What Restrictions Might the TGA Bill Enforce ?

What restrictions are being imposed now, overseas? When these are firmly entrenched, decision makers might decide they should apply here too, to conform to international standards, to facilitate international trade especially by trans national corporations (TNC's) and for reasons of 'safety 'and to tighten therapeutic claims. Pressures to conform can be considerable, *especially obligations under free trade agreements*. Read Suzanne Harris on how Codex Guidelines are implemented, (10), Michael Bending on how Codex could come here (2), and about corporate globalisation (11.)

Codex. Codex 'Guidelines on Food Supplements' were finalised to Level 8 in Nov 2004 in Bonn, and have been on AHHA and ANH websites ever since (7, 4.) These Guidelines act as templates for national governments when they make or change their laws and regs for supplements. In this sense, Codex is the world's regulator for natural medicines (10).
These Guidelines impose restrictions on therapeutic information, ingredients and doses, but do not specify any detail, for these Guidelines are only 3 pages long. The word 'only' was inserted into section 1.3 at the Codex meeting of 9 July, 2005, in Rome, at the insistence of the Australian govt. reps (12). Sect 1.3 now reads -
"These guidelines apply *only* in those jurisdictions where supplements are regulated as food."
This means that our supplement laws cannot be attacked in the WTO Tribunals on the grounds that they differ from Codex Guidelines. Tran's national pharmaceutical corporations (drug TNC's) will have to use other tactics to 'harmonise' Australian laws to EU type restrictions, such as *free trade agreements.*

Primary info on Codex is hard to find (p1, ref 1). Rima Laibow, MD, of USA says she has read 15,000 pages of Codex documents. She says -

- Once a government accepts Codex regs, it cannot repeal them, because of trans national pressure to conform; and that Codex :
- Opposes the use of herbs to treat major illness, and supplements for any illness.
- Restricts medicinal herbs, worldwide, to a short list of European herbs.
- Permits non labelling of GM foods.
- Allows high levels of chemicals in foods.
- Encourages antibiotics in animal feed
- Restricts organic food
- Permits irradiation of food and herbs
- Sets standards for all kinds of food.
- Excludes experts in natural medicine from its decision making. (9)

All this boosts demand for pharma drugs.

New Restrictions on Natural Medicines in the EU.
In recent years, the European Parliament imposed several Directives on each country in the European Union. These include the Food Supplement Directive (FSD), the Pharmaceutical Directive (PD), and the Traditional Herbal Medicine Directive (HD) (4). These directed each EU country to enforce these Directives with laws and admin, taking effect in late 2005.

Supplements. Under these Directives, vitamin and mineral supplements are caught in a pincer attack. On one hand, the FSD bans all therapeutic info on the labelling, advertising and presentation of the supplement (naturopath's instructions??), and bans most therapeutic ingredients (see below), and bans therapeutic doses on most ingredients (FSD 6.2, 4.1 & 5.1). On the other, the PD imposes costly drug testing on each natural medicine, (PD 8.3 i) and another 100 pages of regulations. These PD tests are –
Physio-chemical tests, biological tests, microbiological tests, pharmacological tests, toxicological tests and clinical trials.
In toxicological tests they poison lab animals with huge overdoses of the drug, to determine how much will kill. This gives toxicity values, which can then be compared.
In pharmacological tests, they inject animals with prescribed doses of the drug, to determine how the drug manipulates the physiology, and at what doses.
Clinical trials of nutrients primarily test their physiological activity on people, in isolation to all related nutrients.

There are **exemptions** to all these costly drug tests, (PD 10.1 (a)) for any natural medicine that –
(ii) "has well established medicinal use with recognised efficacy and acceptable safety" or
(iii) "is similar" to another natural medicine that has been authorised for sale for at least 6 years in the EU, and used for the same therapeutic purpose.
But these exemptions do not apply to –
(b) new combinations of ingredients that have "not hitherto been used in combination for therapeutic purposes."
HD also provides exemptions for medicinal herbs that have traditional use for at least 30 years, including 15 years traditional use in the EU. (HD 16c (1) (c), & 16c (4))
But this exemption only applies to herbs that are intended for use "without the intervention of a medical practitioner to diagnose, or prescribe or monitor treatment", ie only for herbs not prescribed by a "medical practitioner." (HD 16a (a))

Will These Exemptions Work for Natural Medicines?
Because drug based medicine, not natural medicine, wields the political power, these Directives could be disastrous for natural medicine in the hands of hostile law makers and/or regulators.
"Well established medicinal use." Will this exclude medicinal use by naturopaths? Doctors rarely use natural medicines.
"With recognised efficacy." Will this be assessed by experts in natural medicine or drug based medicine?
"Similar to another supplement." There is huge diversity in supplement formulae. How different can the formulae be before the exemption is unavailable?
"not hitherto used in combination for therapeutic purpose." FSD will regulate supplements as food, which continues past trends in regulation. Will nutrient combinations in supplements regulated as food be recognised as "used for therapeutic purpose" ?
"not prescribed by a medical practitioner". Will exemption from costly drug tests be denied to herbs prescribed by a naturopath? They practise medicine; natural medicine.

'Scientific' Risk Assessment.
"acceptable safety." People know that natural medicines are usually safer than synthetic drugs. Natural medicines usually have negligible toxicity, and little risk of 'side effects.'
So pharma forces now impose 'scientific' risk assessment on supplements. See FSD 5.1 (a) and Codex 3.2.2 Being 'scientific', these 'studies' deliver much political clout.

In Aug 2002 the British 'Expert' Group on Vitamins and Minerals (GVM) released their 400 page Draft Report "Safe Upper Limits of Vitamins and Minerals". (4) These maximum doses were based on 'scientific' risk assessment.
5 of the 12 GVM members had pharma interests; none were experts in nutritional medicine. The GVM –

- Used risk assessment models based on toxic chemicals in the environment, not adverse event data.
- Excluded studies of therapeutic use.
- Extrapolated levels from in vitro and animal experiments, instead of consulting experts in nutritional medicine.
- Set a maximum for Vitamin B6 at only 10 mg per day. In doing so, they ignored the request from the British Select Committee on Agriculture to drop this maximum of 10 mg per day. (5)

Supplements in Melbourne usually carry 25 to 50 mg of B6. B6 occurs in only moderate to low levels in our food, so

deficiency is common. So it has been assessed in 100 different medical conditions, using doses of 50 to 200 mg per day. (15)
Fortunately, the GVM did admit there was "insufficient data" to set maxima for Ca, B12, B2, B3, Folate, Biotin, Mg, P and Mn. For these nutrients, the GVM suggested limits instead.
The GVM set maxima of : 800 IU for E, 7 mg for beta-carotene (= 12,000 IU), 25 mg for Zn and 0.3 mg for Sel. These maxima are similar to many supplement doses in Melbourne.
The German Fed Inst for Risk Assessment released a 341 pp report in Dec 2004, based on 'scientific' risk assessment. It recommended daily maxima of only 5.4 mg for Vit B6, only 9 mcg of B12 and only 275 mg Vit C. Therapeutic doses are 25 – 50 mg daily for B6, 300 mcg daily for B12 and 500 – 1000 mg Vit C several times daily. (4, 13)
The new Australian regulator, JTA, refers to the Brit GVM, but does not impose it here, YET. ("Nutrient Ref Values," site 24)

Herbs Combined With Vitamins/Minerals.
Natural medicine products that combine herbs with vitamins/minerals are also caught in pincer tactic by these Directives. FSD 4.1 bans the inclusion of herbs in food supplements. It seems that HD 16a (a) only allows indications from herbal medicine on a herbal product. Therefore, it forbids indications from vitamin and mineral therapy if exemption to the costly drug tests is needed.

Misleading Statements Imposed.
HD 16g (2a) imposes a statement on the packaging of the herb that "the efficacy of the product has not been proven clinically", if exemption to costly drug tests is needed. This imposes a misleading statement on traditional herbs, for all have been proven by thousands of practitioners over centuries of clinical practice. Such falsehood weakens people's faith and confidence, either in herbal medicine, or the government regulators for herbal medicines.

ANH Legal Victory, July 2005.
After 10 years of behind-the-scenes preparation (16), these Directives surfaced in 2002. Robert Verkerk PhD then formed the Alliance for Natural Health to fight them, first in the Euro Parliament then in the Euro High Court with experts in European law, costing £ 1 million in legal costs.
ANH won a preliminary hearing in Apr 2005, with the final Court Ruling on 12 July, 2005, being –

- The Court upheld the Directive as usual, but ordered changes as follows :
- Regulators must permit, in supplements, vitamins and minerals "normally found in … the diet".
- Regulators must permit synthetic forms of vitamins and minerals that are "safe and bio-available".
- Regulators must prove a nutrient "poses a risk to public health … based on the most reliable and recent scientific data" before they may ban it in supplements (17).

Before this legal victory, FSD 4.1 banned 320 of the 400 ingredients in UK supplements.

Stance of the Australian CM Industry.
This is important, because the government regulates the industry, not activists like me.
Keen to obtain and retain positions on government bodies, and good relations with govt, the Australian Complementary Medicine (CM) industry no longer criticises government on these issues. In late 2004, the CHC reported, on their website (21) - "Partly as a result of improved relationship with the Therapeutic Goods Administration (TGA), several matters of major concern to CHC members have been satisfactorily resolved directly with the regulator (TGA) without major hassles."
The major manufacture's association (CHC), practitioner association (ATMS), and the Journal of CM all issued widely circulated statements early in 2005 that Codex does not apply to Australia.
They all failed to cite any references to support this important announcement, and all failed to describe Codex Guidelines on Food Supplements, how they are negotiated and implemented, and where you can find them.
They just repeated TGA statements. Yet governments are silent on trans national pressures to 'harmonise' to international standards like Codex and free trade agreements, and even deny their impacts (11). And TGA has a history of driving supplement suppliers out of business, even if their supplements caused no harm. (p5, ref 1)
CHC gave some useful but unreferenced brief facts on Codex issues (21), and ATMS quoted problems about Codex but just dismissed them all (22). J Comp Med (May2005) ridiculed instead of answering Codex articles that disagreed with the author; Stephen Myers. He gave no references to support his 5 'facts' about Codex issues.
By contrast, Eve Hillary cites 54 references in her scathing expose "Codex, the $ickness Indu$tries Last Stand," of April 2005 (1). Writing from personal experience of severe persecution by a govt medical 'regulator', Eve documents problems on : drug toxicity; TGA and Pan; 2003 C'tee on CM; TGA Bill; the new regulator; the new advertising code; pharma front bodies; and Aust involvement in Codex, all in 17 pages.

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Websites and References.
Sites 1 – 6, & 9 are the key activist sites on this issue. Please study them carefully.

(1) www.evehillary.org *
(2) www.ahf-au.org
(3) www.nzhealthtrust.co.nz
(4) www.alliance-natural-health.org
(5) Response by ANH, to Brit Govt GVM on maxima for Vits & Mins, Aug 2002
(6) Email curprior@yahoo.com.au for more info on these topics.
(7) www.ahha.org
(8) www.bionatural.com on Codex
(9) Living Now mag, July 2005
(10) www.thelawloft.com
(11) www.tradewatchoz.org
(12) Diane Miller, Codex 2005, ANH site
(13) 'Vitamins for Dummies," Hobbs & Haas, 1999, 334pp
(14) 'New Holistic Herbal,' D Hoffman, 1990, 284 pp, Element Press, (Penguin.)
(15) Encycl Nutrit Supps, M Murray, N.D. 562 pp, '96. Cites 1000 scientific studies.
(13 & 14) are the best texts I found on natural medicine.
(16) Interview with Robert Verkerk, p3, ANH site
(17) ANH Preliminary Legal Summary, 27 July
(20) www.tga.gov.au
(21) www.chc.org.au
(22) www.atms.com.au
(23) Proposed Def'ns of Comp Meds, 2005, TGA site.
(24) www.jtaproject.com