INTERNATIONAL NUTRITIONAL PRODUCTS ASSOCIATION (NZ)

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SUBMISSION ON PROPSAL P235
"REVIEW OF FOOD-TYPE DIETARY SUPPLEMENTS"

The members of the International Nutritional Products Association (NZ) have not had time to carefully consider the whole of P235 in the time allowed.

In lieu of making a separate submission **we hereby endorse the submission put in by Citizens for Health Choices today.** We particularly want to emphasize the problems that would be created if FTDS and TTDS should be regulated under different regulatory bodies and Acts, and problems that would occur if New Zealand specific labelling were to be imposed.

As we concur that FTDS and TTDS need to be regulated under the same scheme in New Zealand, we have also included below the submission made by the International Nutritional Products Association (NZ) on **"A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS".** There are relevant sections in this submission.

In reading the P235 discussion document, it is very obvious that the problem in the regulation of these products (dietary supplements of all kinds) lies with Australia's "drugs" or "foods" system rather than with the New Zealand system. We strongly believe that the 3 category system that we have in New Zealand and adopted by America and many other countries should be retained. If there is a problem with foods calling themselves dietary supplements, regulations should be written to deal with that situation. There is considerable overlap between P235 and the TTTGA proposal. Due to the reasons outlined above and the reasons in the submission below, we cannot agree with "harmonisation" for any sort of dietary supplement.

COPY OF SUBMISSION MADE BY THE INTERNATIONAL NUTRITIONAL PRODUCTS ASSOCIATION (NZ) on "A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS - JUNE 2002"

SUBMISSION ON DISCUSSION PAPER
"A PROPOSAL FOR A TRANS TASMAN AGENCY TO REGULATE THERAPEUTIC PRODUCTS"

The International Nutritional Products Association (INPA) consists mainly of New Zealand owned dietary supplement companies but also New Zealand branches of international dietary supplement companies. Our members import and distribute dietary supplements mainly from America, Europe and other countries excluding Australia. Some of these New Zealand owned family companies have been in business for up to thirty years importing overseas labelled dietary supplements. Several member companies import supplements from more than one overseas company and more than one country.

Over the past ten years, since it was first suggested that new legislation was needed for dietary supplements, many of our members, not to mention thousands of consumers and other industry people, have spent thousands of hours making numerous submissions, attending dozens of meetings (both industry and Medsafe), and are very concerned that ALL constructive suggestions and agreed positions have been ignored in the latest proposal. It has been made very clear over the past ten years that the Australian TGA system is not a

viable system for dietary supplements in New Zealand due to excessive bureaucracy, red tape and costs.

To the Australian Productivity Commission the Complementary Healthcare Council (CHC) stated ' ***It is worth noting that there is no other complementary healthcare market in the world regulated in the same way as Australia and there is no international comparison*.'**

As the United States of America is probably the largest producer in the world of Dietary Supplements, around NZ$35 billion per year, we do not understand why their Dietary Supplement Health and Education Act of 1994 was not presented as an alternative for evaluation and comparison with the Australian TGA model as basically proposed in the Discussion Paper.

The fact that all the States within Australia are not harmonised under the TGA legislation, it is reasonable that New Zealand should not even consider harmonisation of dietary supplements with Australia.

We also wish to express our concern that the second NZIER Economic Impact Report has still not been released.

Our major areas of concern are: governance arrangements, industry costs including red tape and fee structures, negative impact on the majority of New Zealand dietary supplement businesses, negative impact on consumers, trade mark protection and differences, non-harmonisation within Australia.

A key factor is that this should be a proposed agreement between two sovereign nations, not simply two health bureaucracies.

NOTE: The products in this submission are referred to generally as dietary supplements as that is their legal name in New Zealand. In Australia these products are referred to as complementary healthcare products. CHC is the Complementary Healthcare Council of Australia which is the peak complementary industry body in Australia.

INDUSTRY BUSINESS COSTS AND FEES

This proposal for a joint agency appears to be at odds with the Prime Ministers publicly stated government aims "To get small business up and running well." "Back the up and coming industries." "Work with New Zealand companies, backing the innovators and building partnerships."

It is also at odds with the governments aim to reduce red tape and compliance costs for business. This proposal creates a huge compliance burden particularly for small business.

All of the proposed activities would cause very high fees to be charged by the agency. For the very low-risk posed by Dietary Supplements, most of this activity would not be required – thus fees charged should be negligible. Annual renewal fees are considered unnecessary and unjustifiable on the basis of consumer safety or enhancement of trade - two of the stated purposes.

Based on the current fees of the Australian TGA, and we have no indication that the new fee structure will be any lower, companies within INPA will be faced with annual fees in the hundreds of thousands of dollars. This has the potential to reduce product ranges, create downsizing of businesses and even the very real possibility of making many small businesses financially unviable. It will also cause severe distortions in the retail market as Australian companies and large New Zealand companies are already paying the Australian fees and have built those into their retail pricing.

Currently in New Zealand there is no cost recovery scheme for the regulation of Dietary Supplements as they are classed as foods. Any fee structure would be a huge additional burden to this sector. For

the majority of Dietary Supplements, the risk is less than for many foods. Suppliers of foods pay no fees toward their regulation. In order to be consistent, Dietary Supplements should have no fees that are collected from the industry for their regulation.

The determination of what constitutes "excessive compliance costs" is crucial to this discussion. What may be a fee, which can easily be borne by one sector of the industry, would mean for other sectors that products would unnecessarily be uneconomic to put on the market due to fees; thus essentially "banning" the product due to the fee structure.

Currently in Australia, Complimentary Healthcare Products provide a disproportionate amount of monetary support for the TGA when the risk of the products is assessed, as compared with other products regulated by the agency. This must not happen in any new scheme for New Zealand, be it a joint agency or one that is for New Zealand only.

There is a Public Good component to this scheme – otherwise why is it being done? At least part of the costs of running the agency must come from public funds rather than 100% cost recovery from the industry. The proposal does not take into account the health benefits of dietary supplements.

There must not be over prescriptive application forms, even if electronic, that require a consultant to figure out. All information gathering for listing products must be simple with little time required to perform the activities. Overt fees are only one area of cost for industry; compliance time and staff time are also costs.

There have been moves in Australia to eliminate the "**low volume**" category that at present enjoys lower fees. It is imperative that there be lower fees for Dietary Supplements which have a low volume turnover. Otherwise, very safe, high quality products could be effectively banned from being sold simply because it would be uneconomic to handle the product. Even a $70.00 fee (as currently charged in Australia) for a product sold only in New Zealand could effectively put the product off the market due to the retail price that would be required to be charged for the product due to the necessity to recover the fee.

Medsafe has stated several times that the proposal will provide a bigger market for New Zealand supplement companies. This does not take into account that there are trademark differences in both countries. There may already be a distributor in Australia for the brand of supplements. Many small New Zealand companies are unable to suddenly financially support a huge push into Australia.

To the Australian Productivity Commission the CHC comments "***CHC is aware of decisions taken by many companies not to enter the (Australian) market because of the high direct regulatory cost imposed by Government."***

DIFFERENT REGULATIONS IN THE TWO COUNTRIES

The regulation of dietary supplements/complementary products is vastly different in the two countries at present. Our very strong recommendation is that New Zealand "opt out" of this area of harmonisation. The safety outcomes for dietary supplements (complementary healthcare products) in Australia and New Zealand have been virtually identical despite the overly bureaucratic Australian system and New Zealand's minimalist regulations.

The two systems in the two countries have major philosophical differences in regulation that have been entrenched in business and legislation for many years. The changes proposed for New Zealand are major and will have serious implications and repercussions for business and severe flow on effects for consumers and supporting businesses.

We fail to see how one combined agency can adequately regulate three totally different types of products - medicines, medical devices and dietary supplements.

As stated by Medsafe many times, dietary supplements are considered safe and 95% of products currently on the New Zealand market would be allowed to stay on the market. This begs the question

that given the acknowledged high safety profile, why is such a complex, expensive and overly bureaucratic system for their regulation being proposed.

To the Australian Productivity Commission, the "***CHC notes the TGA comment that 'all regulatory effort by the TGA is undertaken solely because the industry exists'. In the case of the complementary healthcare industry, it is not the existence of the industry which causes the regulation, but the inclusion of the industry in the legal definition of therapeutic goods. In the vast majority of other countries the same complementary healthcare products are regulated as foods, or within a subset of food regulation, are able to make health claims and are not subject to pre market evaluation and associated fees and charges.***

***CHC has long argued that the products of its member companies are inappropriately regulated as if they were higher risk pharmaceutical drugs*.'**

FOOD SUPPLEMENT REGULATION & HARMONISATION

It appears that Proposal P235 of ANZFA overlaps in many areas with the proposal for a Trans Tasman Joint Agency and provides considerable insight into the regulations of dietary supplements.

P235 has identified the basic problem in the international regulation of dietary supplements. "*In some countries regulation is effectively based on a 3 category system - dietary supplements (or another term), foods and medicines. The regulations pertaining to dietary supplements (or other) generally sit under a broader (2 category) legislative umbrella for either foods or medicines. For example the NZ Dietary Supplement Regulations places them under the Food Act while in Australia they are under therapeutic products (medicines) and the TGA. Countries with a 3 category approach include New Zealand, the United States, Canada (proposed system), Europe and Japan.*

Countries using a 2-tier system include Australia and the United Kingdom (although their system is mixed)."

It is obvious from this that New Zealand is similar to the majority of our trading partners and Australia is out of line and that this creates severe legislative problems.

There is a very strong case to be made for the retention of the New Zealand 3 category system which would create a more seamless regulation of products than the Australian 2 category system.

Many of these countries with a 3 category system allow some form of statement of purpose or claims, even though they classify dietary supplements under food.

To the Productivity Commission the CHC states ' *Since the introduction of the full cost recovery on therapeutic goods, there has been an explosion of innovative healthcare food products (**food type dietary supplements**) in the Australian market using the same ingredients as in complementary healthcare products. These products are not subject to the costs that apply under the therapeutic goods regime - both regulatory and cost recovery.'*

This is further evidence that the Australian two tier system is not working and the proposed system has the same faults.

GOVERNANCE ARRANGEMENTS

Despite the assurances from the Minister of Health that New Zealand will have equal authority and voice in the joint agency, this statement cannot be supported by the facts or statements made in the Discussion Paper.

The proposal gives too much authority to one person, the Managing Director, for setting fees and charges, and for setting the requirements that must be met before a product can be sold.

There is no structure for consumers or stakeholders to appeal, advise or influence the decisions of the Managing Director or any other person in authority.

Disgruntled parties will have the option of using courts in either country to lodge their appeals - New Zealand will need to agree to be bound by the decisions of the Australian Courts and Australia by the decisions of the Privy Council or our new Supreme Court.

It is unclear how investigation of "offences" in either country will be carried out.

In general, the governance arrangements as set out would be cumbersome and unworkable for some of the following reasons and comments:

- As both an Australian and a New Zealand minister would oversee this agency and would be in turn be overseen by two parliaments. To what extent, realistically, will the New Zealand Parliament and Government retain any control? Who would in fact be accountable should something need to be addressed? Experience over the past few years indicates that Australia will dominate the decisions.
- As an industry we are aware of the continual and rising debt of the TGA. This means continual fee rises for the "complementary" industry that is out of all proportion to the risk. The TGA's only method for balancing their budget is to raise industry fees rather than reducing costs. There is no budget or accountability presented to the people paying the infrastructure of the TGA for their approval.
- We understand that a treaty can be signed by New Zealand without reference to the New Zealand parliament. We have grave concerns that this treaty may be signed without the approval of the New Zealand legislature or people of New Zealand? Have Maori been consulted and approved the treaty?
- We strongly object to so much ultimate power being given to Australia. All five members of the board should be appointed with the agreement of both ministers. It is proposed that if there is no agreement, 2 of the 3 remaining board positions would be appointed by the Australian Minister and this does not protect New Zealand's sovereignty. That the instruments of appointment would be signed by only the Australian Minister is also unacceptable and not sound business practice if it is an equal partnership. They should be signed by both ministers. This would appear to indicate that the Australian Minister has ultimate power in the agency. Obviously this is not an equal partnership. **We do not see how an equal joint agency cannot be formed under one countries corporate law dominated by the larger country. There is no reason why there should not be total equality in the relationship.**
- New Zealand is currently well served by its Official Information Act and Ombudsman Act. Quite different legislative regimes operate in Australia. Although they do have a Freedom of Information Act, there are blanket categories of exempt documents including Cabinet documents, Executive Council documents and Internal Working Documents.
- The key question is whether the Australians are going to accept a higher level of transparency and openness? Will there be pressure from Australia for New Zealand to accept a lesser standard of transparency and openness?
- What will happen if rules with the status of regulations in both countries are disallowed in one country but not the other? New Zealand has a Regulations Review Committee and a Regulations (Disallowance) Act.

Managing Director

The Managing Director has ultimate and total power for running the agency. This is unacceptable as this person can make decisions on therapeutic product approvals and make technical orders, such as labeling requirements. There are no controls on any actions taken by this person. This person would have more authority than the New Zealand Minister of Health but is not accountable to either the bill payers or consumers. Who would make sure that this person did not make unreasonable

requirements and/or decisions in these areas? The board would not appear to have any ability to exercise control over the Managing Director. This person, in particular, must not have any negative bias against any of the sectors being managed!

At present in New Zealand the Minister of Health makes the kinds of decisions that would be given to this position. The people of either country would have no come back if the person made bad decisions. At present, any person in New Zealand can write to the Minister of Health to try to influence decisions – and ultimately the voters can choose to not elect that person at the next election.

The Managing Director is not accountable to consumers or stakeholders. If his direction, action or ability is brought into question, the ministers in both countries would have to agree to what action should be taken. If they don't agree, who makes the ultimate decision?

This degree of authority given to an unelected official shifts power away from democratically elected Members of Parliament

In previous submissions we objected to the Director General of Health having too much absolute power. It would appear that that power is being transferred to the Managing Director. What part does the Director General of Health play in the proposed new agency?

Stakeholder Input

The statement that the meetings would advise only in general rather than on particular regulatory decisions is an outrageous idea! Stakeholders must be able to question outcomes of all regulatory decisions.

There must be easy and inexpensive systems set up for stakeholders, including consumers, to question and challenge regulatory decisions.

Accountability under other legislation

All laws and Acts in either country should apply to the Agency's actions, not just the two acts concerned with access to information.

Structure - staff

As this is a new agency, present staff of the TGA and Medsafe should not be guaranteed automatic employment. They should have to apply for advertised positions in the new agency in competition with others who are perhaps better qualified. It would be realistic to expect that there would be redundancies in both Medsafe and the TGA due to economies of scale.

The Discussion Paper states "…there may be separate regulatory units for…" There must be a separate regulatory unit for products currently regulated as complementary medicines in Australia and as dietary supplements in New Zealand. As in America under DSHEA 1994, people who make the decisions on their regulation must not be biased or prejudiced against this range of products.

PREFERRED PRODUCT TERMINOLOGY

The word "complementary" indicates that dietary supplements need to be used alongside other products. Some consumers think the term means they are FREE. Many people use these products for their total health care needs, without resorting to prescription medicines except in very limited circumstances

Our preferred name is Dietary Supplements. That is the term currently used successfully in New Zealand, the USA and other countries. The term Dietary Supplement has been used in New Zealand since 1985 and New Zealand consumers understand it. If Dietary Supplements is decided against, then the following could be used:

- Healthcare Products

Complementary or alternative are NOT considered appropriate as they raise the question: Complementary or alternative to what? Orthodox medicine? Complementary in some peoples minds can mean FREE.

We provide the following definitions of dietary supplements for comparison:

CURRENT NEW ZEALAND DEFINITION OF DIETARY SUPPLEMENT FROM "THE DIETARY SUPPLEMENT REGULATIONS 1985"

"Dietary supplement" means any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients, and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders or tablets, which are intended to supplement the intake of these substances normally derived from food.

CURRENT UNITED STATES OF AMERICA DEFINITION OF DIETARY SUPPLEMENT FROM "DIETARY SUPPLEMENT HEALTH AND EDUCATION ACT OF 1994"

The term 'dietary supplement' means-
"(1) a product intended to supplements the diet by increasing the total dietary intake that bears or contains one or more of the following dietary ingredients:
(A) a vitamin, (B) a mineral, (C) an herb or other botanical, (D) an amino acid, (E) another dietary substance for use by man to supplement the diet by increasing the total dietary intake; (F) or a concentrate, metabolite, constituent, extract, or combination of any ingredient described (A), (B), (C), (D), (E), or (F);
(2) a product that-
(A)(i) is intended for ingestion in a form described (tablet, capsule, powder, softgel, gelcap or liquid form).
(ii) complies with
(B) is not represented for use as a conventional food or as a sole item of a meal or the diet and
(C) is labelled as a dietary supplement.

The term 'drug' does not include a dietary supplement

As can be seen these two definitions are very similar and could be satisfactorily adapted for New Zealand to reflect and encompass all the products sold in this category.

Definition of a Medicine includes the phrase: "represented to achieve". Does this mean that if a product makes no claim then it is not a medicine, and therefore would not be covered by this scheme? Would cosmetics that make claims about improving the look and appearance of the skin, for example, be classified as a medicine?

Would products that are designed to prevent health problems be included in the term "medicine" as it is presently defined? No orthodox medicine that we are aware of actually prevents any illness or disease unlike vitamins and minerals. No deficiencies have been identified that can corrected through prescription medicines. There is a need to separate the medicines and dietary supplements.

The extension of the scope of therapeutic products in New Zealand needs to be approached cautiously – statistics show that supplements are much safer foods. The parameters for the regulation of supplements needs to be much different from those proposed for pharmaceuticals, drugs, etc

RISK BASED APPROACH

While we agree that a risk based approach is appropriate, this Discussion Paper does not represent a risk based proposal. **A risk based approach requires that a risk assessment is undertaken to**

determine actual risk -- that has never been done for dietary supplements in New Zealand. Only anecdotal comments have been made by Medsafe.
Dietary supplements need to be put in their appropriate category which is safer than food. If a product is very low risk, such as most dietary supplements, little or no fees should be charged - as for foods. The risk category should not change just because an ingredient can be used for a more serious health problem. No evidence has been presented to show that a dietary supplement ingredient becomes more risky due to a claim.

PRODUCT LICENSING & PROCEDURES

We do not support the concept of product licensing such as is currently in force in Australia and proposed in the Discussion Paper.

The industry since 1998 has supported a simple listing system for Dietary Supplements. In the Discussion Paper, the proposed system is virtually a copy of the present TGA system and is NOT a simple listing system. **It is an expensive pre-evaluation system.**

We do not support the requirement that dietary supplements imported in "ready to sell" packaging be required to have retention samples retained in New Zealand. Under GMP such samples are kept by the manufacturer of the finished goods and would be available for assessment in the country of origin should there be any problems with the product. Retention samples are not required for foods coming into New Zealand. No other country that we are aware of requires retention samples for packaged dietary supplements be held in the importing country as well as the exporting country. For an imported supplement, any analysis required would be initiated through the originating manufacturer.

EXPERT ADVISORY COMMITTEE

The function of these committees is dubious, as they appear to have no real power. It is essential that the makeup of the advisory committee, including the consumer member (Citizens for Health Choices could advise names for selection), for dietary supplements have specific expertise and knowledge of their use. The present members of the Australian CEMEC are not supported by our association.

As the attitudes toward dietary supplements are so very different in the two countries, the New Zealand perspective must be represented equally on any advisory committee dealing with these products.

We have grave concerns that the Managing Director appears to have sole and total authority to decide and recommend members of the Advisory Committees. As the makeup of the committees is not specified, it could well be that they are all Australians.

LABELLING

Standard requirements for labels must not be so prescriptive that labels on products from countries other than Australia or New Zealand would not be accepted. The way that herbs are designated on labels in Australia, which is not accepted internationally or for that matter in any other country that we are aware of, is not acceptable to our members.

Many countries around the world accept American labelled dietary supplements as New Zealand has for well over twenty years. Well over 500 million people in countries around the world have access to American labelled products. In the interests of free trade New Zealand must continue to accept these products as it has for the last 30 years.

As mentioned previously, the claim on the label must be voluntary not mandated and certainly not prescriptive. In Australia, we are aware that the TGA approves label claims for Australian

complementary products using science borrowed from patented dietary supplements from Europe and America. This is official approval of false and misleading claims fro Australian complementary medicines.

Standard names for Dietary Supplement must not be so prescriptive or unique to the system that they eliminate products from other countries and thus form a non-tariff trade barrier.

"**The Agency would adopt appropriate naming conventions for biological and herbal substances.**" **"…the Agency would adopt a system of standard terminology for herbal substances based on that currently in use in Australia."** The wording required on herbal remedies, as to the quantity of the herb in the product, currently in Australia is not recognized worldwide and is deceptive. It "cons" the consumer by giving the impression that the product contains much more of an ingredient than it actually does. Internationally this is not acceptable and also in breach of New Zealand's Fair Trading laws and Commerce Act.

All genetically modified ingredients should be excluded from this agency and come under ERMA or some other body for initial approval.

In dietary supplements often there is a "proprietary blend" of herbs. The names of all the herbs along with the total quantity of proprietary blend should be all that is required – not the exact amount of each herb. This leniency is allowed in other countries and required to protect the manufacturer from others copying their blend.

We agree that sometimes a warning statement is necessary on a product. However, there must be clear scientific evidence that such a statement is required.

The product licence number must not be required to be on the label; the bar code must be acceptable as the unique number, if indeed it can be shown that such a requirement is necessary. Special numbers are not required for food labels. It is 1980's technology to require printed numbers on labels. We need to use existing unique product bar codes with current IT technology.

As with all products purchased and as stated under New Zealand law, if there is a problem the product is returned to the outlet it was purchased from, not directly to the distributor or manufacturer. In many instances in commerce ranging from cars to clothing, food and whiteware, the consumer is unaware of who the importer and distributor is.

PRESCRIBING RIGHTS

For any dietary supplements that meet the criteria of "prescription only": any group of practitioners designated to prescribe must have knowledge of dietary supplements (complimentary medicines). In other words, medical doctors who have not passed recognised long term education courses in these products must not have automatic prescribing rights for Dietary Supplements. It is essential that Medical Doctors obtain appropriate qualifications approved by the New Zealand Charter of Health Practitioners before being allowed to prescribe these products.

MANUFACTURING PRINCIPLES AND GMP

Dietary Supplements must have a GMP requirement that is appropriate for the industry and recognizes the generally low risk nature of the products. Therefore, the GMP standards must be less stringent than for pharmaceuticals that are in a much higher risk category and where even minute amounts of raw material can kill.

For those companies that only bottle product already in tablet or capsule form, the GMP needs to be different than it is for those who actually manufacture the product.

Interpretive guidelines would not be sufficient guarantee that auditors would be able to use them correctly. The actual GMP for dietary supplements needs to be less stringent.

Acceptance of overseas GMP standards, such as the FDA, European, Individual USA State GMP, or NNFA (USA) cGMP, must be acceptable.

"…enhancing the reputation of medicines, exported from the Australia/New Zealand market." As mentioned several time in this response, credibility should not be an objective of legislation. It is not the role of the agency to enhance the reputation of medicines.

If consumer safety is a criteria for the proposed agency, products for export only must contain only those ingredients approved as safe for sale within Australia or New Zealand. Conversely, if they are safe for export they must be safe for local use.

REGULATION OF COMPLEMENTARY HEALTHCARE PRODUCTS

As the current legislation is so different in both countries, it makes common sense for New Zealand to "opt out" of any Trans Tasman regulation for dietary supplements /complementary healthcare products.

One of the stated purposes of this Agency is: "Consumers have an expectation that the complementary healthcare products they purchase will be safe…" Under the current TGA rules are Australian consumers of Complementary Healthcare Products any safer than New Zealand consumers under the Dietary Supplement Regulations? Are the Australian Complementary Healthcare Products any safer? All the evidence points to the answer being "NO".

To the Australian Productivity Commission, CHC states: '***CHC endorses the finding that Australian consumers may be affected by cost recovery indirectly, in that they may pay higher prices or have a smaller range of choice fro some regulated products. This is the case with complementary healthcare products.'***

INTERNATIONAL TRENDS IN THE REGULATION OF DIETARY SUPPLEMENTS

It is indeed curious that the USA Dietary Supplement Health & Eduction Act 1994 has been left out of the Discussion Paper as an example of how dietary supplements are legislated internationally. The USA market, equivalent to NZ$ 35 Billion annually, is one of the biggest in the world, with a very good safety record. It has one of the most liberalised systems internationally for supplements, based to some extent on what we currently have in New Zealand, and it works! What could be the motive behind leaving this USA system out of this Discussion Paper?

"The Australian regulatory system aims to ensure public health and safety and enhance consumer confidence in complementary medicines without ***unnecessary regulatory impost*** *on the industry. This is achieved through an appropriately balanced risk management framework involving Listed (low risk), Registered (higher risk) and Exempt (special cases) complementary medicines."* This statement about the Australian system cannot be supported by the current fee structure of the TGA. It is one of the most draconian and expensive systems in the world. It imposes fees and red tape that is out of proportion to the low-risk nature of these products.

"Low risk complementary medicines are included in the ARTG via a simple, low cost and very quick process known as Listing."

This statement is contradictory to reality and truth. The Australian system has crippled many small businesses entry into this area of commerce by its unnecessary fees and red tape. It often takes Consultants at considerable expense to conduct this process. If the application fails for a small error, another full fee is charged. Since the introduction of the TGA regime, unlike New Zealand, there has been little or no innovation of dietary supplements in Australia.

To the Australian Productivity Commission, the CHC stated '***The Council is aware of many small businesses that have relocated offshore, with loss of jobs and revenue to the Australian economy. It is an attractive and economical option to set up mail order companies in New Zealand and other neighboring locations and mail order back to Australia without incurring the regulatory and cost burden imposed by Australia*****.'**

'US companies have indicated their interest in establishing an Australian presence as a stepping stone into the Asian market but have decided against it because of the associated difficulties and cost.'

LISTING and APPROVAL SYSTEM

The negative listing system used in New Zealand has worked very well indeed for many years. There is no need for an Australian positive listing system (or in more user friendly terms the "white list") for ingredients in Dietary Supplements.

Any electronic lodgment system must be user-friendly, simple, only loosely prescriptive as to wording, and inexpensive. We understand that the current Australian ELF system is lengthy, overly prescriptive as to wording, and the TGA is certainly not helpful to applicants with getting the wording correct. If one word is incorrect, the whole submission is rejected, thus requiring a new application fee to be paid. This process in itself is unfair and overly expensive.

Currently in Australia one thing that makes their system so expensive is that they "randomly" check too large a percentage of the applications. They are not following international recommendations.

Appeal mechanisms, in the first instance, must be inexpensive, using easily prepared evidence.

The requirement for clinical trials for new Class 1 ingredients is in most cases not required internationally and is unnecessary and will be hugely expensive for products that cannot seek patent protection. If humans have used a substance historically and traditionally with safety, then informal clinical trails have already in essence been done! If the ingredient has been approved in say the USA and other acceptable countries, there is no reason why it should not be accepted in New Zealand.

This requirement would effectively stop new ingredients, accepted internationally, from being available to New Zealand consumers.

The suggestion that the work of expanding the positive list "could be funded as part of the Government-funded set-up costs of the Agency" must be honoured in any new dietary supplement legislation. However we strongly recommend a review of the negative list instead. No formal request has been made or advertised for companies to submit ingredients for inclusion on the positive list as it appears to be simply an idea of Medsafe without any substance or legal standing.

Consumers of supplements are generally vehemently opposed to a positive list, as such a system would unnecessarily restrict their ability to access safe, new ingredients and products available internationally. It would also stifle innovation in New Zealand as is the case presently in Australia.

What mechanism(s) would you propose to enable sharing of the costs of evaluation of new substances? Give details.

This idea shows a complete lack of business experience by the writers of the Discussion Paper. It is simply against all international business practice for dietary supplements, and other goods for that matter, and would not be accepted by the international business community. New products and innovation of any sort are closely guarded as they are the life blood of industry.

To the Australian Productivity Commission the CHC stated '*CHC agrees with the finding that direct regulatory charges for generic products may give rise to first mover disadvantages; inhibiting the introduction of new products. Complementary healthcare products are based on substances which are not patentable; the cost of seeking approval for use of a new substance, and the 'free-rider' effect, is a major barrier to development of new products.'*

As there is very little risk with most Dietary Supplement ingredients, there should be so little cost to get them approved that this question becomes irrelevant!

Any collusion by companies acting together is contrary to current New Zealand law and the Commerce Act. It has the potential to eliminate competitive advantages and thus increase prices.

The main problem is that natural products, in general, cannot be patented

There needs to be a broad base of sources and texts that are approved to use for evidence of traditional use.

There would need to be very little post-market surveillance needed for Class I products due to their low-risk.

Overseas approvals by reputable agencies must be accepted.

SURVEILLANCE AND ENFORCEMENT

To even suggest that **criminal sanctions** could be taken by this joint agency for minor issues against dietary supplement companies is unbelievable. The "…power to take prosecutions through the New Zealand and Australian courts to impose criminal sanctions" gives this agency far too much power. This power should remain in the country of origin. In New Zealand the Fair Trading Act and the Commerce Act cover this area adequately, so there is no need for further powers to be given to any other agency.

Tamper-evident packaging

Tamper-evident packaging is used by most of the Dietary Supplement industry already. For these low risk products, one tamper evident seal is sufficient. Many foods only have one seal and numerous foods, bread being the obvious one, are simply provided in plastic bags, thus providing no tamper-proofing at all. We are also aware of the Australian TGA suggestion that as well as having two tamper evident seals all bottles must be shrink wrapped for additional protection. This is not acceptable and is not even required internationally on OTC products. An example being the numerous OTC medicines supplied in cardboard cartons.

We are agreed on tamper evident seals such as bottle lids where the seal is broken to gain entry. We are unaware of any problem of tampering with Dietary Supplements in New Zealand over the past 20 years. There does not appear to be any problem internationally with tampering of supplements. Many American supplement companies use an inner seal and an outer shrink wrap. However, it must be considered that these are major companies with huge turnovers who produce tens of thousands of bottles of supplements daily for hundred of millions of people worldwide. What problem are we trying to solve?

ADVERTISING

Control of advertising must not be part of a joint Australia New Zealand agency in any way.

What problem in New Zealand is there to be solved by this overly bureaucratic and expensive proposal? Present New Zealand legislation via the Commerce Act and Fair Trading Act adequately covers this area. Also the Advertising Standards Authority system works extremely well.

It could be construed that the Complimentary Healthcare Council of Australia would like advertising to be included as they are currently collecting a considerable amount of money (estimated at $100,000 per year) in Australia to approve advertising. But New Zealand needs to keep control of its own advertising rules. Advertising controls do not belong under a Joint Agency scheme, nor should they be under the jurisdiction of the Ministry of Health in New Zealand. They should remain under the other Acts such as Fair Trading, Commerce and also the Advertising Standards Authority.

CONCLUSIONS

Safety and efficacy will not be assured by any system of regulation. With all the regulations, clinical trials, etc., already in place over Class 3 medicines, these products cause hundred of thousands of deaths worldwide each year. Additionally in many cases the side affects are as dangerous as the problem the product is trying to fix. Even with these drugs, that medical doctors are educated to prescribe, errors are frequently made that cause death.

This Joint Agency proposal is all about creating a bureaucratic process and regime. There is no mention of improving the health of New Zealanders or encouraging them to take responsibility for their own health.

It is interesting to see the recent publicity and conclusion that OTC cough medicines in Australia are ineffective and too weak to work. These are products that have been evaluated for quality, safety and efficacy and approved by the Australian TGA system. In other words the Australian regulatory system for therapeutic goods has been proven to be ineffective at stopping rip offs in the OTC medicine category.

- In our opinion this proposal fails to meet the governments stated Code of Good Regulatory Practice. It also does not meet the government's aim of reducing business compliance costs and red tape, particularly for small business.
- Most of the comments made in this submission would apply to the future regulation of Dietary Supplements (including vitamins, minerals, homoeopathics, amino acids and other nutritional supplements) whether they are regulated under a joint agency with Australia or under a New Zealand only regime.
- In many discussions with the present JTA team members overseeing the progression of the idea of a Trans Tasman Agency, it has been stated that one of the purposes is to lend **"credibility"** to the industry. Credibility is surely up to the industry to earn. How, in fact, can credibility be legislated? Creating credibility for any industry is not the role of government or legislation. Also, there is no evidence that as a result of the Australian regime that Australian Complementary Healthcare industry enjoys any more credibility either locally or internationally, than do New Zealand products. In fact New Zealand has an excellent reputation internationally for innovation and high quality in the area of dietary supplements.
- There is an element of public good in these regulations, otherwise why are they being considered. As food regulations and enforcement are funded from public funds, a major portion of costs for the regulation of Dietary Supplements should be paid for from public funds. Remembering that between 60 and 70% of New Zealanders use dietary supplements.
- As a basic concept, the dietary supplement industry should not be controlled through any agency where the staff is biased against it.
- The accountability channels are dangerously flawed in this system. With two ministers in two countries in charge, who would ultimately be responsible? The fact that, in any disagreement, the Australian minister would make most of the final decisions is unacceptable. Too much power, without proper safeguards, is given to the Agency's Managing director.
- There has not been sufficient evidence to show that a costly regime for the regulation of Dietary Supplements is necessary for the safety of or proof of the efficacy of these products in New Zealand. No risk analysis of dietary supplements in New Zealand has been done. This proposal includes proposals that are inefficient, expensive, and effectively restrict the range of products by imposing inappropriate compliance costs, such as licensing fees, unique New Zealand only labelling, lengthy forms, appeals processes, and reams of red tape.
- Any regime must take into account that products with low volume sales must incur very low costs. Low volume sales must be appropriate for New Zealand's low population base. Each member company of INPA distributes many products with the largest distributing around 1000. Many distribute several hundred. People in business understand the 80/20 principle and many

of these products across our members have low volume sales The low volume products are maintained on the market as “service” products for consumers that rely on them. Fees, costs and special labeling would make them uneconomical and could force hundreds of them off the market.

- There must be an allowance for products to be sold that make no claims. If there are no claims being made, then at most, a simple notification to the Ministry of Health that the product is on the market would be sufficient.
- GMP and other manufacturing standards of other countries must be recognized for products sold only in New Zealand, including labeling and packaging.
- A negative listing system is the most efficient and cost-effective. It works in New Zealand and many other countries, and has not been shown to compromise the safety of consumers.
- Given the number of Dietary Supplements on the New Zealand market (conservatively estimated at 20 – 25 thousand), the problem of false claims being made is minute. There appears to be a lack of desire to enforce current laws in New Zealand. They can be regulated under existing laws that just need to be applied, eg the Medicines Act, the Fair Trading Act and/or the Commerce Act. Having said that, any truthful claims and non misleading statements need to be allowed.
- There is no safety justification for any sunscreens being classified as medicines. The proposed regime should apply only to ingestibles.
- The appeal and enforcement regime proposed is over-prescriptive, costly, and unnecessary for the low-risk nature of Dietary Supplements. All regulatory decisions must be open to review.
- In any regulatory environment, Dietary Supplements must have a separate regulatory unit.

All the above comments generally apply to any new legislation or agency to regulate dietary supplements.

After considerable consultation, members of the International Nutritional Products Association have decided, for the many reason stated above, that they must reject the proposal as presented in the Discussion Paper “A Proposal for a Trans Tasman Agency to Regulate Therapeutic Products June 2002” of forming a joint agency with Australia for the regulation of Dietary Supplements/Complementary Healthcare products in particular.

August 2002

Submission on ANZFA - P235 Proposal on the Review of Food-Type Dietary Supplements From New Hope Nutrition Ltd.

INTRODUCTION

While one has to acknowledge that Foods and Dietary Supplements will always have to have some type of regulation, our concern with this proposal, as with others in the Food/Complimentary Healthcare Products area, is the "over the top" approach to regulation.
Surely any regulation should only be commensurate with the risk, and as the risk with these types of products is extremely low, so too should be the regulatory requirement.
Having said that our submission will comprise two parts - Firstly, we will respond to the series of questions you pose in the document, wherever possible, and secondly, we will offer our suggestions as an alternative.

Part 1

a) Comments relating to requested information on the market for FTDS

These questions are virtually impossible to answer with any degree of accuracy given that no definition for FTDS has yet been established.
Therefore generally we will not attempt to guesstimate any figures in response to those questions which seek dollar values or market share, nor can we offer comment in relation to the Australian market, as until very recently we have had no involvement in this area.

However, based on our understanding and experience of importing Dietary Supplements into NZ over the last 17 years, we can offer the following comments;

(i) We would suggest that although there may be only a small number of recognised importers compared to the vast array of manufacturers, both large and small, these importers represent a substantial number of large American Dietary Supplement manufacturers, such as Twinlab, Countrylife, Natures Way, Natures Sunshine, Solgar, Natures Herbs etc.
Therefore based on brand numbers we would suggest that the percentage of NZ products to those now imported from overseas would be no more than 60/40.

(ii) We would also believe that virtually 95% of health companies who deal in FTDS products, also sell many other types of Dietary Supplements, which clearly cover your listing of functional, health or therapeutic products.

b) Comments relating to the addition of nutritive substances

We believe these series of questions highlights the problem which ANZFA are trying to overcome, and that is what is a FTDS.
Surely one has to consider a food as a food and a dietary supplement as just that. Having said that it would then become clear as to what one could or could not add to food, as opposed to the dietary supplement area, which by simple definition and existence already includes nutritive substances - Why try to combine both?

As a result of attending the meeting held by ANZFA in Auckland during July, it became obvious that many of the issues associated with this and similar reviews, revolves around the current problem in Australia, whereby one either has to comply with the food regs or the therapeutic regs.
Compare this to the NZ situation, where of course we have the additional category sitting neatly inbetween the two, that being the NZ Dietary Supplement Regs.

Therefore we will not attempt to answer these questions specifically as we believe there is not a problem with these substances as allowed in Dietary Supplements, but can see complications as to what should be able to be added to foods and what should not.

As regards whether these substances should be restricted in the NZDSR, we would definitely answer no - Clearly the results of the use of the NZDSR over the last 17 years shows virtually a 99% safety record, which in itself justifys the need for limiting the regulations to the level of risk.

c) Comments as to whether FTDS should be classified as "special purpose" foods

Given that all dietary supplements are taken for a purpose and that they are some 300% safer than foods, there is absolutely no justification to label them as a special purpose food, when clearly they are taken to supplement the diet and not replace it.

d) Comments re " purpose" of a product.

(i) If FTDS are to be regulated by the Food Standards Code, then so be it, but they are not foods and should not be treated as such.
As a simply example the labelling required for foods is clearly not appropriate for FTDS.

(ii) Based only on a 2- category system, we would suggest that the distinguishing factor between foods and therapeutic products comes down to one sole characteristic, which is the "risk".
There is no comparison between the risk associated with foods, which are generally 95% safe, and that of therapeutics or medicines (excluding complementary health care products, as they are neither medicines or therapeutic products) which all have side effects and all have varying degrees of moderate to high risk.

e) Comments on Added Substances

(i) Generally -

a) More than necessary. As already stated the risk associated with FTDS or DS is so low that most substances under these headings would clearly be at the extremely low end of any risk assessment.
b) No.

(ii) Nutritive substances -
a) No, again not necessary as there is absolutely no justification
b) Most certainly - One needs to compare substances accepted by major trading partners, such as the USA, and realise that Australia is about ten years behind in terms of recognising safe substances and even in NZ under the NZDSR, there are still substances such as Folic Acid and B12, which based on scientific research are unreasonably restrictive in terms of permitted dose.

(iii) Food Additives -
As we do not distribute food products, we do not feel qualified to comment on this question.

(iv) Botanicals -
Most definitely yes - Again from our recent experience in Australia there are too many unnecessary restrictions and requirements on dose levels of safe botanicals in FTDS.
Examples would be the extremely low and quite frankly ridicious levels of common herbal substances such as Marshwallow, Raspberry Leaf etc.

(v) Single and mixed foods -
a) Yes, if substances such as Creatine powder are going to be classed as FTDS then they must be included.
b) Yes generally FTDS should include for a mixture of " foods", but should exclude general purpose foods, as by name alone, they are not dietary supplements.

(v) Novel foods -
Most definitely yes. As suggested if there is evidence of tradition or safe use, why restrict.

f) Comments on Labelling

(i) Full disclosure of ingredients/ Doseage per serving size/ size or count of container/Statement of purpose/Warnings, but only when proven necessary

(ii) The criteria should be based around use, risk analysis and any history of detrimental effects.

(iii) Again only where there is a proven serious risk (ie pregnancy). It should not have to include advisory statements on labels where either there is little or no risk, or where one is trying to protect " idiots" against any possibility of " overdosing". Currently the regulations are completely over the top in this regard - For example why have limitations on Protein powders for youths compared to adults. In this case any young person taking a protein powder is going to seek advice from anyone who knows, not only because of the cost involved in wasting money, but also to ensure that if they are taking it for a specific purpose they achieve what they set out to do. Further if they happen to take for example two servings at once instead of one, for their application,the most likely result will simply be they will use up the supply sooner than they need.

On the other hand having to provide these unnecessary warnings on a label, not only produces a complicated and excessive type of label, but also prohibits similar overseas products for no logical or risk based reason.

(iv) No, if the ingredients are clearly listed there is no need to try and educate those people who have problems, as in virtually all cases those people are already aware of which ingredients cause a problem and which don`t.

(v) Yes the products we are dealing with in this document are Dietary Supplements, not Food. The only requirements should be the basic information required for Dietary Supplements , as pointed out in (i) above, and required under the NZDSR.

(vi) Yes- this should apply to all dietary supplements, if for nothing else so consumers can make an informed choice.

(vii) In most cases no, because there is no risk associated and therefore no harm to public safety.

(viii) Yes and No, but again this problem would be resolved if these products were all simply treated as dietary supplements and therefore labelled as such.

(ix) Yes

(x) No as already stated the regulators have already gone overboard, and rather than look to further complicate the issue, we would suggest that this review look to simplify the labelling issue and allow a system commensurate with risk which clearly benefits the consumer by allowing as many overseas products as possible without unnecessary restriction and unnecessary compliance costs.
For example,
* Why does the ingredient list need to be listed from greatest to smallest? - What difference does it make if it is not?

* Why not have a nutritional panel consistent with overseas regulators, ie USA? - Why require a different listing procedure to other major trading partners? - How does this disadvantage the consumer?
For example, in the case of expressing the "Energy" value, Australia currently requires this to be described in kilojoules, as opposed to calories, which are commonly used by other major trading partners. In effect this creates an unnecessary barrier, as all of these overseas products then have to be completely re-labelled at enormous cost to the stakeholder, for no real benefit to the consumer.

* While one can appreciate the need to clearly indicate all the ingredients, so that people with allergies can decide whether a product is okay or not, the need to further explain what may or maynot affect a certain minority of people is totally unneccessary and therefore further restricts the use of common labels.

g) Comments on Regulatory Options

As described throughout this submission our thoughts are based around maintaining the status quo in NZ, so we must choose Option 1.

Having carefully considered the three regulatory objectives listed on page 33 of the review document, we agree totally, but fail to see how either option 2 or 3 can support all three objectives.
For example neither Option 2 or 3 show any improvement re the public health or safety issue to that already existing with Option 1, ie the NZDSR.
In addition Options 2 or 3 as proposed could in no way conform with point 3 ie " its impact does not discriminate against any sector of industry" - Well clearly both of these options discriminate against Importers such as ourselves as they both increase compliance costs substantially, at no benefit to anyone, and in many cases prohibit the importation of products as a result of the ridiculous and unsubstantiated setting of too lower levels of ingredients.

h) Answers to the Questions on Regulatory Options

(i) As far as these types of products are concerned currently in NZ, we see absolutely no benefit to the NZ consumer for FTDS - In fact for many of the reasons previously stated, the compliance costs will not only push up the price to consumers, but also mean the selection of products will be reduced as a result of overall need for compliance type costs.
The one benefit needed by the consumer is a "Statement of Purpose", which can equally be included under the NZDSR as it can in any new regulation.

(ii) Same comments for health outcomes and practices as in (i) above.

(iii) If the status quo existed the costs to government would remain as is, ie very low administration and inforcement cost.
We would further suggest that in this area Industry has repeatedly offered self-regulation to the regulators, with little or no encouragement to pursue further.

(iv) Obviously the benefits to Industry in maintaining the status quo could only be described as enormous, which in turn has a flow on effect to the end consumer.

(v) To repeat, our preference is undoubtly to maintain the Status Quo, otherwise all New Zealanders will be disadvantaged.

(vi) We truely believe Industry has a lot to offer in the area of self regulation - Not only is it in our interest to ensure that everyone adheres to the regulations, but through our various Industry Associations, the structure could relatively easierly be put in place at minimal cost to ensure compliance.
We suggest that before one could identify the resource/cost issues associated with this proposition, the Industry and the Regulators would need further constructive dialogue to progress this option before such details could be accurately ascertained.

Part 2

As this review has come hard on the heals of the TTH Discussion Document, it has obviously given us a chance to look closely at our Industry and just where everyone is heading.
We keep hearing and reading from all the regulators concerned, as is also the case in this instance, that these reviews are necessary because of the " public health & safety" issue.
Well we couldn`t agree more, but the two burning questions that keeps popping up in our minds is " Where is the problem? " and "What are we trying to fix?."

In the case of FTDS we have heard how the regulators are grapling with trying to differential between the Food regs at one end of the scale and the Therapeutics at the other end. Well while this may be a problem in Australia, we suggest that in NZ it basically isn`t.
So we say again, the NZDSR adequately covers this issue of FTDS as well as all the other type of dietary supplements. In fact the NZ system and that of the USA are about the only two that are truely commensurate with risk. All others have tried to fix something that is not broken and in the process caused significant upheaval and turmoil to the Industry stakeholders concerned,
With this issue of dietary supplements one only has to look across the Tasman to see the damage that the TGA bureaucratic machine has caused, and their safety record is not even as good as ours.

In a similar manner one has to comment that ANZFA has gone down the same path and although we don`t have all the paperwork produced by ANZFA over the last four years or so, the Industry has been absolutely swamped by the amount produced, which has done little more than distract many business`s and/or their owners away from actually running their business.
All for what - Certainly in the area of FTDS or DS generally I can see not one benefit to consumer, but we can certainly see significant costs to both ANZFA and the Industry stakeholders in order to handle the ever increasing mountain of paperwork resulting in little more than, we suggest, overregulation in all sectors, being produced by the Bureaucrats to seemingly justify their existence.
We were interested to hear Finance Minister Micheal Cullen state recently that he was implementing a system so that bureaucrats could go out into the real commercial world and experience just what small business is up against - Obviously this proposal has not yet reached the offices of the ANZFA people.

Summary

Whilst we acknowledge that there are some areas of the Food Regulations that need to be tighted up slightly, we do not accept that this applies to the area of FTDS or DS, nor do we accept that NZ should become part of the draconian Australian system.
The only area yet to be addressed by the regulators in this sector, which would truely benefit the consumer, is that relating to Statement of purpose claims. This issue could clearly be mutually addressed by both Industry and Regulators to find a cost effective method of implementing such basic, yet informative statements.

Other than that, a few minor adjustments to the NZDSR and we have a perfectly workable system for all, at minimal compliance costs and at no risk to public safety.

Therefore in conclusion although the writers and reviewers of the P235 review would not want to hear what we have been saying throughout this submission, and are about to toss this submission into the wastepaper bin, we can only implore you all to consider what it is you are really trying to fix, be consistent with your stated objectives and regulate commensurate only to the risk associated with the sector involved.

Thank you for the opportunity to express our views and we continue to hope that one day Regulators and Stakeholders can view the problem, where there is one, from the same perspective, and rather than complicate the regulations and therefore all the compliance factors, can jointly produce a simple system applicable to the level of low risk.

[redacted]
Directors.