P235 Review of Food Type Dietary Supplements

Initial Assessment Report

Submission by

Public Health Association of Australia

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Thank you for the opportunity to comment on this proposal. In considering the proposal, the Public Health Association of Australia (PHAA) notes the following:

- The basis of the proposal is the harmonization of food regulations between New Zealand and Australia and to thereby "fix" the problem of "foods", which are currently permissible under NZ regulations but which contravene the joint Food Standards Code (FSC), to be legally manufactured in Australia.

- The NZ Ministry of Health is releasing a discussion document proposing that foods that may be sold under the NZ Dietary Supplements Regulations (NZDSR) will no longer be able to do so when that law is repealed.

- Many so-called food type dietary supplements (FTDS) do not conform to the purposes currently inherent in the FSC, which are based on appropriateness for the general population (ie general purpose foods) or dietary need based on essentiality (ie special purpose foods).

- The Codex principles for the addition of nutrients to foods are:

    - Restoration
    - Nutritional equivalence of substitute foods
    - Fortification to address public health need
    - Ensuring the appropriate nutrient composition of a special purpose food.

- The philosophical underpinnings of the Codex approach include:

    - Controlling risks to health
    - Preserving the nutritional integrity of the food supply
    - Supporting food based nutrition education activities.

- The key element of FTDS appears to be a supplementary role (to the normal diet) and an intended function over and above that provided by the usual diet.

- In this respect, the intent of many FTDS is arguably "medicinal".

- Many substances that are components of these FTDS, or at the levels present, are not well supported in respect to efficacy.

- The standard for Formulated Caffeinated Beverages was not supported by PHAA and should not form a precedent for the establishment of additional standards regulating FTDS.

Fundamentally, **the PHAA supports the underpinning principles (and thereby parameters imposed) of the current standards in relation to addition of nutritive substances**. These principles have served the public well in protecting public health and safety and there is no demonstrated need to alter this position.

The PHAA believes that since these products are claiming enhanced "function" above that provided by the normal diet, then they:

Are medicinal in nature, and
Should be subject to safety (and efficacy) testing before use.

In this regard, the PHAA does not believe these products should be regulated as food and that they **should remain in the domain of therapeutic products and come under the complementary medicines regulations.**

In relation to the options outlined, the PHAA makes the following comments:

Option 1: The status quo is clearly not an option while the NZDSR allow for these FTDS, however, **if the Ministry of Health repeals the NZDSR, then the PHAA would support** a two phase food/drug system, where these products are subject to therapeutic regulations.

Option 2: If these products are to be regulated under the FSC, then PHAA could only support the strongest regulatory approach, ie Option 2b – separating FTDS as discrete products (and include FCB in with this new standard). However, we feel this makes a mockery of the standards in Chapter 1 relating to addition of nutritive substances and essentially undermines the basic principles of the FSC.

Option 3: PHAA would not support a co-regulatory approach. This approach has clearly not worked in relation to nutrient claims and the potential for risk is such that full regulation is warranted.

In regard to these products, PHAA feels that the approach being taken is one where the "lowest common denominator" is being applied. Obviously there is a problem within Australia currently as these products are not covered by Australian regulations, coming into the country via the NZDSR. However, **the aim should not be to make the regulations fit the problem but for the problem to be carefully analysed and**

decisions based on public health and safety issues. The NZ Ministry of Health seem to be moving in this direction, with the release of the discussion paper on these products. The PHAA believes that a decision based on regulation of the products within the FSC, should be postponed until the Ministry of Health has ruled on whether or not these products will remain in the NZDSR. If they are to be removed, the problem of these foods being brought into Australia under the Trans Tasman Agreement ceases to exist and hence any need for regulation under the FSC. They are more appropriately regulated as therapeutic goods.

The PHAA is keen to continue discussions with FSANZ over this issue and would welcome any further opportunities to do so.

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