Introduction...

This is a submission in response to a consultation paper headed "Review of the regulation of products at the interface between cosmetics and therapeutic goods" dated 18 March 2005 and for which submissions close on 5 May 2005.

This submission identifies and discusses alternative approaches to those set out in the consultation paper. This submission is a "big picture" submission. We ask only that you take the time to read this submission, reflect on the issues raised in it and ask:

- given the increasing complexity of the cosmetic / therapeutics / foods interfaces will the solutions currently proposed protect public health and safety? and/or be in the interests of consumers?
- is the level of regulation proposed commensurate with the risk of these products to consumers? "

Required information...

Name of submitter:	Michol Fisher, on behalf of Naturo Pharm Limited
Contact address:	Naturo Pharm Limited, POB 952, Rotorua, New Zealand
Contact email:	mfisher@naturo.co.nz
Contact phone:	07-3471688
Contact fax:	07-3460980
Submission authorised by:	Directors

Confidentiality sought...

None.

Naturo Pharm does not manufacture cosmetics. Naturo Pharm manufactures a range of low risk herbal and homoeopathic products. We trust that, after reading this submission, you will understand that this submission has not been written out of the self-interest of Naturo Pharm Limited. The writer is concerned:

- from a consumer perspective, to ensure the appropriate level of regulation is in place to protect consumer health and safety; and
- from consumer interest and manufacturer perspectives, that there is equitable application of regulation across cosmetics, therapeutics and foods (including functional foods and nutraceuticals) so that the cost of regulatory compliance – initially borne by the manufacturer but ultimately borne by the consumer – is fair and appropriate, given the risk of the products.

The writer is taking this opportunity to propose an alternative solution that may better protect consumer health and safety and consumer interests.

The context...

There exists an amount of uncertainty about the future regulatory environment for cosmetics, therapeutics and foods...

- A Joint Therapeutics Agency has been mooted but it has not yet become a reality.
- The new Australia New Zealand Therapeutic Products and Services Advertising Codes (based on the Codd Report) are in effect, although they lack any real teeth because of the delay in the establishment of the JTA.
- FSANZ's Proposal 293 was released for consultation and submissions are presumably under consideration with a report not far off.
- A Review of the regulation of products at the interface between cosmetics and therapeutic goods is out in the public domain seeking submissions;

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- Proposed changes to the Dietary Supplements Regulations 1985: Discussion Paper No 1/04 was released for consultation and a report is presumably imminent. (Certainly the writer has not been made aware of any report despite making a submission to this Discussion Paper.)
- A Pilot Project on Claims for Foods containing Folates was established – permitting foods to make more claims about folates than CAMs type products (non-registered medicines) containing folates in NZ.

The challenges...

The interfaces between cosmetics, therapeutics and foods have historically been challenging. There is now, more than ever before, significant potential for increased confusion and inequity of treatment between cosmetics, therapeutics and foods given:

- the various regulatory frameworks currently under discussion; and
- the way the world is heading, with consumers likely to see an increase in (a) cosmetics with a therapeutic (preventative and/or treatment) purpose and (b) nutraceuticals* and fortified foods** (many being food/therapeutic combinations, normally preventative supplementation).

* = natural bioactive chemical compounds that have health promoting and disease preventing properties.
** = foods or food ingredients that provide a health benefit beyond the nutrients contained.

The Review identifies that the key issues the regulator is grappling with are "safety of products, consumer protection, the extent of regulatory definition, market fairness and inconsistency between countries" ***. Indeed these are key issues in the regulation of each of cosmetics, therapeutics and foods. Because of its Terms of Reference the subject Review has a narrow focus. However, it is respectfully submitted that a broader focus is needed to identify the solution that will best meet the key issues.

*** = Review, page 15.

A broader approach...the continuums...

Health exists on a continuum. Over simplified this continuum starts with good health and moves on to minor ill health (common self limiting conditions), through to major illness and, ultimately, death.

Like health, food, cosmetics and medicines also exist on a continuum. Over simplified this continuum starts at primary foods and moves through processed foods to fortified foods / dietary supplements / cosmetics* and then on to therapeutics used to treat ill health (including many CAMs and, of course, pharmaceutical medicines).

* = think sunscreens, anti-bacterial agents, toothpastes etc. Some cosmetics are intended for beautification and improving the appearance, whereas other cosmetics have a protective or preventative function – reducing caries, wrinkles, risk of sunburn etc.

Good food / dietary supplement and preventative cosmetic choices (along with exercise, etc) help us to establish and maintain good health, reduce risk of disease and increase our body's ability to prevent the onset of ill health.

Some foods, cosmetics, and therapeutics (i.e. dietary supplements) etc., or ingredients in these products, can be identified as reducing the risk of specific diseases (i.e., folates and foetal neural tube defects,) and increasing our ability to prevent the onset of specific illnesses (i.e., calcium and osteoporosis or fruit and vegetables and some cancers, SPF and sunburn, fluoride ion and caries).

Other foods, cosmetics and therapeutics, because of their ingredients (certain additives like flavour enhancers, synthetic colourants and preservatives (e.g., MSG, Sunset Yellow 110*, Amaranth 123**, sodium benzoate 21*** and potassium sorbate 202) and artificial sweeteners and known allergens (e.g. peanuts, crustaceans, etc.)) or negative side effects may actually cause ill health in certain people. So foods and cosmetics, like therapeutic products, increasingly have risks and may have contra-indications.

* = Sunset Yellow is a synthetic colourant, which can provoke allergic reactions and hyperactivity, increases the incidence of tumours in animals and is banned in Norway.

** = Aramanth is a synthetic colourant which can provoke asthma, eczema and hyperactivity, has been linked to birth defects and foetal deaths in some test animals possibly also to cancer and is banned in the USA, Russia and at least 5 other countries.

*** = In one study sodium benzoate killed the rats it was given to. Okay there is an argument to be had about dosage but do we yet know the cumulative effect of continued ingestion of these products?

Increasingly consumers are and will continue to be offered a wider range of cosmetic and food choices as more "cosmetics" with health benefits and nutraceuticals are developed and more foods become fortified thereby "protecting and improving the health of the population" *(Australia New Zealand Food Regulation Ministerial Council, Policy Guideline on Nutrition, Health and Related Claims, Policy Principle #1*).

Now, assume all that good eating, application of preventative cosmetics and supplementation doesn't completely protect us and we suffer ill health. Ill health may be defined as the experience of negative symptomology, and can include normal "life-stages" such as puberty, pregnancy, menopause, where the person going through that life stage experiences negative symptomology (ill health i.e., acne and/or violent mood swings, morning sickness, hot flushes, etc) as a result of the passage through that life stage. When we suffer ill health we look to products to reduce, treat, relieve, cure and/or alleviate a disease or condition of ill health and / or symptoms of that disease or condition.

It is reasonably clear then that some products (irrespective of their historical classification – i.e., as foods, cosmetics, dietary supplements, therapeutics etc):

- establish and maintain good health, reduce risk of disease and increase our body's ability to prevent the onset of ill health (for simplicity these products are hereinafter referred to as "*Wellness Products*");

while other products (and procedures and devices):

- reduce, treat, relieve, cure and/or alleviate a disease or condition of ill health and / or symptoms of that disease or condition (for simplicity these products are hereinafter referred to as the "*Recovery Products*").

Risk, generally...

The Review identifies that the key issues the regulator is grappling with are "safety of products, consumer protection, the extent of regulatory definition, market fairness and inconsistency between countries". The two key issues are safety of products and consumer protection. All the other issues result from the form and implementation of regulation put in place to achieve the two key issues.

The key to protecting public health and safety is dealing effectively and consistently with the issue of risk.

The key to protecting consumer (and manufacturer) interests is to develop regulation that is appropriate given the level of risk.

Our historical classifications of products as cosmetics, therapeutics and/or foods are becoming obsolete with the development of more and more new products that challenge these classifications - particularly cosmetics with a health (preventative and/or treatment) benefit and neutraceuticals and fortified foods. Products presenting challenges to existing classifications are only going to increase. One way of minimising interface issues is by doing away with the historical classifications of cosmetic, therapeutic and food. It is therefore timely to develop a different classification for products and the starting point for any such new classification is logically the risk to the consumer of the product.

A product may pose a risk to consumers by virtue of **an intrinsic risk**:

1. the ingredients in a product*;
2. the absolute concentration of an ingredient in a product;
3. the impact of the combination of ingredients within a product (i.e. whether the resultant product poses greater risk than the constituent ingredients on their own);
4. the route of administration of a product – *i.e. products taken orally (i.e. foods and some therapeutics) may require more scrutiny than products applied topically;*
5. frequency of usage and extent of area of application - *i.e. it may, for example, be important to have a higher level of scrutiny of sunscreens which are used with high frequency over large areas of the body viz a topical bruise preparation that is used in a targeted area for a relatively short time following an injury; and*
6. the criticality of the purity, concentration and consistency of an ingredient in a product (here the questions may be "would over dosing create a harmful situation for the consumer?" and "would under dosing deprive the consumer of expected protection or create a health hazard?").

* = if the case is unclear whether an ingredient is intrinsically risky i.e. triclosan then the regulator should err on the side of caution.

A product may also pose a risk to consumers by virtue of **an information risk.** An information risk exists if poor, inaccurate, incomplete or misleading information is provided about a product. The information risk increases if a product seeks to make a wellness or recovery claim. Products which seek to make a wellness or recovery claim are likely to require a greater level of scrutiny or regulation to ensure the claim is supported by evidence.

The risk areas set out above are qualitative.

A product may also pose a risk to consumers by virtue of **a quantitative risk**. Quantitative risk is relevant once qualitative risk has been established. It is relevant to prioritisation of product areas for regulation. If the public is consuming a huge volume of a product then the quantitative risks in respect of that product is (or product group are), of course, higher than for a product that is consumed in only small volumes. It follows that regulation for high-risk high volume products should be implemented first and so on.

<u>It is suggested that in future all oral and topical products for human use should be classified by their intrinsic and information risk – including foods, cosmetics and therapeutics.</u> Ideally products would, after an objective assessment (based on guidelines), be classified as:

- low risk;
- mid risk; or
- high risk.

Most foods and traditional cosmetics (that is products purely for beautification) would generally fall within the "low risk" category*, but potentially a number of CAMS, fortified foods and nutraceutical may fall within the "low risk" category; the majority of nutraceuticals, fortified foods and CAMS would fall within the "mid risk" category and most pharmaceuticals would fall within the "high risk" category. A product which is intrinsically "low risk" but which seeks to make a wellness or recovery claim would be likely to be classified as "mid risk" because the claim could potentially mean that higher standards around the criticality of the purity, concentration and consistency of an ingredient through a product would need to be met.

* = it is suggested however that a claim for the reduction of wrinkles etc could result in a product being classified as mid-risk, after all the consumer has a right to expect that a product making such a claim can substantiate that claim and so the consumer is not being misled as to the benefits they can expect when they purchase and use such a product.

In such a system manufacturers would be able to make decisions about the positioning of their product knowing the differing level of regulation required and so be able to fairly weigh regulatory cost and marketing benefit of being able to make health claims etc.

It is also suggested that **all** product manufacture should be regulated, with:

- low risk products being manufactured in licensed premises with product notification to a regulator;
- mid risk products being manufactured in licensed premises with product licensing by a regulator; and
- high-risk products being manufactured in GMP premises with product registration obtained through a regulator.

Low risk products could be manufactured in premises with a basic manufacturing licence which could be obtained once basic hygiene and ingredient quality standards were in place. Notification (of low risk products) could involve provision of information as to product name, ingredients and manufacturer's manufacturing licence details with warranties regarding compliance with labelling requirements, meeting the requirements of low risk products etc – this information would ensure the regulator could check (in post market surveillance) that the product was in fact low risk.

Mid risk products could be manufactured in premises with a mid level manufacturing licence which would focus on ensuring ingredient and process quality to ensure ingredient concentration and consistency in the final product. Product licensing (of mid risk products) could involve provision of information (through a system like "COMET") as to product name, ingredients and manufacturer's manufacturing licence details with warranties regarding compliance with labelling requirements, meeting any levels of evidence requirements, meeting the requirements of mid risk products etc – this information would ensure the regulator could check (in post market surveillance) that the product was in fact mid risk and complying with its licence.

High-risk products would be required to be manufactured in GMP premises and product registration would be required, much along the lines of pharmaceutical registrations under the TGA or Medsafe at present.

It is suggested that any and all material regarding and products seeking to make any sort of claim would be required to be pre-vetted against the product licence or the product registration via a scheme like the Therapeutic Advertising Pre-vetting Service (TAPS) scheme operating in New Zealand at present.

Under this proposal all products for ingestion or application for human use would be:

- known to the regulator;
- subjected to a level of regulation commensurate with the level of risk to the consumer;
- manufactured in licensed premises (with the standards to be achieved for premises licensing determined by the risk of the product to consumer health and safety); and
- classified and regulated according to risk which would enhance public health and safety and market fairness.

Under this proposal statements like that set out at page 80 of the Review: "Absence of risk or at any rate, low risk, does not transform a medicine into a cosmetic product" would be consigned to history.

Information risks...

An information risk exists if poor, inaccurate, incomplete or misleading information is provided about a product. The information risk increases if a product seeks to make a wellness or recovery claim, consequently products seeking to make such a claim require a greater level of scrutiny or regulation. The basic risk can be addressed by minimum standards for labelling. The additional risk, resulting from a product making a wellness or recovery claim, can be addressed by a combination of levels of evidence requirements and pre-vetting through a system like TAPS.

There are numerous (frankly appalling) examples of the way the current claims regime is misused, abused and inadequate to protect consumers – refer Appendix A for examples. Appendix A also contains examples of foods that have become dietary supplements by marketing design and stealth, exposing how our current controls are not protecting consumers. Some of the content of Appendix A makes pretty appalling reading!

A claim should be defined as a statement that the "reasonable man or woman" would understand or perceive to be a promise of a likely (wellness or recovery) result or outcome from purchasing and using a product in accordance with its directions for use. Guidance on claims should be developed with consumer representatives, through the likes of the TAPSCCC (Therapeutic Advertising Pre-vetting Service Code Consultative Committee) meetings that currently take place in New Zealand.

At present the levels of evidence requirements for making a claim are inconsistent and unhelpful. In New Zealand we have the situation where non-registered medicines (including cosmetics) have no status at all and can therefore only make "health outcome claims". In Australia under the TGA there are levels of evidence required before a manufacturer/sponsor can make various levels of claims and the levels of evidence are based on the perceived risk/benefit of the product. Under FSANZ's P293 different sets of levels of evidence are suggested to apply to foods seeking to make nutrition and health related claims. Given the food/cosmetics/therapeutics continuum, is it desirable or logical for different levels of evidence to be required of a product if it is a food or cosmetic or a therapeutic if similar claims are sought to be made in respect of that product?

It is interesting to note that across foods and cosmetics and therapeutic products the similarity of the issues is already leading to consideration of similar (and hopefully equitable) regulatory requirements.

The new Australia New Zealand Therapeutic Products Advertising Code and FSANZ's P293 both cover very similar areas. The Australia New Zealand

Therapeutic Products Advertising Code sets out a system for pre-market approval (TAPS). Cosmetics are already treated as therapeutics in Australia based on risk / claim profile. The Australia New Zealand Food Regulation Ministerial Council Policy Guideline on Nutrition, Health and Related Claims, Policy Principle #10 stated pre-market approval was favoured rather than post–market reaction. Despite this preference FSANZ's P293 suggests a hybrid with pre-market approval for higher-level claims and post-market surveillance for lower level claims. The question is "should all products that wish to market themselves (at least in part) with wellness or recovery claims be required to meet the same standards for similar levels of claims?" Given the potential for:

- foods and cosmetics to increasingly be able to protect and improve the health of the population (through fortification, modified restoration, improved processing, etc) and therefore compete with other products seeking to do the same job; and

- foods and cosmetics to increasingly contain high risk ingredients or ingredients that put sections of the population at risk,

then surely the answer is "yes". Similar levels of claims should be treated similarly irrespective of the nature of the product making the claim, to do otherwise would seem both inequitable and illogical. Indeed the issues are so similar that a single body could be responsible for all pre-market pre-vetting or two bodies could be established - one dealing with high risk products and one dealing with mid risk products.

Of course as more foods become fortified and more foods and cosmetics contain increasingly complex additives consumers will increasingly need to be provided with risk information to enable the consumer to make appropriate choices. So products containing ingredients contra-indicated for sections of the population will clearly need to highlight the risks for those sections of the population in future – as therapeutics do now, so there will be a need for increasing synergies across label information.

Already certain synergies can be seen, for example dietary supplements are required to state on the label that the supplement is not a substitute for a balanced diet and FSANZ's P293 contains comments about "whole-of-diet" claims (s5.6.1).

So where is all this heading...?

At present the following options are under consideration:

- Regulate therapeutics through a Joint Therapeutics Agency;
- Regulate Dietary Supplements through the options set out in the Proposed Changes to the Dietary Supplements Regulations 1985: Discussion Paper No 1/O4 (but this has probably been overtaken by JTA discussions);
- Regulate advertising and therefore claims about therapeutics through a Joint Therapeutics Code with TAPS at the front end and recourse to the JTA for "teeth";
- Regulate cosmetics under any number of regimes depending upon whether they are considered therapeutic products, exempt goods, excluded goods etc;
- Regulate foods (including fortified foods) through the FSANZ;
- Regulate nutrition, health and related claims on foods (including fortified foods) through the options set out in P293.

The primary function of FSANZ, the TGA and Medsafe is the protection of public health and safety. Given:

- these organisations have the same primary function;
- the boundaries between foods and therapeutics and cosmetics are blurring;
- increasingly foods contain added ingredients more traditionally found in dietary supplements and therapeutics; and
- increasingly cosmetics are developed with a health benefit,

it would seem sensible to move towards similar standards. After all if one body has implemented certain standards in the interests of public health and safety in respect of certain products or ingredients then surely those standards should be implemented across the board in the interests of public health and safety, not to mention in the interests of a level playing field.

An additional regulatory option, to those currently under consideration, might involve regulating products along risk lines, with all high risk products being regulated by TGA/Medsafe or the new JTA and all low risk products being regulated by FSANZ with all mid risk products being regulated by a new body that works closely with its parallel regulators in both high and low risk products.

Frankly "who regulates", is less critical than the parity that should be achieved across manufacturing standards, claims and minimum information requirements in respect of products containing common ingredients and carrying similar types and levels of risk for and claims to consumers.

In conclusion...

Our world is becoming increasingly complex. At times we push ahead without time to reflect on the "bigger picture" and we therefore deny ourselves the opportunity to take a more holistic approach. This may well be one of those times. There are currently many strands of regulatory review running in parallel that could (and probably in the interests of public health and safety should) be drawn together. There will be many groups with vested interests who will not want to see this happen.

We trust that our comments are of interest and make some useful contribution. We regret the pressure of "work" and family life have not permitted us to give this Review more time and thought.

Yours sincerely
Naturo Pharm Limited

Appendix A

Introduction

The current definitions of what is or is not a therapeutic claim is problematic in both New Zealand and Australia. There are numerous examples of the way the current claims regime is misused, abused and inadequate to protect consumers – a number of examples are set out below.

Inadequacy of current regime - Australia

The Review acknowledges that the current regime is inadequate in Australia where it states:

- in respect of antibacterial hand washes "how can any member of the public be expected to draw any distinction between the purposes for which these three products are on the market?" *
- in respect of acne washes "it would be hard to accept that a consumer (usually a teenager), no matter how discerning or perceptive, would know or care about such differences."**

** = Review, page 74.
*** = Review, page 78.

Inadequacy of current regime – New Zealand

Because of the currently regulatory scheme in operation in New Zealand, which restricts the making of therapeutic claims to registered medicines, all non-registered medicines (usually CAMS, including dietary supplements) are limited to making health outcome statements. The consequences of this are:

- some "novel" distortions of the English language;
- the existence of statements that are not regarded as therapeutic claims (often phrased as health outcome benefits) which consumers nevertheless understand as claims (see paragraph above);
- despite having an evidence base which reasonably justifies the making of a low level claim manufacturers are denied this option (unless they register their product) which means consumers are being provided with inaccurate information;
- some consumer safety information is excluded on the basis that it would make an implied claim;
- consumers can't be told what a product is for because the condition name is not permitted to be used – meaning manufacturers have to use euphemisms which can be misleading.

Inconsistency in the current regime – New Zealand

Although it is accepted that both the Medicines Act and FSANZ standard 1.1A.2 currently prohibit the majority of health claims by foods, it is clear that these regulations are increasingly flouted by industry. Products with added calcium and vitamins giving rise to many examples. A different example is a convenience packaged muffin mix that states on its label "May be suitable for the following ailments:- Diabetes, AD(H)D, High Cholesterol, Lactose Intolerance."

Inequity of the current regime – New Zealand

An example of an existing area of inequity is the Pilot Project for Folate Health Claims. Prior to the start of this project only registered medicines in New Zealand could make a claim regarding folates and neural tube defects. As a result of this pilot project certain foods with added folates became permitted to make a therapeutic claim. And yet dietary supplements (often made to a higher standard than foods) containing folates are not permitted to make such claims.

As a result of the Pilot Project for Folate Health there is no consistency or equity in the claims that may, at present, be made across foods and Dietary Supplements/CAMs containing folates.

The potential for confusion around bio-availability – an example from New Zealand
What follows is a report of a conversation that took place in a P293 working group at a FSANZ organised seminar in 2004. The discussion revolved around the use of the words "contains" and "provides" on food labels. Apparently if a food states "this food contains x amount of added calcium" then it does just that i.e. it contains added calcium and it is irrelevant that the added calcium is not bioavailable. On the other hand, if a food states "this food provides x amount of calcium" then the stated amount of calcium must be bioavailable. This seemed to be a common and acceptable distinction to those involved in food manufacture and advertising in the working group (much to the writer's horror!). If this kind of use of language is going to be permissible then consumers will have to be very knowledgeable about the nuances of the English language indeed and read the fine print! In many instances, of course, only a percentage of RDI is stated – one has to wonder do consumers and manufacturers share a common understanding of what a percentage of RDI actually means?

Consumer confusion – an example from New Zealand
Our world is becoming increasingly more complex. The understanding of the reasonable or average person is being increasingly over-estimated by the regulators and taken advantage of by marketers who understand that a simple benefit message is a powerful marketing tool – because that message may only be "part of the story".

It is the writer's submission that consumers see a product with added calcium and take a very simple message from it – that product has got to be better for me than a similar product with no added calcium. Consumers do not question the bioavailability of the calcium, the source of the added calcium (i.e. was it sourced from a GMP source? What was the base material for the added calcium etc.), the consistency of the calcium in each serve, whether they get enough calcium already from their diet etc etc.

A quick trip to the local supermarket to look only at water, milk and juice products illustrates the issues. The following table contains information regarding "food" products sitting on shop shelves nationwide.

"Waters"

Manufacturer	Brand	Ingredient	%age of RDI per serve (usually 200mls)	Notes
Powerade	Water Lime	5 vitamins, electrolytes, sugar		
Charlies	Sports Water	6 vitamins, sugar		Sugar from apple juice
Aqua shot	Lime Active Water	5 vitamins, sugar		
Waterplus	Lemon Flavour	Antioxidants, electrolytes and B vitamins		Includes zinc, potassium and magnesium

Milk

Manufacturer	Brand	Ingredient	%age of RDI per serve (usually 200mls)	Notes
Meadowfresh	Calci Trim	Calcium	**50%**	
Anchor	Super Trim	Calcium	37%	
Anchor	Xtra	Calcium	**50%**	
Anchor	Mega	Calcium	40%	

Juice

Manufacturer	Brand	Ingredient	%age of RDI per serve (usually 200mls)	Notes
Charlies	Orange Juice	Vitamin C	**200%**	Does not identify itself as a dietary supplement
Thextons	Cranberry Juice	Vitamin C	40%	
Coke Cola	Mizone Sports Water	Vitamin C	**100%**	
Frucor*	G Force Lifestyle Functional Fruit Drink	Vitamin C	**350%**	***Note this is an 800ml bottle that could easily, given the nature of the product, be consumed in a sitting giving the consumer 1400% of their RDI of Vitamin C in one go!***

*-www.Frucor.com is a fascinating website to visit and contains fascinating nutritional information.

One wonders what was the source of the added Calcium, Vitamin C and other additives in the products listed in the table above? Are these additives distributed evenly in the product so as to ensure the consumer received the stated amount in each and every serving? Do consumers regularly read their food product labels and adjust their dietary intake to take account of these new but increasingly common fortified foods?

It is interesting, in this regard, to recently read that Denmark recently rejected applications for 18 new cereals and cereal bars made by Kellogg's because they were fortified with levels of vitamins and minerals that in the opinion of the Danish Food Administration could cause consumers to exceed safe levels of nutrients in their overall diet.

<u>The consequences of different regimes – the interface issues</u>

At present there is much "massaging" of the system with products endeavouring to "look like foods" or "look like cosmetics" so they remain outside the therapeutic products regime and the system currently offers lots of scope for exactly this sort of "massaging" – but is this acceptable when we are talking about products containing similar (added) ingredients and aiming and claiming to do similar jobs?

During the past year the writer has attended numerous meetings where the main focus of participants has been to understand the food / therapeutic / cosmetics interfaces so as to be able to "develop" products classified as one or other depending upon which jurisdiction is considered more advantageous to the sponsor. The nature of the discussions suggested that the jurisdictions are so different in their standards and implementation of their standards that there is considerable incentive for manufacturers to manipulate their products so as to ensure they fall with in one jurisdiction rather than the other (costs of GMP production being an example). The writer suggests that at present there is a perceived benefit to classification as a food

or cosmetic rather than a therapeutic. There is a game being played and the playing field is not level.

At one meeting the discussion centred on the classification criteria set out in the Proposed Changes to the Dietary Supplements Regulations 1985: Discussion Paper No 1/04. This sort of classification is spurious and quite possibly dangerous. Let us not forget that the primary function of TGA, Medsafe and FSANZ is to protect public health and safety. The public generally assume foods and cosmetics are safer than therapeutics, but with the developments in nutraceuticals and fortified foods and cosmetics offering a health benefit the lower standards demanded of their manufacture, labelling etc. this assumption is quickly becoming erroneous.

We now have the technology to be able to manufacture products that have a composition different to the historical "norm" for such products. We do this by:

- increasing the amount of a substance in a product by adding more of that substance, or by utilising a different manufacturing process that increases or enhances the amount of that substance in the end product; or

- adding into a product substances that are not historically normally found in that product (high SPF sunscreens into moisturisers etc); or

- decreasing the amount of a substance in a product by utilising a manufacturing process, which reduces or eliminates a substance normally found in that product.

Increasingly products are, or will be, enhanced to potentially address a deficit or deliver a benefit to a population group who uses the product according to its reasonable intended use (folates and iodine in foods are already under discussion). Fortification has already (and will increasingly) become a marketing tool and the reasonable or average person will become more confused than they already are.

Labelling confusion

The "Policy Guideline Fortification of Food with Vitamins and Minerals" states, under the heading "Additional Policy Guidance – Voluntary Fortification" (page 4),

> Labelling – There should be no specific labelling requirements for fortified food, with the same principles applying as to non-fortified foods. An added vitamin or mineral is required to be listed in the Nutrition Information Panel only if a claim is made about it and the vitamin or mineral is present at a level for which a claim would not be misleading. An added vitamin or mineral must be listed in the ingredient list under current labelling requirements." (Writers emphasis added).

It is becoming increasingly important that exactly what is in our foods is clearly identified so consumers may make informed choices about, and give informed consent to, what they ingest. There will be an increasing risk of consumers overdosing (unintentionally) on vitamins and/or minerals and/or additives where they are ingesting several products which contain them. Consumers will be at greater risk and will need increased information (on content and risks) to make appropriate choices.

If a food has added minerals or vitamins then the fact that this is the case should be clearly identified on the nutrition panel – with words like "added [name of mineral]"

and amount clearly specified along with (ideally) the source of that added mineral and the bioavailability of the added ingredient should be clearly stated.

Equally if the food has undergone a manufacturing process which process by itself increases the amount of a vitamin or mineral in a food product beyond the level normally expected to be found in that food category then this should be clearly identified on the nutrition panel.

Equally if a food has undergone modified restoration (which in principle permits the restoration up to levels of 25% RDI when the vitamin or mineral was only naturally present at a level which would contribute at least 5% of the RDI in a reference quantity of the food) then the fact of that modified restoration and the increase of that vitamin or mineral now in the food over the RDI level naturally present in the food prior to processing needs to be made clear. Again the source of the added mineral or vitamin should be clearly identified. Consumers expect processed foods to contain less vitamins and minerals than fresh foods. It would therefore be misleading for processed foods not to clearly state the fact, and consequences, of restoration.