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

12/03
8 October 2003

INITIAL ASSESSMENT REPORT

PROPOSAL P278

Use of Nicotine and *Nicotiana* Species in Food

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

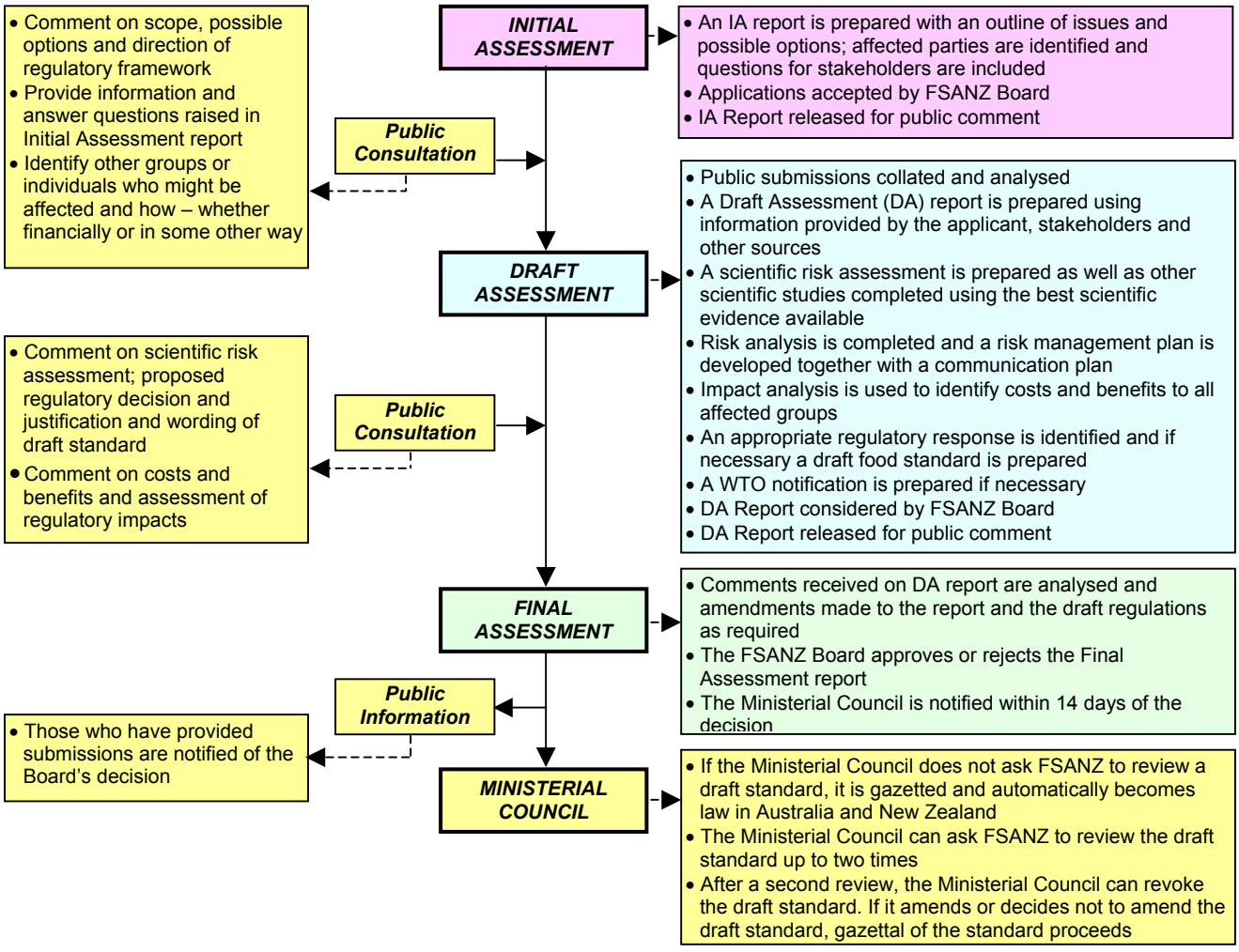
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

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 P278 – Use of Nicotine and *Nicotiana* Species in Foods, which includes the identification and discussion of the key issues.

FSANZ invites public comment on this Initial Assessment Report for the purpose 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
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
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.

CONTENTS

Executive Summary

Nicotiana species, primarily *Nicotiana tabacum* L. (tobacco), are grown for the leaves which when cured, are used for smoking, as cigars, cigarettes, or in pipes, or chewed, or used as snuff along with other ingredients. More recently, there have been a number of attempts to market tobacco extracts in the form of nicotine containing lollipops, lip balm and bottled water through various different distribution channels including the internet.

Like smoked tobacco products, smokeless tobaccos are highly addictive. Nicotine levels from single doses of smokeless tobacco are similar to that from a cigarette, although the levels of nicotine rise faster and decrease slower in smokeless tobacco users. Nicotine is psychoactive, and users of smokeless tobacco show signs of addiction including a pattern of abuse involving escalating use, tolerance, and withdrawal symptoms.

The current food standards do not provide certainty in relation to the use of *Nicotiana* species including *Nicotiana tabacum* L. (tobacco) in food. Currently, tobacco is neither expressly permitted nor expressly prohibited in food. There are a number of instances where products from *Nicotiana tabacum* L. demonstrate functionality appropriate for use in food.

- Removal of leaf proteins could yield a food, with unique nutritional and functional characteristics.
- The seed oil from tobacco is used as an edible oil in some European countries.
- There is an abundance of scientific literature that documents the successful production in tobacco and other plants of protein pharmaceuticals, vaccines and other medicinals, enzymes, polymers and food ingredients.

The positive aspects of tobacco as a food product must be balanced by the perceived public health effects of the use of tobacco in food products by consumers. Further, consideration is also given to the control of use of tobacco products in the community by the Australian and New Zealand governments. Therefore it is proposed that *Nicotiana* species be placed in Schedule 1 of Standard 1.4.4 - Prohibited and Restricted Plants and Fungi to prohibit the use in food of tobacco and any substance derived from tobacco plants. The approach of prohibiting the use of the whole genus rather than a single species such as *Nicotiana tabacum*, prevents circumventing the intent of the standard, to prevent high nicotine containing plant materials from entering the food supply, by utilizing closely related plant material within the genus in food products.

Alternatively, products derived from *Nicotiana* species used in foods could be regulated in Standard 1.5.1 – Novel Foods, whereby the safety consideration relating to the presence of nicotine could be addressed by identifying nicotine as a natural toxicant and establishing a maximum level in food in Standard 1.4.1 – Contaminants and Natural Toxicants. A total prohibition of nicotine in food may be difficult for the reason that many commonly and widely consumed vegetables of the nightshade family (Solanaceae) such as potatoes; tomatoes eggplants and capsicums are known to contain low levels of nicotine. Including nicotine in the Table to clause 5 – Maximum Level of Other Natural Toxicants in Food, could be used to control the addition of physiologically significant intakes of nicotine in food. This approach may facilitate innovation while preventing an increase in the nicotine intake in the human diet.

1. Introduction

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

In recent years, there has been an increase in both the number and extent of use of non-culinary herbs in orally consumed products presented as foods particularly beverages and energy bars. In some countries, this has included the use of tobacco plant extracts resulting in the development and marketing of nicotine containing bottled water and nicotine containing lollipops/sweets.

2. Regulatory Problem

The current food standards do not provide certainty in relation to the use of *Nicotiana* species in food. Specifically, tobacco (*Nicotiana tabacum* L.) is neither expressly permitted nor expressly prohibited in food. Nicotine is not identified as a natural toxicant in Standard 1.4.1 – Contaminants and Natural Toxicants.

A concern expressed by health authorities is that the use of tobacco or nicotine in food may promote or legitimise the smoking of tobacco.

3. Objective

The objective of this proposal is to consider whether there is a need to amend the *Australia New Zealand Food Standards Code* (the Code) to specifically restrict the use of *Nicotiana* species commonly known as tobacco, in foods or alternatively, to restrict the addition of nicotine to food.

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 Historical Background

Smokeless tobacco products have been used worldwide for hundreds of years. In addition to tobacco, the products in some countries include a wide range of other constituents. The manner of use differs widely, although nearly all types of smokeless tobacco are used orally, with only a few rare types used nasally. More recently, this has included the use of tobacco plant extracts resulting in the development and marketing of nicotine containing bottled water and nicotine containing sweets and lollipops.

Like smoked tobacco products, smokeless tobaccos are highly addictive. Nicotine levels from single doses of smokeless tobacco are similar to that from a cigarette, although the levels of nicotine rise faster and decrease slower in smokeless tobacco users. Nicotine is psychoactive, and users of smokeless tobacco show signs of addiction including a pattern of abuse involving escalating use, tolerance, and withdrawal symptoms.

During 2002, Department of Health and Ageing was alerted to the commercial importation of various smokeless tobacco products not covered by the *Customs (Prohibited Import) Regulations 1956*. Following a meeting of relevant agencies it was agreed that FSANZ would investigate the need for specific regulations regarding tobacco and nicotine in food.

4.2 Work Plan Classification

This Proposal had been provisionally rated as Category of Assessment 2 (level of complexity) and placed in Group 1 on the FSANZ standards development Work Plan. This Initial Assessment confirms these rating. Further details about the Work Plan and its classification system are given in *Information for Applicants* at www.foodstandards.gov.au.

4.3 Current regulatory framework

4.3.1 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 moderate to high public health and safety risk. There are many 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 or inadvertent oral consumption.

Schedule 2 in this Standard lists those plants and fungi which are used as flavouring agents in food but which contain ingredients, which are associated with some degree of toxicity. In these cases, a maximum level is applied to the toxic ingredient 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 *Nicotiana* species in all or specified foods.

4.3.2 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 food ingredients derived from those *Nicotiana* species that would be regarded as non-traditional foods. Safety considerations relating to the presence of nicotine could be addressed through this Standard by identifying nicotine as a contaminant and establishing a maximum level in the food in Standard 1.4.1 – Contaminants and Natural Toxicants.

4.3.3 Standard 1.4.1 – Contaminants and Natural Toxicants

This is a broadly based Standard, that sets out the maximum level (ML) of specified metal and non-metal contaminants and natural toxicants in nominated foods. As a general principle, regardless of whether or not a ML exists, the level of contaminants and natural toxicants in all foods should be kept as low as reasonably achievable.

Maximum levels have been set at levels that are consistent with public health and safety and which are reasonably achievable from sound production and natural resource management practices. Control of nicotine in food could be achieved by including the substance in the Table to clause 5 – Maximum level of other natural toxicants in food.

4.4 Regulation in other countries

4.4.1 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.

In the USA, there have been a number of attempts to market nicotine containing lollipops, lip balm and bottled water through various different distribution channels including the internet under the auspices of the DSHEA. In all cases, the FDA removed the products from the market because the products contain a drug that has not been approved by the FDA.

4.4.2 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.

A prohibition for *Nicotiana* species under the Code would be consistent with the current restrictions on the sale of tobacco and tobacco products under the *Smokefree Environments Act 1990* and provisions for nicotine under the *Medicines Act 1981* and general prohibitions on harmful foods under the *Food Act 1981*. However, prohibitions under Standard 1.4.4 of the Code do not apply directly to products sold under the NZDSR, although the general *Food Act 1981* safety provisions (Section 9) apply to all food for sale including dietary supplements.

4.4.3 Canada

In Canada, orally consumed products until recently were regulated as foods or drugs. Nicotine is included in Schedule F is a list of medicinal ingredients, the sale of which are controlled specifically by the Food and Drug Regulations. Specifically this regulation relates to *nicotine and its salts, for human use, except:*

- *in natural substances;*
- *in the form of chewing gum containing 4 mg or less of nicotine per dosage unit;*
- *in the form of a transdermal patch with a delivery rate of 22mg or less of nicotine per day; or*

- *in a form to be administered orally by means of an inhalation device delivering 4 mg or less of nicotine per dosage unit.*

4.4.4 European Union

There is no uniform legislation in the EU to regulate the use of herbs or food products containing herbs at this time. A preliminary draft proposal for a regulation of the European parliament and of the council on the addition of vitamins and minerals and of other certain other substances to food (SANCO/329/03) proposes to address the issue of the addition of nicotine to foods by placing the substance in Annex 3 - *Substances whose use in foods is prohibited or subject to conditions*; Part C – *Prohibited substances and ingredients containing them*.

5. Relevant Issues

5.1 Nicotine in bottled water, lollipops and lip balms

Three types of nicotine containing products have been identified in the USA:

- Nicotine water marketed by S&F Garret and QTF Inc. Bottled water with added nicotine sold as a dietary supplement (2mg or 4 mg per bottle – 1 to 2 cigarette equivalence). Sold over the Internet since 2000, sale in US stores of 'Nico Water' were planned for July 2002 by QTF Inc. FDA ordered all sales stopped in July 2002 saying that federal law prohibits sale of nicotine as a dietary supplement.
- Nicotine lollipops and lip balm marketed by Bird's-Hill Pharmacy, Ashland Drug and Compounding Pharmacy. Presented as sugar-free lollipops or lip balm in assorted flavours containing nicotine salicylate in dosages from 0.5-4mg. Lollipops sold under brand names such as NicoStop, NicoPop and Likatine. Sold in three independent US pharmacies and over the Internet since 2001. FDA ordered sales to stop in April 2002 because these were considered unapproved new drugs dispensed without a prescription, without adequate directions and without warning labels.

5.2 Smokeless tobacco regulation in Australia

A ban on the sale of oral snuff and chewing tobacco has been in place since 1989 under the *Trade Practices Act 1974*. The intention of the underlying policy was primarily to prevent mass importation and distribution of smokeless tobacco products. The ban was pre-emptive, but feasible because of the relatively small number of consumers of these products in Australia. It is estimated that there are between 10,000 and 20,000 consumers of smokeless tobacco product in Australia.

The *Customs (Prohibited Imports) Regulations 1956* prohibit "chewing tobacco, and snuffs intended for oral use, imported in an amount weighing more than 1.5 kg" (Schedule 12, subregulation 4U (1)). However, importation for personal use is permitted:

- a permit is *not* required for the importation of chewing tobacco and oral snuff for quantities *less* than 1.5kg;
- a permit is required for individual consumers with consignments of chewing tobacco and oral snuff greater than 1.5 kg. A maximum limit per permit has not been formally established, however, Department of Treasury officers do not issue permits for consignments in excess of 5 to 6 kg.

5.3 Regulation of nicotine as a poison in Australia

Nicotine is included in various schedules of the *Standard for Uniform Scheduling of Drugs and Poisons* (SUSDP) which is incorporated into State and Territory poisons legislation. Nicotine is a Schedule 6 substance when in preparations containing 3% or less nicotine when labelled and packed for the treatment of animals. However, nicotine is also in Schedule 7 of the SUSDP (dangerous poison) except when it is used as an aid for the withdrawal from smoking or when it is included in tobacco prepared and packed for smoking.

Though nicotine is in Schedule 7 (dangerous poison) – under Appendix A, food is exempt from the SUSDP except *food additives before incorporation into food; or when used as a means of administering a poison for therapeutic use*.

5.4 Nicotine in food – dietary intake

Many commonly and widely consumed vegetables of the nightshade family (Solanaceae) such as potatoes, tomatoes, eggplants and capsicums are known to contain low levels of nicotine. Only a few citations can be found in the literature that addresses nicotine concentration in diverse foods and the ensuing dietary intake of nicotine. A recent study was conducted to determine the feasibility that the consumption of foods known to contain nicotine could contribute significantly to nicotine intake. In the course of this study, nicotine was determined in several fresh fruits and vegetables of the nightshade family (Solanaceae) (with emphasis on tomatoes, potatoes, eggplants, and capsicums) as well as processed foods originating from these fruit and vegetables. Dietary modelling indicated a mean estimated daily dietary intake of nicotine to be approximately 1.4 μg/day, with 2.25 μg/day at the 95th percentile, based on nicotine content of the foods ingested and consumption data. The estimated nicotine intake derived from dietary sources therefore is low, if one compares this to the nicotine intake through smoking, which is reported to be in the range of 1mg per cigarette (Seigmund et. al., 1999).

5.5 Toxicity of nicotine

Nicotine at the intake levels derived from tobacco smoking, is a powerful psychoactive drug. Nicotine exerts its actions on the cardiovascular, respiratory, skeletal motor and gastrointestinal system through stimulation of peripheral cholinergic neurons. High nicotine doses can cause respiratory failure (Woolf et. al., 1996).

In humans, acute exposure to nicotine even in low doses (similar to the amounts consumed by tobacco users) elicits autonomic and somatic reflex effects. Dizziness, nausea, and/or vomiting are commonly experienced in nonsmokers after a low dose of nicotine, such as when people try their first cigarette. However cigarette smokers rapidly become tolerant to these effects.

In the USA a number of poisonings and deaths from the ingestion of nicotine have been report in humans, primarily involving nicotine-containing pesticides. The lethal oral dose of nicotine in adults has been quoted to be 40 to 60 mg, but it has not been well documented. Acute intoxication may occur in children following ingestion of tobacco materials. Four children, each of whom ingested two cigarettes, developed salivation, vomiting, diarrhoea, tachypnea, tachycardia and hypertension within 30 min; followed by depressed respiration and cardiac arrhythmia within 40 min; and convulsions within 60 min.

All recovered and suffered no complication. Another six children who ingested one-half of a cigarette experienced salivation and vomiting only. Although ingestions of tobacco are common, deaths due to ingestion of tobacco are extremely rare, due to early vomiting and first pass metabolism of the nicotine which is absorbed (Surgeon General, 1988).

5.6 Nutritional aspects of tobacco proteins

Tobacco could potentially be developed as an important food crop in combination with its traditional use for smoking and chewing. As a food crop, tobacco grown in dense spacing could produce about four times more protein per acre than soybeans and about five times more dry tobacco than conventional tobacco crops. A simple method has been developed for extracting the proteins from the aerial portions of fresh tobacco. The water-soluble Fraction 1 proteins (Rubisco) have unique nutritional and functional properties that could make them valuable for consideration as components for special dietary purposes and for the packaged food industry.

Crystalline Fraction 1 protein when exposed to trypsin, breaks down into about 80 tryptic peptides demonstrating it high degree of digestibility. The native protein contains many sulfhydryl groups but no disulfide linkages. When fed to rats, crystalline Fraction 1 protein exhibits a somewhat higher protein efficiency ratio (PER) than casein. Crystalline Fraction 1 protein is water soluble, tasteless and odourless and is composed of amino acids of high nutritional value. Its functional properties, such as “heat set”, are similar to egg albumin or casein that are widely used throughout the packaged food industry, offering a vegetable alternative to these animal derived products. Analysis performed on crystalline Fraction 1 protein extracted from tobacco has demonstrated nicotine contamination in the parts per billion (ppb) range far below the concentration of nicotine found naturally in tomatoes, eggplants, capsicums and tea (2 to 3 part per million (ppm)) (Wildman, 1983).

5.7 Nutritional aspects of tobacco seed oil

Nicotiana tabacum L. (tobacco) has small seeds that can give an oil and a subsequent by-product meal. Tobacco seed is a by-product of tobacco leaf production. The oil content of tobacco seed has been found to be in the range from 30-40%, with trilinolein and palmitodilinolein being the main triglycerides accounting for about 90% of the composition of the oil. The proportions of individual fatty acids in the seed oil are linoleic acid 66-76%, oleic acid 17-27%, palmitic acid 7-10% and stearic acid 3%. Drying index and iodine values of the seed oil are in the range of 55-75 and 135-147 respectively. Tobacco has been reported to yield up to 400 kg/ha of seed oil. The nutritional value of tobacco seed oil is also better than groundnut and cottonseed oils and comparable to safflower oil. Refined tobacco seed oil is used as an edible oil in some European countries (Eshetu, 2000).

5.8 Tobacco as a source of food ingredients

The introduction of genes into plants like tobacco, corn, soybeans and alfalfa to enable them to produce and accumulate new substances has been possible for many years. An abundance of scientific literature documents the successful production in tobacco of protein pharmaceuticals, vaccines and other medicinals, enzymes, polymers and food ingredients. A variety of technologies have been developed to make these ‘plant factory’ systems possible, and the leading commercial research is now focused on optimizing the production systems and post-harvest bio-processing aspects to the required standards.

6. Regulatory Options

Possible regulatory options for P278 are given below. Other regulatory options may also be possible.

1. Prohibit the use of *Nicotiana* species and all substances derived therefrom in all foods.

2. Allow the use of *Nicotiana* species, in all foods but restrict the level of nicotine to the level demonstrated to be safe.

3. Allow the use of *Nicotiana* species and all substances derived therefrom in all foods.

7. Impact Analysis

Option 1 recognises the commitment of Australian and New Zealand Governments to control the use of tobacco products in the form of cigarettes, cigars, and chewing tobacco in the community is the issue. This option would not adversely impact on foods currently in the market as no food products containing tobacco are currently marketed in Australia. This option however, may impact on foods developed in the future using substances derived from tobacco or produced in transgenic tobacco.

Option 2 recognises that tobacco is a potential source of useful food ingredients. This option recognises the concern in the community about the addictive nature of nicotine and would address the safety concerns of the community by establishing a maximum level for nicotine in food.

Option 3 assumes that the safety of tobacco can be demonstrated. This option also assumes that it is appropriate to use food as a vehicle for substances that can have a pharmacological effect.

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 submission will also be sought when Draft Assessment is released. Comments are particularly sought on the following:

- the appropriateness of adding tobacco or nicotine to foods
- the safety of adding tobacco or nicotine to foods
- the appropriateness of using food ingredients derived from tobacco
- the regulatory options

8.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obligated to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to allow the control of *Nicotiana* species in foods is unlikely to have a significant effect on international trade as the practice of using tobacco or ingredients derived from tobacco in food is not widespread. This issue will be fully considered at Draft Assessment and, if necessary, notification will be recommended to the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade or Sanitary and Phytosanitary Measure Agreements. This will enable other WTO member countries to comment on proposed changes to standards where they may have a significant impact on them.

9. Conclusion and Recommendation

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 in accordance with section 15AA of the FSANZ Act.

10. References

Eshetu, B. 2000. *Nicotiana tabacum* L. Seed Oil. http://ipp.boku.ac.at/pz/oilseeds/eshetu.html

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.

Seigmund, B., Leitner, E., Pfannhauser, W. 1999. Determination of Nicotine Content of Various Edible Nightshades (Solanaceae) and Their Products and Estimation of the Associated Dietary Nicotine Intake. Journal of Agriculture and Food Chemistry, 47 (8): 3113-3120.

Surgeon General. 1988. The Health Consequences of Smoking: Nicotine Addition. U. S. Government Printing Office. Washington DC.

Wildman, S. 1983. An Alternative Use For Tobacco Agriculture: Proteins For Food Plus A Safer Smoking Material. *in Plants: The Potential for Extracting Protein, Medicines, and other Useful Chemical – Workshop Proceedings* p 63-77 Washington D.C. www.wws.princeton.edu/cgi-bin/byteserv.prl/ ~ota/disk3/1983/8315/831504.PDF

Woolf, A., Burkhart, K., Caraccio, T., Litovitz, T. 1996. Self-poisoning among adults using multiple transdermal nicotine patches. J. Toxicol. Clin Toxicol. 34(6): 691-698.