FOOD STANDARDS
Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

12-03
8 October 2003

INITIAL ASSESSMENT REPORT

PROPOSAL P260

USE OF NON-CULINARY HERBS IN FOOD

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:
19 November 2003
(See 'Invitation for Public Submissions' for details)

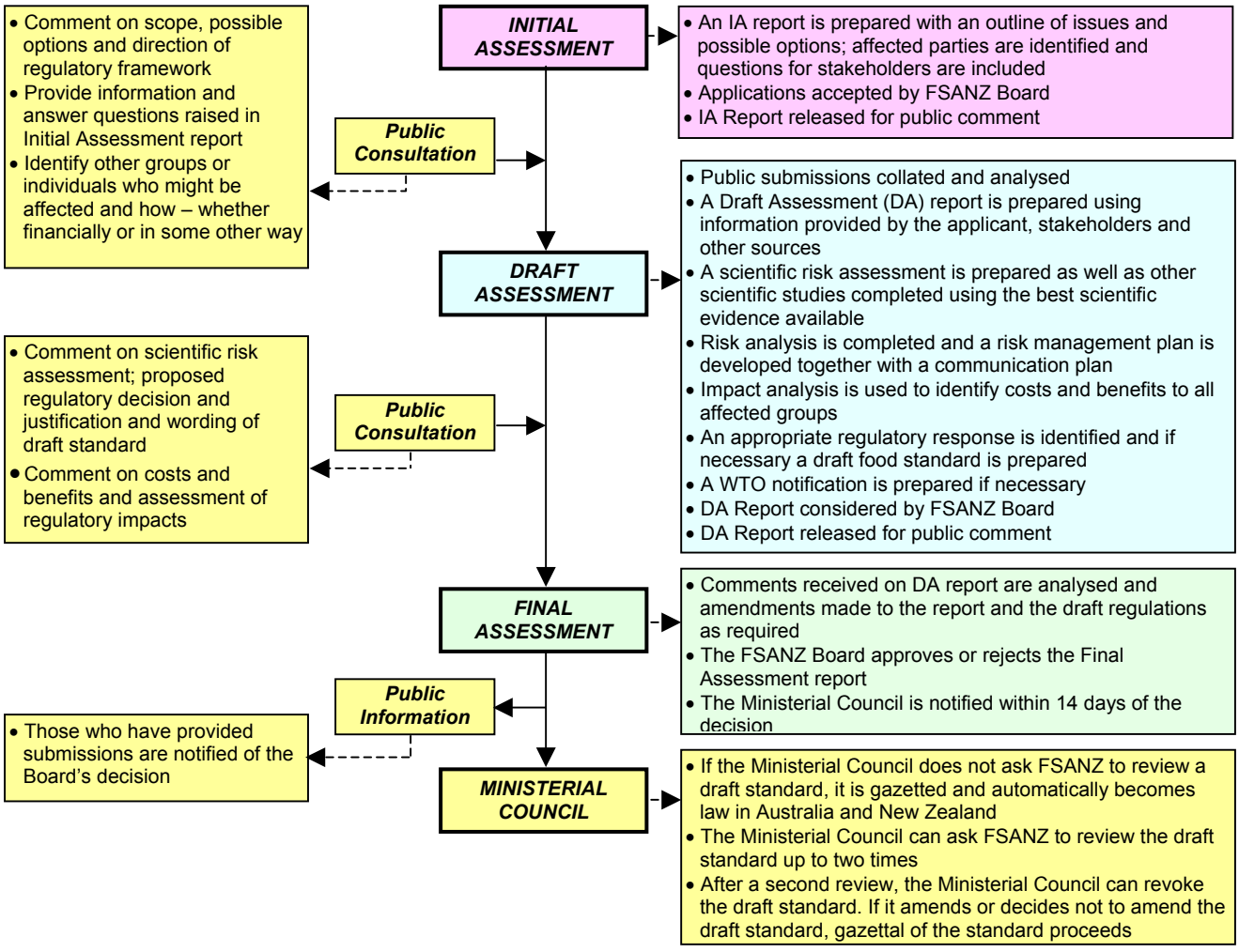
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared an Initial Assessment Report for Proposal P260 – Use of Non-culinary Herbs in Food, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purposes of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment/Final Assessment for this Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942 Fax (04) 473 9855
www.foodstandards.govt.nz

Submissions should be received by FSANZ **by 19 November 2003**.

Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension.

While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the Standards Development tab and then through Documents for Public Comment. Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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1. Introduction

This Proposal has been prepared in order to consider the issues associated with the use of non-culinary herbs in foods and, if necessary, to review the current food standards in relation to this matter in order to ensure that the public health and safety of consumers is adequately protected.

In recent years, there has been an increase in both the number and extent of use of non-culinary herbs in food products, particularly beverages, but also energy bars. The majority of these herbs, while they may have a tradition of use as ingredients in therapeutic goods, have never been assessed for their safety as food ingredients. Their use in foods may potentially present a greater health risk than their use in therapeutic goods since, in the case of food use, the risk management options are fewer and there is greater potential for high exposure to a broader segment of the population.

The purpose of this Proposal is to consider the appropriateness of allowing non-culinary herbs to be used in food and to consider the circumstances under which such use may be permitted. The relevant current standards will be reviewed and, if necessary, modified to reflect the principles established for using non-culinary herbs in food. If non-culinary herbs are considered as appropriate food ingredients a safety assessment of these ingredients in a food context is necessary to fully characterise the risk to consumers.

The progress of this Proposal will depend to some extent on other matters currently under consideration by FSANZ and the Food Regulation Standing Committee (FRSC). In particular, the outcome of consideration by FRSC of food-type dietary supplements and any subsequent direction taken by Proposal P235 – Review of Food-Type Dietary Supplements will be an important factor influencing the direction of Proposal P260. A policy options paper prepared by the FRSC Working Group on Dietary Supplements will be considered by FRSC later this year.

2. Regulatory Problem

The current food standards do not provide certainty in relation to the use of non-culinary herbs in food. While some are prohibited or restricted for safety reasons in accordance with the provisions of Standard 1.4.4 – Prohibited and Restricted Plants and Fungi – the majority are not explicitly prohibited from use in food, but neither are they explicitly permitted. Their use in food raises two fundamental issues – firstly, the appropriateness of their use in food, and, secondly, their safety.

2.1 Appropriateness of using non-culinary herbs in food

The first issue, 'appropriateness', relates to the question of whether food should be used as a vehicle for the delivery of a physiologically or pharmacologically active agent. Therapeutic substances, if used in food as a means of administering a scheduled medicine, would be subject to all the restrictions required of a scheduled medicine, such as restricted sale and labelling requirements. The majority of non-culinary herbs, however, would not fall into this category although there may still be potential for a significant pharmacological effect. The extent of any potential pharmacological effect will depend on the nature of the non-culinary herb and the amount consumed. The use of food as a vehicle for a therapeutic substance may be considered contrary to the primary nature of food – to provide nutrients to sustain life.

Thus, whether it is appropriate to add non-culinary herbs to food may depend on the stated purpose of their addition to food. In most cases, the addition of non-culinary herbs to food will be to provide or imply a therapeutic benefit, or at least to achieve a physiological effect.

The proposal, therefore, needs to address this question of 'appropriateness' of the use of non-culinary herbs in food. The initial question is whether they should be allowed in food at all, and, if so, should there be restrictions on the type of food to which they can be added and/or the maximum level permitted and/or specific labelling advice required.

In addressing this issue, consideration will need to be given to the traditional use of herbs with non-culinary properties as foods by Maori people in New Zealand and by Aboriginal and Torres Strait Islander people in Australia. This Proposal was discussed with the Kahui Kounga Kai (Maori Reference Group) on 6 May 2003.

2.2 Safety of non-culinary herbs in food

In relation to the second issue, safety, there is little in the current standards to ensure that those non-culinary herbs currently in use in food are safe. Most have been added to food products without any regulatory approval or safety assessment. There is little information available on the nature of the herbal material which has been added to the food, or the amount added to the food, or its safety for consumers.

The majority of non-culinary herbs would be considered non-traditional foods and while the recently introduced Novel Food Standard (Standard 1.5.1) has provided a regulatory mechanism to consider the safety of non-traditional foods prior to their entry into the food supply, many non-culinary herbs are being used currently in foods and therefore the Novel Food Standard is not appropriate in this circumstance.

The general provisions of the Food Acts require food to be safe and suitable. In any transition to a new regulatory framework for non-culinary herbs in foods the safety of any currently used food could be reviewed and appropriate action taken to ensure consumer safety. For those products currently on the market, it may be more appropriate, therefore, to review their safety, with the assistance of industry, and to take action where necessary to ensure continued safe use. If continued use of non-culinary herbs in foods is recommended, appropriate risk management strategies will be needed to ensure their safe use.

The standards need to have a mechanism to ensure that an appropriate safety evaluation has been conducted before the addition of non-culinary herbs to food can be considered.

3. Objective

The objective of this proposal is to consider whether there is a need to amend the *Australia New Zealand Food Standards Code* to ensure that non-culinary herbs, if they are to be used in foods, are used in such a way that there is no additional public health and safety risk.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the FSANZ Act. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 Culinary and non-culinary herbs

Herbs consist of leaves, flowers, stems and roots from a variety of herbaceous plants used either in fresh or dried form. Some herbs are used for culinary purposes, eg, basil, bay leaves, marjoram and thyme. Others are generally used for non-culinary purposes only, e.g. Echinacea, evening primrose, St John's wort, ginkgo biloba. Some herbs may be used for both culinary and non-culinary purposes, for example ginger and garlic.

The meaning of the terms 'herb' and 'medicinal herb' vary somewhat between countries and jurisdictions. In the US, the term 'herbal medicinals' refers to those products which are derived from the parts of plants that elicit a pharmacological effect. The herb in this case is generally administered as a whole and not fragmented. The term phytopharmaceutical is also sometimes used to describe plant-based medicines that have been standardized on pharmacologically active ingredients.

In this paper, the term 'non-culinary herb' may refer to the whole herb, a part of the herb, or to a standardised extract of the herb – any of which may elicit a pharmacological effect. Non-culinary herbs are generally claimed to have healing or preventative properties, whereas, culinary herbs are more commonly used to provide flavour and aroma to food. While some culinary herbs may also have pharmacological properties, the term 'non-culinary herb' in this paper refers to those herbs which are generally not regarded as having a culinary function within their history of use by the broad community in Australia or New Zealand.

4.2 Current regulatory framework

4.2.1 Standard 1.4.4 – Prohibited and Restricted Plants and Fungi

This standard regulates some plants and fungi which may adversely affect human health. It lists the species of plants and fungi that must not be added to food or offered for sale as food. It also lists the species of plants and fungi that may not be used in food except as a source of a flavouring substance.

Schedule 1 in this standard lists prohibited plants and fungi. This list, while not exhaustive, is based on known toxicity associated with these plants and fungi – these botanicals are considered to present a high public health and safety risk. There are other plants and fungi which are not on this list which also present a high public health and safety risk, but these are not generally associated with food.

Schedule 2 in this standard lists those plants and fungi which are used as flavouring agents in food but which contain substances associated with some degree of toxicity. In these cases, a maximum level is applied to the toxic substance in the final food. The maximum level of the ingredient is listed in the Table to clause 4 in Standard 1.4.1 – Contaminants and Natural Toxicants.

Standard 1.4.4 could be used to prohibit the use of some or all of those plants defined as non-culinary herbs in all or specified foods.

4.2.2 Standard 1.5.1 – Novel Foods

This is a broadly based standard, the purpose of which is to ensure that non-traditional foods that have features or characteristics that may raise safety concerns will undergo a risk-based safety assessment before they are offered for retail sale in Australia or New Zealand.

Novel Food is defined in the Standard as:

> *A non-traditional food or food ingredient for which there is insufficient knowledge in the broad community to enable safe use in the form or context in which it is presented, taking into account*
>
> *(a) the composition or structure of the product;*
> *(b) levels of undesirable substances in the product;*
> *(c) the potential for adverse effects in humans;*
> *(d) traditional preparation and cooking methods; or*
> *(e) patterns and levels of consumption of the product.*

Non-traditional food means a food which does not have a history of significant human consumption by the broad community in Australia or New Zealand.

This Standard could be used regulate the use of new non-culinary herbs in food since most would be regarded as non-traditional foods for which there are some safety concerns.

4.2.3 Proposal P235 – Review of food-type dietary supplements

The purpose of Proposal P235 is to develop a regulatory framework for food-type dietary supplements in order to achieve harmonised food regulation between Australia and New Zealand. Many of the products that fall into this category are manufactured in or imported into New Zealand under the New Zealand *Dietary Supplements Regulations 1985*. In some cases, these products are imported into Australia from New Zealand under the Trans Tasman Mutual Recognition Arrangement. A significant proportion of non-culinary herbs used in foods are found in food-type dietary supplements.

The Initial Assessment Report for Proposal P235 was considered by the FSANZ Board in June 2002 and circulated for public comment. It contained a number of regulatory options for consideration. The progression of P260 will depend to some extent on the direction taken by P235. While the FSANZ Board considered the issues associated with P235 in March 2003, the Draft Assessment will be deferred until after the Food Regulation Standing Committee (FRSC) considers the policy guidelines later this year and Ministerial Council agrees to particular policy direction. One option being considered in P235 is establishing a standard for foods that are intended for a supplemental purpose, i.e. those foods which are not part of the normal diet. Consideration will be given to restricting the use of non-culinary herbs to this category of foods.

4.2.4 New Zealand Dietary Supplement Regulations 1985 (NZDSR)

The majority of food-type dietary supplements are manufactured in or imported into New Zealand under the NZDSR and from there into Australia under the Trans Tasman Mutual Recognition Agreement (TTMRA). These products do not have to comply with the *Australia New Zealand Food Standards Code*. Such products cannot be legally manufactured in Australia, or imported from countries other than New Zealand.

The New Zealand Food Safety Authority (NZFSA) is aware of the adverse impact of the current NZDSR in relation to FTDS being manufactured in, or exported from New Zealand to Australia by virtue of the TTMRA. The repeal of the NZDSR as it applies to foods is paramount to the harmonisation of food standards for FTDS. NZFSA has recently confirmed that work has commenced on the consultation paper in relation to the future of foods under the NZDSR. NZFSA staff however have reiterated that the paper will only be released after the NZ Government has made certain decisions with respect to the Joint Therapeutic Products Regulatory Agency process and dietary supplements.

Whichever regulatory option is adopted in relation to non-culinary herbs, it will not be fully effective until the NZDSR as it applies to food is repealed.

4.3 Regulation in other countries

4.3.1 USA

In the USA, orally-consumed products are regulated as foods, dietary supplements or drugs. Herbs and foods containing herbs are generally regarded as dietary supplements and are regulated under the *Dietary Supplement Health and Education Act 1994* (DSHEA). According to this Act, *dietary supplements* are products '*intended to supplement the diet to enhance health*' and include '*vitamins, minerals, amino acids, herbs and other botanicals*'.

A dietary supplement is '*not represented as a conventional food or a sole item of a meal or the diet*'. Under this Act, herbal products can be sold without a safety or efficacy review by the FDA, but any ingredient that was not on the market before 1994 when the Act took effect may not be included in dietary supplements unless subject to authorisation by the FDA.

4.3.2 New Zealand

In New Zealand, orally-consumed products are regulated as foods, dietary supplements or medicines. Dietary supplements are regulated under the Dietary Supplements Regulations 1985 (NZDSR). Under the NZDSR, a dietary supplement is defined as *any amino acids, edible substances, foodstuffs, herbs, minerals, synthetic nutrients and vitamins sold singly or in mixtures in controlled dosage forms as cachets, capsules, liquids, lozenges, pastilles, powders or tablets, which are intended to supplement the intake of those substances normally derived from the diet*.

Most of the products containing herbal substances (other than culinary herbs) would be regulated under the NZDSR. The NZDSR are likely to be reviewed in the near future and products regulated under these regulations to be regulated as either foods or medicines.

4.3.3 Canada

In Canada, orally-consumed products until recently were regulated as foods or drugs – on 18 June 2003, the *Natural Health Products Regulations* were published in the *Canada Gazette, Part II* and are scheduled to come into force on 1 January 2004 and will be administered within the Health Products and Food Branch of Health Canada. These regulations provide a separate regulatory category for natural heath products (NHP), which comprise herbal remedies, traditional and homeopathic medicines, vitamins, minerals, amino acids, essential fatty acids and probiotics. Under the new regulations, all NHP will be required to be manufactured in Good Manufacturing practice-licensed premises, and to undergo pre-market review to obtain a product licence and a corresponding Natural Product Number (NPN).

These regulations do not specifically address the addition of herbs and herbal extracts to foods. The Canadian government has expressed concern regarding the increasing use of non-culinary herbs in food products. The safety of food containing herbs is being considered under Section 4 of the *Food and Drugs Act* which places the onus on manufacturers and distributors to ensure that the foods which they are marketing are safe. The Canadian government has also expressed concern over the potential deception of consumers when non-culinary herbs are used in foods at levels below the therapeutic dose.

4.3.4 European Union

A wide range of products, known under the term of food supplements, diet integrators or others are being marketed in Community Member States for a number of years. The national rules applicable to them may differ substantially. The products in question are usually concentrated sources of nutrients and other ingredients, alone or in combination and marketed in dose form. The ingredients include, among others, vitamins, minerals, amino acids, essential fatty acids, fibre, various plant and herbal extracts. The task of covering products containing all these ingredients would be enormous and very complicated. It was therefore decided for practical reasons to deal at this stage in detail with products containing vitamins and minerals.

This has lead to the recent release by the European Parliament and Council of a Directive on Food Supplements that establishes harmonised rules for the labelling of food supplements and introduces specific rules on vitamins and minerals in food supplements. The draft proposal of this regulation is currently investigating prohibiting the use of kava and nicotine in food (SANCO/329/03). The measures may be amended in the future to cover in detail products containing other nutrients and/or ingredients including non-culinary herbs in food.

5. Relevant Issues

5.1 Regulation of herbs by the Therapeutic Goods Administration

The Therapeutic Goods Administration (TGA) regulates herbs and derivatives of herbs presented for therapeutic use. Therapeutic goods are subject to pre-market evaluation and approval prior to supply in Australia, and are either listed or registered on the Australian Register of Therapeutic Goods (ARTG). Whether a product is listed or registered on the ARTG depends largely on the health risk associated with the ingredient and dosage together with the therapeutic indications and claims made for the product. Listed medicines are considered to be of lower risk than registered medicines, and the majority are self-selected by consumers. Therapeutic products containing herbal material are generally in the low risk listed category. The Therapeutic Goods Regulations provides a list of herbs prohibited for use in medicines. In addition, there is also information on the TGA website at www.tga.gov.au which lists the herbs which may be used in listed therapeutic goods.

5.2 Use of non-culinary herbs in food

Recent years have seen a surge of interest in the use of alternative approaches to medicine, including the use of herbal remedies in the form of complementary medicines (Australia) or dietary supplements (New Zealand). While the vast majority of this use has been though therapeutic products regulated by the TGA in Australia and by Medsafe – a division of the Ministry of Health – in New Zealand, there has also been a significant increase in the number of food products on the market that contain non-culinary herbs. **Appendix 1** contains a list of some of the non-culinary herbs that have been identified in a survey of food products in NSW supermarkets – the list is not comprehensive.

As discussed in Section 2.1, the purpose of adding these non-culinary herbs to food is presumably to provide or imply a therapeutic benefit for marketing purposes. On the basis of analytical work that has been undertaken by various laboratories, the amount of a particular non-culinary herb in these food products is extremely variable and in most cases it is not sufficient to produce even a physiological effect, and certainly not a therapeutic benefit. This raises the issue of whether the presence of non-culinary herbs in food is consistent with the third objective of the Authority, namely 'the prevention of misleading or deceptive conduct.' This matter will be considered during Draft Assessment.

In relation to claims on food products, Standard 1.1A.2 states that *any label on or attached to a package containing or any advertisement for food shall not include a claim for therapeutic or prophylactic action or a claim described by words of similar import*.

Thus, if non-culinary herbs were present in a food in a sufficient amount to produce a therapeutic effect, there would be no permission to state this fact on the label.

The issue of health claims on food is currently being considered by the Food Regulation Standing Committee (FRSC).

5.3 Safety assessment of non-culinary herbs in food

While the non-culinary herbs used in foods may have undergone a safety assessment prior to being approved for use in medicines by the TGA Office of Complementary Medicines, their use in therapeutic goods is not considered sufficient to allow general use in foods. Therapeutic goods differ from foods in a number of key respects, including:

(i) therapeutic goods are consumed by people needing or wishing to remedy, alleviate or prevent a particular disease or other physical or mental state;

(ii) therapeutic goods are frequently used on the advice of a third party, such as a medical practitioner, a pharmacist, a herbalist or other health worker;

(iii) therapeutic goods are normally accompanied by advice on use, including safe dosage levels, and the potential for drug-food interactions;

(iv) therapeutic goods are generally used only for a specific limited period; and

(v) there are reporting mechanisms for possible adverse effects, leading to a reassessment of the safety of the substance.

Thus, while there may be some evidence for the safety of a non-culinary herb on the basis of its use in a therapeutic good under specified conditions, this is not sufficient to ensure safety when the same herb is used in potentially unlimited amounts in a food product. The safety of generally available food is based on the premise that it should be safe for the general population in any reasonable quantity, and at any reasonable frequency of consumption.

Another issue of concern is that much of the herbal material added to foods is in the form of an extract, which may have been concentrated. The composition of these materials is not known and may be quite variable and the risks may increase with the degree of extraction or concentration. There are no specifications for identity and purity of such herbal materials available.

A safety assessment of non-culinary herbs when used in a food context would be necessary to fully characterise the risk to consumers, should it be decided that such use is appropriate.

5.4 Health risk associated with products at the food-drug interface

When non-culinary herbs are used in foods, the heath risk is more akin to that of a complementary medicine, but without use and dosage instructions. There is a case, therefore, to prohibit non-culinary herbs in mainstream foods and to restrict their use to a subset of foods which are specifically self-selected by individuals seeking to supplement their normal nutrient intake or to use foods which have an implied heath benefit. This would maintain the low risk status of normal foods but allow the use of non-culinary herbs in a small range of foods for those individuals who wish to supplement their normal diet in this way. This option will be further considered at draft assessment.

5.5 Deception

In most cases, the addition of non-culinary herbs to food will be to provide or imply a specific benefit, or at least to achieve a physiological effect. The extent of any potential effect will depend on the nature of the non-culinary herb and the amount consumed. Currently marketed food products that contain non-culinary herbs may be characterised as carrying an implied claim associated with the efficacy of these ingredients when presented in a food matrix. Implied benefits may be seen as misleading and may contravene trade practices and food legislation. FSANZ invites stakeholder input with regard to this issue.

6. Regulatory Options

The regulatory options for P260 will depend to some extent on the consideration of P235 – Review of food-type dietary supplements. The following options are based on the preferred option for P235. Other regulatory options may also be possible.

1. Allow the use of non-culinary herbs in all foods at levels that are demonstrated to be safe.

2. Allow the use of non-culinary herbs in those foods identified as foods for supplemental purposes only, at levels that are demonstrated to be safe. In this case, the range of foods could also be restricted.

3. Prohibit the use of non-culinary herbs in all foods, including those foods identified as foods for supplemental purpose.

7. Impact Analysis

With option 1, safety is the only consideration. It assumes that the safety of non-culinary herbs can be demonstrated to the same level of confidence as food additives. As discussed above, the available safety data on non-culinary herbs in many cases is quite limited. When used at therapeutic dose levels and above, there are often adverse effects that would not generally be acceptable in a food product. This option also accepts that it is appropriate to use any food as a vehicle for substances that can have a pharmacological effect.

With option 2, it is suggested that some foods may be appropriately used as a vehicle for non-culinary herbs. This option allows individuals to choose foods that are clearly labelled as being supplemental to the normal food supply in order to seek a physiological and/or pharmacological effect. This option would also have an impact on other plant-derived substances, including phytosterols.

With option 3, foods are recognised as being for a nutritional purpose only, and this option would not allow the addition of any substance that has a pharmacological effect or an implied pharmacological effect. This may impact on other plant-derived substances such as phytosterols, which are currently approved for use in edible oil spreads. This option would adversely impact on a range of foods currently on the market.

The regulatory options will be more thoroughly examined at draft assessment.

8. Consultation

8.1 Public consultation

FSANZ is seeking public comment in order to assist in assessing this Proposal. Public submissions will also be sought when the Draft Assessment is released. Comments are particularly sought on the following:

- the appropriateness of adding non-culinary herbs to foods
- the use of non-culinary herbs in general foods and supplemental foods
- the safety of currently used non-culinary herbs
- the purpose of adding non-culinary herbs to foods
- the regulatory options

8.2 World Trade Organization (WTO) Notification

Australia and New Zealand are members of the World Trade Organization (WTO) and are signatories to the agreements on the Application of Sanitary and Phytosanitary Measures (SPS Agreement) and on Technical Barriers to Trade (TBT Agreement). In some circumstances, Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comments.

Amending the Code to clarify the regulation of non-culinary herbs in food may have a significant effect on trade, however, this issue will be fully considered in the context of the Regulatory Impact Statement at Draft Assessment and, if necessary, notification will be made in accordance with the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) agreements.

9. Conclusions

This Proposal is prepared according to section 12AA of the FSANZ Act. Written submissions on the Proposal will now be sought.

After public submissions have been received, FSANZ will prepare a draft assessment as prescribed in section 15AA of the FSANZ Act.

10. References

SANCO/329/03. 17.01.2003. Preliminary Draft Proposal for a Regulation of the European Parliament and of the Council on the addition of vitamins and minerals and of certain other substances to food. Commission of the European Communities, Brussels, Belgium.

Appendix 1

Herbs identified in some marketed products in Australia (this list is not comprehensive)

Herb	Type of Product
Urtica	Energy bar
Horsetail	Energy bar
Acerola	Energy bar
Ginseng	Energy bar
Guarana	Energy bar
Uva ursi	Breakfast bar
Bucca	Energy bar
Senna	Energy bar
Cascara	Energy bar
Segrado	Energy bar
Garcinia cambogia	Energy gum
Echinacea	Honey
Damiana	Energy drink
Shizandara	Energy drink
Lotus root and seed	Herbal beverage
Ganoderma	Herbal beverage
Pearl powder	Herbal beverage
Ginkgo biloba	Energy drink
St John's Wort	Energy drink
Chamomile	Energy drink
Passionflower	Energy drink
Evening primrose	Energy drink
Gotu kola	Energy drink
Maidong	Energy drink
American ginseng	Protein supplement
Saw palmetto	Protein supplement
Acerola	Protein supplement
Garcinia	Energy drink
Quaesita	Energy drink
Siberian ginseng	Energy bar
Heperidin complex	Energy bar
Brindleberry	Energy bar
Humic shale	Energy bar
Suma root	Energy bar
Smilax	Protein suppl.
Sida cordifolia	Energy bar
Citrus caurantium	Energy bar