Submission on Proposed Future Regulation of Nutritive Substances and Novel Foods in the Australia New Zealand Food Standards Code

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Introduction

Thank you for the opportunity for the complementary medicines industry, through the Complementary Healthcare Council of Australia (the CHC), to provide a submission to The Food Standards Australia New Zealand on the proposed new approach to regulation of nutritive substances and novel foods.

The CHC is the peak industry body for the Complementary Medicines (CM) Industry, representing the entire industry supply chain including; manufacturers, importers, exporters, raw material suppliers, wholesalers, distributors and retailers. The CHC is committed to a high growth and sustainable CM industry. Uniquely placed as the voice of both Industry and consumers we promote industry advancement whilst ensuring consumers have access to CMs of the highest quality, contributing to improved population health outcomes. We are the principal reference point for our members, government, media and consumers to communicate about issues relating to the CM industry.

Complementary medicines and natural healthcare products are vitamins, mineral and nutritional supplements, special purpose foods, herbal and homeopathic medicines, aromatherapy products, and natural cosmetics using herbals and botanicals. Complementary medicines comprise traditional medicines, including Traditional Chinese Medicines, Ayurvedic, and Australian Indigenous medicines. Complementary medicines are generally available for self selection by consumers and can be obtained from retail outlets such as pharmacies, supermarkets and health food stores. The majority of complementary medicines are indicated for the relief of symptoms of minor, self-limiting conditions, maintaining health and wellbeing, or the promotion or enhancement of health[1].

There are over 300 complementary medicine companies in Australia generating around $2 billion in annual revenues. Australian companies export around $200 million in complementary medicines to more than 20 countries in Southeast Asia, Europe and The America's, and this continues to grow at higher rates than domestic consumption[2]. In Australia the industry generates around 5,000 highly-skilled manufacturing jobs, and indirectly supports a further 60,000 jobs. The global market has been estimated at $US 83 billion annually[3].

Production of complementary medicines in Australia is a substantial industry, with 59 TGA approved manufacturing facilities for Listed medicines nationally (including CMs, sunscreens and over-the-counter medicines). Over 75% of Australians use complementary medicines, so it is not surprising that the majority of consumers can name the exact CM product they purchase and why.[4]

Australia's complementary medicines industry continues to lead the world in the development of global benchmark standards in safety, quality and efficacy.

[1] Source TGA, http://www.tga.gov.au/industry/cm-basics-regulation-overview.htm

[2] CHC Complementary Medicines Industry Audit May 2011, available by request

[3] The Australian National Audit Office, Performance Audit Report No. 3 2011-2012, Therapeutic Goods Regulation: Complementary Medicines, pp13

[4] My Opinions Research for CHC May 2011

Introduction

The CHC understands that the aim of this consultation is to call for views on a potential new approach to regulating nutritive substances and novel foods. This has arisen due to a degree of regulatory uncertainty over the interpretation and ambiguity of the definitions defined in the Code, and hence issues with enforcing the provisions.

The FSANZ proposed alternative regulatory approach will split foods into eligible foods and non-eligible foods. This approach will apply only to new foods and is not intended to be retrospectively applied to existing foods. Eligible foods will be permitted to be sold without pre-market assessment by FSANZ.

Under the proposed approach, a substance or a food would generally fall into one of three broad regulatory categories.

1. The substance or food meets one of the eligible food criteria in the Code.

The following two categories relate to foods that are considered non-eligible and further consideration is required.

2. The substance or food is defined in the Code (e.g. a food additive or processing aid) and requires specific approval before use. Permission may be provided via an Application to amend the Code.
3. The substance or food does not meet either of the above categories. Permission may be provided:

    (a) via a proposal prepared by FSANZ, based on a pre-market assessment, OR
    (b) via an application. This may arise from the pre-market assessment identifying concerns or if there was insufficient evidence to conclude safety.

The FSANZ states that the majority of foods currently sold in the Australian and New Zealand markets are expected to be considered eligible foods. Non-eligible foods would be prohibited from being sold as food and would require pre-market assessment before they are permitted in the Code. Non-eligible foods would reflect those substances and foods that are considered to require pre-market assessment before they can be sold. The following principle elements are proposed:

- The current Application assessment process for approval of foods and substances, including food additives, vitamins and minerals, processing aids, food produced using gene technology and irradiated foods would be retained.

- The definitions of nutritive substance and novel food would be removed from the Code.

- In their place would be objective criteria (referred to as eligible food criteria) that would permit a broad range of foods and substances already in the food supply.

- The sale of foods and substances that do not meet the eligible food criteria would be prohibited by the Code.

- Non-eligible foods would then be considered through a process that includes an appropriate level of assessment to determine whether these foods are likely to pose a risk to human safety. A similar process is currently followed by the FSANZ Advisory Committee on Novel Foods.

- Foods that the assessment concludes to be safe would be listed in the Code, through the standard FSANZ proposal process, which would be subject to public consultation.

- New foods that the assessment concludes are unsafe, or where there is a lack of evidence to establish safety, would not be permitted in the Code. An Application to amend the Code would need to be submitted to FSANZ in order to have these foods assessed and permitted in the Code.

The proposed alternative regulatory approach

The CHC acknowledges that this consultation paper describes the approach in principle, and does not include all the details. Therefore, industry is commenting at this time on the approach in general, including its feasibility and the potential impacts on industry if such an approach were to be applied to foods in Australia and New Zealand.

The CHC appreciates the difficulty of developing appropriate definitions that make clear the substances and foods considered to require pre-market assessment to establish safety.

Overall, the CHC agrees in general with the key principles proposed by the alternative regulatory approach, that is to classify new foods and substances to be added to foods as eligible or non-eligible.

- Eligible foods will be permitted without the need for a pre-market assessment;
- non-eligible foods will be prohibited by the Code, though may be subject to pre-market assessment and if assessed as being safe, may then be included in the Code as eligible foods;
- in general food-derived substances would not be eligible foods and would require pre-market assessment before they could be permitted in the Code;
- 'Eligible food' criteria will be included in the code to determine whether a new food or food-derived substance is an eligible food or not.

Under this proposed alternative approach, substances intended to be covered by the current definitions of nutritive substance and novel food would be considered non-eligible and would require permission in the Code before use. The CHC agrees with the FSANZ approach that current pre-market assessment requirements set out in the Code for food additives, vitamins and minerals, processing aids, food produced using gene technology and irradiated foods are to be retained.

The CHC notes that the proposed approach seems to acknowledge that the majority of foods in the market are safe for consumption while also maintaining the intent behind the current regulation of nutritive substances and novel foods. The prohibition in the Code of foods and substances that are not eligible foods is intended to ensure that food-derived substances, in particular, are subject to greater regulatory oversight. This would give greater certainty for regulators and for industry.

Q1. Will the eligibility criteria efficiently identify when a pre-market assessment is required for a food or substance?

Yes, the CHC considers that this is a substantial improvement on the current situation. In the past industry has experienced several instances where a considerable degree of uncertainty existed on the acceptability of certain ingredients in new products that were reviewed for product ranges. In some cases, it was considered, that the advice of "experts" was not clear and not always consistent with other advice. The eligibility criteria will give industry more certainty.

Q2. Do you have any suggestions for improvement of the eligibility criteria? Please provide details of your suggestions, including justification or rationale for your suggestions, and examples.

The CHC does not have addition suggestions for improvement at this time. However, as no system is perfect, pursuing the eligibility criteria and developing a more detailed proposal is encouraged.

Q3. Can you identify examples of substances that may not meet the eligible food criteria, but should be considered eligible foods? For example, foods or substances that are well characterised and understood to be safe, but may be considered non-eligible because of the above criteria? If so, please provide examples, including justification or rationale and any suggestions for improvement of the criteria.

The CHC suggests that some examples may include ingredients commonly used in Sports Supplements ie some electrolytes and various amino acids, though we can not offer suggestions for improvement of the criteria for these ingredients at this stage.

However, the CHC suggests that this issue could be dealt with during the review of the Standards related to Sports Supplements (2.9.3, 2.9.4, 2.6.4 etc) and provisions made for the inclusion of these ingredients within the revised Sports Food Standards only.

The intended market for these products is different and warnings are included on labels to ensure that vulnerable groups are not exposed to ingredients that have not had the same safety assessments as those of general foods eg pregnant/lactating women, children, and those with health problems eg heart disease, diabetes etc. The CHC suggests that for certain standards a Supplemented Food Standard could be developed much like the NZFA have developed for example.

Evidence requirements for new foods:

Q4. Can you provide comment on suitable evidentiary requirements for the type of information/data that should be held by industry to support the safety of human consumption of new foods?

The CHC suggests hat food suppliers must hold evidence of safety for new foods (i.e. not previously sold in Australia) which should include:

- evidence that the new food has a safe history of use in overseas jurisdictions, and/or
- scientific justification that the safety of the food is equivalent to other foods consumed in Australia or New Zealand.

Overall approach:

Q5. Are you supportive of the general approach described in this paper?

The CHC, in general, is supportive of the general approach described in this consultation paper. However, the CHC would like to ensure that the next step (FSANZ proposal) does not introduce new concepts or challenging requirements.

Q6. Do you have any suggestions for alternative approaches, or aspects of the approach that could be improved? Please provide details of your suggestions, including a justification or rationale for your suggestions, and examples.

No, the CHC does not have any additional suggestions to offer for an alternative approach.

Industry:

Q8. Will your organisation submit more (or fewer) requests under the proposed assessment of non-eligible foods element (see element 6 in section 4.1)?

The preliminary information provided by industry, suggests that more requests may be under the proposed system.

Q9. Will your organisation submit more or fewer applications to have foods approved in the Code?

The preliminary information provided by industry, suggests that more applications may be made under the proposed system.

Consumers:

Q10. FSANZ encourages comment on the potential impacts of the proposed alternative regulatory approach on consumers.

Conclusion

The CHC thanks you again for the opportunity to make this submission. In general, the CHC is supportive of a system that provides industry with greater certainty for the safety of new ingredients, without the undue increase in regulatory burden. While the CHC, in general, acknowledges the proposed benefits of the alternate regulatory approach outlined, we look forward to a FSANZ proposal which will provide more specific details on compliance requirements.

Yours sincerely,

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