

Foods as medicines? It's a mess out there on the supermarket shelves. Food manufacturers, striving for the slightest marketplace advantage, are sticking so many medicinal herbs and stimulants into soft drinks and foods — of uncertain health impact — that government supervision has been left lagging at a ridiculous distance. As control breaks down, CLARE HUGHES calls for interim action from food and health regulators.



TAMARA GRAHAM

Dog's breakfast

Looking for an afternoon pick-me-up but don't drink coffee? How does a chocolate energy bar with added guarana sound? Or would you prefer an 'uplifting' tea with a hint of ginseng, or a cup of ginkgo tea for a 'sharp' mind and memory? Perhaps a 'wellbeing' drink with added ginseng, guarana, ginkgo biloba or echinacea is more your thing. No longer do you have to go to a health food store for these types of products — they're available at a supermarket or convenience store near you.

CHOICE recently carried out an investigation into the addition of herbal supplements to juices and smoothies sold at juice bars. There are a number of chains and independent outlets marketing products on the basis that they will have a specific beneficial effect on the health of consumers as a result of the addition of a range of herbal supplements such as echinacea, guarana, ginseng, ginkgo biloba and citrin.

The CHOICE investigation found

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that in most cases the amount of herbal supplements added to these products was not sufficient to bring about the health effect that is often stated or implied in the marketing or name of these products. Other herbal supplements, such as citrin — added to a number of 'slimming' juices — have no proven health benefits in any quantity. There are also safety implications associated with several herbal supplements — for example, echinacea, guarana and some other herbal supplements are not suitable for children and pregnant women.

Not just juice

While juice bar products might currently be a well-publicised food vehicle for herbal supplements, they are not the only food or drinks on the market with added medicinal herbs.

On a recent trip to the shops, ACA found a number of products blurring the boundaries:

- teas with added ginseng, St John's Wort and ginkgo;
- drinks with added ginkgo, guarana, echinacea and ginseng;

- a range of 'therapeutic soft drinks' containing ginkgo biloba and numerous other ingredients approved by the TGA for use in complementary medicines;
- bottled water with added stevia rebaudiana extract — a sweet herb with no calories;
- a chocolate bar with added guarana;
- a range of pre-packaged juices with added ginseng, ginkgo, echinacea.

These products were found in supermarkets, newsagents and convenience stores. Some products were in the special 'health food' aisle of the supermarket while most of them were sitting alongside their non-medicinal counterparts.

Food or medicine?

The range of Herbal World therapeutic soft drinks is listed with the TGA. Many of the ingredients are not permitted to be added to food so they are produced to complementary medicines regulation. This also allows manufacturers to make health claims about the products, and so they come in varieties such as 'Rejuvenator', 'Energiser' and 'Recover

& Revive', and make various claims about their ability to promote wellbeing, increase energy vitality and stamina, and help recovery.

On the other hand the Solis range of beverages is not listed with the TGA and the drinks are therefore considered to be food products, regulated by the Food Standards Code. These products have names like 'Defence', 'Power' and 'Adrenalin'.

While the Herbal World drinks were found in the health food section and the Solis beverages in the soft drink aisle and convenience stores, the average consumer could be forgiven for asking, "What's the difference?" Both are drinks that contain herbal ingredients and claim or imply that they are beneficial for health.

The regulations

The drinks listed in the table are classic examples of the regulatory grey area between foods and therapeutics, and the ever-increasing number of products that are falling in between the boundaries of what is considered a food and what is considered a medicine. Here's what the regulations say:

Therapeutic Goods Act

Complementary medicines such as medicinal herbs in capsule form fall under this regulation. Manufacturers simply enter product information on a TGA database and voilà! — their product is listed and manufacturers are allowed to make certain health claims about the product based on the ingredients. Unless it is picked up in the TGA's regular market surveillance, or a complaint is made, the TGA may not actually assess a specific product, its ingredients and the claims made. The TGA is currently in negotiation with the sponsor of the Herbal World drinks as soft drinks are not recognised by the TGA as a dose form, so the term 'therapeutic soft drink' could be potentially misleading to consumers.

Food Standards Code

Novel food standards: If a food or ingredient doesn't have a history of safe consumption then it is considered a novel food. Phytosterol esters added to

cholesterol-reducing margarines are an example of a novel food. A novel food must be subject to safety assessment before it is allowed on the market. Once a novel food is permitted for use there may be certain conditions around how much can be added and what sort of foods the novel product can be added to.

Stevia rebaudiana is a non-culinary herb found in Divine Water. Stevia is used for its sweetening properties but contains no calories. FSANZ considers stevia to be a novel food and does not permit the addition of stevia to food because there is insufficient safety data. However, stevia rebaudiana is permitted in complementary medicines, so the manufacturer of Divine Water has listed the product with the TGA. ACA has brought this product to the attention of the TGA as ACA believes that, like the Herbal World therapeutic soft drinks, consumers could be misled by this product and the fact that it looks like and sits alongside regular bottled water in the supermarket

Prohibited and restricted plants and fungi: This standard lists those plants and fungi that are specifically prohibited and those for which there are restrictions around their use in food. If a plant or fungus does not appear in this list then it can be added to foods or drinks without restriction. While St John's Wort appears on the restricted plants and fungi list, other medicinal herbs mentioned in this article don't.

Formulated supplementary sports foods: This standard is intended to regulate food specifically formulated to assist sports people to meet their specific nutritional and performance goals. This standard lists a range of vitamins, minerals, amino acids and other substances that can be added to formulated supplementary sports foods. The standard also carries specific provisions for labelling these products, including the following mandatory warning statement: "Not suitable for children under 15 years of age and pregnant women. Should only be used under medical and dietetic supervision."

Some of the juice bar products found by CHOICE were legally made to the supplementary sports food specifications.

However, these products are consumed by the general population not just sports people.

Formulated caffeinated beverages: These are non-alcoholic water-based flavoured beverages intended to enhance mental performance. There are specific requirements around how much caffeine they contain but they may also contain carbohydrates, amino acids, vitamins and other substances. These must carry warnings that they are not suitable for children, pregnant women or anyone sensitive to caffeine. Drinks containing guarana, a herb naturally high in caffeine, are made to this standard.

Nutrition and health related claims: It is illegal, under the Food Standards Code, for food manufacturers to make a health claim. The only exception relates to the role of folate in the prevention of neural tube defects. A transitional health claim standard is in place while FSANZ develops a more detailed standard. Despite this we see many products, including those that contain medicinal herbs, claiming or at least implying a specific effect on health. A number of juice bars have been doing this, prompting action by some State authorities to ensure that illegal health claims are not made.

Product names include, or use words, such as memory, protector, stress relief, skinny, slimmers, trim, flu fighter and so on. Product information carries claims such as, "boosts immune system", "assists weight loss", and "reduces inflammation". In ACA's opinion consumers are led to believe that these products will have a specific effect on their health. However, if the products do not contain sufficient quantities of the active ingredient to have any affect — as the CHOICE investigation found — then the product names and claims are misleading.

Trans-Tasman Mutual Recognition Arrangement: This agreement allows foods to cross the border between Australia and New Zealand without the quarantine regulation that would normally be required for products imported from other countries. Currently, food-type dietary supplements — a category of products

A tale of two herbal beverages

Brand	Herbal World	Solis
Product label description	Therapeutic soft drink	A wellbeing drink
Relevant regulator	Therapeutic Goods Administration	Food Standards Australia New Zealand
Product names	Rejuvenator Energiser Recover & Revive	Defence Power Adrenalin
Beneficial ingredients added	Ginkgo Biloba Matricaria Recutita Malpighia Punicifolia Dioscorea Villosa Turnera Diffusa Oenothera Biennis Eleutherococcus Senticosus	Echinacea Siberian ginseng Guarana Ginseng Ginkgo Biloba Green tea B Vitamins Vitamin C Zinc
Purchased from	Supermarket 'health food' aisle	Supermarket soft drink aisle and convenience stores
Labelling information	"Drink one bottle three (or four) times daily" — dosage varies depending on drink type. Full ingredients list not required but active ingredients listed. Nutrition information panel provided.	"Contains caffeine. Not recommended for children; pregnant or lactating women; individuals sensitive to caffeine." "Consume no more than 3 bottles per day" (only on varieties containing guarana). Nutrition information panel and ingredients list required.



that fall somewhere between foods and complementary medicines — cannot be made in Australia but can in New Zealand. And regulation in place before the joint Food Standards Code was developed, and the Trans-Tasman Mutual Recognition Arrangement, mean they can be imported into Australia from New Zealand. So while St John's Wort tea cannot be produced in Australia, it can be made in New Zealand and then imported into Australia.

Effective regulation is years away

Work is underway to develop policy guidelines for the addition of these types of substances to food. Policy guidelines are due to be completed by October 2005 at the earliest. Once policy has been approved by Ministers, FSANZ will then have the task of developing standards

in this area. FSANZ was previously in the process of developing a standard for 'non-culinary' herbs but this was put on hold so that broader policy guidelines could guide the development of the standard.

So while specific regulation of the use of medicinal herbs may be some years away, manufacturers will continue to push the boundaries between foods and medicines, delivering medicines disguised as foods, making illegal health claims, misleading consumers about the benefits of consuming herbal supplements in food and, worse still, putting the health of a small number of consumers at risk.

Safety of medicinal herbs in food

If a medicinal herb has the capacity to bring about physiological changes or

pharmacological effects then it must be treated with a greater level of caution than conventional food ingredients. Therefore ACA believes that all medicinal herbs must be subject to safety assessment before permission is given for them to be added to food products. If safety cannot be demonstrated then permission should not be given. Existing products containing these herbs must be withdrawn from the market.

When medicinal herbs are taken as complementary medicines they should be taken on the advice of a health professional who is able to discuss the side effects of taking such complementary medications. Consumers often have the misconception that just because something is considered 'natural' then it must be safe. In reality, for some consumers, medicinal herbs will have negative interactions with

other medications or could cause allergic reactions.

Concern is also raised about the production of supplements that are added to foods. It is unclear whether these supplements are being produced to TGA standards or whether they are being produced specifically for addition to foods. This raises the following questions:

- Are these supplements being produced by registered therapeutic goods manufacturers?
- Do these manufacturers and products meet the TGA requirements for the manufacturing of therapeutic goods?
- If not, why should the requirements for the production of supplements being added to food products be less stringent than requirements for the production of supplements to be sold as complementary medicines?

Efficacy

ACA believes that non-culinary herbs, if permitted for use in food, should not only be added at a level that is safe for consumers but also at levels that bring about the intended physiological effect whether stated or implied. The mere mention of the medicinal herb in labelling or promotion will imply to consumers that the product will deliver some physiological benefit.

Consumers have a right to expect that the food or drink they are purchasing will deliver the intended health benefits. If medicinal herbs are not present in efficacious amounts there will be no benefits for consumers, only for manufacturers who market these products on the presence of these herbs.

Medicinal herbs should not be added to foods that are otherwise considered unhealthy. The Herbal World therapeutic soft drinks contain more than 30g sugar per bottle. Consumers are advised to drink 3 or 4 bottles per day. If consumers want to achieve the health benefit implied on the label they could be consuming as much as 135g sugar or around 27 teaspoons of sugar, in order to feel 'rejuvenated', 'energised' or 'revived'.

Similarly, the Solis beverages each contain around 8 teaspoons of sugar. While food products are not permitted to

provide dosage information, it is unlikely that one bottle will provide adequate amounts of the herbal supplements to have the implied health benefit. Simply adding a herbal supplement should not be a way of making 'bad foods better'. Sugary soft drinks should never be promoted as a healthy beverage and as a way of getting non-essential medicinal herbs.

Immediate action

ACA is calling for immediate action to be taken by Food Standards Australia New Zealand and State and Territory Health and/or Food Authorities, in conjunction with the Therapeutic Goods Administration and the Australian Competition and Consumer Commission.

Until adequate regulation and enforcement measures are in place we need interim measures to ensure that any product coming onto the market shall not be 'immune' from future regulation. Without some immediate action, it is likely that future regulations will be based on having as little impact as possible on the products already on

approved for use in foods. They must also be added at levels that are efficacious so that consumers are not misled by marketing claims that offer a specific health benefit when it is unlikely that they will consume enough of the product to have the intended health benefit.

Ministers should not be afraid to consider a ban on these products. These types of herbs are not essential like some vitamins and minerals. Consumers use foods and complementary medicines in different ways. It may be safer and more effective if these medicinal herbs can only be taken as complementary medicines, where consumers can seek information about the benefits of these herbs and be better able to control the amounts consumed.

Regulators must acknowledge that these products cut across the food, therapeutic and consumer protection domains. All regulators must work in partnership to act in the absence of clear regulatory boundaries.

State and Territory enforcement agencies and the ACCC must act swiftly on products containing medicinal herbs



the market so as to avoid these products having to be pulled off the shelf.

Ministers should call for a cessation of the sale and further development of these foods until such time as specific standards are in place. Alternatively, manufacturers should be warned that getting their product onto the market before standards are developed will not protect them from a recall once the standards are in place.

Regulation must ensure that medicinal herbs are subject to pre-market safety assessment before they are

claiming or implying benefits that could potentially mislead consumers about the impact of a specific product on health. No longer should government agencies hide behind a flimsy health claims standard, allowing products to slip through gaps in the current patchwork of food standards, or buck pass them to another regulator or enforcement agency. While these products remain a regulatory grey area product development and marketing will race ahead creating a situation where regulations will simply shut the gate long after the horse has bolted.

