



Legal and Regulatory issues in the Food-Therapeutic Goods Interface

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Why is there a food-therapeutic goods interface?

- Similarities between foods and therapeutic goods
 - Both can be consumed orally
 - Both may contain natural or added nutrients and may be consumed for particular functions
- Legal interface arises from difference in regulations
 - Food:
 - Relevant laws: **Australia New Zealand Food Standards Code** and the **Food Acts** of each State and Territory
 - Standards set by: **Food Standards Australia New Zealand (FSANZ)**
 - Enforced by: **Local municipal councils** or the **NSW Food Authority** (in NSW).
 - Therapeutic Goods governed and enforced federally by the **Therapeutic Goods Administration** under the **Therapeutic Goods Act**.

Different commercial implications for foods and therapeutic goods

- Manufacturing process
- Auditing requirements
- Manufacturing premises
- Marketing and claims
- Location of sale

Classification of a product as a food rather than a therapeutic good may have commercial benefits

Factors to distinguish Foods from Therapeutic Goods

- Four factors:
 - Composition
 - Form or presentation
 - Claimed Function
 - Dosage

Legal Avenues and Opportunities: Dietary Supplement under NZ law

- Trans Tasman Mutual Recognition Agreement
- Applies specifically to Dietary Supplements in New Zealand
- No restrictions on the forms of certain vitamins and minerals being added to products
- Still must not be regarded as a “therapeutic good” in Australia
- Moves are afoot to close this avenue from the New Zealand side

Legal Avenues and Opportunities: **Special Purpose Foods**

- Infant Formula Products
- Foods for Infants
- Formulated Meal Replacements and Formulated Supplementary Foods
- Formulated Supplementary Sports Foods

Legal Avenues and Opportunities: **Foods for Special Medical Purposes (Proposed)**

- Foods specially formulated for the dietary management of individuals with certain medical conditions
- Currently at the second last stage of assessment by FSANZ (Preliminary Final Assessment Report published 4 August 2004)
- Special approval for certain nutritive substances not otherwise permitted in food
- Restrictions on advertising to consumers and additional labelling requirements apply

Legal Avenues and Opportunities: Health Claims (Proposed)

- Current laws prohibit health claims being made about food
- New health and nutrition claims Standard 1.2.7 finalised by FSANZ and awaiting approval from the Food Regulation Ministerial Council
- 9 specific high level health claims will be permitted
- Substantiated general level health claims will be permitted

Legal Avenues and Opportunities: Health Claims (Proposed)

However:

“A claim must not refer to the prevention, diagnosis, cure, alleviation or symptom of a disease, ailment, defect or condition.”

(Clause 3(2), Proposed Standard 1.2.7)

A Food Lawyer's role

- Work with companies to overcome legal problems
- Clarify and interpret what is legally possible and what is not
- Aim to give clients the best possible solution within the parameters of the law

Common food law issues to be aware of

- Composition
- Tradition as a food
- Statements that the food gives you benefit
- Product name or descriptor that could potentially be misunderstood or ambiguous



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