Codex – Some Facts

1. The Codex Alimentarius Commission was created in 1963 by FAO and WHO to develop food standards, guidelines and related texts such as codes of practice under the Joint FAO/WHO Food Standards Program with the main purposes of protecting health of the consumers and ensuring fair trade practices in the food trade.

2. Codex Alimentarius is Latin for "code" and "food". Simply translated, it means "food code".

3. The General Principles of the Codex Alimentarius state:
   "The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade."

4. A principal objective of the CODEX Code of Ethics is to stop exporting countries and exporters from dumping poor-quality or unsafe food on to international markets.

5. Codex standards are increasingly being used as benchmarks in World Trade Organisation (WTO) dispute settlement processes, and many developing countries rely on Codex because they don't have the resources to develop risk-based food safety systems of their own.

6. The Guideline being proposed for Vitamins and Minerals has been under development now for some 15 years and is still only at Step 5 of an 8 step process. The Guideline specifically states that this Guideline applies "*in those jurisdictions where the products (defined as vitamin and mineral supplements that derive their nutritional relevance primarily from the vitamins and minerals they contain) are regulated as foods*".   As Australia regulates vitamins and mineral supplements as medicines under the Therapeutic Goods Legislation this Guideline is not intended to apply in Australia.

7. Countries establish their own upper levels of vitamins and minerals in supplements and can use CODEX standards and limits as a model if deemed appropriate by their regulatory authorities. Most European countries, including France and Germany, currently have very low upper limits and have argued strongly that upper levels should be based on a risk basis. As the current low levels cannot be justified it is expected that they will eventually be raised.

8. Vitamin and mineral supplements making therapeutic claims and presented in a therapeutic form with dosage instructions have been regulated as medicines in Australia since February 1991 by the Therapeutic Goods Administration (TGA). The Therapeutic Goods legislation has had the power to declare products to be therapeutic goods since that time.

9. The TGA does not attend CODEX meetings which develop guidelines and standards for foods, and is represented from Australia by the Food Standards Australia New Zealand (FSANZ).

10. As Codex standards are increasingly being used as benchmarks in World Trade Organisation dispute settlement processes, it is not clear what impact the Guideline will have under the Free Trade Agreement between Australia and the United States if the US adopts the Codex standard.

11. The CHC (Complementary Health Council) is the peak body representing the natural medicine industry in Australia and covers over 80% of the industry. The Corporate 'drug' companies belong to Medicines Australia (MA) whilst the peak body for non prescription pharmaceuticals is the Australian Self Medication Industry (ASMI).

12. Val Johanson resigned from her position as Executive Director of the CHC in July 2004 and now provides a consultancy service to the natural healthcare industry and other stakeholders continuing her passion for ensuring that Australian consumers have freedom of choice to a wide range of good quality natural health products and balanced truthful information about the use and benefits of those products to help them make informed choices about their health.

13. Eastman Chemical Company, Bayer, Monsanto and Wyeth pharmaceutical company are not members of the CHC.

14. The Interim Advertising Council (IAC) was established as a Joint Australian/New Zealand Committee to establish an advertising regime that will enable socially responsible advertising of medicines, including dietary supplements, and medical devices in both Australia and New Zealand. Prescription medicines can currently be advertised to the public in New Zealand, but it has been made very clear by the TGA that prescription medicines will NOT be permitted to be advertised to the public in Australia. Therapeutic claims are not currently permitted for Dietary Supplements in New Zealand, but will be permitted after the Joint Australian /New Zealand Agency is established, now expected in July 2006.

15. The Australian Traditional Medicines Society (ATMS) was invited to participate in the IAC as an alternate to the New Zealand natural practitioner association and attended two out of the nine IAC meetings.

16. The warning label required on Royal Jelly is in fact a 'death' warning (*'may cause fatalities')*, following four deaths worldwide <u>possibly</u> linked to royal jelly> it is of note that there are no similar warnings required on analgesics which are known to cause hundreds of deaths yearly.

17. The CHC and its members are consulted on TGA issues and sit on TGA committees representing the complementary medicines industry.

18. Pan Pharmaceuticals was the largest manufacturer of natural products (nutritional supplements or complementary medicines) in the Southern Hemisphere, with over 1600 products registered with the TGA. Pan Pharmaceuticals did not produce raw materials and was not a major ingredient supplier.

19. Australian TGA licensed contract manufacturers are not aware of any requirement to *"sign confidentiality agreements and other agreements demanding that the proprietor will not hold TGA liable for the loss of their business after such 'regulating activities'"*

20. TGA has not audited in New Zealand since 1994 as manufacturing facilities producing medicines and those supplying Australia are audited by Medsafe. All other supplement manufacturers are currently food manufacturing plants and approved by the NZ food safety authority via a 3rd party commercial audit.