GNC LiveWell Response to P235 Initial Assessment Report – Review of Food-Type Dietary Supplements

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Summary

P235 discusses possible options for the development of a standard to govern food-type products that are currently manufactured or imported under the New Zealand Dietary Supplements Regulations (NZDSR). This report has been carefully put together to address all the relevant issues.

Currently food-type dietary supplements (FTDS) are not governed by the ANZFSC, even though there is a consumer demand for these products. FTDS can be manufactured and sold in New Zealand and imported into Australia via the Trans Tasman Mutual Recognition Agreement (TTMRA). This is a true disadvantage to Australian manufacturers and importers of goods from countries other than NZ as they cannot compete.

It is essential that any new standard that is developed to govern the future manufacture and importation of FTDS be flexible enough to allow products that are currently manufactured or imported under to the NZDSR to continue. Also, the standard must be flexible to encompass the growing rate of this new food type, as it is falls within the growing industry of supplementary foods.

After reviewing the Options, Status Quo, Full Regulation and Co-Regulation, we have come to the conclusion that the most sensible and relevant recommendation to the Australian market is option 2b. This Option is for full regulation of FTDS as a separate category to other food types.

The relevance of the current ANZFA policy on the addition of vitamins and minerals to FTDS:

The NZDSR, and the range of food-type substances currently available which are manufactured conforming to it, show the inability of the current standards in Volume 2 to govern any such products. In order for these products to continue to be sold in Australia and NZ (irrespective of country of manufacture) an entire new standard must be developed for inclusion in the ANZFSC.

The restrictive nature of the ANZFSC is to the detriment of the supplementary foods industry. This issue is noticeable when comparing to these types of products that are sold elsewhere throughout the world.

If a new standard were implemented specifically for FTDS it would have to be more liberal with regards to composition than any of the other current standards. If the new standard was restrictive in regards to composition (vitamins, minerals and amino acids), many products currently sold under the NZDSR would no longer be available.

The appropriateness of the current permissions on the NZDSR for nutritive substances:

The NZDSR allows for a number of vitamins, minerals and amino acids to be added to dietary supplements. If an additional mineral is to be added (other than those specifically present in the NZDSR) it must not exceed the US Recommended Dietary Allowance. This guide allows for a greater range of products to be manufactured and imported for sale in NZ and therefore, in Australia, than could possibly be if comparing to the FSC.

It might be more feasible for an Australia New Zealand (ANZ) Recommended Dietary Allowance to be developed for those minerals not specified in the standard, this should also take the SUSDP into account.

Should these [NZDSR] permissions be restricted regarding: the types of substances (please give name and reason); and/or amounts of substances (please give details):

The NZDSR should not be restricted with regards to types or amounts of substances as it is this piece of legislation that all current dietary supplements are based on. If the compositional allowances of the NZDSR were restricted, then foods that are currently available to the consumer would be no longer. This would be detrimental to manufacturers, importers and retailers in both Australia and New Zealand.

Even though the NZDSR contains ingredients and amounts of ingredients that are not currently permitted by Volume 2, in order for this type of new food to prosper on the market it is imperative that Volume 2 be altered. However, once Volume 2 has been altered to include FTDS, the NZDSR should be revoked, or amended so that foods of this nature are not governed by it.

QUESTIONS RELATING TO PURPOSE OF SUBSTANCE

If FTDS, as they are currently on the market, are to be regulated by the *Food Standards Code*, do you consider that the relevant permission should be made applicable to all foods (ie be 'horizontal' permissions) or do you think that FTDS should be kept separate (ie 'quarantined') from the general purpose and/or special purpose foods?

The new standard for FTDS should be kept separate from all other standards. This is because FTDS are a specialised type of food and may not be suitable for all consumers. The relevant consumer group for which the food is intended can be indicated on the product label.

On the basis of a 2-category food/therapeutic products system, what are the distinguishing characteristics that should be taken into account in order to clearly distinguish between foods and medicines (such as complementary medicines or TTDS)?

Presentation of the goods should determine whether they are considered a food or therapeutic. Tablets and capsules should all be deemed therapeutic, whilst other presentation forms could be considered as FTDS provided they meet the relevant

requirements of the standard. For example, this would include powders, liquids, bars, drinks, or anything that can be consumed as a food based item.

If claims or therapeutic indications are to be made on a product which might otherwise be considered a FTDS it should be deemed a therapeutic good.

QUESTIONS ON ADDED SUBSTANCES

Does the approach to risk-based assessment reflected in Figure 2, Section 2.4.1 adequately address safety concerns around FTDS?

Figure 2 shows an adequate approach to risk-based assessment.

Are there any 'gaps' such that there are categories of 'added substances' in FTDS that are not captured by the framework and thereby, current standards?

No, Figure 2 is adequate for FTDS.

Should the definition of nutritive substance be extended beyond nutritional purpose to broader 'functional' purposes? If so, how should that purpose be described?

We have no comment on this issue.

Are there particular micronutrients that are not permitted, or are restricted under standard 1.3.2 Vitamins and Minerals, that require further consideration on relation to FTDS?

Yes, further vitamins and minerals require consideration, however, these are all currently permitted under the NZDSR which should be the basis for composition requirements for FTDS.

Are there food additives (ie added for a technological purpose) that are not currently permitted in Standard 1.3.1 Food Additives, that may need to be considered for FTDS?

Yes, technology is constantly changing and improving. The supplement industry is based on cutting edge technology, which means that the standard for FTDS must be flexible to ensure that the standard is not constantly being updated.

Are there particular botanicals that are not prohibited or restricted under Standard 1.4.4 Prohibited and Restricted Plants and Fungi that require further consideration in regards to FTDS?

There are no outstanding issues with any botanicals on the Australian or New Zealand market.

Should permissions for FTDS include single ingredient foods (eg barley/wheat grass powders; conjugated linoleic acid; creatine)?

Yes, FTDS should have permission to contain single ingredient foods. The action of this specific food type is dietary supplement and it is possible to supplement a certain aspect of the diet of a particular person, or subgroup with a single ingredient. The purpose of the food type should be considered when making compositional guidelines or rules.

Should FTDS be generally permitted to be a 'mixture of foods' ie are there particular foods that should be specifically excluded from mixing with FTDS (eg general purpose foods such as soft drinks, breakfast cereals, biscuits, confectionary)?

FTDS could be allowed to be a mixture of foods, however to ensure that this is a safe practice, specific labelling requirements will need to be devised. The NZDSR did not intend for this type of application, however with the introduction of the new standard modifications and allowances could be made to allow for a greater variety of 'functional' type foods.

Should permissions for some substances, that may be considered 'novel' be given on the basis that they are currently included in a variety of products (outside the domestic market); or they occur naturally; or there is reasonable international evidence if tradition of safe human use?

There may be some substances that should be considered for inclusion as a novel food, however information for this can be provided at a later date.

QUESTIONS ON LABELLING

What labelling statements are considered important for consumers to make informed choices with respect to FTDS?

It is important that labelling requirements for FTDS contain adequate provisions for the purpose of the food to be conveyed. Each different Food-Type Dietary Supplement has been formulated specifically to act in a supplementary manner, the action of the food should be detailed sufficiently on the label. However, care must be taken to ensure that this claim is not therapeutic. Labelling guidelines should be established specifically for FTDS.

In addition to the purpose of the product, it would be useful for the target consumer group to be indicated on the product label as well as warnings for any consumer groups who are advised not to take the particular product.

How should underpinning criteria be set for content claims for added nutritive substances where there are no nationally accepted reference values?

If the substance has been used in New Zealand under the NZDSR, this could be taken into account for use without any specific nutritive content claims. Background checks should be performed to determine whether any adverse effects have been recorded for the substance.

Reference values for the substance could be reviewed from other countries.

Is the labelling of products with general advisory statements that warn against consumption by vulnerable groups an appropriate risk management strategy for FTDS? Should other strategies also be adopted? If so, what other strategies are needed and why?

Labelling as to the product's intended consumer group and warnings against taking the product for those in vulnerable groups is sufficient advice for the consumer. The consumer must be provided with all the necessary information regarding the products purpose and target consumer groups, and any information and warnings for regarding vulnerable consumer groups. However, the ultimate decision on whether the product should or will be consumed ultimately lies with the consumer. Provided that the consumer is provided with all the necessary information they should be given the right to make their own food consumption decisions.

If the customer is determined to purchase a good regardless of the warnings, they are making an informed choice. Manufacturers and industry ensure that labels are detailed as to the intent of the product in order to dissuade inappropriate consumption. Education as to the reasons why a particular food, or ingredient is not appropriate for a particular person may help to dissuade them from buying it, however warnings on labels are there to provide this information.

Are there other substances, specific to FTDS for which advisory or warning statements may be required (eg allergens, caffeine)? If so, what are the substances, and why are such statements necessary?

The presence of caffeine in a product should always be specified on the label, also the amount of caffeine that is in the product should be specified. If a product contains an ingredient that may cause allergies, such as bee pollen, nuts and royal jelly, warnings should be present on the label. Labels should be such that the consumer can make an informed decision regarding the food that they are buying.

It should be noted that there is no common list of ingredients that the general population are allergic to. Many people have allergies to foods such that they must read the ingredient lists for all products that they purchase to ensure that they do not consume an ingredient that may cause them an adverse effect. It is impossible for warning statements for all such ingredients to be devised and included on labels.

Should FTDS be exempt from the nutrition information requirements of Standard 1.2.8 in Volume 2? If so, why, and what alternative nutritional/ content information would be appropriate?

It would be appropriate for FTDS to conform to the labelling requirements of other foods in Volume 2. It is important for consumers to have nutritional information regarding the foods that they are consuming. It is important for product information to be displayed on all foods, FTDS should not be an exception.

If health claims are permitted in the future, should this permission extend to FTDS?

Yes, clearly it is in the best interest of the consumer to have a full understanding of any health advantages for food they may be consuming.

If so, is the contextual statement referring to the *context of the total diet* appropriate?

FTDS are formulated to be supplementary to the diet, so they will probably contain ingredients or nutrients that are not necessarily available in the general diet, or contain ingredients that may be available in a general diet, however, the consumer may want to elevate levels of the particular nutrient. Therefore, it may not always be relevant to refer to the context of the total diet.

Should FTDS regulated as foods be required to carry either a 'prescribed name' or an advisory statement to the effect that this is a supplementary food?

Yes, it would be useful to the consumer to understand that the food is intended to be supplementary to the diet, not to replace the normal diet. A prescribed to be included on all FTDS will allow consumers to easily recognise the food as supplementary only.

Are instructions regarding 'dosage' (ie amount and frequency) appropriate for FTDS?

Use of the word 'dosage' implies Therapeutic Type Dietary Supplement (TTDS) rather than FTDS; this may confuse consumers as to the intention of the products. It would be more appropriate to use the word 'serve' and to recommend the number of serves and frequency of intake relative to the product.

Are there any other general labelling issues that should be considered for FTDS?

The labels for FTDS should be in keeping with other food types. Prescribed names and standard warnings are applicable and should be utilised, however other warnings may be required depending upon individual ingredients.

THE REGULATORY PROBLEM

The issues discussed throughout this paper have raised three potential problems relating to effectiveness.

"FIRST – The current regulatory structure may not be sufficiently clear to adequately address the full range of FTDS products. This product range, with food characteristics and enhanced nutrition, functional, health or therapeutic properties, has grown rapidly in recent years and is expected to continue to grow in future years. Lack of clarity if the regulatory structure presents a risk of inadequate protection of public health and safety."

As mentioned, the industry is growing and any standards that are written must account for this. The standard must be such that it allows for growth, possibly rapid growth, once Australian manufacturers are also permitted to produce these products. Secondly, in response to possible inadequate protection of public health and safety, these products are not new to the Australian or New Zealand markets, they are merely new to the Food Standards Code. Review of any adverse effects or past endangerment of public health and safely in relation to these types of products should be taken into account prior to making any decisions on this point.

"SECOND – lack of clarity of the current regulations implies a range of information to consumers that is inconsistent and confusing, and may be insufficient for them to make informed choices."

Possible confusion to the consumer can be overcome with adequate labelling. Prescribed names enable consumers to have a constant indication of exactly the type of product they are purchasing and the intention of the product. This is a name that they can look for when shopping and con be assured that they are making an informed choice with every purchase as to the products intention.

"THIRD – the current regulations combine with the TTMRA to impact inequitably on industry. In particular, they prevent Australian industry from manufacturing FTDS products for the Australian domestic and export markets. Currently these products are available to Australian consumers, supplied by imports from NZ under the TTMRA."

In order to combat this problem, the NZDSR will have to be revoked, or a clause will have to be written to amend it along the lines of *"…except where a standard exists in Volume 2, FSC"*. Or, the FTDS standard could be written to mirror exactly the NZDSR.

REGULATORY OPTIONS

Option 1 – Status Quo

This option is not satisfactory as the current situation is inequitable. Australian manufacturers are unable to produce these products; therefore, all products of this type to be sold in Australia must be imported from New Zealand.

Option 2 – Full Regulation

This option allows for the revocation of the NZDSR and implementation of a new standard in Volume 2, which is applicable in both Australia and New Zealand.

Option 2a. Option 2 – Full Regulation has been split into two, 2a allows for a 'horizontal' approach with changes across all standards making them more liberal with respect to addition of such ingredients as vitamins, minerals and herbs.

The other option 2b allows for a 'vertical' approach with a new chapter or standard being included in the current Food Standard Code, which will keep FTDS separate from other food types and provide requirements for management such as labelling.

The preferred choice for this paper is option 2b. It is considered that option 2a will not be appropriate as it unnecessary and unlikely that levels for the addition of such ingredients as vitamins, minerals and herbs could be elevated throughout the entire code to the levels that would be required for FTDS. If such alterations were made throughout the Code, provisions for warnings and other label requirements would also be necessary throughout other standards.

Option 2b allows for the addition of only one standard and for the rest of Volume 2 to remain unchanged.

Once having decided upon Option 2b, it must then be decided upon whether the new standard should be added to an existing chapter, or whether an entire chapter should be created for the standard.

It may be more appropriate to have a new chapter created for formulated supplementary foods and move the current standards for supplementary foods into this chapter. This might be a more reasonable option than trying to fit the standard for FTDS into the only other available category – Special Purpose Foods, as the purpose of a FTDS does not specifically meet the definition.

Option 3 – Co-regulation

This Option is the same as for Option 2, however, rather than full regulation, an industry Code of Practice would be created to establish co-regulation.

The idea of a voluntary code of practice requires much further investigation. How would this code be enforced? How would shared enforcement between industry and government be co-ordinated? How could adherence to the code be enforced if it is a *voluntary* code?