Submission To:
**Ministry of Health Regarding the Natural Health and Supplementary Products Bill naturalhealthproducts@moh.govt.nz**

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## OVERVIEW

This submission begins by addressing the ambiguities and problems evident in the current wording of the Bill. It ends by suggesting a simple heuristic or decision tree to facilitate implementation of the Bill. It proposes additional clauses in the Bill to protect traditional approaches to medicine as well as ethnic and cultural practices. It suggests definitions of key terms. It clarifies the purposes of the Bill by suggesting means to exclude beneficial foods from regulation which would otherwise fall foul of the provisions of the Bill. It discusses fundamental problems with the economic model of the Bill which in its present form will favour large companies and lead to the closure of small alternative medicine practices and cottage industries. It describes fairer and simpler approaches to regulation used in the EU.

## SUMMARY OF MAIN CONCLUSIONS

The Natural Health and Supplementary Products Bill should be amended to take account of the experience in the EU. The Ministry of Health should be specifically forbidden from taking arbitrary decisions concerning products without just cause. That means the present draft 'white' list borrowed from Australia and Canada should be removed from the Bill and abandoned by the MoH. Instead products with a history of safe use should be assumed to be safe and constitute the initial draft white list. We should adopt the EU concept of *plausible efficacy* to register traditional medicines: whereby one generation, or 30 years prior use is considered sufficient to approve a traditional medicine (not the 75 years currently envisioned). There should be an extended period of consultation with industry representatives so that the fresh comprehensive white list can be compiled based on history of safe use. The onus should be on the MoH to present evidence if it wishes to exclude any product from the list. These provisions will ensure a smooth transition towards a well regulated, safe natural products environment. The restrictions on speaking about and communicating about natural medicine in clause 40C should be deleted.

## PROBLEMS WITH THE BILL IN ITS PRESENT FORM

BACKGROUND

The apparent purposes of the Bill are to prevent people from making unwarranted health claims for products, to ensure the public is correctly informed about potential benefits and pitfalls of natural medicines and of supplements, and to protect the public from potential adverse effects of products. In its current form the effect of the Bill may be quite opposite to this. The central problem with the Bill and its interpretation lies in the distinction between a food and a medicine.

DISTINCTION BETWEEN A FOOD AND A MEDICINE

Products that will be regulated are broadly defined as anything that is sold accompanied by a claimed health benefit. Furthermore if a food/product is verified to have a health benefit it may be classed as a medicine and regulated in the same way as a pharmaceutical. The central problem with this concept is the fact that virtually all natural foods have a health benefit. We eat food to maintain our health. Plants, foods, minerals, and herbs are a gift of Nature; an natural part of our food ecosystem with which we all have a symbiotic beneficial relationship. The effect of the Bill could be to restrict the capacity of the public to choose our food for ourselves as we have traditionally done for millennia.

For example the juice of apple, ginger, carrot and beetroot is advertised as a 'liver detox', should it be regulated? Strictly speaking the current wording of the Bill will require that. The comments by the Health Select Committee examining earlier drafts reveal that they are well aware of the problem. They sight the case of honey. They state that clearly honey has therapeutic effects which are widely publicised and researched, and therefore honey should strictly speaking be classified as a pharmaceutical and regulated by Medsafe. To remedy this, they suggest an exception be made for honey. Next they sight herbal teas. The Committee states that it is not the purpose of the Bill to regulate tea, that is unless an exaggerated claim is made for health benefits. So where are the Ministry of Health going to draw the line? Somewhere between relaxing tea and sleepy time tea one might suppose. Take the example of Turmeric. Research shows that Turmeric has a powerful effect in preventing bowel cancer. Is it then a medicine? No, it is a food. Very quickly it is clear that the Bill in its present draft will require tens of thousands of individual exceptions unless a simple decision-making process is specifically mandated by the Bill (see below for my draft process)

APPROACHES TO THE PROBLEM OF DEFINING FOODS AND MEDICINES

The Bill charges the Ministry of Health with the task of policing and implementing the Bill and specifically allows it to make changes to the scope of the Bill by way of regulation and process. This grants very broad powers to the Ministry of Health which will result in mistakes unless safeguards are written into the original legislation. The Ministry of Health would like to assure us they intend to be kind,

considerate, and careful. Are we sure this is possible within the framework of the current Bill? In Australia, an almost identical law concerning Therapeutic Products has been in place for years. Faced with a huge diversity of health products and traditional medicines including tens of thousands of products, the bureaucrats charged with implementing this law took a pragmatic decision to ban most traditional products from sale or import and made it very hard and very costly to apply to register a product. The result is that you can't buy most traditional medicines in Australia. It is important to realise that this was a pragmatic approach. Our Ministry of Health does not have the resources or the knowledge base to classify and investigate thousands of products, so it appears to have decided to take a similar pragmatic view.

It appears the basis of the Australian approach was to decide that health products with multiple ingredients were suspect and should be banned, that exotic plant ingredients for which they could not source information should be banned, that the onus of proof of safety should lie exclusively with the provider, that traditional use could not be cited as a full proof of safety, that anecdotal reports of isolated incidents of adverse effects and impurities, however minor, were sufficient reason to ban products from sale, that if products were prescribed by Natural Health practitioners it would constitute a red flag which implied that they should be banned until regulated. This is because authorities in Australia applied the *'precautionary principle'* or so called *'rule of doubt'* in the preparation of their list of approved ingredients. Under this rule, any ingredient about which little is known by the regulating authorities is by implication in doubt and therefore is banned until the supplier can accumulate enough scientific evidence of its safety. Considering there are tens of thousands of plants, herbals, extracts, and minerals used in natural products, this effectively excluded many products with useful properties. For example traditional Ayurvedic supplements and medicines cannot not be sold in Australia since some of their ingredients do not appear on the approved list. Efforts to gain approval for products in Australia have often failed over the years due to the high cost (as high as $150,000 for one ingredient) of meeting the regulatory hurdles mandated by the Australian therapeutic products authority. This was and is a draconian interpretation of the legislation pertaining to therapeutic products.

Presently, in New Zealand there is a **black list** of products which are deemed to be unhealthy, everything else can be sold without regulation. Under the Bill this system will change. There will be a **white list** of approved products and everything else will be banned until proven safe. The MoH have taken the lists of approved ingredients of health foods/supplements directly from Australia and Canada and used these to create a 'white' list of approved ingredients in New Zealand. This list includes about 5000 ingredients. All other ingredients will be banned until they can be proven safe. This amounts to an essentially ad hoc or a priori process. There are hundreds of thousands, if not millions of plant varieties on this planet and a similar number of foods. They constitute our food base. They constitute the basis of our health. Yes plants are therapeutic, food is life, without food you die, but they cannot and should

not be regulated as medicines. They are foods. To plan that everyone claiming a health benefit for a plant, mineral, or herb or a combination of them will require regulation, and to limit the availability of healthy food choices is an enterprise whose vast scale is completely unworkable. Moreover most people would consider it a violation of our basic human right to choose what we eat and how we live. Its worth noting that moves in USA to regulate the natural products industry have been drastically scaled back or abandoned for just these reasons.

PROPOSED WHITE LIST WILL SEVERELY RESTRICT NATURAL MEDICINE

It is clear that the Natural products providers and traditional medicine practitioners have very significant reasons to be afraid of the consequences of this Bill and its implementation. For millennia traditional approaches to health have realised that herbs and foods have synergistic properties when used together. This is no more strange than the modern concept of a balanced diet or meal. Under the Bill, multiple ingredient products will tend to disappear from our shelves. This is because in a multi-ingredient preparation it will often be the case that one of the ingredients has been omitted from the white list and therefore the whole product will be banned. In many cases the business model of practitioners and suppliers will collapse as they find themselves banned from promoting or selling products that have been previously sold for years.

An examination of the proposed 'white' list of approximately 5000 products, indicates that it is grossly inadequate. For example here are about 200-300 ingredients used in the dozens of common over the counter Ayurvedic food supplements or remedies. Over one third of the ingredients do not appear on the 'white' list. Under the Bill, most Ayurvedic food supplements and medicines could effectively be banned in New Zealand as has happened in Australia. A similar situation will apply to traditional Chinese medicine.

For example, the effect of the Bill may be to impose a blanket ban on products claiming to benefit health. Previously I suffered from asthma, a few years ago I came across an Ayurvedic product that had twelve herbal ingredients. I took that for a few months and I haven't had a recurrence of asthma since. Under the Natural Health and Supplementary Products Bill, the seller of this product under certain circumstances may be able to continue to prescribe it but he will not be able to make any public beneficial health claim or sell it publicly. If the supplier had not been able to advertise a health claim, I would never have found the product.

A person I know visited a hot country, lost weight and appetite on return. GPs in New Zealand ran blood tests and suggested an eating disorder as a probable cause. Eventually an Ayurvedic health consultant diagnosed a parasite and recommended a product with multiple ingredients that is traditionally used in such cases. The problem was resolved. Appetite, health, and weight returned. Under the Bill, this product, formulations of which have been used for thousands of years to cure a simple condition common in hot countries, could be banned as it contains

ingredients about which little is known in New Zealand or because the company selling it has not been in existence for more than 75 years. The Bill in its present form will allow the Ministry of Health to mandate that years of scientific research be completed before acceptance. Who will decide if this is the case? NZ doctors receive very little training in nutrition (a few hours over three years) and along with nutritionalists have virtually no expertise in traditional medicine. Ministry employees and advisors coopted from NZ industry will have even less experience in these fields.

Earlier versions of the Bill stated that products made by an individual practitioner for an individual patient will be exempt from regulation even though these same products will not be allowed to be sold over the counter. Our Bill also initially suggested that some traditional medicines prescribed for a minimum of 75 years could be exempt from regulation. How this is achieved in practice is difficult. Very few companies currently selling Ayurvedic products are older than 75 years, although their products are based on formulas that are thousands of years old. However further restrictions have been imposed in the Supplementary Order Paper, the latest version of the Bill, which differ from this entirely in as much as it states that all natural health practitioners administering to an individual will be unable to use non-permitted ingredients. This is highly restrictive as ingredients can only be added to the white list following a a process of application to and consultation with the Ministry of Health. Nor will products presently allowed as a “practitioner only range” be exempt from the Bill.

**We suggest that we simplify these highly restrictive approaches by adopting the practice used in the EU, where there is a broader concept termed *plausible efficacy* to register traditional medicines. One generation, or 30 years prior use is considered sufficient to approve a traditional multi ingredient medicine even if some ingredients are not on the white list.**

PROPOSED CONSULTATION WITH INDUSTRY

We have been hearing reassuring news that the MoH is committed to undertaking a consultation process with natural products industry and traditional medicine representatives. However it now appears that this consultation as planned will be insufficient in duration. Up until the Bill is passed (which is scheduled for mid 2016), coopted representatives of natural products industry and traditional medicine are planned to meet by teleconference occasionally. They will have a role to provide information only, whilst decisions about products will be taken by an MoH panel. Subsequent to the passing of the Bill in mid 2016 the MoH envisions that this ‘regular’ consultation may be curtailed or cease whilst the whole process is taken over by the MoH panel with little knowledge of the health products and traditional medicines they are regulating. The MoH also believes that products already on the present ‘white’ list coopted from Australia and Canada may be sufficient for the purposes of the Bill. They envision that providers will have to do research and provide compelling evidence in order to add to the white list. The foregoing

illustrates very clearly that the consultation envisioned by the MoH is too short in duration to even begin to consider the thousands of products affected by the Bill. **We suggest there should be an extended period of consultation with industry representatives so that a completely fresh and comprehensive white list can be compiled based on history of safe use.**

FUTURE TRENDS IN NATURAL HEALTH

Does the Bill sufficiently reflect current approaches to healthcare? Research into diet and health is a rapidly evolving field. The pivotal role of food combinations and specific foods in protecting against cancer and other diseases is increasingly being recognised; and the role of diet and alternative health products in DNA repair and immune system protection is an expanding research field that the Ministry of Health panel cannot hope to keep abreast of. Plant foods play a role in creating and maintaining our individual epigenetic environment which is also a key factor in promoting health. Molecular shape has been discovered to be a factor in disease creation and prevention. The aetiology of disease is recognised as having multiple determinants within complex physiological and biochemical pathways. Many of these factors which are in some cases early precursors of disease are recognised in traditional systems of medicine such as Ayurveda and Chinese medicine which specialise in the prevention of disease.

Modern research is beginning to reveal the complex responses of individual body types to everyday foods. For one person sugar will disrupt the digestive process, for another it will fulfil a useful purpose. Research is beginning to reveal that custom diets and medicines can target specific problems for particular individuals. This is not news, we as individuals have been managing our diet for millennia. We know that one man's meat is another man's poison. Our taste and responses to food assist us in making choices along with publicly available information. In many cases traditional practitioners are leading the field by implementing simple treatments for modern ills that are effective, inexpensive, preventive, and free from side-effects and specifically suited to their individual patients.

These same practitioners will effectively be outlawed from practicing in New Zealand because they will be unable use the products that they know to be effective. Information about health choices will be severely restricted as has happened in Australia. In fact it will become an offence to send any communication in NZ suggesting that a natural product can benefit health. Given that the incidence of chronic illness is ballooning, this is not good news. Incidence of asthma, cancer, allergies, digestive disorders, heart disease, diabetes, anxiety, high blood pressure, and attention deficits are all increasing. There is evidence in every case that diet can play a role in reducing incidence of these conditions. Most traditional and natural health practitioners are using principles of preventive diet in prescribing their traditional products. Restrictions imposed in clause 40C of the Bill would kill all capacity to discuss the effects of Natural medicine in any context. This is absurd.

MULTICULTURAL IMPLICATIONS OF THE BILL

New Zealand has become a multicultural society with existing relationships to information and knowledge from a wide range of sources and traditions. To arbitrarily cut off large segments of the population from their traditional medicines is a form of cultural and ethnic discrimination that will have implications for the health of large groupings of our population. This is not desirable or just. The Bill should recognise the central role of traditional medicine practitioners in preserving cultural integrity. Any other approach amounts to a form of discrimination which has no place in our society. In British India, the authorities tried to wipe out Ayurvedic traditions, hospitals, and libraries which were kept alive by dedicated practitioner families and revived in more recent times. No one needs laws which will have the effect of suppressing these traditions in this more enlightened day and age.

ECONOMIC FRAMEWORK OF THE BILL

The regulatory framework of the Natural Health and Supplementary Products Bill is custom made for large companies with high profit margins. A pharmaceutical medicine may only cost us $6 at the pharmacy, but it may cost the government thousands, tens of thousands, or even hundreds of thousands of dollars every year in subsidies for each individual taking them. A company producing such a medicine can afford to comply with complex regulations which may run into millions of dollars for even one product. It can use government subsidies to pay for marketing, research, and lobbying on a grand scale. A natural products practitioner offering plant-based alternatives that have been tried and tested for thousands of years has insufficient means to comply with the proposed regulations. There are no huge profit margins in the plant based natural products food chain and therefore the regulatory model proposed under the Bill, whereby the user pays, discriminates against traditional medicine and encourages large companies to capture markets by offering synthetic products designed to be similar to natural products. **The proposed charges should be reduced or eliminated**

IS THE BILL NECESSARY?

No one is dying as a result of traditional medicine and food choices advice. Quite the reverse, there is a great benefit in the individual regulating his or her own health based on traditional or new knowledge. No scientific evidence has been presented that Natural Products are causing or pose any risk to public health. In contrast iatrogenic illness and death (illness caused by a prescribed treatment itself) is on the rise among patients taking allopathic medicine (In the United States 100,000 people die each year from *correctly* prescribed allopathic pharmaceuticals). It would be hubris for government to seek to regulate our ‘food as medicine’ choices. Many people have found that specific Natural Products enable them to stay healthy and avoid the effects of life threatening illness. They will be affected by this Bill and everyone’s future health choices will be compromised irrevocably. So the Bill is in effect a gross assault on the human right to choice, free speech, and cultural integrity. And why, we ask, are cigarettes and alcohol, which do kill thousands of people each year, going to continue to be sold unregulated while our health choices

are about to be restricted? The answer could be that some very clever lobbyists have persuaded our MPs that food is the next frontier for regulation. Yet there is little or no political capital to be gained from this Bill nor any viable social progress that will result.

**RELEVANT INFORMATION CONCERNING EU LAW AND PRACTICE**

One of the central problems with our Bill is that its implementation will establish a no-win situation for natural practitioners. If you practice natural medicine, you can only prescribe products on the white list, therefore you will be unable to use the full range of plants, herbals, and minerals used in your discipline. If you present evidence that your banned products do improve health, they will be regulated as pharmaceuticals by medsafe and you will not be able to afford to register them. The EU courts have recognised that the distinction between a food and a medicine is a problem area and they have ruled to rectify this situation.

AMBIGUITIES IN EU REGULATIONS HAVE BEEN RECTIFIED BY THE COURTS
In the EU similar efforts by member states to regulate plants and botanicals as medicine have run into trouble in the courts. According to EU law, a product can be considered medicinal either if it is *"presented as having properties for treating or preventing disease in human beings"* (medicinal product "*by its presentation*") or if it *"may be used in or administered to human beings either with a view to restoring, correcting or modifying physiological functions by exerting a pharmacological, immunological or metabolic action, or to making a medical diagnosis"* (medicinal product *"by its function").* These definitions (which are very similar to those proposed in the NZ Bill), whilst sounding detailed, are in fact so vague that EU member states have applied these same legal definitions differently to such an extent that it has hampered inter state trade. The courts have reprimanded states who have sought to restrict the sale of medicinal herbs by classifying them as medicines.

EU case law on the subject revolves around the fact that many plants, herbs, and foods are medicinal but this does not mean they should be regulated as medicines. For example in the Garlic Judgment (ECJ Judgment of 15 November 2007, Commission v Germany, Case C-319/05, ECR 2007 Page I-09811.) the German authorities classified a garlic extract powder capsule as a medicinal product *by function* without taking into consideration the extent of the therapeutic effects of the product. However, the Court confirmed that products containing medicinal plants are not medicinal products *per se*. As it is the case with vitamin and mineral preparations, the ECJ stated that *products which, irrespective of their composition, do not significantly affect the metabolism and do not strictly modify the way in which it functions should not be classified as medicinal products by function.* In the *Garlic Judgment*, the ECJ extended this case-law to botanical foods. The Court held that a garlic extract powder capsule could not be classified as a medicinal product *by function* precisely because its physiological effects were "*no more than the effects*

*of a foodstuff consumed in a reasonable quantity*"; the physiological effects alleged by the German authorities, essentially with respect to the prevention of arterio-sclerosis, could also be obtained by ingesting 7.4 g of garlic as foodstuff. Whilst this reasoning might have been motivated because garlic is commonly used as a foodstuff in its natural state, thereby limiting the legal implications of the ruling, the ECJ later confirmed that this understanding should be extended to virtually all medicinal plants.

EU COURTS RESTRICT THE BANNING OF INGREDIENTS

Some national states in the EU have sought to justify their stricter interpretation of EU directives concerning food supplements and medicines by referring to the so called *'rule of doubt'* provided under Article 2(2) of the Medicinal Products Directive. In this case, they argued that they were justified in classifying a food as a medicine because they were in doubt as to its exact physiological effect. (A similar approach is being used in Australia to compile its 'white' list which NZ is planning adopt) This approach was also thrown out by the courts who stated that if there is doubt, the authorities themselves must conduct and fund detailed research to justify their position before imposing restrictions on a food. The court ruled that the Medicinal Products Directive *"does not apply to a product in respect of which it has not been scientifically established that it is a medicinal product by function, even if that possibility cannot be ruled out"* (ECJ Judgment of 15 January 2009, Hecht-Pharma GmbH v Staatliches Gewerbeaufsichtsamt Lüneburg, Case C-140/07). In other words, botanical food supplements are presumed to fall out of the scope of the Medicinal Products Directive unless the national authorities, having regard to the entirety of the products' characteristics, prove to the contrary. This principle closed the door to those Member States who rely on the application of the precautionary principle in order to justify the aprioristic or ad hoc classification of "suspicious" (i.e. borderline) products as medicinal products.

**CONCLUSIONS**

* The purpose of the Bill should be reviewed. The government should withdraw this Bill as they have presented no evidence of harm from Natural Products
* That natural medicines made exclusively from plants and non plant material known to be safe should be excluded from regulation
* That traditional medicine used safely for 30 years or based on traditional formulas should be automatically included in a new 'white' list
* That a product cannot be black listed unless a good reason to do so is demonstrated.
* That restrictions on communication concerning natural products should be removed from clause 40C. It is a violation of free speech and human rights.
* That a rational decision tree be adopted for deciding which products fall under the scope of the Bill
* Some Natural therapies are so effective that the government should fund them rather than ban them. In USA 75% of all medical colleges offer training in alternative and complementary medicine and NIH funds promising alternative therapies.

DECISION TREE FOR REGULATION OF NATURAL PRODUCTS

1) Does it contain a known dangerous toxin? (important see note below, definition of a toxin)

No - Go to 2 Yes - MoH to prove that this is the case

2) Is it composed exclusively of natural unprocessed plant material? (see definition of unprocessed below)

No - Go to 3 Yes - exclude from regulation

3) Is it a traditional medicine including plant material and other non-plant ingredients used safely for over thirty years or based on a traditional formulation?

No - Go to 4 Yes - exclude from regulation

4) Does it contain natural plant extracts obtained through destructive processes?

No - Go to 5 Yes - obtain information and go to 5

5) Is there a history of safe use over recent decades?

No - Go to 6 Yes - exclude from regulation

6) Does it contain manufactured identicals of plant materials or so called active extracted ingredient(s)(see note below)

No - Go to 7 Yes- regulate

7) Does it contain novel synthetic chemicals?

No - Go to 8 Yes - regulate

8) Does it contain minerals in dosages exceeding current statutory limits?

No - Go to 9 Yes - regulate

9) Does it contain vitamins exceeding allowable doses?

No - Go to 10 Yes - regulate

10) Does it contain synthetic biologically active ingredients

No - Go to 11 Yes - regulate

11) Is it produced through genetic engineering or by using some GMO ingredients?

No - Go to 12 Yes - regulate, refer to HASNO

12) Does it contain novel products not included in Q1-11 above?

No - investigate Yes - regulate

**NOTES**

DEFINITION OF DANGEROUS TOXIC OR SEVERE ADVERSE EFFECTS
When classifying plant materials it is important to be aware of the limitations of designating a plant as toxic. Food allergies are common. Anecdotal reports of one or more minor adverse effects are not sufficient reason to impose blanket bans on products without thorough investigation. Some nuts are dangerous for some people and beneficial for others. Historically this has not been a reason to ban nuts from sale. Where it is an issue, it has been sufficient to require the manufacturer/retailer to label the presence of possible allergens clearly. The permitted maximum dose of a product should also be stated. Occasionally in traditional medicine, ingredients that could produce adverse effects on their own are entirely safe when used in combination with other ingredients or when prepared in a specific way. Regarding this, traditional use and supporting evidence of safety should be relied upon.

DEFINITION OF PROCESSING
Preparation of traditional medicines can involve a number of techniques which do not constitute processing. These can include mixing, compressing, dissolving in water or alcohol, extraction of oils through pressing, boiling, decoction, tinctures, etc. They may also include minute quantities of proven safe agents to facilitate the preparation of tablets and the preservation of plant materials. Processing should be defined as including destructive processes likely to cause chemical changes of composition such as high heat treatment, extraction of active ingredients using catalysts, biological, chemical, or hot fractionating techniques.

DEFINITION OF PLANT IDENTICALS
Much has been made over recent years of the creation of chemical or biochemical substitutes for natural ingredients. These are claimed to be identical to the naturally occurring plant components they are designed to imitate. In fact, most plant identicals are different from their naturally occurring relatives and may have unintended side effects. This area requires regulation. It is also the case that some natural products contain the so called ‘active ingredient’ of naturally occurring products. An extract of a natural product does not necessarily have the same effect as the whole plant. Health benefits proven for the consumption of an unprocessed whole plant or part of a plant cannot be ported to a highly processed extract without proper investigation.