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Draft 6. 18<sup>th</sup> June 2016

**Kiwi Herbs Ltd. “Maori Traditional Medicine”  
generic submission/application request to add  
substances onto the Permitted Substances List.**

<b>Requester's name and designation</b>	Mr Fred Allen. Managing Director
<b>Company/organisation name and address</b>	Kiwi Herbs Ltd. PO BOX 37263 Stokes Valley Lower Hutt. 5141 New Zealand
<b>Contact phone number and email address</b>	CELL+64 (027) 222 2100 PH +64 (04) 934 0559 FAX +64 (04) 934 0557 <a href="mailto:fred@kiwiherbs.com">fred@kiwiherbs.com</a> <a href="http://www.kiwiherbs.com">www.kiwiherbs.com</a> SKYPE: kiwi.plants

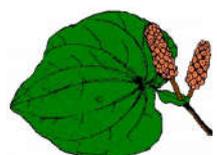
Sent to: [naturalhealthproducts@moh.govt.nz](mailto:naturalhealthproducts@moh.govt.nz)

Date: 28 / 05 / 2016

Kiwi Herbs Limited

Member of Natural Products New Zealand and Member of Te Kahui Rongoa Trust

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*(Copy and paste the section below for each substance requested and complete accordingly –ie. If you wish to submit 10 substances for inclusion on the Natural Health Products Permitted Substances List, then copy and paste this section 10 times into the document before completing details for each individual substance)*

**Name of the substances**

31 Taonga/Treasures lists of New Zealand endemic, indigenous substances and other materials being lists of: Freshwater, seawater, aquatic plants, forest floor, algae, ants, bacteria, zoospores and viruses, bats, beetles, birds, bryophyte, earthworms,, fleas, freshwater fish, freshwater Invertebrate, fungi no1, fungi no2, human, Insects, marine fish, marine Invertebrate, marine mammals, vitamins and minerals, moths, micro-organisms, molluscs, plants, reptiles, seaweeds, snails, soils and spiders.

The PSL subcommittee criteria for individual substance applications may apply for the many thousands of substances within this application. This applicant emailed [naturalhealthproducts@moh.govt.nz](mailto:naturalhealthproducts@moh.govt.nz) with a request for guidance from the subcommittee on 17<sup>th</sup> May 2016 or for information on preparing this generic application, and received no reply.

This application is for all the organisms of New Zealand being all “Taonga” and all their genes and associated micro-organisms. All plant or plant material, algae, fungus, mineral, human or a non-human animal material. All substances or mixtures of substances, being a Rongoa Maori Traditional preparation derived from any material, organic and/or inorganic.

This application is a single Maori Traditional Medicine generic submission and application, not a species by species application. This application being for Kiwi Herbs Ltd Maori paradigm substances, being all the constituents, substances and all other materials (organic and inorganic) listed within all of the attached ‘Taonga’ lists.

There is ample evidence that Maori very quickly integrated many exotic herbal materials within their Rongoa Maori Traditional Knowledge, for introduced Pakeha diseases and Maori continue to utilize exotic substances within Rongoa Maori to this day.

KHLTD will need to submit a separate generic single application for all the exotic herbal substances within the Rongoa Maori paradigm and also as many applications for the individual substances in the Western paradigm (not already on the white list) that KHLTD wishes to manufacture within NZ and/or export.





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<p><b>Scientific name. (Latin binomial) (if applicable)</b></p>	<p>Attached 29 files of substances: Taonga lists being: Freshwater, seawater, aquatic plants, forest floor, algae, ants, bacterium, viruses + zoospores, bats, beetles, birds, bryophytes, earthworms, fleas, freshwater fish, freshwater invertebrate, fungi, human, insects, marine fish, marine mammals, micro-organisms, minerals, moths, molluscs, plants, orchids, reptiles, seaweeds, snails and spiders.</p> <p>Example: Attached list of 2,622 NZ indigenous vascular plants with scientific names, common names and occasional Maori names.</p> <p>Example; Attached file titled: KHLTD PSL MOH. NZ Vascular Plants 2016</p> <p>Attached x 29 Taonga/Treasures files with all scientific names in Latin.</p> <p>KHLTD emailed <a href="mailto:naturalhealthproducts@moh.govt.nz">naturalhealthproducts@moh.govt.nz</a> on the 17<sup>th</sup> May 2016 requesting guidance and information on submitting this applications species and materials files. Asking if there was a data cap or another process to supply digital information. KHLTD attempted to submit one application on 25 May 2016. This one application being the native vascular plants (flora) file. The email failed. Due to these circumstances KHLTD then made the decision to combine all the applications into one and to courier the data stick.</p>
<p><b>Other names for the substance. (if known, each name on a separate line)</b></p>	<p>Maori names are not recorded for 95% of the attached scientific nomenclature.</p> <p>KHLTD does have a file with Maori names, but it is presently unavailable for this submission</p>





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<p><b>Legal questions and information specific to PSL application.</b></p>	<p>KHLTD has non-disclosure/confidentiality agreements with org's and partners within the NZ jurisdiction.</p> <p>The requirement of the PSL regime to disclose/identify information/COA for a substance to be permitted would create a breach of such legal agreements. Is there a privacy policy and conflict of interests register for subcommittee members?</p>
<p><b>Intellectual Property safeguards.</b></p>	<p>The issues are of Western NZ intellectual property protection (NZ Patents Act), Maori Traditional Knowledge (Sui Generis) and biodiscovery rights have not been transparent in this PSL regime.</p>
<p><b>Income Tax and Koha .</b></p>	<p>Income tax and GST treatment of koha. NZ IRD:</p> <p><b>E aku nui, e aku rahi, tēnā koutou katoa</b></p> <p>“Koha is sometimes given as a payment of money or by providing goods or services. It's given without any expectation on the part of the person receiving it. Although the term koha is used to describe these payments, the tax treatment of koha is assessed on a case by case basis depending on the type of payment. An unconditional gift is a voluntary payment to a non-profit body where the person making the payment doesn't receive any direct benefit from it in the form of goods or services.</p> <p>KHLTD's interpretation of the IRD koha criteria/interpretation indicates IRD accepts koha as currency when currency is used for a Maori Traditional purpose and is solely for the traditional activity/purposes only. IRD says, “A reimbursement of actual expenses (is) not income to the kaumatua and kuia, so tax doesn't need to be deducted”. KHLTD interprets this as meaning “If there is no profit. Maori within the purposes of Rongoa Maori Traditional Medicine, may receive currency for actual expenses and do not have to pay tax.</p>
<p><b>Human substances.</b></p>	<p>Human substances were used within Rongoa Maori Traditional Knowledge. Certainly pre-colonial and pre-Christian periods (NZ Archives records for pre 1840) and continued sporadically for some years post 1840 to the 1860's. The use of body parts did not continue within the Christian Colonial Government rule and continued within the contemporary context to included stomach organisms, urine, saliva, stem cells, blood etc.</p>





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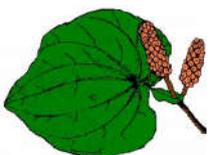
**KHLTD Natural  
Products Bill  
Statements specific  
to this application.**

KHLTD believes that for the Crown to incentivise the health system and to expand Rongoa Maori services (Wai262 report 9.2.9 "Protecting Rongoa Services". Maori who wish to commercialize within the Western paradigm, must adhere to the Western paradigm regulations of the MOH PSL (subcommittee) regime and the Legislation of the Natural Products Act.

KHLTD believes, that the Natural Health and Supplementary Products Bill/Act Authority and the Advisory Committee, have misinterpreted parts of the Bill. Koha being a significant example. That Rongoa Maori practitioners must only use permitted substances and cannot be paid for their products and services is not a correct interpretation of the Bill.

KHLTD agrees that the Medicines Act 1981 is outdated for natural products, that the ANZTPA regime was not suitable for NZ and Maori, and that the proposed Natural Products Act is the best framework forward for Western complementary medicine.

KHLTD recommends, that the Rongoa Maori national organisations representative of Rongoa Maori, Rongoa Maori Clinic's, Rongoa Maori practitioners and Rongoa Maori enterprises, should be resourced (like those already funded within the MOH framework) for Maori to hold Hui and Wananga. So Maori practitioners will be given sufficient time to converse the issues and tutor themselves to prepare and participate within the PSL regime (Natural Products Act).

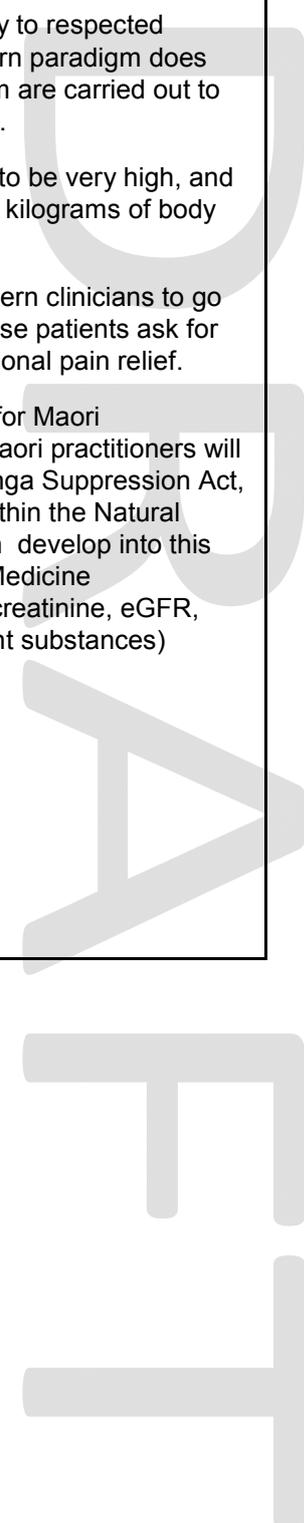




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<p><b>Additional Dosages information.</b></p> <p><b>Example of risks of usage of organic materials by Maori Tohunga.</b></p> <p><b>How the Natural Products Act can minimise these risks.</b></p>	<p>KHLTD for an example, supplies the analgesic' pukateine only to respected Tohunga, within the TK Maori (koha) paradigm. As the Western paradigm does not apply here. Lethal dose (LD) trials within a Maori paradigm are carried out to LD test the individual batches of this alkaloid (13+) substance.</p> <p>For example, LD's for one Pukateine batch trial found the LD to be very high, and for that specific batch/harvest, a dose above 10 grams per 80 kilograms of body weight, may be fatal.</p> <p>Once Maori, stage four patients, have been released by Western clinicians to go home and are offered Western palliative care. Sometimes these patients ask for the cultural familiarity of a respected Tohunga with their traditional pain relief.</p> <p>KHLTD contends that by the MOH integrating Rongoa Maori for Maori practitioners within the Natural Products Act appropriately. Maori practitioners will not have to go underground now, as they did during the Tohunga Suppression Act, That the safety and nurturing of Maori Traditional Medicine within the Natural Products Act framework, is possible, so that practitioners can develop into this contemporary "space" and "at their pace" integrate Western Medicine tools/practices into Rongoa Maori. ( for example: Blood tests-creatinine, eGFR, potassium etc to monitor the patients bodily responses to plant substances)</p>
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**Kiwi Herbs Limited  
PSL Statements  
specific to this  
application.**

KHLTD acknowledges that the Crown has the right of management, through statutory mechanisms such as the Natural Products Bill/Act Authority, Advisory Authority and PSL Subcommittee legislation. That the interpretation of the Natural Products Bill/Act by the MOH is causing alienation to KHLTD's Maori paradigm rights due to selected advice from advisors, being advice lacking overall comprehension of the Rongoa Maori paradigm co-existing with a Western paradigm.

KHLTD wishes to enter into an agreement with the Authority, Advisory Authority and PSL Subcommittee, for KHLTD's Rongoa Maori Taonga/Treasures lists, (x29) which are all within the Maori paradigm, to be all recognized and accepted as being all on one application, and all being on the "white list" of permitted substances for sole utilization within the Maori paradigm.

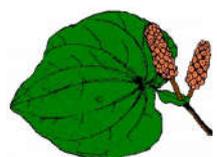
KHLTD wishes that if a singular substance application for each species or material is insisted upon, that the closing date of this PSL regime for KHLTD's Maori paradigm PSL application process be extended indefinitely for KHLTD and that there are no costs at all for the whole process indefinitely.

KHLTD sighted and heard Crown Law Barrister statements (transcript of closing statements, Wai 2358 Waiwhetu Marae) that, there exists "The right to develop Taonga", of which Maori had customary use, prior to 1840 as a development of Maori as a people and that Maori also have the right under the partnership principle to "The development of Taonga not known in 1840".

KHLTD contends that KHLTD has the "customary rights" to produce and supply contemporary developed materials within a contemporary Maori, Rongoa Maori paradigm.

KHLTD has included contemporary information (COA's MSDS, KHLTD catalogues etc) into this PSL application because KHLTD's has the "right of Maori development within two worlds".

KHLTD believes there is ample evidence that Maori integrated many exotic herbal materials within their Rongoa Maori Traditional Knowledge, for introduced Pakeha diseases and Maori continue to utilize exotic substances within Rongoa Maori to this day. There therefore will be another separate application for the exotic herbal substances within the Rongoa Maori paradigm from KHLTD to the PSL subcommittee.





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**Chemical Abstract  
Services (CAS)  
number.  
(if applicable)**

Not available because it would cost hundreds of millions of dollars to provide Certificates of analysis (COA's) for 50% of the species listed in the attached Taonga lists.

No Crown (C.R.I) or NZ Government S.O.E has undertaken and completed C.O.A's or M.S.D.S for a fraction of the materials within the NZ endemic and indigenous medicinal biota "space". For example E.S.R's most senior virologists and the head of NZ research. met with Fred Allen, to work through research potential of anecdotal Maori Traditional Knowledge for virus medicines not in the public domain, to scope potential research projects. That they were surprised at the number of remedies/species discussed and that there had/has not been any science research on these species.

The point KHLTD is making is that, in all of the past to the present, the Crown, NZ government, CRI's and SOE's with substantial science resources/capacity, has not chosen to undertake laboratory analysis of 0.2% of the organisms and materials listed in all 29 KHLTD's "Taonga" lists (aquatic plants, forest floor, algae, ants, bacterium, viruses + zoospores, bats, beetles, birds, bryophytes, earthworms, fleas, freshwater fish, freshwater invertebrate, fungi, insects, human, marine fish, marine mammals, micro-organisms, minerals, moths, plants, reptiles, seaweeds, snails, spiders and waters).

That for Rongoa Maori practitioners to submit singular PSL applications, to the applications criteria, within the allowable timeline of the regime, for even 10% of the species within KHLTD Taonga lists, is a huge task.

That there being no approved Maori Traditional Medicine Pharmacopoeia available for this process and that the evidence shows the total absence of any Ministry of Health programme of development of such a Maori Pharmacopoeia.

That during all of the timeline of M.O.H governance of the succession of national Rongoa Maori representative organisations, the MOH's District Health Boards funded Rongoa clinic's and Rongoa practitioners. That for this predictable development of natural and supplementary products, there has been no funding or programme to build Rongoa Maori practitioners, to have any capacity or to have any "natural justice" within the development and implementation of this Act, as a Treaty Partner.

There should not have been the removal of funding from the national Rongoa Maori organisation, the Te Kahui Rongoa Trust. ( Fred Allen was a trustee of this organisation)

This demonstrates an immediate breach of the Tiriti o Waitangi principle statement, in "The Natural Products Act (Bill)"

Natural Products Bill pge 14.

" In achieving the purposes of this Act, all persons exercising functions and powers of this Act under it, shall honour the articles of Te Tiriti o Waitangi"

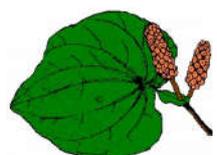
**No development  
programme  
implemented and  
funded by MOH**

**Breach of Natural  
Products Bill Tiriti o  
Waitangi principle**

**Kiwi Herbs Limited**

**Member of Natural Products New Zealand and Member of Te Kahui Rongoa Trust**

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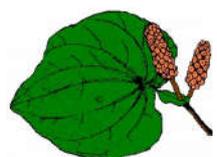




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<b>Name of reference publication / internet database . (that mentions the substance)</b>	Attached KHLTD "Taonga/Treasures Lists (with acknowledgements)  29 KHLTD's NZ Taonga/Treasures Lists being: Freshwater, seawater, aquatic plants, forest floor, algae, ants, bacterium, viruses + zoospores, bats, beetles, birds, bryophytes, earthworms, fleas, freshwater fish, freshwater invertebrate, fungi, human, insects, marine fish, marine mammals, micro-organisms, minerals, moths, molluscs, plants, reptiles, seaweeds, snails and spiders.			
The substance used is a native New Zealand species (please tick if applicable) <input type="checkbox"/> + The substance used is an introduced New Zealand species (please tick if applicable) <input type="checkbox"/>				
Ingredient Type: (please circle or underline applicable category below)  <b>+Alga Animal Bacterium Chemical Culture Enzyme Fungus Mineral +Plant +Yeast</b>				
The substance is used as; <b>an active ingredient</b> <input type="checkbox"/> <b>excipient</b> <input type="checkbox"/> (e.g. colouring agent, preservative, filler) (please tick where applicable)				
<b>Please tick proposed routes of administration for this substance.</b>	+	Cutaneous (to the skin)	+	Otic (ear)
	+	Dental	+	Rectal
	+	For Dental or Otic use only	+	Sublingual (under tongue)
	+	Gingival (gum)	+	Topical (applied to the surface of the body)
	+	Inhalation	+	For Topical or Dental use only
	+	Irrigation (rinse)	+	For Topical or Inhalation use only
	+	Nasal	+	For Topical or Nasal use only
		Not applicable	+	Transdermal (eg. medicated patch applied to the skin)
	+	Oral	+	Ungual (nail)
	+	For Oral or Sublingual use only	+	Vaginal
	+	Oromucosal (application to mouth, cheek or throat)		





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<p><b>List all proposed dosages / strengths for this substance.</b></p>	<p>Concentrated formulations are produced and traded to other manufacturers overseas or occasionally within NZ. For example 10Litre/7 Kg buckets of concentrated substances, to be mixed into an aqueous cream base for a skincare product ( specialised factories blend concentratrs into base cream, pot/sachet,label, carton + ship) .</p> <p>For the substances traded within NZ and the Maori paradigm, we have attached a range of labels, fact sheets (dosages), COA's and MSDS's which are dosages supplied with such materials.</p> <p>Raw and semi processed raw materials of 650-900 substances.</p>
<p><b>Proposed label advisory or warning statements.</b></p>	<p>We provide labels (for everything) with warnings and also fact sheets to our manufacturing customers.</p> <p>Our large customers always get a COA + MSDS. Bacterial counts and allergy testing are collaborative with shared costs.</p> <p>The extent/detail of the MSDS depends on the customer, as it is 'user pays'</p> <p>Science facility services in Asia are a fraction of the cost of same services in NZ.</p> <p>Attached sample labels, fact sheets, COA's and MSDS's with warnings.</p>
<p><b>Parts of the plant / animal / organism used.</b></p>	<p>Polysaccharides, Resins, Oils and Alkamides, Pectins, Mucilages, Fructans, Alkaloids, Omegas, Fatty Acids, Triterpenoids and Saponins, Terpenes, Glycosides, Phenols and Polyphenols.</p> <p>Amino acids, vitamins, mineral compounds, micro-organisms</p> <p>Including new constituents of endemic NZ medicinal plants not listed above.</p> <p>Attached range of sales catalogues describing parts used.</p>

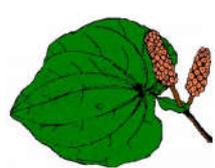




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<p><b>Method of manufacture / extraction / purification.</b></p>	<p>Supercritical CO2 extraction, Supercritical fluid extraction, Tincture, Homeobotanical, Distillation (copper, silver, glass and stainless steel), Direct organic extraction, Dispersive liquid-liquid micro-extraction, Aqueous two phase extraction, dehydration, grinding (powders), cold pressed.</p> <p>Presently extractions, distillations, purifications and productions of expressions, production of formulations, of active ingredients, of aqueous solutions, soluble concentrates, emulsifiable concentrates, suspension concentrates, wettable powders, dry powders, surfactants, tinctures, cold pressed materials and other liquids and oils. Raw materials and semi-processed materials inclusive of creams, balms, gels, ointments, tinctures, decoctions, syrups, infusions, capsules, tablets, compresses and dressings. Also raw and semi-processed raw materials (leaf, stem, bark, roots, moss), from dehydrated leaf flakes, clays, slime, insects etc to powdered bark etc.</p>
<p><b>List the extraction solvents used (other than ethanol and/or water). (if applicable)</b></p>	<p>CO2, Methanol, Vodka, Brandy, Toluene, Benzene, Xylene, Acetone + C2Cl4</p>
<p><b>Additional information on produced material.</b></p>	<p>Presently we extract, distil, purify and produce expressions in NZ and produce formulations of active ingredients of aqueous solutions, soluble concentrates, emulsifiable concentrates, suspension concentrates, wettable powders, dry powders, surfactants, tinctures, other liquids and oils within a Western paradigm. Raw materials and semi-processed materials are also gifted/koha to Maori within the Rongoa Maori paradigm and include creams, balms, gels, ointments, tinctures, decoctions, syrups, infusions, capsules, tablets, compresses and dressings. Also raw and semi-processed raw materials (leaf, stem, bark, roots, moss), from dehydrated leaf flakes, clays, slime, insects etc to powdered bark are gifted/koha to Maori.</p> <p>Kiwi Herbs Ltd markets itself as a Wholesale Supplier of Medicinal Raw Materials and Natural Resources of New Zealand.</p>





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Toxicity or safety data to support the use of the substance at the proposed doses and routes of administration is attached.

Yes  No

Reports of adverse events associated with the use of this substance are attached.

Yes  No

**List relevant reports (attached): -**

29 KHLTD's NZ biota medicinal and other materials catalogues being: Freshwater, seawater, aquatic plants, forest floor, algae, ants, bacterium, viruses + zoospores, bats, beetles, birds, bryophytes, earthworms, fleas, freshwater fish, freshwater invertebrate, fungi, human, insects, marine fish, marine mammals, micro-organisms, minerals, moths, molluscs, plants, orchids, reptiles, seaweeds, snails and spiders.

C.O.A's x 5, M.S, D.S x 5, Fact Sheets x 5, and Flora Parts Used: NZ Wholesale Catalogue, Label sample sheets, Whakapapa doc,

PREPARE

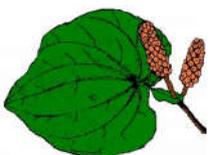




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<p><b>Tiriti o Waitangi.</b></p> <p><b>Natural Products Bill Tiriti o Waitangi Statement.</b></p> <p><b>Crown Law statements at Wai 2345 Freshwater Hearing 2011.</b></p> <p><b>Maori, Rongoa Maori “interests” statements.</b></p>	<p>Recognition of Te Tiriti ( Treaty of Waitangi):</p> <p>Natural Products Bill pge 14.</p> <p>“ In achieving the purposes of this Act, all persons exercising functions and powers of this Act under it, shall honour the articles of Te Tiriti o Waitangi”</p> <p>Taonga were protected, and the rights to develop Taonga exist under Tiriti o Waitangi Article Two.</p> <p>The Crown has a fiduciary duty to protect Taonga known at 1840 or discovered later for Maori</p> <p>There exists “The right to develop Taonga”, of which Maori had customary use, prior to 1840 as a development of Maori as a people.</p> <p>Maori also have the right under the partnership principle to “The development of Taonga not known in 1840”.</p> <p>Maori have “special interests” over concerns of over allocation, to over use of Taonga substances.</p> <p>Maori have “tribal interests within Rongoa Maori, above those of the general public”.</p> <p>The interests of non-Maori traditional medicine frameworks are not protected by Te Tiriti and are outside this KHLTD Maori paradigm PSL application.</p>
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**KPLTD Fred Allen acknowledged as a Rongoa Maori Tohunga, declares that these attached Taonga Lists are Rongoa Maori, therefore Traditional Medicine.**

**Natural Products Bill statements on traditional medicine.**

**Fred Allen's is a descendant of Maori and is a repository of Rongoa Maori Traditional Knowledge (TK) information.**

**Maori epistemology lore/law that all Taonga are interconnected for Rongoa Maori.**

Fred Allen was mandated by Hui and a vote, by his Iwi Hapu and Whanau, to represent Rongoa Maori for the Taranaki Whanui, Whanganui a Tara Rohe. I declare, as an expert (Rongoa Maori Tohunga) and based on the principles of the Natural and Supplementary Products Bill, that the species and all other materials submitted within KHLTD's Taonga/Treasures lists are traditional medicines.

NPBill 20 (b) "in declaring whether a substance should be declared a permitted ingredient", "whether a substance is recognized in traditional medicine".

NPBill Part 2.8 (b) "Traditional Evidence: "traditional evidence is evidence derived from the use of a substance based on knowledge, beliefs or practices passed down through generations

Fred Allen travels extensively to receive traditional knowledge (TK) from the last of the very old tohunga, being in the forest in May 2016 with a 94 year old tohunga who specifically wished to pass onto him his traditional knowledge before he died. The levels of intimacy within the whole of the environment, specific to Maori Traditional Medicine, being compatibility, actions, combinations of unassociated organisms across, kingdoms, classes, genera of organisms, between unassociated materials, specific organisms ingesting specific organic material, for the organism to be a medicine, to complex gathering of materials from specific soil types at specific times of year/day, south or north facing etc is beyond the science knowledge of the Western complementary medicine paradigm. Fred's most respected Taranaki Whanui Kaumatua, Uncle Sam Jackson (deceased), asked Fred specifically not to share this TK of "compatibility and their actions" with CRI's and allow this TK into the public domain.

Taonga were protected, and the rights to develop Taonga exist under Tiriti o Waitangi Article Two. Fred Allen derives his ancestral hereditary rights from his Tupuna. "Nga Atua, the interconnections, Whakapapa of each Kaitiaki ( without Nga Atua you have no Taonga), Mauri, the integrity of all Taonga, Kaitiakitanga, the body of wisdom for guardianship and custodianship relating to all things Maori, Taonga, are all the treasures created on earth, and Tikanga, the practice of policies and procedures for implementation".

**Kiwi Herbs Limited**

**Member of Natural Products New Zealand and Member of Te Kahui Rongoa Trust**





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