomplete information; or~~

~~(c) reinstate any product notification that has been suspended under **subsection (2)(b)** if the concern referred to in that subsection is not justified.~~

~~(4) The Authority may cancel a product notification of any product if it is satisfied that any of the events described in **subsection (1)** or **(2)(a)** have occurred, or that any concern referred to in **subsection (2)(b)** is justified.~~

~~(5) The Authority must, as soon as practicable, give written notice to the sponsor of any suspension, cancellation, or reinstatement of the product notification.~~

~~(6) If a product notification for a natural health product is suspended or cancelled under this section, the sponsor of the product—~~

~~(a) must stop distributing the product on and from the date and time that the suspension or cancellation takes effect; and~~

~~(b) must not complete another product notification for the product.~~

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

(1) The ~~sponsor~~ product notifier of a notified natural health and supplementary product must notify the Authority as soon as

the ~~sponsor~~ product notifier becomes aware of any serious adverse reaction to the product.

~~(2) In this section, **serious adverse reaction** means any reaction causing death, danger to life, hospitalisation, prolongation of hospitalisation, interruption of productive activity, or birth defects.~~

(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 product, there is any change in the product's manufacturing arrangements, health benefit claims, or ingredients, the sponsor of the product~~ 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 ~~more~~ 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) The sponsor may change the sponsor's contact details on a product notification without the need for a new product notification.~~

(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 ~~Sponsor~~ Product notifier may cancel product notification

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

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 ~~Authority may declare substances to be natural health product~~ Permitted ingredients

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

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

(a) may~~, if it raises a concern,~~ 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 ~~natural health~~ 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 ~~natural health product~~ permitted ingredient must be listed on the ~~natural health product~~ 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 ~~natural health product~~ ingredient.

(2) In considering whether to declare ~~the~~ a substance to be a prohibited ~~natural health product~~ 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 ~~for administration to~~ by human beings:

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

(3) Every substance declared to be a prohibited ~~natural health product~~ ingredient must be listed on the ~~natural health product~~ 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 belongs to a class of substance listed in the **Schedule**~~ that is, or belongs to a class of substance, listed in **Schedule 1** and that is not—

(a) a ~~natural health product~~ permitted ingredient; or

(b) a prohibited ingredient.

(2) If a product notifier ~~manufacturer or distributor~~ intends to use a new ingredient in a natural health and supplementary product ~~that is intended for distribution~~ for sale in New Zealand,—

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

(b) if, within the ~~90 working days~~ 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 ~~sponsor~~ product notifier may, after receiving ~~notice~~ written confirmation from the Authority ~~under this paragraph~~ that the new ingredient may be used, complete a product notification for the product; ~~and~~ but

(c) if, within the ~~90 working days~~ 90-day period, the Authority raises a concern and commences a safety assessment, the product must not be notified under **section 13**, or sold~~, or distributed~~ 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 ~~natural health product~~ permitted ingredient in accordance with **section 20**; and

(b) list the new ingredient on the ~~natural health product~~ 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 ~~distributed~~ sold in New Zealand must comply with the labelling requirements prescribed in regulations.

Exports

25 Export certificate

(1) A ~~sponsor~~ 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 ~~sponsor~~ 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 ~~sponsor~~ product notifier has completed a product notification for the product.

~~(4) If the sponsor is seeking an export certificate for a natural health product that is manufactured in New Zealand but not distributed in New Zealand, the sponsor must, in addition to completing a product notification for the product, hold a licence to manufacture.~~

(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 cer-

tificate 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 with any person or organisation that the Authority considers is likely to be affected by the code or the proposed amendments to it.~~

(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 ~~that is publicly available at all reasonable times:~~.

~~(c) is available for purchase in hard copy, at a reasonable cost, from the Authority.~~

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) ~~The following persons are exempt from **subsection (1)**.~~ **Subsection (1)** does not apply to—

(a) any ~~exporter of a natural health product who is not also seeking an export certificate for the product; and~~ 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 ~~health~~ 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 manner.

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

(a) the Authority ~~has conducted an audit of the manufacturing facilities and~~ 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—~~

~~(i) any offence involving or relating to the manufacture of any product for human consumption; or~~

~~(ii) any offence specified in the regulations:~~

(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 ~~duties~~ requirements:

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

(4) A licence to manufacture remains in force for ~~3~~ 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) For the purpose of assessing compliance with the code, the Authority may at any time conduct audits of the manufacturing facilities of any holder of, or applicant for, a licence to manufacture.~~

(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 ~~audit may be conducted~~ 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 ~~facilities have~~ 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 ~~return for the purpose of this Act, or destroys, cancels, conceals, alters, obliterates, or fails to provide any document, record, return, or information required to be~~

~~kept or communicated~~ 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, ~~or~~ certificate, or declaration attached or relating to a natural health and supplementary product ~~that is subject to any provision of this Act~~, 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.

~~(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.~~

(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~~ $250,000:

(b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding ~~$100,000~~ $50,000.

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

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

(a) any natural health and supplementary product for which, to the ~~sponsor's~~ person's knowledge, ~~a product notification has not been completed:~~

(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 ~~sponsor's~~ person's knowledge, does not meet—

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

(ii) applicable standards for labelling or manufacturing.

(2) A ~~sponsor~~ 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 ~~notification~~ label contains additional health benefit claims ~~or the product is manufactured elsewhere~~ not included in the product notification).

~~(3) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.~~

(4) A ~~sponsor~~ 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)**.

~~(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.~~

(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 46**~~ **section 31A or 45**.

~~(2) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.~~

(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 ~~sponsor~~ 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 ~~sponsor~~ 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.

~~(3) A prosecution for an offence against this section may be proceeded with either summarily or on indictment.~~

(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 Product~~ 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.

~~(2) The appeal must be made in the prescribed manner and within the prescribed time.~~

(3) An appeal ~~on a question of law~~ 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 ~~sponsor~~ 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) dispose of the product.~~
(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 ~~sponsor must arrange for the recall of the product or dispose of the product.~~ product notifier or manufacturer must comply with the notice.

(3) ~~The sponsor must, as soon as practicable, advise the Authority—~~ 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 ~~sponsor~~ 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 ~~Natural health products before commencement of this Act~~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), (c), and (d)**~~ **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 does not belong to a class of substance listed in the **Schedule**.~~

(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 ~~sponsor~~ 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 ~~made under this Act~~ 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 ~~of Health~~, make regulations—

~~(a) amending the **Schedule**:~~

(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 the standards of evidence required to support a health benefit claim:~~

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

(d) prescribing the information that must be provided by the ~~sponsor~~ 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:

~~(g) specifying any offences that the Authority must take into account for the purposes of **section 29(3)(a)(ii)**.~~

(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, conduct, and time required for appeals:~~

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

(k) prescribing requirements relating to access to the ~~natural health product~~ 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 ~~with~~ any person or organisation that the Minister considers ~~has an interest in, or will~~ 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.

~~(3) Regulations made under **subsection (1)(c)** may require that different levels of health benefit claims may require different levels of evidence.~~

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 ~~of Health~~ 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 product**—has the meaning given to it by **section 6** of the Natural Health and Supplementary Products Act **2011**

~~"(a) has the meaning given to it by **section 6** of the Natural Health Products Act **2011**; or~~

~~"(b) means a product that complies in all material respects with the requirements of that section."~~.

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~~**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.

Schedule 1

ss 5, 20(1), 22(1), 46(1), 47(1), (2A)

Suitable ~~classes of~~ substances

Item	~~Class of substance~~ 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
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	~~Class of substance~~ Substance or class of substance
8	Any of the following amino acids: 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

ss 5, 12B(3), 47(1)(a)(c)

Approved pharmacopoeia

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

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Legislative history

7 September 2011	Introduction (Bill 324–1)
15 September 2011	First reading and referral to Health Committee

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