

## **RESPONSE SHEET**

### **POLICY OPTIONS FOR THE REGULATION OF THE ADDITION TO FOOD OF SUBSTANCES OTHER THAN VITAMINS AND MINERALS**

Name: Sue Cassidy

Title: Professional Services Dietitian

Organisation: Dietitians Association of Australia

Address: 1/8 Phipps Close, Deakin ACT 2600

Telephone: 02 6282 9555 Fax: 02 6282 9888

Email: nationaloffice@daa.asn.au

#### **1. Please comment on the adequacy of the current regulatory regime to manage the addition to food of substances other than vitamins and minerals. (pg. 4)**

The current regime is not adequate as many substances would not be captured. For example the current regulatory regime is not specific on what it regards as a "bioactive" component of food. This definition is being left up to those who want to make content or health claims on such components. Some guidelines would be useful, particularly if these substances are being added to foods. Examples include antioxidants other than vitamins that may be derived from some natural sources and added as an extract to other foods.

#### **2. Please comment on the need for a policy guideline for the addition to food of substances other than vitamins and minerals. (pg. 5)**

Policy guideline is essential for the protection of public health and safety in relation to possible toxicity and to prevent misleading representations as a result of ineffective doses.

This is an area of rapidly increasing knowledge and we are still discovering components in food with functions relevant to human health. Examples are the phytochemical category. Claims concerning the benefits of these food components are widely made and will influence the food selection decisions of some people. We do not know the safe levels of most of these phytochemicals. Phytochemicals may have interactions with other nutrients so we need to know if they positively or negatively affect the bioavailability of vitamins and minerals. We do not know the levels required for these phytochemicals/phytonutrients to demonstrate the benefit claimed. There are similar concerns with other substances that may be added to food that do not fall under the categories of vitamins and minerals, food additives or novel foods.

#### **3. Please comment on the scope of the policy guideline. (p.6)**

The scope of the policy guidelines is fine as long as it also considers the safety of the substance, the interactions the substance may have with other nutrients including the bioavailability of other nutrients and the cumulative effect of the substance in the total diet not just an individual food. An example would be the effects that fibre may have on absorption of nutrients in the total diet.

#### **4. Can you envisage a requirement for the mandatory addition to food of substances other than vitamins and minerals and if so what different factors might need to be considered from those considered when contemplating voluntary additions? (p.6)**

Mandatory addition of food substances other than vitamins and minerals may be required in future if some "essential" nutritional component is discovered within foods that is not a vitamin or mineral and the levels of which are significantly reduced during some methods of food processing. Nutrition is still a developing science and this area is currently undergoing change. Should the definition of vitamin be "essential for life" and how do we determine the differences between essential versus non-essential substances. The policy on what constitutes an essential nutrient is not fixed and must be able to accommodate discoveries in nutritional science in the future.

**5. Should the addition of substances other than vitamins and minerals be limited to situations where there is a purpose or reason for adding the substance? (p.7)**

Yes.

1. The first principle needs to be that there is a need or purpose to add the substance.
2. There is also a requirement to ensure safety and informed choice by consumers.
3. The substance must be of sufficient quantity and quality to make a purpose claim and there needs to be a formal process to substantiate the claim and or benefit.
4. The additional substance ought to be considered in the context of the total diet.

Adding a substance where there is no proven benefit may have unintentional negative consequences if the substances interact with other nutrients for example by reducing or increasing the bioavailability into the ineffective or toxic ranges.

**6. Would the acceptable purposes/reason be limited? If so what would the limitations be? (p.7)**

Demonstrated benefits with no demonstrated adverse effects.

**7. If a purpose/reason is required how and to whom should the manufacturer/supplier be required to justify the addition? (p.7)**

Justification should require peer-reviewed, controlled trials published in respected scientific journals which show that the substance is efficacious and non-toxic over the long term in humans. This evidence should be included in the application to FSANZ and be reviewed by all stakeholders.

FSANZ could use the same criteria as voluntary supplementation of vitamins and minerals and/or other food additives (safety must be proven not assumed)

**8. Should safety assessments be made of the substance to be added or the substance in the final food? (p.7)**

Yes. Safety assessments should be made for both the substance to be added and the substance in the final food.

**9. Should any safety assessment include consideration of the final food as a component of the total diet? (p.7)**

Yes. Safety assessments run across total population and subgroups to determine the cumulative impact of multiple submissions for the same substance or related substances. An example is phytosterols being added to a greater range of food, the safety level for the consumption of added phytosterols in one food may be lowered if phytosterols are consumed as additives in other foods there will be a cumulative effect in the total diet.

**10. Should the policy only apply to future applications or should a review of current permissions be carried out to achieve consistency across the Food Standards Code? (p.7)**

DAA strongly supports review of all existing permissions. Currently there is an inconsistency between Australian and New Zealand regulations for dietary supplements. This area has shown significant change in recent years and there should be a review of current permissions to achieve consistency, especially as knowledge regarding these substances has increased since some of the permissions may have been granted.

**11. Please comment on whether there is evidence that food consumption patterns may change because of the addition to food of substances other than vitamins and minerals. (pg. 7)**

There is substantial evidence from increasing sales of products with substances other than vitamins and minerals added.

- Plant sterols to margarines
- Omega 3 fatty acids added to multiple product categories
- Amino acid supplements
- Culinary herb extracts and cross over products such as ginseng and guarana added to juices and other "health" products

Note the rapidly increasing number of juice bars supports the increased consumption of these products as does the introduction of "juice bar" style juices in supermarkets and other retail outlets. Food databases now include more products with phytosterols, added fibre, omega 3 fatty acids etc compared with 5-10 years ago.

DAA recommends that FSANZ accesses marketing data on the number and sales of these products to review increasing consumption trends.

**12. Please comment about whether there is significant concern about the 'medicalisation' of the food supply. (pg. 8)**

Yes, DAA is concerned that many non-culinary herbal and other substances are being added to foods, blurring the boundaries between supplements and foods. Diet is important for the maintenance and promotion of good health, whereas substances such as non-culinary herbs are used for the treatment and/or prevention of disease. The addition of these substances to foods, particularly now that health claims are to be approved, encourages self-diagnosis which may be inappropriate and result in delay of treatment by appropriately trained health professionals.

**13. Please comment on the food medicine interface and how the delineation between the regulatory systems might be clarified for industry and regulators?(p.9)**

The primary purpose of the product needs to be defined, if the product contains more than 80 kJoules energy per 100 ml as a beverage or 170 kJoules per 100 grams as a solid then it should preferably be covered by food regulations.

Substances that are not found in foods, in particular non-culinary herbs, should not be added to foods. These substances are for treatment and/or prevention of specific conditions and require an accurate dose. Those people who need treatment for a condition should be encouraged to consult with qualified practitioners so that they are properly assessed and are prescribed the appropriate treatment, appropriate dose and using substance of standard quality and biological activity.

Substances other than vitamins and minerals that occur naturally in food, such as plant sterols, antioxidants and probiotics could be covered by food regulations.

**14. Are there additional issues for consumers? (p.10)**

Yes, potential confusion between selection of foods from fresh and minimally processed foods and processed food products with suggested health benefits because of the addition of substances other than vitamins and minerals. There are cost and access issues to consider in consumers believing that the supplemented products may offer better nutrition which may not be the case.

Potential allergic reactions also need to be considered. Even clinical trials cannot ensure that there will not be a small section of the population who may develop allergic reactions to new food

additions. Echinacea is an excellent example of a non-culinary herb that can cause life-threatening anaphylaxis which is currently being added to fruit juices and other food products.

Consumers face confusion regarding the indistinct delineation between food and therapeutic goods and where to seek advice. DAA supports a single consumer advice line with the one 1800 number to improve access to information.

**15. Are there additional issues for industry? (p.10)**

No comment

**16. Are there additional issues relating to enforcement, monitoring and surveillance? (p.10)**

Yes because this is a rapidly growing area. Depending on the regulations used to support the addition of substances other than vitamins and minerals there may be a proliferation of "new" products creating an increased load in enforcement, monitoring and surveillance. There are potential difficulties with enforcement spread across two national and eight state/territory jurisdictions.

There is a need for a nationally consistent approach for example the establishment and adequate resourcing of a government department or agency that is specifically devoted to the enforcement, monitoring and surveillance of the food standards.

A national 1800 number for consumer complaints and enquiries.

**17. Which policy option do you prefer and what are your reasons for this preference? (p.11)**

The addition of substances other than vitamins and minerals to food has already happened. The regulation needs to be consistent with the criteria for vitamins and minerals.

It is difficult to define exactly which substances occur naturally in food.

There needs to be a stronger delineation between therapeutic goods and food e.g. homeopathic medicines and food including some added active ingredient such as fruit juice with non-culinary herbs like Echinacea.

**DAA supports option 2 with the following considerations:**

It is interesting to note that the TGA has established safe levels of active ingredients added to complementary medicines and also considers the appropriate standard indications and claims that can be made, yet several of the options suggested do not afford this level of control to foods. There are no established safe levels of non-culinary herbs for use in food.

Whichever option is selected, it must allow the flexibility to consider the regulation of different classes of substances in different ways (lycopene is not similar to probiotics and neither is comparable to ginko for example). The safety of individual substances must be ascertained and safe and effective levels determined. It makes nutritional sense to control the foods to which the substances can be added. The effect on and sometimes targeting of population sub-groups needs careful consideration on a case-by-case basis.

**18. Please comment on the applicability of the specific order policy principles for the Fortification of Food with Vitamins and Minerals (Attachment 1, pages 2 & 3) to the addition of other substances to food. (p.12)**

These are comprehensive and the same standard of care should apply to other supplementation whether mandated or voluntary.

The policy paper asks us to consider the application of policy principles established for vitamin and mineral fortification. However, it seems ironic that substances which are known to be essential for human health (vitamins and minerals) are strictly regulated to address demonstrated nutritional needs in particular population groups, while the substances currently under discussion are not essential to human health and depending on the policy option settled on could be much less tightly controlled.

**19. Please provide any examples, and data if available, of the benefits and costs that might arise as a consequence of the policy options explored in this paper? (p.12)**

These would be difficult to predict as benefits would accrue on a case by case basis. The same would apply to costs but compliance/regulation and education of the public costs may be higher than anticipated.

**20. Are there any other comments you would like to make about the issues discussed in this paper? Please describe your reasons for raising them and offer solutions where possible?**

While the paper states in paragraph 58 that a clear division between therapeutics and foods is vital and a situation must not be allowed to develop where food regulations are seen as a less rigorous option, the policy document does not clearly set out how a 'marketable health benefit' might differ from a 'therapeutic effect'. It seems unlikely that consumers will be in a position to discriminate between these nuanced meanings and will most likely interpret 'health benefit' to mean 'therapeutic benefit or effect'.

- DAA recommends a better working relationship in areas of overlap between relevant Australian and New Zealand, national and state bodies responsible for therapeutic goods and food.
- There is a need for a national single point of contact for consumers to make enquiries and complaints.
- It is important for a consistent approach to therapeutic goods and foods to ensure appropriate classification and regulation.
- DAA seeks representation on any advisory group established to assist with implementation of the policy.

**Acknowledgement**

The submission was developed by the DAA Food Standards Advisory Committee