Direct Selling Association of New Zealand

Submission on Proposal P235

Review of Food-Type Dietary Supplements

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The Direct Selling Association of New Zealand is available to clarify any comment offered in this submission document.

Background

Description
The Direct Selling Association of New Zealand Inc (DSANZ) consists of 37 member companies who market their products by Direct Selling.
There are three forms of Direct Selling. These are Multi-level or Network marketing, Party Plan and Door to Door or Traditional Direct Selling.
Therapeutic Food-Type Dietary Supplements as defined in Proposal P235 are sold through all three forms of Direct Selling with a majority of Dietary Supplements being sold through the Multi-level system and devices being sold through both Multi-level and Door to Door sales.

Multi-national companies and product availability
In general terms those products sold in New Zealand are also sold in Australia however we do have a number of members who find that they are not able to market all of their range of products in the dietary supplements area in Australia. This is particularly true for those companies which are multi national and headquartered in the United States where indications are that between 10% and 30% of members dietary products available and sold in New Zealand currently are not able to be sold in Australia.
These products are considered safe internationally and are sold in most jurisdictions without issue or problem.

Statistical background
The nutritional supplement market in Direct Selling is worth around $36 million at wholesale figures and approximately $60 million at retail per annum. This segment of the Direct Selling market makes up 19% of the Direct Sales in New Zealand
We do not have data which allows us to analyse the break out of Food-type Dietary Supplements from our overall supplement market but from members polled are aware that this is likely to be a significant portion of some members products.

The percentage changes when measured by selling type to 36% under Multi-level sales, 2% under Party Plan and 0% under traditional door to door selling.

A recent economic impact study by Otago University of the Direct Selling industry concluded that the economic impact for Dietary Supplements by the Direct Selling industry is worth $334 million in New Zealand and excluded export sales by industry members.

Direct Selling Association members export around $100 million dollars of products. Those exported include dietary supplements and food type dietary supplements
Over 50% of the Colostrum produced in New Zealand is marketed by New Zealand Direct Selling companies in eight countries as a food type dietary supplement and is not a market to be taken lightly. The majority of the manufacturing of this product is done by an associate member of the Direct Selling Association.

Participation in Consultation

The DSA New Zealand has submitted previously on the scooping stage.

SUMMARY STATEMENT

The DSANZ has found that operation under the dietary supplements regulations combined with the Medicines Act for its food type dietary supplements has not created any issues in relation to health and safety and that the products sold under the existing regime are safe and manufactured to a Food GMP.

The issue of claims made is well covered under the Advertising Standards Authority Therapeutics Advertising Code of Practice and its pre-vetting system (TAP'S) for mainstream media.

The DSANZ Code of practice governs other forms of advertising and claims made during the sales process for literature and verbal claims and to date no complaints have been lodged under this code that relate to such claims and a member company.

While the DSANZ supports Trans-Tasman harmonisation in principle, it must not be at the sacrifice of products ability to be marketed unless there is a defined health and safety risk of that food to the public.

We are concerned that Proposal 235 will jeopardise products on the market both under Direct Selling and in normal retail and it is our desire to ensure that such products are not compromised by the adoption of harmonisation with Australia.

SUMMARY POINTS OF SUBMISSION

- Products that are normally considered a food would fall into the category of being a FTDS
- All products currently covered by the NZDSR should continue to be available in New Zealand.
- We oppose any move to repeal the NZDSR (1985) in conjunction with the Foot Act Regulations 1984
- The inclusion of botanicals or the like should place the products into the category of TTDS and not be considered in conjunction with the Food Code.
- The growth of Dietary Supplements in New Zealand is consistent with other product lines and has not seen any abnormal growth over the past 5 years.
- The US regulatory framework is close to the New Zealand model and it is our belief that this is be best model for such dietary supplements overall.
- Concern is expressed that the level of additive levels may be excessively low and that these must be based on true scientific evidence.
- Some work is required on products such as caffeinated beverages as this area is one that is currently poorly covered.
- The issue over products like Kava must look at the reasons for such incidences and the inherent safety of the product before deciding what additional precaution needs to be implemented based on that risk.
- If a product is a FTDS then the coverage of Food labelling is considered desirable. If however the product is a TTDS and falls under the proposed Joint Agency, the food labelling should be exempt although other labelling controls may be applied by the Joint Agency if appropriate to risk.
- The DSANZ argues that the Australian industry should be able to import or manufacture or export products on the same basis as New Zealand and that there needs to be a fundamental shift in the Australian regulatory position.
- The DSANZ preferred Regulatory option 1 as its first choice but accepts regulatory option 3 as a second choice.
- The DSANZ is opposed to regulatory option 2 unless significant changes are made to the Australian system and acceptance of Nutritional products under this option.
- The DSANZ would see any impact of the existing Australian model as removing between 10 and 30 percent of products from the market and having an economic impact of around $36 million on the New Zealand Economy from this industry alone.
- The potential benefit to the Australian economy of easing of such restrictions is estimated at around 5 times the adverse impact to New Zealand in relation to Direct Selling.

Specific Comment

Food Type Dietary Supplements

We advocate that the definition of a product that includes dietary properties such as additional Vitamin A or C or the like and is normally considered a food would fall into this category.

The DSANZ has submitted to the Joint Agency Proposal based on those products that are likely to be considered above the line (Therapeutic Type Dietary Supplement – TTDS) in the introduction of what is a Food Type Dietary Supplement (FTDS) and this submission is focused on those products that are likely to be below that line.

Issues

It is the DSANZ's contention that any products currently covered by the Dietary Supplements Regulations (NZDSR) should continue to be available in New Zealand regardless of whether they are a FTDS or TTDS under a future set of regulations.

We oppose any repeal of the Dietary Supplements Regulations (1985) in conjunction with the Food Act 1984 Regulations as this would expose our products above the line to a lack of coverage in any form since the proposed Joint Agency could not be implemented by that time. Some interim mechanism must be in place for such products and to arbitrarily repeal both sets of regulations knowing that to do so will revoke coverage of products that are not covered by new regulations is short sighted and potentially dangerous to the publics health. It is imperative that the current NZDSR remain in place until all arrangement have been settled for all forms of dietary supplements.

We also see that this could be used to argue that there is no regulation in New Zealand and that new regulations should then be imposed when in fact we have a perfectly good set of regulations that have served this country well.
We do not accept the argument that foods imported or manufactured to the NZDSR will damage the ability for food harmonisation and would argue that in fact the issue lies with the Australian rigidity under their current arrangements.

The DSANZ advocates that the changes should reflect the existing situation in New Zealand and not the imposition of the Australian situation on New Zealand. We accept that there may need to be some minor modifications to accommodate particular needs and modernisation for new and innovative products.

Nature of Product

We note that the composition of products is questioned in this section and would highlight that these products that contain such banned botanicals under the Food Code would be considered TTDS and not FTDS by the Direct Selling industry. We would not consider them as foods and should not be regulated to the Food Code on that basis.

We can only highlight those statistics held by the Direct Selling Industry for the overall Dietary Supplement Market and not for the FTDS market with these figures covered in our background data statement

We are aware that there has been growth in this market however this has averaged no more than 2% per annum for the Direct Selling industry over the past 5 years and is consistent with our normal growth across all product types.

We find the WHO Codex is an accepted method for special dietary uses however; this has little relationship to the FTDS products sold by our members.

Regulatory Framework

We are conscious of the differences worldwide for regulation of Dietary Supplements but would point out that those that treat these products as "Food" generally include those products that are likely to fall into the TTDS area under the proposed Joint Agency. The Canadian model has gone towards the Food model but as a separate dietary supplement entity. This model has some acceptance to some part of the industry although even so has raised some concerns at the nature of the regulations and cost issues.
The US has continued to maintain a Food set of regulations.

The DSANZ would advocate that the existing NZDSR are based on the US model and that this continues to provide the best model for New Zealand irrespective of the Australian position. We believe that these should form the basis of any new harmonisation between the countries on FTDS.

If a FTDS contains a prohibited Botanical then it should be treated as a TTDS and subject to the structure that applies for those product types and not necessarily prohibited as a product. There may be controls over the levels of the botanicals set within those regulations which are the basis on which the current NZDSR operates.

We are concerned that the levels at which permissions are set, may be excessively low for additives and there needs to be an appropriate industry consultation of those levels based on scientific evidence. A critical issue will be educating all industry on what levels are accepted and how enforcement of such levels will occur for them.

We point out that the use of novelty structures for some products are designed to provide child formulation products and therefore formulations are normally consistent with child use. E.g. Gummy Bear vitamin enriched or nutritional sweets.
We do not accept that such products are a health risk and argue that while some control of what is stated may be necessary, the principle purpose of the product should be taken into account in the definition of what is a novel food.

Formulated caffeinated beverages are a more recent type of food to which little or no restriction has been applied, however the DSANZ does not see these products as being defined as a FTDS and that any controls need to be covered in the general food category and would most likely be in the form of labelling to identify the caffeine levels. International best practice should be followed in any labelling requirement rather than an Australasian solution.

We would see products such as Kava as generally safe when used in recommended dosage however the need to ensure a food GMP and recommended safe dosage may be appropriate given the concerns raised in Europe where there is a lack of familiarity for such products. The DSANZ considers the reports from Europe as both inconclusive in the cases described and lacking statistical backing to substantiate the claims.

In once case the excessive use was a clear contributor and had maximum or recommended safe dosage been in place, the likelihood of the adverse event might have been prevented.

Added Substances

It is the DSANZ's position that the risk based assessment of safety as expressed in Figure 2 of Section 2.4.1 of the proposal, is appropriate.
We wish to make it clear that risk assessment should be based on genuine science and analysis of reports or findings internationally as well as through consultation with local industry experts.
The Kava example is one where an over reaction based on 2 reports from Europe has made it difficult to market what is essentially a very safe product in a number of markets. Full analysis of the reports does not support the reaction but do support some action being required to ensure safety in use and manufacture.

The DSANZ is happy with the term Nutritional Purpose and would see functional purpose as likely to pick up foods that are able to be used as a FTDS rather than as just a food but are not sold as a FTDS.

Labelling and Claims

The DSANZ advocates that if the principle purpose of the product is that of food then it should comply with the food labelling requirements and include such requirements as ingredient percentages. Such products would be brought into the coverage of Genetic Modification labelling etc.
Health and Nutritional claims would be over and above the fact that it was a food but should be accepted without further assessment.

If however the principle purpose of the product was that of a dietary supplement and making such claims as health and therapeutic claims (as shown in Figure 3 of 2.4.7 then the labelling should be consistent with that required for therapeutic products and it is then questioned whether in fact the product has changed from being a FTDS to a TTDS and would fall under the proposed joint agency.

We accept the definitions for claims as set out in figure 3 and would highlight that the DSANZ would consider any food type product that makes prevention, alleviation, treatment or cure of a disease, disorder, or particular physiological condition as a TTDS and not a food type dietary product.

Regulatory Position

It is the DSANZ position that the Australian industry should be able to import, manufacture, and export the same products that are available to New Zealand manufacturers as long as this change does not impact on the ability of New Zealand manufacturers to produce and export those products they currently are able to produce.

It is our position that the New Zealand manufacturers have clearly demonstrated the safety of those products not presently allowed to be manufactured in Australia and therefore the false safety concerns that exist within that market and needing serious correction.

Regulatory Options

Option 1 provided in Figure 4 under point 4 is the DSANZ's preferred position for New Zealand based companies and is seen as the least impactive on our members and the industry as a whole.
Recognising that options 2 and 3 may be preferred by the bureaucrats and some consumer advocates we comment on those options with option 3 being our second preference.

If option two was to be implemented then the Horizontal approach is considered the best option since it gives a firm foundation of example and model to work from and providing this is not an adoption of the Australian model which is totally unacceptable but a rework of the NZDSR to a unified set of regulations/standards, then we may accept very reluctantly this model.
This is our least preferred model and we consider it likely to impose additional compliance costs to industry which are unacceptable.

Option 3 being our second choice would require industry to work with ANZFA or Food Safety NZ to develop a Code of Practice. We would see this as largely based on the NZDSR but with enhancements to cover those products that are not well captured or need more appropriate guidance.
We consider that this should be done using a voluntary code of practice supplemented by standards where necessary.
The DSANZ would be happy to work to implement such a Code and standards as applicable to the Direct Selling industry.

Impact Analysis

Direct Selling companies fit into the first category and while generally in the multi-national group do have a range of manufacturers who are New Zealand based.
It is our contention that any change will impact in similar degrees both large multi-national and domestic only small to medium business with the only real difference being the ability to absorb the cost.

If labelling becomes Australasian specific for example all will have to make a decision of whether to reduce product ranges in order to lift the volumes to cover the cost of the additional labelling.

Those multi-nationals that produce for Australia already will have the least impact under such a requirement but will then need to consider whether it is viable to maintain the range they presently have on the New Zealand market which is generally between 10 and 30 percent more choice for consumers.

The DSANZ considers that at least 10 percent of its member products would be shed if the Australian situation was imposed on New Zealand immediately and that this could be as high as the 30 percent figure if there was no relaxation in the regime once costs of compliance were assessed for products that were of lower volume.
Our market information is shown in our background statement as far as this industry can gather such data.

This means that a minimum of the $36 million wholesale around $3.6 million dollar per annum would disappear in sales potential and at retail value this would grow to $6 million.

If the Otago economic impact study calculation is extrapolated then this would impact on the country by some $34 million dollars.

We would argue that the reverse applies if the Australian market restrictions were eased with a lift in the sales potential and economic impact. This is estimated at around 5 times those of the figures assessed for New Zealand based on market size.