

APPLICATION TO FOOD STANDARDS AUSTRALIA & NEW ZEALAND (FSANZ)

EXECUTIVE SUMMARY

Hemp (*Cannabis sativa*) is a plant of great antiquity. It has been grown by many different cultures across many continents since well before recorded human history. During the nineteenth century Hemp was the most cultivated crop on Earth and Hemp fibre was the world's most traded commodity. The Hemp seed was and is a valued component of the diet of many people across many different cultures.

The factors leading to the demise of Hemp as an industrial crop are the subject of ongoing debate. Certainly, changes to the industrial landscape such as the replacement of wind power by steamships, the invention of the cotton gin and manufacture of synthetic fibres contributed to the reduction of Hemp's prominence in commerce. However, the major impetus in Hemp's demise was not industrial, but political. The political influences reached a global crescendo in 1937 when the American congress passed the "Marijuana Transfer Tax Act", despite the opposition of the Hemp industries and the American Medical Association.

Modern research has cast doubt on the validity of the assumptions underlying the global prohibition of Hemp. Proponents are hailing Hemp as a wonder crop, capable of positively impacting on climate change, agricultural sustainability, human nutrition and disease prevention and as a natural and effective medicine for a diverse range of human ills. Around the world legislative changes are paving the way for a resurgence of Hemp in agriculture and commerce. In Australia, most States have now modified their laws to exclude Hemp, defined as any species of *Cannabis* which produces less than 0.3% of THC, from prohibition, paving the way for a redevelopment of the Hemp industries. This is entirely congruent with the United Nations Single Convention Article 28.2, which unequivocally states that for the production of seed and fibre and for horticultural purposes Hemp is not to be prohibited.

This application seeks an expeditious modification of Australia's Food Standards to recognise the scientific research which validates this application to include Hemp foods as a beneficial addition to the Australian diet.

3.1.2 APPLICANT DETAILS

Applicant: Dr Andrew Katelaris MD (UNSW)
Address: 3 Luton Place, St Ives 2075
Postal: P.O. Box 3261, North Turramurra 2074
E mail: akatelar@bigpond.net.au
Telephone: 0414 306 306
Occupation: medical research scientist & Hemp agronomist

3.1.3 PURPOSE OF THE APPLICATION

This application seeks to amend the current restrictive Australian regulations which prevent the nutritional benefits of Hemp seed (*Cannabis sativa*) and Hemp seed products from being freely available for human use in Australia.

Current regulations allow Hemp seed oil as a human food in New Zealand but not in Australia. This presents an intrinsic contradiction in a uniform code and requires remedy.

Amending these regulations will have a secondary benefit of harmonising Australian regulations with the rest of the world and preventing conflict with WTO regulations concerning free trade.

The larger purpose of this application is to make available to the population of Australia and New Zealand the same considerable benefits of Hemp seed nutrition that are freely available to the rest of the world. Evidence will be presented to support the assertion that the current western diet has been considerably devitalised and severely reduced in its content of the essential human nutrient, alpha-linolenic acid (omega 3) and that this is having a demonstrable negative effect on the population's health. Food products based around Hemp seed can provide an easily assimilated source of this essential fatty acid, suitable for all age groups, as well as those with special dietary requirements.

3.1.4 JUSTIFICATION FOR THE APPLICATION

This is not the first application concerning Hemp as a human food to be placed before FSANZ. In 1998 an application was made by Ecofibre Pty Ltd. A careful assessment by FSANZ followed in which it was determined that Hemp seed was a valuable nutrient which posed no risk of harm. Notwithstanding the scientific validity of these findings the application was not passed by the Ministerial Council, citing politically based objections such as “sending the wrong message” and “difficulties with policing”.

The justification for re-submitting the application are several. The political climate

has changed considerably since the initial application, with the increasing acceptance of the need for urgent action on climate change and environmental protection. The critical role played by the essential fatty acid omega-3 in human health is also receiving increasing attention. Its role in immune regulation, mood stabilisation and down regulation of the inflammatory response place it in the forefront of preventative and treatment medicine in areas as diverse as cardio-vascular disease, arthritis and depression.

The industrialisation of the western world's food supply has drastically reduced the average omega-3 content of the average diet. The currently recommended supplementary source of omega-3 is fish oil. Fish oil is generally unpalatable necessitating encapsulation and the looming collapse of the global marine ecosystems will further restrict availability and increase cost of marine omega-3.

Around the world plant sourced omega-3 is enjoying a resurgence. Flax seed contains the highest concentration of omega-3 of any food, but is difficult to incorporate into foods due to taste issues. Hemp seed, especially the hulled kernel, has a pleasant nutty taste. The ratio of omega-3 to omega-6 averages 1:3, making it ideal for long term use. As an additional benefit Hemp seed contains an almost completely balanced amino acid profile, high levels of vitamin E and magnesium, as well as a range of other nutrients.

The cultivation of Hemp offers several advantages over other oil seed crops. It is a hardy annual with modest water requirements. It is a self mulching plant with modest nutrient demands and a deep tap root, which aerates and improves the soil. It is an efficient weed smother crop and can be grown without herbicides or pesticides. When used as a rotation crop it can significantly increase the yields of following crops. After seed harvest there remains 10-12 tons of dry stem material, comprising 30% long fibre (bast) and 70% short fibre (hurd). Each ton of Hemp derived cellulose removes 1.5 tons of carbon dioxide from the atmosphere. When this fibre is incorporated into durable material such as cellulose cement (hempcrete) the crop acts as an efficient carbon bio-sequestration process. Hence, Hemp simultaneously addresses many of the current critical issues facing Australia including greenhouse warming, water shortage, agricultural chemical use, land degradation and poor returns to farmers.

Australia currently lacks any significant textile industry, the once vibrant Victorian mills having been progressively closed due to poor government planning and policy. An industry based on Hemp seed for food can be established profitably on a small scale of 10-100 hectares and requires only modest capital investment. Amending the Food Standards to permit the use of Hemp seed as a human food will have the secondary benefit of allowing the Hemp fibre industry to establish itself and grow to the point where the major investment needed to restart textile production can be considered.

3.1.5 INFORMATION TO SUPPORT THE APPLICATION

The agronomic advantages of Hemp cultivation have been known for centuries. In 1893 the Agricultural Gazette of New South Wales (Maiden) reported on agronomic trials of Hemp and noted its ability to smother weeds and repel grubs and caterpillars. In 1916 the United States Department of Agriculture (Taylor) published these very prescient words. “There appears little doubt that under the present system of forest use and consumption the present supply cannot withstand the demands placed upon it.” It went on to discuss the role of Hemp fibre in the paper making process and noted that one acre of Hemp could supply as much fibre as four acres of forest. In 1938 the Popular Mechanics Magazine (Popular Mechanics) published an article describing Hemp as the “New Billion Dollar Crop”. The article explained how improvements in the mechanisation of Hemp processing had opened the way for a great expansion of the Hemp industries and that Hemp could be used to produce up to 25,000 different items of commerce. The article stated “ The connection between Hemp as a crop and marijuana seems to be exaggerated and regulations could be drawn up which would not prevent the legitimate culture of Hemp”. A documentary “Billion Dollar Crop” was screened in 1996 as part of the ABC “True Stories” series. This film outlined the political basis of the Hemp prohibition and the links between petrochemical industrialists and corrupt and racist police in the genesis of this prohibition. It is essential viewing for the serious student of history who seeks to understand the truth behind the current rhetoric and propaganda.

Hemp seed has been used in human nutrition since antiquity and has been continuously available as a rustic food in Russia, Latvia and other eastern European countries. (Calloway) In parts of China it is prepared as a dish referred to as “longevity soup”. The nutritional benefits of Hemp seed are several, but this application will focus on the protein and oil content. While not addressed in this current application, a potential area for future consideration is the examination of the relative glycaemic value of Hemp seed and Hemp seed products, due to the low percentage of non-fibre carbohydrates present. Glycaemic index values provide an indication of the impact that a given food may have on raising post-prandial blood glucose and insulin values. Higher glycaemic index foods produce larger fluctuations in blood glucose, and thus may confer a greater risk to individuals for developing diabetes and other co-morbidities. (Ludwig) Due to the high proportion of total carbohydrate present as dietary fibre, Hemp seed has a low glycaemic index, but this needs further testing. One additional area for consideration relates to the ash content of Hemp products relative to other nut products: Hemp, in particular the Hemp kernels, have two to three times the ash content of other nuts, a reflection of the total mineral content. Hemp seed and Hemp kernels can therefore serve as a rich sources of minerals and trace elements.

Selection of cultivar (cultivated variety), location and cultural factors lead to some minor variation, but the average crude protein content of whole Hemp seed is 25%

and around 40% for the hulled seed. From a nutritional standpoint, numerous factors influence the quality of dietary proteins, most notably the amino acid composition and the digestibility of the protein. Hemp protein is in the form of edestin and albumin and is complete in terms of amino acid composition, except for a relatively mild deficiency of lysine. In practical terms this poses no problem, as Hemp seed is not proposed as a sole protein source and the WHO has determined that it is suitable for the nutritional needs of children over the age of two years. In comparison to other nut proteins Hemp protein yields a higher amino acid score. Combining Hemp protein with a modest quantity of lysine rich pulses will provide a complete dietary protein for human use. Hemp seed alone does provide a complete protein for a range of farmed animals including chickens and pigs and is already in use on a small scale in the pet food and equine industries. An area of research interest of high ecological value is the future use of Hemp seed in aquaculture. Farmed fish generally rely on wild caught bait fish for feeding, because omega-3 is an essential fatty acid for pelagic fish, as it is for humans. The ecological footprint of aquaculture could be significantly reduced by using pelleted Hemp seed to provide the protein and oil needs from a non-marine source.

A complete description of the nutritional quality of a protein must include not only the relative contribution of the amino acid profile of the protein but the digestibility of the protein. This is the concept behind the protein digestibility corrected amino acid score. (Wang) The use of a reference protein, such as the high quality protein casein, provides a benchmark for comparisons against other studies assessing protein quality in foods. The digestibility of casein is 97.6%, that being the proportion of protein absorbed along the digestive tract and assumed to be utilised to meet the protein needs of the organism. For comparison, the widely used soy protein isolate has a score of 70%. The digestibility of the protein from intact Hemp seed averages 85.2%. A similar protein digestibility score was observed for Hemp protein flour. This result provides evidence that the process used in expelling the oil from the Hemp seed does not lead to a reduction in the digestibility of the protein contained in the seed. The net protein efficiency ratio (PER) is the same for Hemp seeds and the Hemp protein flour. The PER provides a different measure of the quality of the protein and reflects the ability of the test subject, such as the laboratory rat, to deposit body protein. The data provides further evidence of the stability of Hemp protein under ordinary processing conditions.

The seed coat or hull contains most of the non-digestible fibre (NDF) in Hemp seed. Removal of the hull led to an average increase in protein digestibility from 85.2% to 94.9%. The Hemp nut samples with the lowest protein digestibility also had the highest content of non-digestible fibre, indicating that the non-digestible fibre is responsible for the reduction in protein digestibility. The provision of Hemp nutrition in the form of the hulled seed can therefore be seen to improve taste and digestibility, whilst at the same time allaying concerns that may be conceivably attached to the widespread distribution of whole seed. When the whole seed is used as garnish neither of these concerns could be viewed as important.

In the industrialised western countries protein deficiency is rare, except in isolated special groups such as those with medical conditions predisposing to malabsorption, but in third world countries protein deficiency is widespread and a major problem, leading to stunting of growth and increased susceptibility to disease. In times of natural or political calamity protein shortages often become critical and mass starvation may only be averted by emergency relief aid. Dried milk powder is usually sent, but many people in Africa and Asia have an inherited or acquired lactose intolerance. A suitable prepared Hemp based food could circumvent this problem, providing yet another humanitarian impetus for the modernisation of schedule.

As important as the protein aspects of Hemp seed nutrition are, it is the fatty acid profile of Hemp seed that has provoked the most interest and provides the main driver for a prompt revision of the schedule. The essential fatty acids (EFA) play a critical role in human health and disease. (Simopoulos) Individuals and groups concerned about the population aspects of nutrition have been dismayed by the deterioration in the quality of the diet generally available in industrial societies and by the resultant dramatic increases in obesity, hypertension, cardiovascular disease, mood disorders and degenerative diseases of all types suffered by a broad sector of the community. The perception that the various governments and regulatory agencies have been delinquent in their oversight of the nation's health, with the impression that the profits of transnational corporations are more important than the health and well being of the population, is sometimes hard to avoid.

The human organism requires two fatty acids, alpha-linolenic acid (omega 3) and linoleic acid (omega 6), to be provided exogenously. For this reason they are referred to as essential fatty acids because they cannot be synthesised and must be provided by the diet. These substances are of extreme importance in the correct functioning of the human body and have critical roles in neural development, membrane function and the regulation of the immune system and inflammation. They also function to regulate blood pressure, wound healing and in haemostasis. The definition of what constitutes the minimum daily requirement (the amount needed to prevent deficiency) and the optimal daily requirement (the amount needed to promote optimal health and well being) has been the subject of some debate but insufficient quality research. Due to metabolic competition between the two EFAs for access to the enzyme *delta-6* desaturase, the significance of a dietary ratio for the intakes of *omega-6* and *omega-3* fatty acids is important to consider in health and in the interpretation of results from clinical studies. (Richard) Previously, an optimal *omega-6/omega-3* ratio was considered to be somewhere between 5:1 and 10:1, which is similar to the ratio found in soy bean oil of 7:1. More recent considerations suggest an optimal ratio to be somewhere between 2:1 and 3:1, which reflects the ratio found in the traditional Japanese and Mediterranean diets, where the incidence of coronary heart disease has been historically low. The ratio in most commercial Hemp seed oils is typically around 2.5:1 making it an ideal choice for long term use. Thus, its unique fatty acid profile may give Hemp seed an important role in therapeutic nutrition. The cardiovascular benefits of the long chain polyunsaturated fatty acids EPA and DHA

are well recognised. Both these fatty acids, which are found in cold water fish, can be synthesised in the human from the parent alpha-linolenic acid, but the opponents of plant based oil supplements argue that the metabolic conversion rate is low. Recent evidence has established that a significant anti-thrombotic and therefore cardio-protective effect is seen due to the direct effect of alpha-linolenic acid. (Richard)

As well as the previously mentioned linoleic and alpha-linolenic acids, Hemp seed contain significant quantities of stearidonic acid. Stearidonic acid is converted much more efficiently to EPA than alpha-linolenic acid. In addition, stearidonic acid appears to have important therapeutic actions itself, including a role in tumour suppression, that is independent of the delta 6 desaturase enzyme reaction. (Guil-Guerrero)

In the 1930's the Randolph Hearst press launched a media campaign which came to be known as "Reefer Madness", after the film bearing that name. This film made various assertions concerning the effects of Cannabis and claimed to have evidence showing that the inevitable consequence of even casual use of Cannabis was violence, insanity and death. When viewed today the film appears as grotesque propaganda but the negative effects of the campaign is still being felt today. It has caused the arrest and criminalisation tens of millions of people and has squandered countless billions of dollars of public money, whilst fuelling police and political corruption on a massive scale. The science behind this campaign was always suspect. Many formal studies have been done. The Indian Hemp Drugs Commission Report (1894) comprising some seven volumes and 3,281 pages, is by far the most complete and systematic study of marijuana ever undertaken. Many of the issues concerning marijuana being argued today were dealt with in the Indian Hemp Drugs Commission Report, which found no significant evidence for any physical, mental or moral deterioration in users. These findings and calls for removal of legal sanctions have been reiterated by the British House of Lords study and others.

3.1.6 ASSESSMENT PROCEDURE

The regulatory obstacles to Hemp seed as human food are twofold. The inclusion of all cultivars of Hemp in the prohibited botanicals schedule needs to be re-considered and the various State regulations governing industrial Hemp can serve as a useful model. In NSW industrial Hemp must contain less than 1% THC. In some other States the level is set at 0.3%. The restricted botanicals schedule could be modified by way of amendment to exclude from the schedule those plants demonstrating such levels, whilst maintaining restriction on high THC cultivars. The advantage of this approach would be to streamline regulatory procedure, as the policing aspects of this would be covered under the grower's license.

Secondly, the issue of Hemp as a novel food needs to be re-examined. The definition of a novel food as one that is not widely used in the community needs consideration.

For example, some animal types such as goat and certain organ meats may only be consumed by a tiny percentage of the population but they would in no way be considered “novel” foods. Although documentary evidence is limited as to its food use, Australia has a history of Hemp cultivation dating from colonial times. In the past decade significant quantities of Hemp oil and other Hemp seed products have been imported into Australia and New Zealand or manufactured locally. Whilst the oil must be marked “not for internal use” and nominally intended exclusively for the cosmetics and body care industries, much of it has been consumed by health conscious individuals, aware of the important supplementary role Hemp seed can provide in a superior diet. Premium prices are paid by this group of generally well-informed consumers who recognise that nutritional value for money is being provided.

The unique advantage of Hemp seed foods is that they can provide an essential (and currently neglected) source of omega-3 in a form acceptable to diverse groups of the population, including vegetarians, vegans and all those interested in minimising their consumption “footprint” on the planet. When suitably processed, Hemp seed can be used to produce a high quality non-dairy ice cream, greatly simplifying a parent's ability to provide brain enhancing omega-3 to their children. For those with allergy to soy or dairy products Hemp milk and other products would provide a welcome alternative. For vegetarians and vegans the advantages of Hemp products are obvious. For the prevention and management of cardiovascular disease Hemp seed provides an ecologically superior alternative to fish oil capsules. As a convalescent food Hemp is an obvious choice. A very interesting application for Hemp seed has surfaced recently in the sports and body building area. Many world class athletes have attested to the benefits they have received by utilising Hemp seed nutrition.

FSANZ has already conducted a detailed toxicological assessment of Hemp seed as a human food. Congruent with the findings of all other food regulatory authorities around the world the conclusion has been that it is not only safe, but also highly beneficial in terms of its nutritional benefits. Considering all of the above it would be best if this application were to be considered in the general category.

3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION (CCI)

The intention of the applicant and most others involved in the Hemp food industry is the rapid and widespread acceptance of Hemp food in the wider community. To this end all useful knowledge will be shared. Apart from what restrictions that may apply under Plant Breeders Rights and certain proprietary agronomic and manufacturing processes yet to be developed, all information concerning the agronomy, harvesting and nutritional uses of Hemp are in the public domain and not restricted as CCI.

3.1.8 EXCLUSIVE CAPTURABLE COMMERCIAL BENEFIT

The applicant does not seek nor claim any exclusive capturable commercial benefit from any preparation of Hemp seed or Hemp seed products. The Hemp seed has

been used in the service of humanity since time immemorial and belongs in the public domain for the beneficial use of the entire population.

3.1.9 INTERNATIONAL AND OTHER NATIONAL STANDARDS

Of the countries to which we have knowledge there are no restrictions on the use of Hemp seed as food. Specifically, the United States, Canada, United Kingdom and European Economic Community, all countries of eastern Europe, China and Japan do not restrict the sale and consumption of Hemp seed as human food. In the western countries maximum permitted levels of THC are mandated. With the exclusive use of specifically bred low THC cultivars for the Hemp seed industry compliance with reasonable standards will not pose a problem for Hemp processors. The THC levels indicated by FSANZ in the prior application could serve as a starting point.

REFERENCES

Maiden, J. H. Agricultural Gazette of New South Wales Vol. IV Part 12 Dec, 1893

Taylor W. M. United States Department of Agriculture Bulletin No. 404. Oct, 1916

Popular Mechanics Magazine 1938 p 238

Callaway, J.C. Hemp seed as a nutritional resource. *Euphytica* 140:65-72, 2004

Ludwig, D.S. The low glycaemic-index diet. *Lancet* 369: 890-892, 2007

FAO/WHO expert consultation on protein quality evaluation. Food and Agriculture Organisation of the United Nations, Rome, 1990.

Wang, Xian-Sheng. Characterisation, amino acid composition and in vitro digestibility of Hemp proteins. *Food Chemistry* 107, 11-18, 2008

Simopoulos, A.P., Essential fatty acids in health and chronic disease. *American Journal of Clinical Nutrition* 70: 560–569S, 1999. 424-5, 2007

Richard, M. N. Dietary Hemp seed reduces platelet aggregation. *Journal of Thrombosis and Hemostasis*; 5: 424-5, 2007.

Guil-Guerrero, J. L. Stearidonic acid: Metabolism, nutritional importance, medical uses and natural sources. *Eur. J. Lipid Sci. Technol*; 109: 1226-36, 2007.

CHECKLIST FOR STANDARDS RELATED TO CONTAMINANTS AND NATURAL TOXICANTS

General Requirements (3.1)

- ☐ Form of application
- ☐ Assessment procedure
- ☐ Applicant details
- ☐ Confidential Commercial Information
- ☐ Purpose of the application
- ☐ Exclusive Capturable Commercial Benefit
- ☐ Justification for the application
- ☐ International standards
- ☐ Information to support the application
- ☐ Statutory Declaration

Chemical Contaminant and Natural Toxicant Maximum Levels (3.4.1)

- ☐ Nature of contaminant or natural toxicant
- ☐ List of foods where maximum level is proposed
- ☐ Analytical detection method
- ☐ Survey data on contaminant levels in foods
- ☐ Toxicokinetics & metabolism information
- ☐ Impact on food industry – Like most new industries it will take a period of time for Hemp food products to achieve significant market penetration. However, there are several factors which will accelerate this growth such as the growing acceptance of Hemp as a functional food with significant health advantages and ecological benefits and a steady accumulation of scientific data on these subjects. Apart from a slight substitution in the marine omega 3 area Hemp foods will be added to the diet and not used as substitutes.
- ☐ Toxicity studies
- ☐ Impact on trade – Harmonising Hemp food legislation with the rest of the world may permit the development of an export food market. However, compared to the grain and meat markets the impact would not be great.
- ☐ Human studies relevant to safety. – see prior FSANZ assessment

Microbiological Limits (3.4.2)

- ☐ Raw inputs, production and manufacturing process
- ☐ Evidence of nutritional benefit of change – Hemp seed products are amongst the most nutritionally dense food sources available to humans. They contain a high quality protein, substantial quantities of minerals and most importantly generous quantities of essential fatty acids. Medical evidence linking many of the modern diseases to omega 3 deficiency provide

impelling motivation for a rapid positive assessment of this application.

- Food technology – The processing of Hemp seed will largely be along the same lines as other seed products such as soy.
- Food consumption data
- Nature of the microbiological hazard
- Impact on food industry
- Source & prevalence of contamination
- Impact on trade
- Consumer handling and use

Prohibited and Restricted Plants and Fungi (3.4.3)

- Nature of plant or fungi – All cultivars of Cannabis are currently listed in the prohibited schedule. This application invites FSANZ to modify the schedule to exclude from prohibition those cultivars of Cannabis grown under licence and producing less than 1% THC by weight. This is entirely congruent with the United Nations Single Convention Article 28.2, which specifically excludes from prohibition the cultivation of Hemp for fibre, seed or horticultural purposes.
- Human toxicity case studies
- Identity and levels of natural toxicants
- Use in other countries – hemp foods are freely available in all other countries of the world. It is a regrettable anomaly
- Toxicity studies

3.1.10 STATUTORY DECLARATION

I, Dr Andrew Katelaris, medical research scientist and Hemp agronomist make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge
3. no information has been withheld that might prejudice this application

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

.....
Signature

Declared at _____ on the _____ of _____, 2009

Before me,

.....
Signature of person before whom the declaration is made

.....
Full name, qualification and address of person before whom the declaration is made