New Zealand Health Trust & New Health - Submission on the Natural Health Products Bill

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1 Title This Act is the Natural Health Products Act **2011**.	The industry has consistently requested that the Bill cover "Natural *and Traditional* Health Products". This reflects the fact that some of the products commonly sold by the industry are "traditional" rather than simply natural. We are unsure of the rationale for omitting the reference to "traditional" products in the Bill's title.	Add "and Traditional" to the Bill title and elsewhere the term "natural health products" is used in the Bill.
2 Commencement	We have no comment on this clause, although we refer to it elsewhere in our submission.	
Part 1 Preliminary matters		
Preliminary provisions		
3 Purpose The purpose of this Act is to establish a system for the regulation of natural health products in New Zealand.	We do not support this clause. The Legislation Advisory Committee Guidelines on Process and Content of Legislation notes that "Purpose provisions are of key importance given the injunction in section 5(1) of the Interpretation Act 1999 that enactments are to be interpreted in the light of their purpose. Every provision of an Act should, if possible, be interpreted consistently with that purpose provision". (ch 3A.1.2) Against this background we are somewhat perplexed by the inclusion of a purpose statement which appears to do no more than state the obvious. If the provision is to be of any use as an interpretative tool we believe that it should not just state what the legislation does (ie. regulate) but also "why" it is being enacted – ie. its purpose. On this point we note that the purpose statements in other recent legislation introducing regulation of sectors has been rather more helpful (eg. s3 of the Lawyers and Conveyancers Act 2006, s3 of the Real Estate Agents Act 2008, s3 Financial Advisers Act 2008). If anything it is even more imperative that the NHP Act contains a clear statement of purpose, given it has been drafted as essentially a framework Act with much of the detail of the new regulatory regime to be provided in regulations. We believe the paramount feature of the Bill is that it introduces a risk proportionate regulatory system for NHPs in New Zealand. As is stated at page 7 of the Regulatory Impact Statement for the Bill (RIS) the main objective of this is "*to provide assurance that natural health products are safe, true to claim and true to label*". We believe that if it is to be any use as an interpretation tool then at the very least clause 3 should refer to these matters. It might also usefully mirror some of the wording from the purpose statement in clause 4 of the Food Bill, which like the NHP Bill has underlying purposes of promoting public health and providing certainty to those who operate in the affected industry as to their obligations under the law. This latter [idea] is particularly pertinent to the NHP industry given the current uncertainty in the laws that govern the industry which we hope will be addressed by the Bill.	Amend and expand clause 3 to provide that the purpose of the Act is - "...to establish a risk proportionate system for the regulation of natural and traditional health products in New Zealand that – (a) provides assurance [to consumers] that natural and traditional health products are safe, true to claim, and true to label; and (b) promotes public health; and (c) Provides certainty for manufacturers and distributors of natural and traditional health products in relation to how the requirements of the Act will affect their activities.
4 Principles	We partially support this clause.	Amend and expand clause 4 to provide that the Act is based on the following principles –

[1] RIS p 7

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This Act is based on the following principles: (a) that natural health products must be fit for human consumption or use: (b) that the regulation of natural health products must 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.	We support paragraph (a). Given the wide regulation making powers given by the Bill, and the extensive powers given to the Authority in relation to such matters as ingredients, product notifications and licensing, it is imperative that Parliament gives clear direction to the executive as to the matters that should be considered when these powers are exercised - in particular, that the Bill introduces a "risk proportionate" regulatory regime and given the long history of safe use of natural and traditional health products and their low risk, in most cases, safety will be able to be assured by a tool kit comprising education, labelling, restrictions on ingredients, or manufacturing standards rather than prohibiting ingredients or products. In our view, the principle in paragraph (b) of clause 4 is only part of the story and needs to be expanded to cover these matters and give better guidance to the regulator on appropriate decision making under the Bill (that is, what risk proportionate responses would be under the Act). While paragraph (c) may be intended to cover the objective in the RIS that "consumers should be supported to make informed choices about their use of NHPs"[1], in our view is too specific for a "principle" (seeming to suggest that the Bill covers the giving of specific information to consumers when it does not) and should be reworded.	(a) that natural and traditional health products must be fit for human consumption or use: (b) that the regulation of natural and traditional health products must be proportionate to the risks associated with their use, and in particular – (i) natural and traditional health products with a history of safe use in New Zealand or their country of origin should be considered safe until proven otherwise; (ii) requirements in relation to information labelling, restrictions on ingredients, or specific manufacturing standards should be preferred over prohibition where any identified harm is reversible and the risk is voluntarily undertaken; (c) that persons who manufacture and distribute natural and traditional health products should take responsibility for the safety and suitability of their products; (d) that information provided to consumers should be accurate and support consumers making informed decisions about the use of natural and traditional health products.
5 Interpretation In this Act, unless the context otherwise requires,— **appeals committee** means the Natural Health Product Appeals Committee established under **section 42** **authorised person** means any person to whom the Authority has delegated any powers, functions, or duties under **section 45** **Authority** means the Natural Health Products Regulatory Authority established under **section 8**	We have no comment on these definitions which are generally descriptive rather than containing substantive material.	
code means the code of practice for manufacturing natural health products established under **section 27**	We support this definition.	
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	We do not support this definition. The definition of a NHP in clause 6(1)(d)(i) states that a NHP means a product "that is not a food". We have no problem with this conceptually (ie. the idea that a NHP is different from a "food"), but believe that the current definition of "food" in the Bill is unworkable and would leave almost nothing to be regulated under the new NHP Act. This is because, even if the main part of the definition was workable (which we will come back to), paragraphs (a) and (b) extend the definition well into NHP territory. For example, paragraph (a) could be read as covering ingredients or nutrients such as vitamin C or calcium when consumed or represented for consumption by itself or to be added to a drink. Paragraph (b) could likewise be read as carving out as a food any of the many NHPs that are designed to be mixed with or added to food or drink (for	Delete the definition of "food" in clause 5 as unnecessary. Amend the definition of "natural health product", as discussed in relation to clause 6. Amend the Food Act so a food complying with the NHP code is deemed to be manufactured in accordance with a food risk management plan under that Act..

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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	example bee pollen, colostrum, or manuka honey). This overlap is not surprising given that the definition of "food" has been taken from the Food Act 1981, and many NHPs are currently regulated under the Dietary Supplements Regulations 1985, which are made as a subset under that Act and thus explicitly acknowledge that dietary supplements are "foods" under the current law. Quite apart from this issue, so far as the lead in words (the chapeau) are concerned, we would note that some NHPs are technically food or drinks (eg. manuka honey with glucosamine or a nutritional supplement in powder form). Many NHP ingredients that will be on the database are also foods. In short, simply attempting to carve "foods" out of NHPs is unworkable. We anticipate that the issue is a drafting one, rather than a substantive policy issue, given that the consultation document (p20) suggested the carve out would be for products presented as foods, including such things as muesli bars containing herbal ingredients or bottles of orange juice fortified with vitamins and minerals. We support products like this remaining and being regulated as "foods" under the Food Bill. We submit further that from a policy point of view, it is sufficient that the code for NHPs is robust enough to deal with any risks associated with ingredients that are both "foods" and NHP ingredients. It is unnecessary and unworkable to try to carve out foods from the definition of a NHP. In our view with the comfort of the ability of the code to limit any safety risks of manufacturing, and the offence provisions for those who manufacture products in breach of the NHP Act, it should be irrelevant whether a product is manufactured under the NHP Act standards or under a risk management plan under the Food Bill. (In fact as we go on to say under other headings we would like it more explicit in the Act that manufacturing under the Food Bill standards is equivalent compliance with the code for the purposes of the NHP Act). We submit that where a product could fall within the ambit of either the Food Act or the NHP Act (eg. manuka honey), the manufacturer should be given an alternative of complying with the Food Bill regime and marketing the product as a food, or if the manufacturer wishes to make health benefit claims about the product, notifying it as a NHP under the NHP Act. This can be achieved by simply deleting the definition of "food" from the Bill, and amending the definition of a "natural health product" to remove the "food" exception. We suggest that to reduce compliance costs, where a manufacturer manufactures NHPs and foods in the same premises then the Food Act should recognise the Code as equivalent to a food risk management plan for the purposes of the Food Act.	
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	We do not support this definition. The definition of a "health benefit" is not only crucial to determining whether a product is a NHP, and therefore falls under the Bill, (ie. to be a NHP a product must be intended by the sponsor to bring about a health benefit") but also to the claims that can be made about it (ie. a claim of benefit from a NHP that did not fall within the definition of a "health benefit" would not be a "health benefit claim". In our view, the definition of "health benefit" does not clearly cover all the characteristics of a NHP. That is, many NHPs do more than maintain or arguably promote health or wellness, and relieve symptoms, but actively assist in treating conditions and restoring health or wellness and indeed in preventing illness. For example, iron tablets may, in a person who is iron deficient, not only promote their health, but actually restore it. The same is true of giving vitamin D tablets to a person with a vitamin D deficiency. It is accepted science that Vitamin C both treats scurvy and prevents people getting it. Scientific studies have also shown that the taking of Echinacea reduces significantly the chances of people catching the common cold,[2] while it is scientifically proven, commonly accepted and recommended by public health advisers and medical practitioners that folic acid nutritional supplements should be taken by women wishing to get pregnant to reduce the chances of neural tube defects by some 85 percent. In fact, folic	Add a new paragraph (aa) as follows: "(aa) the prevention of illness" Amend paragraph (a) to read "(a) the restoration, maintenance, or promotion of health or wellness" In para (e), delete "that is not a serious condition".

[2] ***"Evaluation of echinacea for the prevention and treatment of the common cold: a meta-analysis."*** *The Lancet Infectious Diseases* 2007; 7:473-480 DOI:10.1016/S1473-3099(07)70160-3 Sachin A Shah, Stephen Sander, C Michael White, Mike Rinaldi, and Craig I Coleman.

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	acid is now so widely accepted for this purpose that it is mandatory to add it to flour and/or bread in Australia and over 50 other countries; and MAF is currently consulting on legislation to do the same thing in New Zealand. *Para (a)* While arguably the definition of "health benefit" *would* permit claims to be made about these products such as "nutritional support", "vitamin or mineral supplementation", or as products "affecting or maintaining the structure or function of the body" we are concerned that paragraph (a) may be read narrowly as not enabling claims to be made about the role of such products in treating or preventing conditions. This is especially so given the sometime tense relationship there has been in the past between conventional and [so-called] alternative health industries,(although of course an increasing number of doctors now embrace both areas of practice). That many of these products have therapeutic properties is beyond debate, and in fact therapeutic benefits of folic acid are provided for by both the Medicines Act, and the food standards under the Food Act. Fortified foods such as cornflakes with only 10 percent of the scientifically proven amount of folic acid are permitted to make therapeutic claims, and yet paradoxically, it is illegal for scientifically proven natural health products to do so. Other NHPs such as herbal remedies are currently regulated as a category of "medicine" under the Medicines Act (being a substance or article that is manufactured, imported, sold, or supplied wholly or principally for administering to a human being for a therapeutic purpose). In our submission it would therefore be a travesty if narrow wording in the definition of "health benefit" prevented scientifically proven claims being able to be made for products that may [otherwise] provide an important public health benefit. We submit that, given the requirement that evidence be available to back any claims made about the health benefits of a NHP (cl 13(3)(b)), and the ability for the regulator to prohibit or restrict certain types of ingredients (presumably high risk) being used in a NHP, there is no policy rationale for possibly limiting via the current unclear definition of "health benefit" evidence based claims being made about the efficacy of a NHP in preventing and treating illness and restoring wellbeing. We submit that these criteria should be added to the definition of "health benefit" *Para (e)* Similarly, we support the inclusion of a criteria relating to relief of symptoms in the definition, but can see no policy rationale for preventing, via the definition of "health benefit", evidence based claims being made about the efficacy of a NHP to provide relief from the symptoms of *serious* conditions. If a product that otherwise meets *the* definition of a NHP and is safe and well tried can give such relief then we believe it should be able to be marketed as a NHP and should be subject to the softer regulatory regime in the NHP Act rather than the onerous pre-approval regime under Medicines Act regime. (As is noted in the RIS obtaining an approval for a natural health product under the Medicines Act is not a viable option as, unlike medicines, producers cannot generally patent natural products and recoup the costs associated with product approval (RIS p2)) We also see major issues (as we return to below) in relation to drawing the line between "serious" and "non-serious" conditions. For example, studies have shown topical arnica, commonly used as temporary pain relief for the symptoms of arthritis, to be effective; arthritis *could* conceptually be considered a "serious condition". In our view, the requirement for a person making a claim to have evidence to support that claim means that there can be no policy reason why a sponsor should not be able to make a claim about the efficacy of arnica for this purpose, however the drafting of paragraph (e) casts real doubt as to whether such a claim would be within the Act. Similar examples include St John's Wort efficacy in treating mild depression.	
health benefit claim means a claim of a health benefit	We support this definition.	
licence to manufacture means a licence to manufacture natural health products granted under	We have no comment on these definitions which are generally descriptive rather than containing substantive material (although we note that the subparagraph (a) of the definition of a natural health	Insert a definition of "manufacture" along the following lines:

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section 29 **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 **natural health 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 product** means a natural health product for which a product notification has been completed **prescribed manner** means the manner prescribed in regulations **product notification** means the product notification required under **section 13**	product ingredient appears to be redundant given the operation of clause 20). However, we think that the Bill should also contain a definition of "manufacture". The reason for this is that in many cases different people carry out different roles in the manufacture of NHPs – for example, one person may import ingredients, they may be mixed in a mixing plant, then transported to an encapsulation plant, then transported back to a bottling plant, and then be sent somewhere else for labeling and final packaging. In other cases, product may be prepared to a certain stage in accordance with, say, a risk management programme under the Animal Products Act, but then transferred to another site to be made into a NHP and packaged. Or in some cases, natural health products may be imported in bulk and then packaged when they reach New Zealand. In our submission to ensure the regulatory regime is flexible, robust and meets international standards, each of the persons involved in the manufacture of the product in New Zealand should be a "manufacturer" under the Bill and be required to meet appropriate risk management criteria. To achieve the policy goal "manufacture" should be defined in the Act in a manner which is broad enough to cover all stages of the manufacturing process up until the NHPs are packed into containers for the purposes of sale. A definition of "practitioner" should also be added, as discussed in relation to clauses 13(6) and 28(2)(b).	**manufacture**, in relation to a NHP, - (a) means to make up, prepare, produce, or process the NHP; and (b) includes encapsulation, bottling, packaging and labeling and all other stages of the manufacturing process up to and including the packing of the NHP into a container for the purposes of sale.
prohibited ingredient means any ingredient declared by the Authority to be a prohibited ingredient under **section 21**	We support this definition with amendments. Given the fact that many herbs especially have been classified a prescription medicines as a de facto means of prohibiting their distribution, it is our strong submission in relation to clause 6(1)(d)(ii) below, that prescription medicines and pharmacy only medicines should not automatically be banned from being natural health products ingredients, but that where they fall into a class of substances in the Schedule, and a person can show that they are safe to use in an NHP, with appropriate controls if necessary, they should be able to be included in the database of allowable natural health product ingredients. To achieve this policy we suggest that they be classed temporarily under the Bill as "prohibited ingredients" that can, via the process submitted in relation to clause 20 and clause 22 be included in the NHP ingredients database. This will require amendment to the definition of "prohibited ingredient".	Amend the definition to read **prohibited ingredient** means – (a) a prescription medicine or pharmacy-only medicine, as those terms are defined in the Medicines Act 1981, unless the medicine has been declared by the Authority to be a natural and traditional health product ingredient **under section 20 and section 22**; or (b) any other ingredient declared by the Authority to be a prohibited ingredient under **section 21**.
recognised authority means a person or body declared to be a recognised authority under **section 9** **regulations** means regulations made under this Act	We have no comment on these definitions.	

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	The Food Bill provides the following definition of safety: "**Safety –** (a) means a condition in which food, in terms of its intended use, is unlikely to cause or lead to illness or injury to human life or public health; and (b) includes a condition in which hazards are identified, controlled, managed, eliminated or minimized." We suggest that a definition of "safety" similar to that provided in the Food Bill would provide clarity.	Add the following definition: "**Safety –** (a) means the condition in which a natural and traditional health product ingredient, in terms of its intended use, is unlikely to cause or lead to illness or injury to human life or public health; and (b) includes a condition in which hazards are identified, controlled, managed, eliminated or minimized."
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	We do not support this definition. The term "serious condition" is only used in paragraph (e) of the definition of "health benefit" so will only be used to determine whether a product is a NHP, and if so, the claims that may be notified about it. We noted in our submission on paragraph (e) of the definition of "health benefit" why we think that the reference to a "serious condition" should be deleted from that paragraph. Namely, that it is arbitrary, indefensible from a policy point of view, and unworkable from an operational point of view. Adopting this approach is a hangover from a previous era. This second submission is enhanced when we consider the proposed definition of "serious condition" which in our view contains a major flaw in that it does not define *who* the non-suitability for self-diagnosis or self management must be "generally accepted" by before a condition becomes a "serious condition" eg. medical practitioners, natural health practitioners, or the general public. Clearly this will make a big difference to the claims that can be made about a NHP under the Bill. For example, the RIS acknowledges that there is evidence to indicate that St John's Wort is effective in managing the symptoms of *mild depression*". Thus, whether a health benefit claim could be made about relief of such symptoms will depend on a judgment as to whether "mild depression" is "generally accepted" as not suitable for either self-diagnosis or self management. There is document research published in peer review medical journals that a significant percentage of cancer patients undergoing treatment use natural health products to alleviate symptoms of both cancer itself and treatment.[3] This would indicate that the use of natural health products by cancer patients is generally accepted by both the public and medical practitioners and yet under the proposed definition such generally accepted use may well be banned. 5 people would no doubt have 5 different views on this question. We would note that even in relation to scientific evidence the "generally accepted" standard" has been commented on adversely by the courts especially with regards to preventing adoption of new or innovative evidence; in other words, it stifles progress.[4] Finally we note that paragraph (e) of the definition of "health benefit" talks about the *symptoms* of a condition that is a serious condition, and then the definition of "serious condition" includes any *symptom* of the condition. This drafting is particularly difficult to unravel.	Delete the definition of "serious condition" consequential on removing the reference to a "serious condition" from the definition of "health benefit".
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.	We do not support this term nor the definition. Quite apart from the overall policy, we do not support the use of the word "sponsor" in the Bill, as it is closely associated with the pharmaceutical industry and may therefore lead to misinterpretation of the role of the "sponsor" under this Act. Australia is, as far as we are aware, the only country that defines the term 'sponsor' in legislation in this context; it is not used in New Zealand law. The origin relates to the pharmaceutical industry's sponsorship of trials of pharmaceuticals and is not consistent with the purposes of this legislation	Delete the Bill's definition of "sponsor" and substitute – **product notifier**, means a person [or organisation] that [is registered under section 12 as a product notifier].

[3] See Journal of the New Zealand Medical Association, 24 January 2003, Vol 116 No 1168 http://journal.nzm.org.nz/journal/116-1168/296/

[4] See Tipping J in R v Calder (HC ChCh, T-154/94, 12 April 1995)

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	In our view, this definition of "sponsor" and the way it is used in the Bill are confusing and it is not sufficiently clear who a/the sponsor for a product should be. That is, under the definition any or all of the importer, manufacturer, and a person who arranges the import or manufacture of a product is a sponsor (note, this is not a "may be a sponsor" but "is" a sponsor.) However other provisions of the Bill suggest that "sponsorship" is in fact an opt in arrangement and the list is meant to delineate who "may" be a sponsor for and distribute a product, rather than make all the listed people sponsors. This is obviously key to the Bill's regime because many of the offence provisions relate only to "sponsors" of a product. This confusion as to the role of "the/a" sponsor" is highlighted in the following provisions – • cl 12 which provides that "*a* sponsor" must be resident in New Zealand, while cl 13(5) recognizes that not all manufacturers will be in New Zealand; • cl 13(2) which refers to "*the* sponsor" as the person who must complete the product notification for a product before it can be distributed (but begs the question as to whether this means, for example, a manufacturer must complete the notification before distributing to a person who "arranged the manufacture of a product"); • The definition of an NHP which provides that a product is not a NHP at all unless "*the* sponsor" intends the product to have a health benefit etc; • Cl 40 which makes the "manufacturer or sponsor" liable in certain cases. Separately we are concerned that the definition of "sponsor" limits who could apply for an export certificate for a product under s25. The role of "sponsor" is essentially the role of the "licensee" under the proposal put forward by the Joint Industry Group in February 2009 ("the Joint Industry Proposal). That is – it is that person who is responsible for notifying the product on the register, including any health benefit claims that are to be made, and for recalls of the product where there is just cause. However the key difference is that the definition attempts to define (or limit, we are not sure) who will be the sponsor for a product by reference to a group that in our view is too limited to adequately cater for the way the NHP industry works. It also does not cater for the fact that – • There could be many persons involved in the manufacture of a NHP; • NHPs may be manufactured in bulk under arrangement with a wholesaler, who then provides the product to different parties who bottle it and label it before distributing and marketing it through different channels, possibly with different health benefit claims depending on the target market. If the group of people who can notify products as a "sponsor" is too early in the chain, then it may be that those people will not have all the information available to them to fill in a product notification. For these reasons we believe that the definition of sponsor is unworkable, and unnecessary. It is sufficient to meet the purpose of the Act (that NHPs be safe, true to claim, and true to label) that someone has notified the product before it is distributed to the public and thereby become the registered "product notifier" for that product, incurring all the associated liabilities. We return to that under clause 12 below.	
6 Definition of natural health 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	We support the concept of this definition, but believe it needs amendment to be workable. As drafted, it may exclude unnecessarily some products that can safely and reliably be regulated under this Act. In line with our suggested amendment to the title of the Act, this definition should be "natural and traditional health product" *Subcl (1)(a)M* If, as we submit, the "sponsor" of a product should be the registered product notifier who wishes to distribute the NHP to the public, it does not work to include the words "the sponsor" in paragraph (a). If that person is, for example, a distributor, further up the chain, then it cannot be the case that the product is not a "natural health product" until the sponsor is identified and the necessary intent formed.	*Subcl (1)(a)* Delete and amend per the Medicines Act approach to [In this Act, unless the context otherwise requires, a **natural and traditional health product** means a product that –] (a) is manufactured, imported, sold, or supplied wholly or principally for administering to a human being for the purpose of bringing about a health benefit; and (aa) is intended

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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.	However, we believe this is an issue under the current drafting too. As noted above, we are confused as to whether the Bill envisages that both of any manufacturer/importer and any persons who arranged the manufacture/import are sponsors for a product, but do wonder, if that is the Bill's intention, how paragraph (a) can work. That is, is it is necessary for all those persons to have the necessary intent eg. in relation to a health benefit, or is it sufficient that one of them does? In this regard we would note that many manufacturers of NHPs are contract manufacturers who simply manufacture to the contracted specifications and will not give any thought to the benefits or otherwise of a product. Nor would they wish, by being made a "sponsor" to incur liabilities under the NHP Act if a product is found not to have the benefits the person who arranged the manufacture either a) intended or b) notified under clause 13. This situation needs to be fixed and we suggest that the policy can be achieved by removing the words "the sponsor" from paragraph (a) and using the more general words in the definition of a "medicine" in the Medicines Act (and which are replicated in the new Medicines Amendment Bill provisions, namely the product "*is manufactured, imported, sold, or supplied wholly or principally for administering to a human being for the purpose of* bringing about a health benefit..." In our submission this wording is much clearer and will work much better in practice than the current wording. *Subcl (1)(b)* See our submission on cl 20. At the moment the list of "classes of substances" that can be used in natural health products in the Schedule to the Bill does not include excipients, or some ingredients that are traditional so that these ingredients could not be used in a NHP. Unless the Schedule is amended to provide for these they should be added to subclause (1)(b)of this definition. *Subcl (1)(c)* See our submission on cl 21. We support the concept of a "prohibited ingredient" list, but believe there must be a process to contest and have ingredients removed from that list if new evidence of safety and efficacy becomes available. Such evidence may include the ability to utilize manufacturing standards to manage risks, advisory or warning statements, upper safe levels or simply that what was thought to be a hazard has been demonstrated not to be the case. *Subcl (1)(d)(i)* We have already commented above in relation to the definition of "food" in clause 5 why we think the carve out for food in subcl (1)(d)(i) is unworkable and the reference unnecessary. *Subcl (1)(d)(ii)* In our view, the carve out in subcl (1)(d)(ii) for prescription and pharmacy-only medicines is also unnecessary and lacks a policy justification in terms of the Bill's principles. "Prescription" and "pharmacy-only" medicines under the Medicines Act include a number of substances – for example, many plant extracts - that could be used safely and efficaciously in a NHP. In our view it is sufficient that to be included on the NHP ingredient register they would need to go through a vetting process by the Authority. If an ingredient that is listed in these classes on the Schedules to the Medicines Regulations is safe and a person can show evidence of its efficacy, perhaps in a low dose, to provide a health benefit, and/or with suitable manufacturing standards we believe it should be able to be added to the natural health products ingredients list. Red Yeast Rice is a recent example of Medsafe banning its use in dietary supplements but allowing its use in foods (even though dietary supplements are currently regulated as foods) Medsafe have refused to release a risk assessment under the Official Information Act because one doesn't exist; 'no risk assessment exists because the classification of red yeast rice in a capsule as a prescription only medicine was simply a technical adjustment. Such apparent historical unusual or unexpected use of the powers conferred by the statute need to be able to be addressed by the NHP Act to ensure that arbitrary historical decisions are not legitimized by the Act In order to achieve the flexibility to achieve this policy goal, without requiring the regulator to consider individually the reasons why various ingredients have been placed on the Schedule to the Medicines Regulations, we suggest that the Bill provide a process for the Authority or potential product notifiers of a	(i) to be administered by any of the methods specified in subsection (2); and (ii) not to be administered by any of the methods specified in **subsection (3)**; and *Subcl (1)(b)* Either amend para (b) to include excipients/traditional ingredients, or amend the Schedule to cover these matters. *Subcl (1)(d)* Amend subcl (1)(d) by deleting sub subparagraphs (i) (food) and (ii) (prescription medicines and pharmacy-only medicines) and substituting references to • "precursor substances" under the Misuse of Drugs Act; and • "restricted substances" under the Misuse of Drugs Amendment Act 2005.

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	product to seek to have those ingredients removed from the prohibited list and declared natural health product ingredients. In the absence of such a process an issue will arise when ingredients/products allowed in a country with a recognised authority continue to be banned in New Zealand for historical, not scientifically valid reasons. The current drafting means that it will continue to be very easy for pharmaceutical regulators or drug companies to capture an ingredient by having it added to the pharmacy only or prescriptions medicines lists and thus remove it from the mass market, with associated reduction in choice and increased costs for consumers. Industry has seen this happen with a variety of ingredients, where they have been declared to be one of these classes of medicine with very little investigation and out of an abundance of caution. An example of this is melatonin, which is currently a prescription only medicine, yet is freely available in the United States and elsewhere and is only listed as a medicine because it is a hormone. The government intends pharmaceutical medicines to be regulated by the joint New Zealand/Australia therapeutics agency, and given the heavy regulation of NHPs in Australia, the NHP industry in New Zealand is most concerned that the agency cannot, effectively by stealth, limit what is available as a NHP in New Zealand; this would clearly be at odds with government policy *Subcl (1)(d)(iii)* We are comfortable with the carve out for controlled drugs in subcl (1)(d)(iii) but wonder whether the prohibition should also relate to • "precursor substances" under the Misuse of Drugs Act; and • "restricted substances" under the Misuse of Drugs Amendment Act 2005. We do, however, see the need for distinctions to be made between synthetic substances such as ephedrine and natural ephedra. There is no evidence that ephedra has or can be used as a precurser for drugs such as 'P'. The evidence suggests it isn't and can't be. Regulators have claimed that there is no distinction between natural and synthetic forms of ingredients but we contend that often there is, as natural ingredients usually have other substances extracted which can buffer or moderate the affects of the plant derived ingredient. Any potential adverse effects of ephedra alkaloid itself can be managed with restrictions on dose levels and manufacturing standards.	
(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.	We are generally comfortable with the approach in subcl (2) but note it does not clearly cover aromatherapy products. While we understand from some of the First Reading speeches that it may be the intent to exempt aromatherapy and homeopathic products from certain aspects of the Bill (we imagine the notification requirement) in our view, whether that approach is taken or not, such products should be regulated under the Bill at least as to manufacturing standards. The Bill should be amended to clearly cover them so that they do not fall between the cracks and potentially distort the marketplace. We note that the explanatory note to the Bill states that natural health products include herbal remedies, traditional treatments, homeopathic remedies and dietary supplements. Subclause(2) should also include application to ears.	Add a new para (e) "smell". Add a new para (f) "ears".
(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.	Paragraph (c) means that a product is not a NHP if it is intended to be administered by "parenteral infusion" or administration to the ear. Thus ear drops can not be a NHP. This is the first suggestion that we have seen that such products (which include such things as almond oil which is marketed as and accepted as efficacious as a wax softener) should be excluded from the NHP definition. In our view there is no policy rationale for excluding products applied to the ear that have long been on the market from the NHP regime and have a long history of safe use. In fact we wonder if they are not NHPs, where, if at all, they are expected to be regulated. (If the Medicines Act, it seems completely over the top that a simple oil with a long history of safe use should be required to comply with that Act). We submit that paragraph (c) should be deleted. We suggest that paragraph (a) be clarified as the term "parenteral" can be interpreted to include	Delete paragraph (c) Clarify "parenteral"

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	application to the vagina – which is specifically provided for in sub-clause (2).	
7 Act binds the Crown	We support this clause.	
Natural Health Products Regulatory Authority		
8 Natural Health Products Regulatory Authority (1) This section establishes the Natural Health Products Regulatory Authority. (2) The Authority is the Director-General of Health. (3) The office of the Authority must be administered by the Ministry of Health.	We generally support this clause noting that industry has been promised that the NHP Act will not be administered by the office regulating pharmaceutical medicines. This clause does not deliver on that promise. As drafted the Director General could install the office of the Authority within Medsafe.	Amend (3) to add [“and separately from any regulator of medicines under the Medicines Act”]
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 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.	We support the ability of the regulator to recognise authorities for the purpose of this Act, but believe that further process is desirable around this. Firstly, although industry has been given the message consistently that it will be “business as usual” after the Bill is passed (ie a smooth transition with overseas regulators recognised at the commencement of the Act), to provide certainty to industry, we believe that the Bill should contain a Schedule of “recognised authorities” with a process to add to or remove those authorities. With no process around “recognised authorities” there is simply insufficient certainty for importers about what will be acceptable to sell in New Zealand. Industry needs to be making decisions now about product going forward, and it is currently at risk that some jurisdictions from which product is currently imported may not make the grade. We think there should be some process for industry to request that authorities be recognised for the Act’s purposes. This would essentially “require” the Authority to make a decision on the point, that could be appealed or reviewed if the applicant was not satisfied with the outcome. As presently drafted the Authority could simply fail to act in response to a request by a distributor and it is unclear what, if any, recourse the distributor would have. We suggest 60 days to make a decision on such an application would be appropriate. Whether there is a Schedule or not, there must be some process for withdrawing recognition, that requires consultation and gives industry time to react. For example, the business of a person who imports product that complies with the standards of a recognised authority in say, India, would be severely affected were recognition to be withdrawn, and should have both an opportunity to submit on the proposal, and, if appropriate, a transition period to source other product. We submit that there would also be WTO obligations and potential trade barriers involved in such a decision. Finally, to ensure transparency for those in the market, we believe a list of recognised authorities, and the purposes for which they are recognised should be required to be maintained on the Authority’s website.	Amend and expand this clause to – • require consultation with persons likely to be interested in the decision before decisions are made to declare or remove recognition of an authority; • provide a process for manufacturers or distributors to apply to have an authority recognised, with decisions on the application required to be made by the Authority within 60 working days; • include a transitional process where recognition is withdrawn. Insert an initial list of recognised authorities in a Schedule [Schedule 2] to the Bill that can be amended by Order in Council. The Schedule might list the following including competent authorities from; • Australia • Canada • China • European Union • India • Japan • Korea • Singapore • South Africa • United Kingdom

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		• United States • Any other authority declared to be a recognised authority by the Authority under section 9.
Natural health products advisory committee		
10 Natural health products advisory committee (1) The Authority must establish an advisory committee to provide expert advice to the Authority on matters referred to it by the Authority. (2) The committee must consist of not more than 8 members. (3) The members of the committee must 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. (5) The Authority may give terms of reference— (a) on the advice that the committee provides to the Authority; and (b) on the use of external experts to assist the committee. (6) The committee may, subject to any provision in this Act, the regulations, and the terms of reference, determine its own procedure.	While it is clearly appropriate for the Authority to take advice where it lacks expertise, we query the intent of clause 10 of the Bill. That is, it is not clear whether the Authority, having established the committee, is required to use it, or whether it can use its own experts without having to use the committee (see cl 10(5)). Relatedly the NHP industry is very diverse and we question whether subcl (4) is sufficient to ensure a balanced committee with expertise in the matter before it? We submit that this clause should contain a requirement to include on the committee industry participants with expertise relevant to any particular issue before the committee (on a case by case basis if necessary). Appointments to the committee should be by the Minister not the Authority.	Amend the clause to provide: • for appointments to be made by the Minister; • for more flexibility in the make-up of the committee utilising industry participant's expertise.
Natural health product database		
11 Natural health product database The Authority must establish and maintain a natural health product database.	We support this provision however the clause should be extended to include natural health product "ingredients" and product notifiers. This database must be accessible on-line for addition and modification purposes.	Amend to "The Authority must establish and maintain an online database for the notification and maintenance of appropriate product notifier, natural and traditional health product ingredient and natural and traditional health products details
Sponsor		
12 Sponsor must be resident in New Zealand A sponsor of a natural health product must be resident in New Zealand within the meaning of section YD 1 or YD 2 (excluding section YD 2(2)) of the Income Tax	We are comfortable with the requirement that the person taking responsibility for distribution of a product in New Zealand be required to be resident here so that the enforcement regime can be invoked if necessary. However, we believe clause 12 should otherwise be redrafted. Firstly, from a drafting point of view, the provision is somewhat ambiguous. As defined in the Bill a	Delete cl 12 and substitute a simple process for registration of "product notifiers" that covers • process for applications for registration as a product notifier;

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Act 2007.	sponsor, in relation to a NHP, is a person who imports or manufactures, or arranges the import of manufacture of a, a natural health product. Under clause 12 a sponsor must be resident in New Zealand. Taken literally this means that a manufacturer of a NHP must be resident in New Zealand. However, that cannot be the intent. It must mean that one of the persons listed as a sponsor in the definition must be resident in New Zealand.
	
	However, more substantively, as discussed in relation to the definition of "sponsor", we believe that the concept of a "sponsor" as someone at the start of the distribution chain is unworkable and a sponsor should essentially be the person who wishes to, and is willing to, take the role of sponsor under the Act in order that they can distribute natural health products – ie. It should be a self-elected role we suggest is called a "product notifier"..
	
	The role of the person under the Bill is –
	a) To have the intention that the product produce a health benefit (cl 6(1), (although as noted earlier, we believe cl 6(1) should be reworked to remove the reference to a "sponsor";
	b) Notify the product before distribution (cl 13(1));
	c) Act on any recalls etc of the product;
	d) Be responsible for the product's safety and claims when distributed
	
	In short, the person is the crux of the Bill and is essentially responsible for meeting its purpose ie. that NHPs in the market are "safe, true to claim, and true to label".
	
	There should be a simple registration process for notifiers, which contains pre-conditions relating to recall plans (to ensure that in the event that there are safety concerns about a product, it is able to be recalled without any delay. Only a registered product notifier should be able to notify NHPs under cl 13 and registration should be able to be revoked for continued non-compliance with the Act and other serious issues.
	
	This suggested approach is consistent with that requested in the Joint Industry Proposal developed and supported by and estimated 95% of those involved in the NHP industry and focuses on what we believe to be the main focus of Bill – a risk proportionate regime regulating "who" is in the market and "what" is in the market".
		• criteria for registration ie. the applicant –
		  • is resident in New Zealand;
		  • has in place a recall plan that complies with prescribed requirements;
		  • meets any other reasonable prescribed requirements
		• registration – we suggest this have no time limit, but be subject to audit from time to time of the person's recall plan;
		• suspensions for continued failure to notify product before it is distributed, or serious concern about the product being distributed;
		• cancellation of registration if person no longer meets the requirements for registration (including the fit and proper person test);
		• surrender of registration

Part 2 Regulation of natural health products		
Product notification of natural health products		
13 Product notification of natural health products required before distribution (1) A natural health product must not be distributed in New Zealand without a product notification having been completed for the product. (2) The product notification must be made to the Authority and must be completed by the sponsor in the prescribed manner.	We support the Bill containing a pre-requisite that NHPs be notified on a products database before being distributed to the public, but believe amendment is necessary to this clause for it to be workable. Under cl 13(1) a NHP may not be distributed in New Zealand without a product notification being lodged in the NHP database. We support the policy behind this provision, but believe that it and cl 13(2) need further refinement before they can be workable. Firstly, with no definition of "distribution" it could capture, for example, distribution by an importer to those who had commissioned the import of a product. It could also capture a person who imported a	Amend cl 13(1) to provide that a product [must not be distributed *for sale to the pubic or sold to the public* in New Zealand unless *a registered product notifier* has completed a product notification for the product.] Amend references to "the sponsor" in the clause to refer to the "registered product notifier". Add a provision clarifying what is considered an individual "product" for the purposes of the notification provision.

[5] Note, as an Act provision subcl 7 will be used to determine the scope of the regulation making power, which seems to cover only: the manner in which a product notification may be made (presumably electronically) and the name of the product, the product details, the sponsor, the manufacturer, and the health benefit claims. That is, the regulation making powers do not seem to extend to defining what should be considered a separate product for the purposes of the Act.

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	product and gave some to a friend. We believe this problem can be fixed by adding "for sale to the public or sold to the public" after "distributed" in cl 13(1). Secondly the definition of a sponsor makes it unclear whether cl 13(2) means that each person who is a sponsor under the definition is required to complete a product notification or only one. For example, if a product is imported in bulk under commission from more than one person do all those persons have to register the product? As noted above, in relation to clause 12, we believe only a registered product notifier should be able to notify products. Adding this concept to clause 13 would assist its clarity. However another issue is that it is not clear in clause 13 what makes a "product" unique and requires separate notification eg. is vitamin C in 500mg a separate product – or is it "Blackmores vitamin C". (Note, it could be that regulations are intended to provide that detail however, this is not clear from the drafting);[5] Clause 18 would seem to suggest that it is intended that something is a separate product if all its other features are the same, but it has a different manufacturer. Given that, as noted earlier, there may be several manufacturers involved in the manufacture of a product, we believe that that is too onerous. It should be sufficient that the product notifier is required to update the information in the product notification. While it is unclear from the drafting, we believe it likely that the Authority will impose a fee for product notifications. Indeed, the RIS implies that this will be the primary source of funding the Authority. In our view it would impose unnecessary cost on distributors were they required to pay to make a product notification each time some minor aspect of the manufacturing changed. The imposition of such compliance costs would not be in accordance with the purpose of the Act that regulations be risk proportionate. If the provision defined what would be considered an individual "product" for the purposes of notification this would itself define the scope of the regulation making power.	
(3) The product notification is complete when— (a) the sponsor has provided— (i) information as required by regulations relating to the name of the product, the product details, the sponsor, the manufacturer, and the health benefit claims made for the product; and (ii) any other information required by regulations; and (b) the sponsor has provided a declaration that— (i) the information provided is complete and accurate; and (ii) the sponsor holds evidence to support the health benefit claims made for the product. (4) The sponsor must, if requested by the Authority, provide the Authority with the evidence described in **subsection (3)(b)(ii)**.	*Claims* The Bill does not state explicitly whether a sponsor is required to include a health benefit claim in the notification at all, but seems to presuppose that people will wish to. In our view it should be explicit that there is **no** requirement for a health benefit claim to be made. For example a distributor may wish to sell vitamin C simply as "vitamin C", without being required to state why it is desirable for someone to take it. Again we can see no possible rationale why a sponsor (product notifier) should be *required* to make claims, just that if they make claims they have the evidence to back them up. *Evidence* Subclause (3) b)(ii) requires the sponsor to hold evidence to support the claims made. Under subcl (8), the level of evidence may be *either* "scientific evidence that is consistent with the prescribed standard", or "evidence based on traditional use of a substance or product that complies with the prescribed standard". There is no list of accepted claims. Given the international market that exists, Industry has consistently asked that distributors be allowed to notify "accepted claims" or other claims about a product. We had understood that this policy position had been accepted by government and would be reflected in the Bill. However, it is evident from this subclause that it has not. The basis of industry's submission on this point was that there is no policy rationale for imposing the cost of "proving" claims, or even requiring the holding of evidence, where the claims are generally accepted as true. We have earlier given as examples of such claims, vitamin C for scurvy, folic acid to prevent neural tube defects, and St John's wort for mild depression. In industry's submission the preferable policy position was that the database contain next to each natural health product ingredient, any claims about the characteristics of the product that were "accepted" as being correct. These claims	In subcl (3)(a)(i) add "(if any)" after the words "health benefit claims" Amend subcl (3)(b)(ii) amend to "*unless the claim is an accepted claim*, the *registered product notifier* holds evidence to support *any* health benefit claims". Add a new provision here, or in sections 20 and 22, requiring the regulator to add "accepted claims" to the entries for individual ingredients in the NHP ingredients database within 40 working days unless it has reasonable grounds not to. [These claims should be derived from the sources listed in relation to clause 20(3)]. Add a further provision giving guidance for the purposes of the regulations, as to the types of evidence that would be appropriate in relation to different types of claims. (At the least, a "principle or "have regard to" factor should be added along the following lines: "evidence to be required must be proportionate to the health benefit claims and the harm if the claim is not true"

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	would not require evidence to be produced to support their veracity. We had in previous submissions to the Ministry outlined sources of claims that we considered should be accepted via the Bill; we submit that a schedule 3 be included in the Act including appropriate recognised sources of acceptable claims We maintain that this policy should be reflected in the Bill. In fact, we have heard no arguments as to why the cost of finding evidence to support what are generally accepted claims about products should be imposed on each industry participant who wants to, for example, notify a product based on that ingredient; nor, for the uncertainty that will result from the Bill, as to whether the regulator will require "scientific evidence" or evidence based on traditional use to be held to support that category of claims. In our view, where claims about NHP ingredients fall into the category of "generally accepted as true" they should be listed on the ingredients database and should be explicitly excluded from the requirement for the sponsor (product notifier) to hold evidence. Where claims are not on the "accepted" list, however, we support the requirement for the sponsor (product notifier) to include such claims on the product register and to hold evidence to support the claim, and the ability of the regulator to request the evidence if it wishes. Finally, on the latter point, while we support having differing levels of evidence able to be required by the Authority, we are concerned, particularly because of the lack of direction to the Authority in the "principles" and purpose of the Act, that the Act give clear guidance as to the type of evidence that is desirable for different types of product. This may strongly influence the claims that can be made and therefore the livelihood of those in the industry. We believe it is more than a matter of "policy detail" that is suitable for regulations, and is actually a matter of substantive policy that should be stated in the Act.	
(5) If a manufacturer of a natural health product is not in New Zealand and is not listed on the natural health product database, the sponsor of the product must satisfy the Authority that the manufacturer complies with the code after providing any documentation or information required by the Authority.	This provision is somewhat lost in the "product notification" provision and its intent is unclear. That is, - • The Bill provides that a manufacturer in New Zealand must be licensed (cl 28(1)); and • The licensing of a manufacturer is dependent on an audit of the facilities by the Authority and the Authority being satisfied that the facilities meet the requirements of the code (cl 19(2)(a)); • A manufacturing facility in which NHPs are manufactured under a licence granted by a recognised agency is deemed to be compliant with the code (cl 33); • A product notification must include "the manufacturer". If the intention of cl 13(5) is that an importer cannot notify an NHP that has been manufactured outside New Zealand unless the foreign manufacturer is deemed to be compliant with the code under cl 33 then it would be useful for it to say so in as many words (ie. what appears to be missing is a statement that a product cannot be notified unless it has been manufactured by a licenced manufacturer or a foreign manufacturer who is deemed to comply with the code) It would also be useful for the Bill to state clearly whether "deemed" compliance under cl 33 meets the requirement in cl 13(5), or whether the Authority could require evidence of "actual" compliance with the code. Finally, it is assumed that the words "a manufacturer … is not listed on the NHP database" means that there has been no earlier product notification that includes a product manufactured by the foreign manufacturer and that was accompanied by evidence the manufacturer complied with the code. However, again this is somewhat ambiguous, given the NHP database is for "products" rather than "manufacturers". It also begs the question of what happens if a manufacturer already with a product on the database loses its licence. We suggest that there should be an on-going requirement for a declaration in this regard.	Amend to clarify that a product may not be notified unless all persons involved in its manufacture fall within the following group • a person with a licence under cl 28: • a foreign manufacturer who is deemed to comply with the code under cl 33: • a foreign manufacturer, who [a] product notifier has satisfied the Authority complies with the code after providing any documentation or information required by the Authority.

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(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.	This subclause contains the exceptions for prior notification of a NHP. One is for a NHP made by a "practitioner" to be administered to a particular person after being requested by or on behalf of the person to use the practitioner's own judgment as to the treatment required. While the term "practitioner" is undefined, there is a possibility it will not be read as relating to the people (eg. rongoa Maori practitioners) that it is intended to relate to. This is because – • a "practitioner" under the Health Practitioners Competence Assurance Act 2003, means a registered health practitioner; • the equivalent provision in the licensing provision in cl 28(2) actually refers to a "health practitioner"; • the equivalent provision in s32 of the Medicines Act refers to a "natural therapist or other person" rather than a "practitioner. We suggest that to avoid argument the Bill should define and use the term "practitioner" in a manner that makes it clear that it is not limited to a registered health practitioner. More substantively, as we outline in relation to clause 14 below, we do not believe it is appropriate to have a power to exempt categories of NHP from the notification requirement. In our view, para (c) should be deleted.	Add a definition of practitioner along the lines of – **practitioner** means a naturopath, herbalist, Chinese medicine practitioner, practitioner of rongoa Maori, or other person who prepares natural or traditional health products for clients on an individual basis. Delete para (c)
(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.	See entry for cl 13(1) above. We think further work is necessary to define what is a separate "natural health product" for the purposes of the Act. It is most unclear, for example, whether notifying a product that contains 250mg of vitamin C would mean that no further product notification is necessary for a product that is otherwise the same, but varies from the notified product in size and weight eg. it contains 500mg of vitamin C. We wonder if this should read weight or size of the packaging, rather than referring to the weight or size of the product?	Amend to provide clarity around what is a single "product" for notification purposes.
(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) evidence based on traditional use of a substance or product	As noted above, we support there being different levels of evidence for different types of claim (outside accepted claims). However, we believe that, particularly if accepted claims are not added to the Bill, there should be at least 3 possible levels of evidence – scientific, evidence from the sources listed in respect of clause 20(3), and other evidence based on traditional use of a substance or product. As industry has submitted previously, we believe, in the interests of administrative efficiency, and in order to reduce compliance costs and industry uncertainty, that sources of acceptable evidence for generic ingredients should be listed is a schedule with provisions for the Authority to amend either at its own initiative, or on request.	Add another category of evidence – evidence from the sources listed by us in the proposed Schedule [3] (as set out later in these suggested amendments). Add a provision for Schedule [3] to be amended by the Authority or on request.
14 Authority may exempt natural health products from product notification The Authority may, by notice in the *Gazette*, exempt a natural health product or category of natural health product from the requirement to have a product notification under **section 13**.	We can see no policy reason for a blanket exemption clause. If this clause is to remain in the Bill, it should have defined parameters around the power of exemption.	Delete clause 14.
15 Authority may audit notifications	We support this clause in principal but believe its intent is unclear. That is, what appears to be an audit is intended to check whether the notification complies with the Act and regulation requirements rather than	Amend to clarify what "auditing" a product notification means. Is it intended for example, to extend to testing of the product to see if it

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(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.	whether the product complies, but we are unsure. The purpose of the audit should be clarified and therefore how the principles might apply to it. We note that if it is intended that audits include requiring information from people who have notified products, or testing of products, the Act contains no powers to support this.	contains the ingredients it says it does? If so, we would suggest that further powers are necessary – otherwise the power to audit the notification appears to be a simple tick box audit.
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	We support the inclusion of a “suspension and cancellation" of notification power but believe this clause needs substantial amendment. In our view, subcl (1) should provide only that the Authority “may” suspend the registration where “serious” harm to any person has been identified. While we agree that suspension may be the appropriate response in some of the situations listed it could be that it would be sufficient for the Authority to make a statement or recall the products to manage any risk to consumers (for example, by relabeling). For those reasons we say that suspension is unnecessary as a tool of first resort. Similarly, “harm” appears a very low threshold, especially when it may only be a hypothetical harm that might cause any harm sometime in the future. Does that include, for example, that the product made a person nauseous, or made them sleepy, or “might” trigger an allergic reaction? We believe the threshold should be “serious harm” as used in pharmacovigilance, or when adverse effects are unacceptable and unmanageable using best risk management options. Our major concern, apart from these matters, is the lack of a prescribed process and time restrictions on suspension in the Bill, which is a stark contrast to equivalent provisions in other Acts such as s30A of the Agricultural Compounds and Veterinary Medicines Act 1997 or for building products under the Building Act 2004. In our view such a process for suspensions and cancellations is imperative to the Act and the lack of process may mean the Act is inconsistent with the Bill of Rights Act and the LAC Guidelines. The Bill of Rights Act 1990 reaffirms the broad principle: "Every person has the right to the observance of the principles of natural justice by any tribunal or other public authority which has the power to make a determination in respect of that person's rights, obligations, or interests protected or recognised by law" (s 27(1)). The LAC Guidelines state that “The most significant powers are those that affect individuals. In general, the greater the potential for public powers to impact on individuals, the greater the protections there should be, in terms of the independence of the decision-maker, the procedure to be followed, the specificity of the criteria for the decision, and the rights of appeal and review available” (Ch 8). This is even more pertinent given that most businesses involved in the natural and traditional health product industry are individuals and family units. In general, the more serious the consequence of the decision for individual rights and interests then the more protection should be given the persons affected. This "protection" should take the form of: • the independence of the decision-maker…, • the procedure to be followed (rights to provide submissions, to be heard and to call witnesses rather than no express procedural protections at all), • the specificity of standards, criteria and rules for decision, and • rights of appeal and review. The main qualification to this is when a broader public interest prevails over an individual right or interest. The suspension or cancellation of a product notification could, in our submission, be a death knell for a business. In this regard we believe it requires strict process provisions around it, to meet the requirements of natural justice. The “broader public interest” we believe can be met by the power of the Authority to require a recall. Given it is not an offence under the Bill for a person other than “the sponsor” to sell a	Amend subcl (1) by • changing “must” to “may”; • adding “serious” before “harm”. Move this clause to be with clauses 43 and 44 as part of the “toolbox” of responses the Authority may make in relation to notified product. Add provisions setting out a process for suspensions that reflects natural justice requirements including – • the period for which notification may be suspended (we suggest up to 3 months is appropriate) • that notification of the suspension must include (a) the reason for the suspension; and (b) the period of the suspension; and (c) the date on which or time at which it commences (which may not be earlier than the date or time of notification); and (d) any conditions or requirements in relation to the suspension. • That if the Authority considers it necessary in the circumstances, and after having notified the product notifier of the proposed extension and the reasons for it, and having given the product notifier a reasonable opportunity to be heard, the period of suspension may be extended once for such further period not exceeding 3 months as the Authority notifies to the registrant in writing before the expiry of the original suspension. • Where notification is suspended under this section, the Authority may direct the product notifier to take action appropriate to deal with any affected product Add provisions setting out a process for cancellations that reflects natural justice requirements including – • the Authority may not cancel a product notification unless it has • notified the relevant product notifier of its intention to do so and • given the product notifier a reasonable opportunity to be heard; • where the Authority determines to cancel the product notification it must give written notice to the product notifier of the fact, give reasons, and specify the date on which the

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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.	product for which a notification has not been made (or we presume suspended), and subcl (6) does not contain a general prohibition on any person other than the sponsor from continuing to sell a suspended product, a recall would in any case be required to protect the public if a product were suspected of being harmful. There is no reason why, having initiated a recall, and quarantining any affected products, the Authority could not follow due process before suspending the product's product notification and/or cancelling it. We believe the current drafting of subcl (2) which appears to give the Authority a discretion to *reinstate* a product notification if satisfied of certain things, rather than providing that the suspension simply expires unless action is taken to cancel the notification is entirely inappropriate. We are slightly confused as to the intent of subclause (6) but it may be clearer once the Bill clarifies what is a "product" requiring individual notification. For example, if a product has been recalled and its notification suspended because the notification contained incomplete information, it may be entirely appropriate for a new notification to be made. We suggest that subclause (6)(b) be qualified by the words "without the approval of the Authority" so that in an appropriate circumstance, the Authority could approve a new product notification containing complete information. Finally, we also believe this clause should be cast as one of the toolbox of measures that the Authority can take if it is concerned about a product. The provisions in the "toolbox" should all appear together in the Act. They should also be subject to the requirement (hopefully by application of augmented principles in clause 4) that, the response of the Authority is risk proportionate.	revocation takes effect, which may not be earlier than the date of notification Subclause (6)(b) add "without the approval of the Authority" .
17 Sponsor must notify Authority of any serious adverse reactions to natural health product (1) The sponsor of a notified natural health product must notify the Authority as soon as the sponsor 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.	We support mandatory notification of serious adverse reactions by a sponsor (product notifier) but in our view the definition of "serious adverse reactions", is too broad and inconsistent with established best practice. In particular we consider the reference to "interruption of productive activity" to be far too broad in a definition of "serious adverse reactions". Does the fact that a person felt nauseous after taking a product and had to lie down thus interrupting their "productive activity" constitutes a "serious adverse reaction"? Serious adverse events are defined already by the World Health Organisation and utilized by the Ministry of Health as; "- events where the patient either died, required hospitalisation or prolonged existing hospitalisation, required intervention to prevent permanent disability/incapacity, resulted in a congenital abnormality, or where the event was life-threatening.6 We think this definition is preferable to the ambiguously worded definition in subcl (2).	Subcl (2) should be amended to mimic the Ministry of Health's definition, namely serious adverse event - events where the patient either died, required hospitalisation or prolonged existing hospitalisation, required intervention to prevent permanent disability/incapacity, resulted in a congenital abnormality, or where the event was life-threatening.
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 must— (a) withdraw the product notification for the product; and (b) complete a new product notification for the product that more accurately reflects the change. (2) The sponsor may change the sponsor's contact details on a product notification without the need	We support a provision that clarifies when a separate product notification is required as, as noted earlier, we think the current drafting is unclear. However, while this clause sheds some light, in doing so in our view suggests that the approach is too narrow. For example, a "change in the product's manufacturing arrangements" as referred to in subcl (1) may be as little as the products used to be produced on one production line within the manufacturer's facility and now they are produced on another. Or perhaps they were in white capsules and now they are clear. Given that the only requirement for the sponsor (product notifier) is that the product notification specifies the manufacturer (and we note there may be several for one product), we think at the least this reference should be refined to refer to "the product's manufacturers. Different manufacturers could be identified through tracing their respective batch numbers. However, as also noted earlier, we think that a separate product notification should not be required if all that has happened is that a new manufacturer is being used. All manufacturers will by definition be code compliant, and while we support a requirement for updating details of manufacture or health benefit claims (in the same manner as updating of the sponsor (product notifier)'s contact details is required in subcl (2)) we can see no rationale for a separate product notification to be required (and presumably a separate fee	Amend subcl (1) to make it clear that a change in manufacturer or health benefit claims requires amendment to the product notification, but not a new notification. In subcl (1)(b) amend "more accurately reflects the change" to "contains the updated information".

6 **Complementary Medicine Corner: Reporting adverse reactions,** *http://www.medsafe.govt.nz/profs/puarticles/complementary medicine corner - reporting adverse reactions-nov09.htm*

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for a new product notification.	at considerable compliance cost). On a more minor note, we find the wording in subcl (1)(b) odd – should it not refer to a new product notification containing "amended" or "up to date" information, rather than "more accurately reflects the change" (to which the question must be asked "more accurately than what?) It would also be helpful if the provision stated how a product notification withdrawal could be made (eg. in the prescribed manner.)	
19 Sponsor may cancel product notification A sponsor of a notified natural health product may cancel the product notification of the product if the product is no longer sold or supplied.	We support this clause, however, it again raises the issue of whether there can be more than one sponsor (product notifier) for the same product ie. this provides that "a" sponsor of a product may cancel *the* product notification of "the product if the product is no longer sold or supplied." Under cl 13(1) of the Bill, a product may not be "distributed" unless a product notification has been completed. It is unclear whether "sold or supplied" is the same as "distributed"; or whether a sponsor (product notifier) needs to be satisfied that no other sponsor (product notifier) is selling the product (eg. there may be someone who has stocks somewhere) before the registration can be cancelled. We suggest that the wording be aligned so that the obligation is for the person who notified the product to cancel the notification if the distributor no longer wishes to sell or supply the product. Obviously at this point there may still be stock on the shelves in retail outlets, but the regulator will still have the records of the notification in case enforcement action against the distributor is required.	Amend "A sponsor" to "The product notifier" Amend "product is no longer sold or supplied" to "product notifier no longer sells or supplies the product".
Ingredients of natural health products		
20 Authority may declare substances to be natural health product 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** to be a natural health product ingredient. (2) The Authority may impose restrictions on the use of any substance it has declared to be a natural health product ingredient.	We are comfortable with the process of having a list of "allowed" natural health product ingredients so long as that list is simple to amend. However, we believe that the Bill has several issues that require fixing in this regard. Firstly, as noted earlier, natural and traditional health products contain a variety of ingredients that could be categorized as "natural ingredients", "nature identical ingredients" "traditional ingredients" (the latter being an ingredient used in a traditional remedy whether it is a natural or nature identical ingredient or not), and excipients. We are concerned that the classes of substance in the Schedule do not cover some of these ingredients. We return to that in our submission on the Schedule below. Secondly, we are concerned that there is no process for automatic inclusion of ingredients as "natural health product ingredients" that are already available on the market in New Zealand. We return to this in relation to subclause (3) below. We support the ability to impose restrictions on the use of ingredients, provided it is clear through the principles in clause 4, that such restrictions must be risk proportionate.	Add a provision clarifying that "to avoid doubt, an ingredient may be listed on the natural and traditional health product database despite the fact that it is a pharmaceutical medicine classified under the Medicines Act, including a prescription or pharmacy only medicine.
(3) In considering whether a substance should be declared a natural health product 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:	We agree that the Authority should consider safety when it determines whether to prohibit a natural and traditional health product ingredient from being an allowed natural health product ingredient, but we think paragraph (a) is too blunt a tool. That is "if it raises a concern" gives no help to the Authority as to what that concern might be. In our view, the standard for a safety assessment should be if the Authority has reason to be concerned about the safety of the substance and as noted above "safety" should be defined. More specifically, we note that while paragraph (b) provides that the regulator must "have regard to" overseas jurisdictions, it does not go so far as to require the regulator to include in the ingredients database ingredients currently permitted by trusted overseas regulators. This is contrary to the indications	Add a new provision requiring the Authority to declare the following ingredients to be natural and traditional health product ingredients immediately following the date of commencement – • all ingredients specified in the sources in Schedule [3]; and • all ingredients in any product that meets the description in section 46(1). Amend subcl (1)(a) or provide that the Authority "may, "if the

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(i) whether a recognised authority permits the use of the substance in a natural health 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.	we had had from the Ministry, and we note is also contrary to Sue Kedgley's statement in her speech on the first reading, 'that "ingredients used in countries with recognized regulatory schemes will be automatically recognized." We wonder therefore whether the lack of a provision relating to unilateral recognition of decisions made by trusted overseas regulators in relation to approved manufacturers and the ingredients that would be permitted in natural health products from commencement of the Bill is a mistake. In this regard, while we acknowledge and support the grandfathering clause in clause 46, we do not think that goes far enough as it relates only to products and not ingredients. Also, if a "product" is as narrow as being defined by reference to its manufacturer, a sponsor (product notifier) who uses that provision to notify a product containing ingredients that are not subsequently declared to be NHP ingredients could lose that ability to notify simply by changing manufacturer. We therefore believe that it is necessary to give certainty to industry that the regulator be required to declare the ingredients in such products to be NHP ingredients under this clause. In our submission the Bill should require via this route automatic inclusion of all natural and traditional health product ingredients specified in sources such as in the British Pharmacopoeia, Australian "substances that may be used in listed medicines in Australia" etc as included in a new schedule 3) and any ingredients used in a dietary supplement at the commencement date. In other circumstances we consider paragraph (b) to be appropriate.	Authority has reason to be concerned about the safety of the substance, conduct a safety assessment of the product". A new Schedule [3] should be inserted with the following entries – Natural and traditional health ingredients marketed in New Zealand in the three year period prior to the commencement of this Act. Australia New Zealand Food Standards British Homeopathic Pharmacopoeia British Pharmacopoeia; British Herbal Pharmacopoeia and associated Compendium; Canada Health Department NHP database; Codex Alimentarius food standards EU Traditional Herbal Medicine Directive; EU Food Supplements Directive European Pharmacopoeia; European Scientific Cooperative on Phytomedicines (ESCOP); German Commission E Monographs; German Homoeopathic Pharmacopoeia Indian Herbal Pharmacopoeia; Nga Ringa Whakahaere o Te Iwi Maori Incorporated Society; Pharmacopoeia of the People's Republic of China: including traditional Chinese medicines; TGA: Substances That May Be Used in Listed Medicines in Australia The Homœopathic Pharmacopœia of the United States (HPUS) **The Ayurvedic Pharmacopoeia Of India** United States Pharmacopoeia (USP): USP Verified Dietary Supplements; • World Health Organization: Monographs on Selected Medicinal Plants
(4) Every substance declared to be a natural health product 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	We support this provision.	

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declaration is published.		
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 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 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.	We support the policy of having a prohibited list of ingredients as a part of the risk management tool-kit, but as submitted [in relation to clause 22(1)] believe that there should be a process in the Bill for ingredients that have been declared to be prohibited to have that restriction reviewed. We suggest that this be built into clause 22. We are concerned to ensure that decisions taken under this provision are risk proportionate and that the regulator should also be required to consider other risk management options (such as labelling or restrictions on use) before prohibiting a product. . The provision should also require the regulator to balance the health benefits associated with the use of the ingredient against any risk associated with its use before prohibiting its use.	Amend subcl (2) to require the Authority to consider, • as well as the risks of any harm arising from the use of the substance, the health benefits associated with its use; • whether any risks associated with the use of the substance could be adequately met by imposing restrictions on its use.
22 If new ingredient intended for use in natural health product (1) In this section and **section 23**, **new ingredient** means any substance that belongs to a class of substance listed in the **Schedule** and that is not— (a) a natural health product ingredient; or (b) a prohibited ingredient.	We support the inclusion of a provision permitting notification of new ingredients, including ingredients that are prohibited ingredients but which a person wishes to include in a NHP in light of new evidence. However, clause 22 needs amendment to be workable and achieve this policy goal. *Cl 22(1)* We submit that, in a provision that enables the Authority to seek information from the notifier and undertake a safety assessment, there is no policy rationale for subcl (1)(b). A person should be able to notify an ingredient as a "new ingredient" where it is currently a prohibited ingredient. We imagine this might happen where, for example, an ingredient has been declared to be a prohibited ingredient for historical reasons, but a notifier can show that in a particular dose, with specific manufacturing conditions, or with particular restrictions, it is safe and suitable for use in a NHP. This is the process we support being used if, for example, pharmacy-only or prescription medicines are declared to be prohibited ingredients, and a person wishes to include one of these ingredients in a NHP. In our view subcl (1)(b) should be deleted.	Amend by deleting subcl (1)(b) so that a prohibited ingredient can be notified as a "new ingredient" Add a new provision clarifying that a prohibited ingredient may be notified as a new ingredient.

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	We suggest that (similar to the Resource Management (Discount on Administrative Charges) Regulations 2010) this clause should include a provision for a refund of any fee if the Authority does not complete a safety assessment within the required timeframe.	
(2) If a manufacturer or distributor intends to use a new ingredient in a natural health product that is intended for distribution in New Zealand,— (a) the manufacturer or distributor must notify the Authority in the prescribed manner and no later than 90 working days before the sponsor intends to complete a product notification for the product; and (b) if, within the 90 working days, 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; and (ii) the sponsor may, after receiving notice from the Authority under this paragraph, complete a product notification for the product; and (c) if, within the 90 working days, the Authority raises a concern and commences a safety assessment, the product must not be notified under **section 13**, sold, or distributed until or unless the Authority determines that the new ingredient may be used in the product.	This clause requires 90 working days prior notification if a manufacturer or distributor intends to use a new ingredient in a NHP intended for distribution in New Zealand. Unless the Authority raises a concern and commences a safety assessment within the 90 days, the new ingredient may be used in the product. While we generally support this disallowance process, we have several concerns about this provision, namely - (a) it is unclear how a person who intends producing a NHP for export only would go about getting a new ingredient onto the list, given the provision is limited to products that are "intended for distribution in New Zealand". We submit that the words "or for which the manufacturer or distributor intends to seek an export certificate". Otherwise we think that people will simply state an intention to distribute it here, whether or not they ever do so; (b) cl 22(2)(b)(ii) states that if the Authority does not raise a concern or commence a safety assessment within 90 working days the new ingredient may be used in the product and the sponsor may "after receiving notice from the Authority under this paragraph" complete a notification for the product. Thus while it might be sufficient to rely on lack of notification of a concern by the Authority to start manufacturing a product, it appears it cannot be notified on the database for distribution unless the Authority has given notice that it has no concerns. The drafting should be amended to clarify no "approval" is necessary. This is a "notification" provision; (c) the time periods specified in the clause are too long. It should be possible for the Authority to conduct a safety assessment within 30 working days. (d) cl 22(2)(b) refers to the Authority raising a concern OR commencing a safety assessment. Cl 22(2)(c) refers to the Authority raising a concern AND commencing a safety assessment within the same time frame. We think cl 22(2)(b) should also refer to both. (e) we note that this process contains three steps; (i) does the substance notified comply with the definition of a natural and traditional health product ingredient? if not, then the Authority should notify the applicant as soon as practicable. (ii) does the Authority intend to undertake a safety assessment? If not then the Authority should notify the applicant as soon as practicable. (iii) undertake the safety assessment and notify the applicant of the result as soon as practicable.	Amend subcl (2) • by adding a reference to export certification • to make it clear that it is a "notification" provision • to refer to 30 working days, not 90. Subcl(2) might look something like the following: "If a manufacturer or distributor intends to use a new ingredient in a natural and traditional health product that is intended for distribution in New Zealand or for which the manufacturer or distributor intends to seek an export certificate"– (a) the manufacturer or distributor must notify the Authority in the prescribed manner no later than 30 working days before a product notification is intended to be made for the product; (b) if, within the 30 working days, the Authority does not notify the manufacturer or distributor that it [has grounds for concern about the safety of the ingredient and has commenced a safety assessment – (i) the new ingredient may be used in the product; and (ii) a product notification may be completed for the product; (c) if, within the 30 working days, the Authority notifies the manufacturer or distributor that it has grounds for concern about the safety of the ingredient and has commenced a safety assessment , the product may not be notified under section 13, 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)**.	We support this subclause but think it requires expansion to reflect the fact this is a distributor rather than Authority initiated process and that the initial decision is actually whether to commence a safety assessment. A positive decision on whether to allow use of the ingredient will only be needed if the Authority does undertake a safety assessment. In making its decision in that situation we think the Authority should look at the cl 21(2) criteria rather than the lighter criteria in cl 20(3) which were pertinent when it decided whether to undertake the safety assessment.	Amend to provide that • when determining whether there are grounds for a concern and whether or not to commence a safety assessment the Authority must have regard to the matters in section 20(3)(b)(i) to (iii); but • when determining whether the ingredient may be used in a product following a safety assessment, the Authority must have regard to the criteria in section 21(2).

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(4) If the Authority determines that the new ingredient may be used in the natural health product, the Authority must, as soon as practicable,— (a) declare the new ingredient to be a natural health product 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)**.	We support this subclause however to reflect the fact that ingredients may be used simply if the Authority does not decide to undertake a safety assessment within 30 days it should refer also to this scenario.	Add “does not have grounds for concern and does not commencement a safety assessment within 30 working days or” before “determines”..
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.	This provision requires the Authority to decide and notify the applicant “as soon as practicable” if a safety assessment of a new ingredient will be undertaken. If so, the Authority has 30 working days to notify the *applicant* of the outcome of the assessment or if further time is needed to complete the assessment. We are concerned that there is no standard for a safety assessment to be undertaken in this clause (although clause 22 refers to “a concern” which we think is too low a threshold. The word “applicant” is inconsistent with the “notification” of the ingredient in cl 22. Similarly subclause (2) provides the Authority may request *further evidence* of the safety of the new ingredient from the applicant. However, cl 22 did not explicitly require evidence of the safety to be provided with the notification or held by the notifier. It is noted that there is no provision for the Authority to approve the new ingredient with restrictions. It appears to be an all or nothing process. We do not accept that the time period for a safety assessment should be able to be extended beyond 30 working days. We submit that clause 23(1) should be amended to – • set out the grounds on which the Authority may initiate a safety assessment, namely “if the Authority has reason to be concerned about the safety of the substance. (The same standard we submit should be included in clause 20(3)); and • delete clause 23(1)(b)(ii). Subclause (2) should be amended to • require the Authority in conducting the assessment to • consider any evidence provided by the applicant in support of the notification; • permit the Authority to seek further evidence of safety from the manufacturer or distributor or other sources.	Amend by - • adding a new para (aa) before subcl (1)(a) to read “the Authority may, if the Authority has grounds to be concerned as to the safety of the product, undertake a safety assessment; • para (a) by deleting “applicant” and substituting “manufacturer or distributor”; and • deleting cl 23(1)(b)(ii). Amend subcl (2) so that it • requires the Authority in conducting the assessment to • consider any evidence provided by the manufacturer or distributor in support of the notification; • consider the matters in cl 21(2) (ie. the criteria for prohibition; and • permits the Authority to seek further evidence of safety from the manufacturer or distributor or other sources.

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Labelling		
24 Labelling A natural health product that is distributed in New Zealand must comply with the labelling requirements prescribed in regulations.	We support this clause but think that the Bill needs to provide more guidance for labelling than is found in this clause and the associated regulation making power. We are disappointed that no recognition has been given to the Joint Industry Proposal regarding labelling. A definition of "label" is necessary to clarify that it relates to more than just the label on the product itself. (The definition in s7 of the Food Bill is we believe appropriate for this purpose). We believe the Act should contain matters that the regulator is required to have regard to when exercising the labelling regulation making power. These should be based on clause 346(5) of the Food Bill and should state that each product needs to be labelled sufficiently so that individual batches can be identified for recall purposes. We submit that any regulating making powers should ensure that labelling requirements do not create technical barriers to trade. For example, whilst we agree that individual products should be identified with specific information enabling efficient recall in emergencies, enable informed choice by consumers. Unique labelling requirements may include information normally present on packaging such as brand and product names, bar-codes, batch numbers of combinations thereof, and must not require a mandatory NZ identification number.	Insert definition of "label" similar to clause 7 of the Food Bill, which reads: **label** includes any written, pictorial, or other descriptive matter that— (a) relates to any food or any package containing food; and (b) appears on, is attached to, or is associated with that food or package Insert a provision requiring the following matters to be had regard to when labelling regulations are made: [(a) the need to protect public health]; and [aa] the desirability that each product is labelled sufficiently so that individual batches can be identified for recall purposes; and (b) the desirability of avoiding unnecessary restrictions on trade; and (c) the desirability of maintaining consistency between the regulations and any relevant standards, requirements, or recommended practices that apply or are accepted internationally; and (d) the need to give effect to New Zealand's obligations under a relevant international agreement, convention, protocol, or treaty; and (e) any other matters that the Minister considers relevant.
Exports		
25 Export certificate (1) A sponsor may, subject to **section 26**, apply to the Authority for an export certificate for a natural health product. (2) Any application under this section must be accompanied by the prescribed fee (if any) and the sponsor 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 product if the sponsor 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. (5) The Authority may determine the form and content	We support the Bill providing for export certification but are concerned that the effect of the current drafting is that subclauses (1), (3) and (4) effectively limit the ability to get an export certificate to the manufacturer of a product (ie. a sponsor can be an importer, manufacturer or person who arranges import or manufacture but in subcl (4) "the sponsor" must also hold a licence to manufacture". Thus a person who arranges the manufacture but does not manufacture itself (eg. an exporter) could not get an export certificate for a product). This would stop many of those persons who currently export NHPs from getting an export certificate and should be amended. We can see no policy rationale for restricting export certificates for those products manufactured in New Zealand to those who hold a manufacturing licence, when it appears that an export certificate can be applied for imported products by a person who arranged the import. In short, a product for which a product notification has been completed has by definition met the manufacturing standards in the Act and a sponsor (product notifier) should be able to seek an export certificate for it. In our view subcl (4) should be deleted and it could be usefully explained in subclauses (3) or (4) that the person who applies for the export certificate must be the product notifier. In subclause (6) – it would be preferable to precede these words with a statement as to what the certificate "does" do, not just what it doesn't do (as in sections 61 and 83 of the Animal Products Act).	Amend subcl (3) to provide that "the Authority may grant an export certificate for a natural and traditional health product to any person who has completed a product notification for that product." Delete subcl 4. Amend subcl (6) so that it states what the certificate "does" do, not just what it doesn't do (as in sections 61 and 83 of the Animal Products Act).

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of the export certificate. (6) An export certificate is not a guarantee that the natural health product— (a) necessarily meets the commercial requirements of the consumer; or (b) necessarily meets the specific requirements of overseas markets.		
26 Natural health products that are animal products Despite **section 25**, if a natural health product is also an animal product within the meaning of the Animal Products Act 1999, any application for an export certificate or a similar statement for that product must be made in accordance with that Act instead of this Act.	We are comfortable that NHPs that are animal products require an export certificate under the Animal Products Act, but find the interface between this clause and clause 25 unclear. For example, it is unclear whether a product for which an export certificate is sought under the APA would need to have been notified under s13. Under the current drafting it appears it would not. Nor would s25(4) apply in the section 26 situation. However, quite apart from the drafting issue, we question why an export certificate should be sought under the APA *instead of* under the NHP Act. Clearly an APA certificate would not cover the matters in the NHP Act, including the packaging of the product in accordance with the code. These are matters which foreign importers and governments will want comfort on. In our view clause 26 should provide that if an NHP is also an animal product, an application for an export certificate must be made in accordance with that Act*, as well as*, under section 25 with appropriate recognition of common criteria.	Amend clause 26 to provide that if an NHP is also an animal product, an application for an export certificate must be made in accordance with that Act*, as well as*, under section 25.
Code of practice for manufacture of natural health products		
27 Code of practice for manufacture of natural health products (1) The Authority must establish a code of practice for the manufacture of natural health products. (2) In developing the code and any amendments to the code, the Authority must— (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. (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.	*Cl 27(1) and (2)* The code should be required to comply with the principles of the Act (particularly in relation to containing requirements for manufacture that are risk proportionate). However our main comment in relation to the code, is that the consultation document on the Bill and other material provided by the Ministry has consistently stated that manufacturers will be able to comply with, for example, the Animal Products Act, Food Act or Medicines Act in relation to processing of their products rather than the NHP manufacturing code and this does not appear to be reflected in the Bill.[7] We support that policy, which will limit compliance costs and ensure manufacturers are not necessarily required to comply with two regulatory regimes. However, note also, that while equivalent compliance may be suitable for some parts of the manufacturing process (eg. the processes up to encapsulation) it may not be suitable for the latter stages. For this reason we believe that the code needs to be flexible to allow equivalent compliance under other New Zealand regimes for certain parts of the manufacturing process, while requiring strict compliance with the code for other purposes. To ensure certainty for those who currently comply with the APA or Food Act regimes, we would like to see explicit mention of those regimes in the Bill. We suggest that section 27 should be amended to provide explicitly that the code may cross reference to risk management programmes under the APA or food safety programmes under the Food Act 1981 (or risk management plans under the Food Bill) and provide that for certain purposes those programmes may be deemed to be part of the code. *Cl 27(3)*	Add references to the possibility of the code cross referencing to provisions of the APA, Food Act or Medicines Act, or regulations or risk management programmes/food safety programmes under those Acts. Subcl (2) – add (aa) “have regard to the principles of the Act” Subcl (3) – align wording with cl 22. Add matters which have to be had regard to in relation to the making of the code akin to those listed above in relation to clause 24.

[7] On this point, we note recognised authorities are restricted to those who regulate NHPs, and do not extend to bodies who regulate other products so s33 cannot be intended for this purpose

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	Unlike the "ingredient declaration" provisions this clause does not require the code to be published on the Authority's internet site but rather on "an Internet site that is publicly available at all reasonable times". It is unclear why this site is different from the other provisions. We suggest the provisions for publication should be aligned to provide a one-stop-regulatory-shop. Finally, we believe that, in developing the code, it is also appropriate that the regulator be required to consider international best practice and what is accepted in other jurisdictions for export purposes. This could be achieved by adding principles such as those we suggested in relation to labelling in clause 24 and acknowledging the fact that, as the MOH has acknowledged, the vast majority of product is already manufactured under equivalent GMP codes from a variety of national jurisdictions.	
Manufacture of natural health products		
28 Licence to manufacture natural health products (1) A person must not manufacture a natural health product without a licence to manufacture granted under **section 29**. (2) The following persons are exempt from **subsection (1)**: (a) any exporter of a natural health product who is not also seeking an export certificate for the product; and (b) any health practitioner who makes a natural health 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.	We generally support this clause, but note that it may – • inadvertently capture those who prepare a product that is technically a NHP for own use, or for a non-commercial use such as research; and • not clearly capture those who do jobs associated with "manufacture" eg. pack and label the products. These matters should be clarified in the drafting, we suggest by adding a reference to distribution to the public in subcl (1).. Also, as noted above, the use in cl 28(2)(b) of the words "health practitioner" may be read as referring to a registered health practitioner under the Health Practitioners Competence Assurance Act. It is assumed this is not the policy intent but it should be clarified. As noted, we believe a definition of "manufacture" is necessary in the Act to ensure that all persons involved in the manufacturing process are licensed and comply with the code.	Add the words "that is intended for distribution for retail purposes" before "without a licence" Add a definition of "manufacture" and "practitioner" to the Bill per our comments on clause 5. Amend subcl (2)(b) by deleting the word "health" in the phrase "health practitioner"; and
29 Application for licence to manufacture (1) An application for a licence to manufacture natural health products must be made to the Authority in the prescribed manner. (2) The Authority may grant a person a licence to manufacture natural health products if— (a) the Authority has conducted an audit of the manufacturing facilities and is satisfied that the 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 products, the Authority must take into account the following: (a) any conviction of the person or any director or manager of the person for—	We support the licensing of manufacturers under the Bill, but believe amendment is necessary for this provision to work in the manner we believe is optimal. Firstly, despite indications in previous documents published by the Ministry, the provision does not allow persons to be licensed in New Zealand based on compliance with alternative New Zealand regimes or equivalent overseas regimes. In our view it should be sufficient to meet licensing requirements if a person complies with equivalent or superior manufacturing standards under another Act rather than an audit of premises necessarily being required against the code (for example, it should be enough that the premises comply with requirements of. the Animal Products Act, Food Act, or Medicines Act or a foreign regime administered by a recognised authority. (This latter policy may in fact be the intent of clause 33, but if so we believe it is insufficiently clear under the current drafting),. This policy would ensure the safety of products while limiting the amount of compliance costs for manufacturers. To ensure it is workable under the Act we believe the following amendments are necessary - • amend the code provisions so that the code can cross reference to other regimes as outlined in relation to cl 27 above; • amend this clause so that licences can be granted to those operating under other regimes without an unnecessary audit being carried out;	Amend subcl (2)(a) to refer to compliance with other regimes Delete subcl (2)(b) and (3). The new subcl (2) might look something like* – (2) The Authority may grant a person a licence to manufacture natural and traditional health products if the Authority has either - (a) conducted an audit of the manufacturing facilities and is satisfied that the facilities meet the requirements of the code; or (b) is satisfied that the person is – (i) an operator of a risk management programme that is registered under the Animal Products Act 1999 and the natural and traditional health products that will be manufactured by the person under the licence will be manufactured in accordance with that programme as provided for in the code; or (ii) an [operator] of a food safety programme that is

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(i) any offence involving or relating to the manufacture of any product for human consumption; or (ii) any offence specified in the regulations: (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: (d) any other matters that the Authority considers relevant. (4) A licence to manufacture remains in force for 3 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.	Secondly, in our view there is no need for a fit and proper person test. The fit and proper test provision is a carry over from the Australian regime which introduced it after the Pan Pharmaceuticals debacle where Australian officials committed malfeasance resulting in the Australian government paying out over $100 million in settlements. We are not aware of a fit and proper test applying to natural health product manufacturers elsewhere. So long as a manufacturer complies with the code (which will be audited) there should be no safety concerns, and therefore no need for separate vetting of those involved at a management level in the business. On this point, we note that the Food Act (and the Food Bill) does not require those operating food safety programmes to be "fit and proper". Quite apart from thinking the step is unnecessary; we are concerned that it may set the bar too high for the recognition of foreign authorities for the purposes of section 33. That is, we are unsure what, if any, foreign jurisdictions have "fit and proper person" tests as part of their licensing or regulatory regimes. We are also concerned that if they do not, these jurisdictions may not be able to be recognized as authorities administering a system that is equivalent to or more robust than the system administered under the Act. For this reason, if nothing else, the fit and proper person test should be removed from this clause. We believe that provision should also be made for a licence to be longer than 3 years where long term compliance is established.	registered under the Food Act 1981 and the natural and traditional health products that will be manufactured in accordance with that programme as provided for in the code; or (iii) operates in compliance with a pharmaceutical code of good manufacturing practice; or (iv) is the holder of a licence or other document granted by a recognised agency; and Add to subcl(4) 'or longer' [period]
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 conditions on the licence as the Authority thinks fit.	We generally support subclause (1) but think it is too blunt a tool to cover those who, for example, gain licences based on compliance with risk management programmes under the APA. Either subclause (1) needs to be amended so that it provides that it is a condition that the licence holder at all times complies with either a) the code; or b) if the manufacturer has been granted a licence based on holding a licence or other document granted by a recognized agency, that the person operates in accordance with that licence or other document in relation to any specified matters, and complies with the code in all other respects…. We support subclause (2), but submit that to prevent unreasonableness, subcl (2) should be subject to a "reasonableness" standard. We are unsure whether the conditions might be used to require manufacturers to give access to premises etc, but would suggest that these powers should be provided for separately in the Bill?	Subcl (1) amend to provide that it is a condition that the licence holder at all times complies with either a) the code; or b) if the manufacturer has been granted a licence based on compliance with a risk management programme under the APA/ licence being granted by a recognized agency, that the person operates in accordance with that programme/licence in relation to any specified matters, and complies with the code in all other respects…. In subcl (2) add the word "reasonable" before "conditions"
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. (2) The audit may be conducted in any manner that the Authority considers appropriate and consistent with the principles of this Act.	We agree that an audit power is appropriate but would suggest that such audits should be either – • regular (eg. every 3 years or longer) to ensure compliance for relicensing purposes; or • based on a legitimate concern of the regulator about compliance. The first will tie in with cl 29(4) and ensure the robustness of the regulatory regime and the second will stop arbitrary use of the power, which is especially important if the costs of audits are to be recovered from manufacturers. In regard to subcl (2), if the purpose of the audit is to audit compliance with the code, it is hard to see what a manner consistent with the principles of the Act could mean in practice. If it is meant that the manner of the audit would be determined on a risk-proportionate basis –ie low risk means minimal audit, we would support that. People who have gained licences based on APA compliance, or a licence issued by a recognized authority should not be subject to additional audits under the Act. It should be sufficient that their licence is conditional on continued compliance with those regimes, and that this can be vetted every 3 years when	Amend cl 31(1) to provide for audits to be conducted – • regularly (eg. every 3 years or longer) for licensing purposes (where the person has been granted a licence based on a previous audit under this Act; or • if the Authority has reasonable grounds for concern as to whether the licensee is complying with the conditions of their licence. Clarify what is meant by "consistent with the principles of this Act"

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	they seek a replacement licence.	
32 Authority may issue compliance notice The Authority may issue a compliance notice to any person whose manufacturing facilities have 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 licence to manufacture.	We support this provision, but consider it to be part of the toolbox of responses that the regulator can make when concerns arise about compliance. As such it should sit with cl 34. We would also support a requirement that any non-compliance issues that arise during an audit need to be managed in a risk proportionate manner.	Move clause to be before cl 34. Insert a clause requiring non-compliance issues that arise during an audit need to be managed in a risk proportionate manner.
33 Deemed compliance with code A manufacturing facility in which natural health products are manufactured under a licence granted by a recognised authority is deemed to be compliant with the code.	We support recognition of appropriate overseas manufacturers as being equivalent to those operating in accordance with licences under the Bill. However we are rather confused as to what this provision is intended to cover. That is, at first glance this provision appears to suggest that a manufacturer in New Zealand could comply with an international risk management framework, including as to audit requirements and meet the requirements of clauses 28 to 32 that way – a policy which we support. However, on further consideration the intent of this provision is less clear. It provides that a manufacturing facility in which NHPs manufactured under a licence granted by a recognised authority is deemed to be compliant with the code. What is unclear is whether this means- (a) A New Zealand manufacturing facility could be granted a licence by a foreign recognised authority and not require a licence under the NHP Act; or (b) a foreign manufacturing facility in which a NHP is manufactured under a licence granted by a recognised authority is deemed to be compliant with the code. We support both these scenarios and suggest that – • if the provision is clarified, our suggested cl 22(2)(b(iv) may be unnecessary (ie. its intent is merely to ensure those operating in New Zealand in accordance with, say, the Australian regulations are not required to also comply with the NZ code. • The reference to a “licence” granted by a recognized authority be expanded so that it does not limit the jurisdictions that can be “recognized” by the Authority to those with a full “licensing” regime (ie. there may be some jurisdictions who do not have a “licensing” regime per se but do have a regime for overseeing manufacturing practice that is otherwise deemed to be equivalent to the New Zealand licensing regime. As noted in relation to cl 13, it also needs to be clearer how cl 33 it is intended to tie in to cl 13(5).	Amend to ensure that – • unless they are able to be licensed under cl 29, NZ facilities that comply with recognised international risk management frameworks automatically comply with NZ law. • The reference to a “licence” granted by a recognised authority does not restrict the jurisdictions that can be “recognised” by the Authority (eg. by inserting a reference to “other documents granted by a recognised authority”) • It is clearer how cl 33 it is intended to tie in to cl 13(5).
34 Authority may revoke or suspend licence or certificate for non-compliance with code (1) The Authority may revoke or suspend a licence to manufacture if 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 it is satisfied that the holder of the certificate has failed to maintain compliance with the code.	We accept that it is appropriate that the Authority has the power to revoke or suspend licences or export certificates for serious non-compliance with the code or conditions of licence. However as drafted this provision gives no guidance to the regulator as to the appropriateness of suspension and revocation decisions, nor meets the requirements of natural justice in relation to serious processes that will affect the rights and livelihood of manufacturers. As with the product notification provision we submit that further provisions need to be inserted in the Act to provide safeguards in relation of the use of those powers and to ensure the Bill meets the Bill of Rights Act and LAC Guidelines. These provisions should be similar to those in the Animal Products Act when operations under a risk management programme are suspended. They should also reflect the fact that suspending or cancelling a manufacturing licence is not a matter of public health, as products produced by the manufacturer can be dealt with by recall, and by suspension or cancellation of product notifications,	Amend provision to provide for suspensions that - • Suspension is possible for a period of up to 3 months if the holder of the licence/export certificate has repeatedly failed to maintain compliance with the code or any condition of the licence or export certificate, following (in the case of a licence, the issuing of a compliance notice) or where the non-compliance identified has led to serious safety concerns that can not be managed by product recalls or compliance notices; • The Authority must give the manufacturer a reasonable

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	and that given the generic nature and competitiveness of the natural and traditional health product industry, any suspension or revocation of a manufacturing licence would almost certainly be the death knell of the company. We would expect in most cases that manufacturers would be issued with compliance notices before suspension was discussed.	opportunity to comment before suspending the licence or certificate • Where the Authority suspends a licence or certificate it must give written notice of that fact to the manufacturer, or certificate holder specifying— (a) the reason for the suspension; and (b) the period of the suspension; and (c) the date on which or time at which it commences (which may not be earlier than the date or time of notification); and (d) any conditions or requirements in relation to the suspension. • If the Authority considers it necessary in the circumstances, and after having notified the manufacturer of the proposed extension and the reasons for it and having given the manufacturer a reasonable opportunity to be heard, the period of suspension may be extended for such further period not exceeding 3 months as the Authority notifies to the manufacturer in writing before the expiry of the original suspension. • Where a licence or export certificate is suspended under this section, the Authority may direct the manufacturer or export certificate holder to take appropriate action to deal with any natural and traditional health products [held by the manufacturer or export certificate holder Amend provision to provide for revocations that - • The Authority may at any time revoke a licence or export certificate if the Authority is satisfied that— • the Authority would be justified under [the previous provision] in suspending the licence or certificate but, in light of repeated suspensions of the licence or certificate in the past under that section, it would be more appropriate to revoke the licence or certificate; or • there is or has been such a serious failure to comply with the code as to cast doubt on the fitness for intended purpose of the product produced under the licence or to be exported under the certificate. • The Authority may not revoke a licence or export certificate under this section unless it has first— • notified the manufacturer/certificate holder (whether orally or in writing) of the intention to revoke and the reason for revocation; and • given the manufacturer or certificate holder a reasonable opportunity to be heard. • Where the Authority determines to revoke a licence or certificate, the Authority must give written notice of that fact to the manufacturer or certificate holder, giving reasons and specifying the date on which the revocation takes effect (which may not be earlier than the date of notification); and • Where a licence or certificate is revoked under this section, the Authority may direct the manufacturer or certificate holder to take action appropriate to deal with any affected natural and traditional health products

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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. (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.	We do not support this clause, which provides for fees to be prescribed by the Authority in the *Gazette*. This model is very unusual in legislation as fees under most Acts are set by regulation thus requiring Cabinet approval and being automatically subject to scrutiny by the Regulations Review Committee. In our view cl 35 as drafted is entirely inappropriate for the collection of fees under the Act. Quite apart from our major concern that it gives an arbitrary power to the executive that will not be subject to Parliamentary oversight, it also ignores the consistent submissions of industry for many years that any funding from industry should provide for the large diversity in the industry with individual businesses marketing anything from one product to over 1,000 products. A simple product fee means of funding is crude and would not be proportionate to risk as a company with a very high market share, but few products, would pay much less than a business with a vast number of products with small market exposure. We contend that risk to the public is a balance between the number of products and market share. A large company with few products but high market share would in fact be posing a greater risk to society as they would be exposing a large number of customers to their products. It is noted that in the MOH summary of submissions, large companies favored a product fee means of funding and small companies argued that a product fee system would severely impact on their viability and supported a turnover/levy basis of funding. This does not surprise us; large companies can absorb extra costs and will benefit from increased market share as small companies exit the market. The funding mechanism was one of the very few issues that the joint industry proposal could not agree on for this very reason. The RIS noted that if the MOH costings and estimates of the number of products in the market were correct then the funding mechanism was not viable. We are concerned that despite 20 years of consultation, the MOH appears to have ignored industry submissions regarding the demographics of the industry and information obtained through MOH costings workshops attended by industry representatives as recently as early 2011. We submit that the committee considers whether it would be fair for Fonterra to pay the same fees as a small boutique dairy factory making the same range of milk products and cheeses despite the disparity in market share? Industry has previously provided the Ministry of Health with evidence that a simple product fee basis for funding the Authority (as proposed in the Bill) would decimate many small businesses or any business with a large product range and stifle innovation. As noted, the funding mechanism was one of two issues that the JIP could not agree on. As noted in the Ministry of Health summary of submissions on the discussion document,[8] in general large companies favored fees and smaller companies generally favored levies. We have no problem with cost recovery being a part of the funding mechanism of the Authority, but we do object to a product fee only mechanism and submit that the Bill provide for the ability to impose charges and/or a turnover levy to at least part fund the Authority. We also have significant concern that the Ministry of Health has determined that the Authority will cost approximately $4,000,000 to run and yet has provided no evidence whatsoever to support this figure. Indeed, the RIS claims that the cost of administering the NHP Act would be the same whether 6,000 products or 20,000 products were notified; this is a mystery to us. Many products on the market are low volume and their distributors will be unable to sustain the costs associated with their registration. For example, the RIS proposes a fee of $550 per product. A small company with turnover of $1,000,000 and 273 products and NPBT of 15% were become unviable with	Omit cl 35. Insert partial cost recovery provisions giving power to recover costs via regulation in a variety of ways, akin to those in the Biosecurity Act to ensure that cost is proportionate to risk. Add a “principles of cost recovery clause” including a provision to require consultation with affected persons. Provide for levy for funding of Authority (as provided in the Food Bill) and for funding of industry research etc as provided for under the Commodities act.

[8] MOH, The Development of a Natural Health Products Bill: Summary of Submissions, June 2011

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	such costs, and it is noted that compliance costs extend beyond the costs of fees. Industry has also asked for inclusion of a provision allowing levies to be charged by an industry organization for the purposes of supporting research and education in relation to NHPs, in the event that an industry organization can get sufficient support for the levy, against a threshold such as that in the Commodity Levies Act 1990. The RIS for the Bill proposes that some costs be recovered from industry via a fee for services and others by levy but notes that further work is necessary in the area of fees in consultation with industry. We agree with this last statement and support inclusion in the Bill of a cost recovery regime for those costs not provided for by way of appropriation by Parliament, which will enable different options for cost recovery to be considered during consultation on cost recovery regulations under the Bill, including the possibility of a levy, by the Authority, or by an industry organization or both. We suggest amending the Bill to include a regulation making power to impose fees, charges and levies for the purposes of funding some or all of the functions of the Authority (similar to the powers provided in clauses 171, 175 and 177 of the Food Bill) and provide for exemptions, waivers and refunds from those levies similar to that provided in the Food Bill (clause 178). As currently drafted cl 35 gives no other options for recovery of costs and we would question whether it is sufficient to empower many of the things the RIS suggests it would like to do. For example, the power for it to set a fee for an audit is unlikely to be read as allowing cost recovery of the same sort, for example, as is set out in cl 155 of the National Animal Identification and Tracing Bill (which allows for charging on an hourly rate etc). A related concern is that while the regulation making power in cl 47 requires prior consultation to be carried out with those with an interest in or who will be affected by regulations, cl 35 contains no equivalent. While we would hope that as a matter of good practice the Authority *would* consult on any fees notices before we are made, we are concerned that this is not specifically required by the Act, meaning industry may get no voice before fees notices are published, cannot complain to the Regulations Review Committee, and may be forced to take an action for judicial review in order to contest any fees that are set. We suggest the addition of a "principles of cost recovery" clause similar to that in the Food Bill (clause 170) which requires consideration of equity, efficiency, justifiability and transparency in determining the most appropriate method of cost recovery and consultation with stakeholders. To that could be added specific reference to the principle of risk-proportionate regulation.	
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 under this Act; or (b) falsifies, removes, misuses, alters, misapplies, misrepresents, or fails to apply any label of a natural health product; or (c) misrepresents, substitutes in whole or in part,	We have no problem with this provision conceptually, but note that it includes references to processes that don't actually appear in the Act, such as requirements relating to records or returns, sampling and testing of products. Nor are there any powers to require the provision of records or returns under the Act. We submit that penalties under this clause be commensurate with similar low risk industries in other legislation.	

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adulterates, or otherwise tampers with any natural health 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 declaration attached or relating to a natural health product that is subject to any provision of this Act, or tampers with a natural health product that is subject to such notification, notice, 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: (b) in the case of an individual, to imprisonment for a term not exceeding 5 years and a fine not exceeding $100,000.		
37 **Sale of natural health products that have not been notified or do not meet standards** (1) A sponsor commits an offence who sells or offers for sale— (a) any natural health product for which, to the sponsor's knowledge, a product notification has not been completed: (b) any natural health product that, to the sponsor's knowledge, does not meet— (i) applicable standards of evidence required for any health benefit claims for the product; or (ii) applicable standards for labelling or manufacturing. (2) A sponsor commits an offence who knowingly sells or offers for sale any natural health product that is different in any way from its description in its product notification (for example, the product notification contains additional health benefit claims or the product is manufactured elsewhere). (3) A prosecution for an offence against this section	We find this provision confusing and wonder if it adequately captures those who should be caught under the Act? *Subcl (1)(a)* This offence provision relates to "knowingly" selling a product that has not been notified. However, the offence is limited to a "sponsor" who sells the product. Thus, under the current definition of a "sponsor", a manufacturer or importer who sells a NHP which they know has not yet been notified commits an offence, but a retailer who sells such a product does not. We wonder whether this gives the correct incentives to those operating in the NHP space. That is, it should be an easy thing for a retailer or other distributor to ask when purchasing NHPs for sale whether they have been notified and seek assurance that they have been before selling them. To ensure safety we also believe that product that is distributed to the public, other than by way of a sale, should be subject to an offence provision if it has not been notified. In our view, it should be an offence for "any person" to distribute an NHP (other than one covered by an exemption) to the public for which to the person's knowledge no product notification has been made. We are also unsure how internet sales of NHPs would be regulated. There could be a separate offence for a sponsor (product notifier) who distributes a product without first notifying it. *Subcl (1)(b)* This wording for sub-sub-paragraph (i) is somewhat strange. i.e it is an offence to sell a product that does	References to "sponsor" be amended to "product notifier" Amend subcl (1) to provide that – • It is an offence for any person to distribute an NHP (other than one covered by an exemption) to the public for which to the person's knowledge no product notification has been made; • It is an offence for a product notifier to distribute product that has not been notified • If is an offence for a product notifier to • notify a claim, other than an accepted claim, for a product in respect of which the product notifier has no evidence, or has evidence that the product notifier knows the does not meet the required standards • sell or offer for sale a product that, to the product notifier's knowledge was not manufactured in accordance with the code [or any alternative manufacturing regime which the Authority considers to be equivalent etc] or does not meet prescribed labeling requirements Amend subcl (2) to remove the example about product notifications

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may be proceeded with either summarily or on indictment. (4) A sponsor 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.	not meet applicable standards of evidence required for the claims made for the product. We suggest that it is not the product that needs to meet the evidential standard, but the claims. In fact the Bill provides for a sponsor, when notifying the product to declare that they hold evidence to support the health benefit claims being notified for it. In our view, the associated offence provision should therefore be for notifying claims for a product for which the sponsor has no evidence or evidence that the sponsor knows the evidence held does not meet the required standards (ie. essentially for making a false declaration). We agree it is appropriate for it to be an offence for a sponsor (product notifier) to sell or offer for sale an NHP that does not meet applicable standards for labeling or manufacturing. *Subcl (2)* We are unsure of the policy rationale for making a person liable for selling a product with less than the notified health benefit claims. That is, we can see that if a person sells with additional claims which are not notified and for which the person has no evidence some liability should attach, but surely there is no harm to the public and therefore no criminality should attach if the person makes *less* than the claims they are entitled to make. We wonder if the wording in the example in this clause is a mistake.	that contain "additional benefits". Amend subcl(2) to substitute in "any significant way" for "any way" from its description in its product notification
38 **Manufacturing without licence** (1) A person commits an offence who knowingly manufactures a natural health 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.	We support this provision, however unless cl 28 is amended to exempt those who manufacture products other than for distribution to the public (ie. those who manufacture for own use or research), then we would suggest this needs to be addressed in cl 38.	
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**. (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.	We have no issue with this provision generally except we note that normally it would support provisions relating to enforcement officers in a regulatory regime. The Act does not include any enforcement powers so we wonder why if it is necessary. The provision contains a wrong reference to section 46. It should be section 45.	
40 **Endangerment of human health** (1) A person commits an offence who, being the	This provision is another example of where it is not clear whether a manufacturer is automatically a sponsor or not. The drafting suggests not in this case.	

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manufacturer or sponsor of a natural health 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 of a natural health 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.	We agree it is desirable for manufacturers and product notifiers (as defined in our proposed definition) to be liable if they knowingly act in breach of the Act or regulations. To us the provision makes more sense if it is possible that a manufacturer in New Zealand will not automatically be a sponsor under the Bill.	
Disputes		
41 **Appeals committee** (1) This section establishes the Natural Health Product 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.	We support the concept of an appeals committee for decisions from the Authority. However believe that this provision provides insufficient detail, including as to who they should be. In our view, the appeals committee should be established via provisions equivalent to those in the Medicines Act relating to the Medicines Review Committee which has a similar role. That is it should contain provisions covering – • The number of members – on this point we think 3 is too few to allow for possible conflicts of interest or special expertise and at least 6 members are necessary. We note the Medical Review Committee has 6 members plus the possibility of appointing deputies where there is incapacity among the other members. It also has the possibility of operating by sub-committees. This same flexibility should be given to the appeals committee under the NHP Act;	Amend by – • amending the number of committee members from 3 to 6; • add requirements as to the type of expertise the members should have including technical and natural and traditional health products industry; • provide for the committee to be chaired by a lawyer; • provide for deputies to be appointed, and/or the committee to operate via subcommittees.

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(4) The appeals committee may, subject to any provision in the regulations relating to the conduct of its proceedings, regulate its own procedure.	• the type of expertise the members should have (this should set out a balance between technical and NHP industry expertise). • The committee should be chaired by a lawyer so procedures are determined with input from someone with experience of interpreting legislation and the rules of natural justice. There is a mistake in subcl (3) which refers to "decisions of the Authority made by.... this Act"	• Amend subcl (3) by deleting "by or"
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. (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 may be made to the High Court in accordance with the rules of court.	We support appeals being available but believe that this should be after an internal review by the Authority of any decisions made under delegation. This is a standard provision under many Acts containing, for example, licensing regimes, and means that those who may be affected by adverse decisions have access to a quick and costless review process, which ensures that the decision taken by the delegate is robust. We note also, that the material published by the Ministry has consistently stated there would be such a right of review, and we are surprised it was not included in the Bill. So far as clause 42 itself goes, we are concerned that the wording may limit those who can appeal decisions. That is, the appeal right is given to "a person who "is party to a decision of the Authority". However, it is unclear what "being a party" to a decision may mean. For example, is the sponsor (product notifier) of a product that is recalled "a party to the decision"? What about the manufacturer, or importer? Or if a "distributor" tried to get a new ingredient included in the database and failed, could the manufacturer appeal – or indeed the distributor – or indeed an Industry body? Given the lack of process around suspension of a manufacturing licence under the current drafting it is not even clear that a manufacturer whose licence was suspended need be a "party to a decision". In short, we believe that the reference to a "party to a decision" fails to take into account the fact that the Act sets up a "notification" regime rather than an application regime and the lack of process around suspension and revocation of licences and product notifications, The correct threshold should be a person who is adversely affected by a decision" We believe further that, while it is implicit, the Act should state in as many words that the appeals committee may confirm, modify, or reverse a decision of the Authority as it seems fit.	Add a provision providing for an internal review process. Amend "who is a party to a decision" to "who is adversely affected by a decision". Add a provision that the appeals committee may confirm, modify, or reverse a decision of the Authority as it seems fit.
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 products of any description; or (b) any matter contained or implied in advertisements, either generally or in any particular advertisement, or any class or classes of advertisement relating to natural health products of any description. (2) Every statement published under this section is protected by qualified privilege.	We support this clause, but note that it and clause 44 appear to be other tools for the regulator to use to ensure NHPs on the market are safe and true to label. The statement provision could be used for example, in conjunction with the recall power or another power. As part of the tool box, clauses 43, 44 and 16 (suspension or cancellation of product notification) should in our view be together in the Act in that order.	Move clauses 43 and 44 so they sit together as "tools" of the regulator. The correct order would be – • Cl 43 – statement; • Cl 44 – recall • Cl 16 – suspension or cancellation of notification
44 **Recall of natural health products** (1) If the Authority has good reason to believe that a	We agree that the Bill should provide for recall. However, several issues arise in relation to this clause, namely –	Amend subcl (1) so that it is clear that para (b) is subject to an "appropriateness" standard and is not automatic.

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natural health product is not fit for its intended purpose, or is mislabelled or incorrectly identified, the Authority may, by written notice, require the sponsor 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. (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. (3) The sponsor must, as soon as practicable, advise the Authority— (a) of the manner and time in which the sponsor proposes to comply with the notice, unless those matters are already specified in the notice; and (b) when the notice has been complied with.	• It requires "the sponsor" to arrange for the recall of the product *and* dispose of the product (cl 44(1)) on receipt of a notice from the Authority given where the Authority "has good reason to believe that a natural health product is not fit for its intended purpose or is mislabeled or incorrectly identified". The requirement to dispose of products is draconian and does not allow for the possibility of, for example, relabeling products; • The recall must be as directed by the Authority, or if no such direction is given, as the sponsor (product notifier) determines and advises the Authority. We believe these matters are too important to be left to ad hoc responses and that the sponsor (product notifier) should, as part of the registration criteria, be required to already have in place a "recall plan" and comply with it.	Amend subcl (2) so that it requires recalls to be in accordance with the product notifier's recall plan.
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	We do not support this clause. The Director-General is able, under the State Sector Act, to delegate within the public sector. Unusually, this provision allows the Director-General (as the Authority) to delegate the Authority's powers and functions outside that arena to "any person" We have no problem with, for example, the audit function being carried out by delegates outside the public sector, but are very concerned that this provision may be used to, for example, to simply give the proposed Australia New Zealand Therapeutic Products Agency the powers under this Act whilst maintaining a token office as provided for in clause 8. While the Director General would of course remain responsible for the exercise of the powers, the whole point of having a separate Bill is to enable separate regulation of NHPs in New Zealand. We are therefore very concerned such a delegation could undermine the purposes and principles of the Bill. In our view, this provision should only relate to certain specified powers under the Bill eg. The provision of third party auditors and should include a requirement that any auditor be a "fit and proper person". On a related issue, it has previously been indicated that the regulator will sit within the Ministry of Health and that it will be separate to Medsafe. We would be very concerned if that separation did not occur.	Redraft to limit the powers that can be delegated by the Authority under this clause to – • The power in clause 31 (audits); Amend to include a fit and proper person test.

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accordance with the terms of the delegation.		
Transitional provisions		
46 **Natural health products before commencement of this Act** (1) This section applies to any product that— (a) was sold before the commencement of this section; and (b) complies with **paragraphs (a), (c), and (d)** of the definition of natural health 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**. (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 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.	We support the policy of allowing products that are on the market at the date of commencement to continue to be sold. However we note the possibility of a mismatch if the ingredients in that product are not declared to be natural health product ingredients by the Authority. In such case the product is not technically a "natural health product". As noted under cl 20, we believe that there should be a requirement for the Authority to declare the ingredients from any products notified under this clause to be natural health product ingredients. Alternatively, the products should at least be deemed to be natural health products for the purposes of the Act. We note that the Hazardous Substances and New Organisms Act contains a transition mechanism that provided for approximately 110,000 chemicals already on the market to be grandfathered for the purposes of that Act in order to prevent the distortion of existing legitimate markets and a subsequent amendment was passed to provide for the bulk of those ingredients to be approved quickly and simply. Given the low risk profile of the natural and traditional health product industry, and the long history of safe use, we believe a similar provision should be provided in this Bill (via our proposed Schedule 2). Individual ingredients legally able to be sold in New Zealand prior to enactment of the Bill should automatically be included in the acceptable Natural and Traditional Health Product Ingredient Database, as should any ingredient on the market in any similar markets involving imports and exports to and from New Zealand. It would be reasonable for the Authority and industry having 1 year after the online ingredient database is available to populate the database with such ingredients with the Authority being able to undertake safety assessments as provided for in the Act. After that period any ingredient not on the database would need to be notified as a new ingredient in order to be marketed. The Ministry of Health has already been provided with a database of several thousand ingredients on the market in New Zealand as a part of the work undertaken on the joint agency proposal, A related issue is that products on the market at commencement may contain excipients or traditional ingredients that do not fall within the classes of substances in the Schedule – so may not be eligible for grandfathering under subcl (1). This problem may be met if, as we have suggested elsewhere, the Schedule is amended to extend to these products. We suggest that any excipient used in food or pharmaceutical production should automatically be permitted in the manufacture of natural health products. We also have a small concern that clause 2 of the Act provides for different provisions to be brought into force on different dates. Obviously it will take time for the database to be up and running and the Ministry to be in a position to run the NHP regulatory regime. Clearly the 1 year for product notification should run at the earliest from the date the database is up and running and the prohibited list has been put in place. We seek assurance in this regard, otherwise businesses will be subject to significant planning and budgetary constraints and may well find it impossible to comply within a particular timeframe. Finally we note that the Bill does not explicitly cover the policy expressed by Kris Faafoi in his speech on the first reading "to phase in some of the regulations to collect information, and also to see what products are out there in the market at the moment and to figure out what kinds of fees and levies can be charged over time" We anticipate that what is being talked about is that at the end of the first year, the Ministry will have sufficient data from product notifications to know "what" is on the market. However, there is no provision that would find out the volume of sales and thus permit a fee to be set in relation to turnover. In our view, the Bill should include a further regulation making power to permit the regulator to request information from those notifying products, about the number of products they have sold and the turnover of their products in the previous year. This regulation could be put in place to provide information in the set-	Ensure subcl (1) extends to excipients and other traditional ingredients that are currently in NHPs on the market to ensure products containing these are grandfathered too. Add a regulation making power (and supporting operational provision) that permits the Authority to seek information from those making product notifications in the first year about the number and turnover of those products.

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	up phase of operations.	
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**: (b) prescribing the manner in which a product notification for a natural health product must be completed: (c) prescribing the standards of evidence required to support a health benefit claim: (d) prescribing the information that must be provided by the sponsor 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 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 products must be made: (i) prescribing requirements relating to the manufacture of natural health products: (j) prescribing the procedure, conduct, and time required for appeals: (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 **subsection (1)**, the Minister must consult with any person or organisation that the Minister considers has an interest in, or will be substantially affected by, the regulations. (3) Regulations made under **subsection (1)(c)** may require that different levels of health benefit claims	As noted in our submissions under other clauses, we think that – • Para (b) - see our submission on cl 13(2) on the need to define what is a single "product" for the Bill's purposes • Para (c) - see our submission on cl 13(5) on the principles that should be considered when this power is exercised; • Para (e) – we have been unable to find where this power would be used in the Bill • Para (f) – see our comments on cl 24 and the principles that should be considered when this power is exercised • Para (i) - see our comments on cl 27 and the principles that should be considered when this power is exercised Our major submission on this clause is that it should include a power to set fees, charges and levies by regulation akin to the provisions in the Biosecurity Act and the Food Bill (clause 15(2)(b)(iv),(v) and (vi)).	Add a provision allowing fees to be set by regulation.

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may require different levels of evidence.		
Review of Act		
48 **Ministry 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 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.	We are comfortable with the concept of a 5 year review but we are very concerned at the breadth of the review and that this might extend to whether there should in fact be a separate regulatory regime for NHPs. Our concerns stem in part from the fact that Medsafe has recently stated that that this regime will be reviewed for that purpose on its website.[9] We would be extremely concerned if Medsafe or the proposed joint agency had any involvement in any review of natural and traditional health product legislation. In our submission the review should be restricted to "the operation of the Act" rather than "the policy". It should also be carried out in consultation with stakeholders. We suggest that 5 years should only start running from the date of commencement of the natural health products database being up and running and clause 13 being in force. Given the ability in clause 2 to make Orders in Council that bring different provisions into force at different times, we believe that this should be explicit.	Amend subcl (1) to refer to "after commencement of section 13" Amend "the policy of the Act" to "the operation of the Act" Amend so that the review process requires stakeholder consultation.
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 product**— "(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 product" after "medical device". (2) Section 3(1)(b)(iii) is repealed. 52 **Section 28 repealed**	We support these clauses that would have the effect that NHPs are not covered by the Medicines Act. We note further that, with removal of the carve out of "food" from the definition of a natural health product (which we consider to be simply unworkable) a further provision will be necessary to prevent double up between the Food Act and NHP Act. We suggest that it would be sufficient to amend the Food Act to provide that, to avoid doubt, "food" does not include an NHP. We also suggest that s5(3) of the Sale of Liquor Act be amended to exclude NHPs from the provisions of that Act.	Add new provision amending the definition of "food" in section 2 of the Food Act 1981 so that it provides that to avoid doubt, "food" does not include a natural and traditional health product as defined in section 6 of the NHP Act". Amend section 5(3) to add a new sub-paragraph ["any person who supplies a natural and traditional health product as defined in the Natural and Traditional Health Products Act]"

[9] http://www.medsafe.govt.nz/hot/anztpa.asp#28Jan2012

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Section 28 is repealed. 53 **Exemptions for agents and employees** Section 31(1)(c) is repealed. 54 **Duty of importer and manufacturer to have and produce specifications of medicines** Section 42(1) is amended by omitting "other than a herbal remedy".		
Amendment to Misuse of Drugs Amendment Act 2005		
55 **Amendment to Misuse of Drugs Amendment Act 2005** Section 56 amends the Misuse of Drugs Amendment Act 2005. 56 **Interpretation** Paragraph (b) of the definition of **substance** in section 31 is amended by repealing subparagraphs (iii) and (vi) and substituting the following subparagraph as subparagraph (vi): "(vi) natural health product (as defined in **section 6** of the Natural Health 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):"	We support these amendments that retain the status quo, ie. that a NHP will not be a "substance" for the purposes of the MDAA 2005.	
Revocation		
57 **Dietary Supplements Regulations 1985 revoked** The Dietary Supplements Regulations 1985 (SR 1985/208) are revoked.	We support revocation of these regulations consequential on enactment of the new regulatory regime.	
Schedule **Suitable classes of substances** **Item** **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	We are very concerned that this list of classes of substances contains obvious omissions and may effectively mean that many substances used in the manufacture of NHPs for decades would be prohibited (for example, it would ban the use of commonly used synthetic sweeteners such as aspartame and others. We are concerned that industry-wide submissions on the definitions of natural and traditional health products (such as the JIP) have been ignored and instead a definition derived from Australian input into the abandoned Trans-Tasman Therapeutic Products Agency appears to have been adopted.[10] The schedule makes no provision for retaining existing ingredients, innovative manufacturing processes or even simple common processes such as fermentation. We are also somewhat confused by the use of the term "medicinal form" in the context of classifying substances as natural and traditional health product	To reflect the current position with NHPs, the following amendments to the Schedule are required. • Paragraph 6 (referring to micro-organisms) should be moved up to become paragraph 2 and the remainder re-ordered. • Para 1 – add "microbial [raw materials]" • Para 2 – (new para 3) and in (a) add a reference to "fermentation" and extend "a material described in **item 1** or

[10] See Australia New Zealand Therapeutic Products Regulatory Scheme (Medicines) Rule 2006 Schedule 1 Complementary medicines, (section 1.05) Part 1 Complementary medicines substances www.anztpa.org/consult/dr-medrule.pdf

BILL CLAUSE	SUBMISSION	SUGGESTED AMENDMENT
preparation of a material described in **item 1**; and (b) not subject to any other process involving chemical transformation other than hydrolysis 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 8 Any of the following amino acids: Alanine Arginine Asparagine Aspartic acid Cysteine Glutamic acid Glutamine Glycine Histidine Isoleucine Leucine	ingredients. The list of classes of substance makes no provision for ingredients, including excipients used in foods or tableting and encapsulating ingredients used in pharmaceutical products. The list has a number of peculiar absences given the class of substances included and the stated intention to encompass substances currently used in the natural and traditional health products industry. For example the list of amino acids is not complete (and we do not understand why they are all not listed). Prebiotics are included but probiotics are not. There is no provision for microbial materials or substances that occur naturally in the human body. We do not understand why nature identical substances (a term we prefer to synthetic equivalent because it is well-recognised in international guidelines) is limited to only items 2, 3 or 8. We think that this should also apply to a micro-organism extract, vitamins and amino acids. We also do not understand why the processes referred to in item 2(a) – distillation, purification etc are not extended to micro-organisms. We suggest the list be reordered with micro-organisms be listed as item 2 so that both items 1 and (new) 2 are allowed for those processes. We suggest that there is no need to list individual vitamins and amino acids but simply include them as a class of substance in a similar way that minerals, bioactives and micro-organisms are not individually named. We request that a substance normally present in the human body be included as a suitable class of substance as proposed in the industry JIP as many ingredients currently available may otherwise be excluded. Obviously human tissue should be excluded in item 1, but we propose that item 4 includes reference to nature identical substances present in the human body.	**2”** • Para 4 –(new para 5) and amend “synthetic equivalent” to “a substance that is chemically identical to a substance in items [2, 3, 6 or 8]” … • Add “and includes nature identical substances present in the human body.” to new para 5. • Para 7 - add “probiotic” • Add a new para referring to “excipients” • Add a new para referring to [a substance normally found in the human body]. • Exclude individual vitamins and amino acids from their respective paragraphs and list vitamins and amino acids as a “class” of substance.

BILL CLAUSE	SUBMISSION	SUGGESTED AMENDMENT
Lysine Methionine Phenylalanine Proline Serine Threonine Tryptophan Tyrosine Valine		
Schedule 2 **Recognised Authorities**		[Include a schedule of recognised authorities including competent authorities from; Australia United States Canada [China] European Union India Japan Korea Singapore South Africa United Kingdom Any other authority declared to be a recognised authority by the Authority under section 9.]

BILL CLAUSE	SUBMISSION	SUGGESTED AMENDMENT
Schedule 3 **Recognised natural and traditional health product ingredients**		
		Natural and traditional health ingredients legally able to be marketed in New Zealand in the three year period prior to the commencement of this Act. Australia New Zealand Food Standards British Homeopathic Pharmacopoeia British Pharmacopoeia; British Herbal Pharmacopoeia and associated Compendium; Canada Health Department NHP database; Codex Alimentarius food standards EU Traditional Herbal Medicine Directive; EU Food Supplements Directive European Pharmacopoeia; European Scientific Cooperative on Phytomedicines (ESCOP); German Commission E Monographs; German Homoeopathic Pharmacopoeia Indian Herbal Pharmacopoeia; Nga Ringa Whakahaere o Te Iwi Maori Incorporated Society; Pharmacopoeia of the People's Republic of China: including traditional Chinese medicines; TGA: Substances That May Be Used in Listed Medicines in Australia The Homœopathic Pharmacopœia of the United States (HPUS) **The Ayurvedic Pharmacopoeia Of India** United States Pharmacopoeia (USP): USP Verified Dietary Supplements; World Health Organization: Monographs on Selected Medicinal Plants