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PRELIMINARY ASSESSMENT REPORT

APPLICATION A428

DHA- RICH DRIED MARINE MICRO ALGAE (*SCHIZOCHYTRIUM SP.*) AND DHA- RICH OIL DERIVED FROM *SCHIZOCHYTRIUM SP.* AS NOVEL FOOD INGREDIENTS

Applicant: Omega Tech Inc.

Date received: 13 March 2001

BACKGROUND:

Application and proposed food uses

An application has been received from Omega Tech Inc. to amend Standard 1.5.1-Novel Foods of the *Food Standards Code* to approve the use of (i) dried marine micro algae (*Schizochytrium sp.*) which is rich in the omega-3 long chain polyunsaturated fatty acid DHA (docosahexaenoic acid) and (ii) DHA- rich oil derived from the same species as novel food ingredients. The dried marine algae is proposed to be used in the following foods (use levels ranging between 200-300mg):

- Bread and other baked goods such as crisp-spreads;
- Breakfast foods;
- Table spreads;
- Dressings/mayonnaise;
- Modified milk products; and
- Special purpose foods such as Formulated Meal Replacements/Supplementary Foods and infant foods.

The DHA- rich oil derived from *Schizochytrium sp.* may also be used in some of the above foods.

Role of DHA in humans

Omega-3 long chain fatty acids, specifically, DHA have been identified as important dietary nutrients with specific roles in developing foetuses and preterm infants. It has also been cited in the literature recently that DHA as one of the omega-3 fatty acids may have an important role in cardiovascular health and effects on the immune system.

In assessing this application, ANZFA will not be assessing the role of DHA in human nutrition but will be assessing the safety of DHA in the food products at the proposed levels of use.

Dietary considerations

The principal dietary sources of DHA are oily fish species such as salmon, tuna, sardines, and herrings which feed on the micro algae. Game meat is also a source of DHA. However, the consumption of fish/game meats in Australia and New Zealand is relatively low and therefore the normal exposure to DHA is low.

Various international organisations have recommended intakes of Omega-3 fatty acids from 650-1200 mg/day. The Australian National Heart Foundation in 1999 recommended at least two fish meals/week, should be consumed, although they did not specify a recommended daily intake of DHA *per se*.

The applicant has estimated the dietary intakes of DHA if it was incorporated into all of the above food products. A total daily DHA intake of 303 mg may occur if all the foods detailed above were enriched with DHA. If this is added to recent data which estimated the average daily intake of DHA in Australian adults as 106mg, an approximate average intake of 400 mg of DHA is expected. This would be well within the range recommended by various health organisations (650-1200 mg).

At full assessment ANZFA will calculate dietary exposure to DHA for Australian and New Zealand consumers for a range of ages using data from the 1995 National Nutrition Survey and the 1997 National New Zealand Survey.

Safety issues

The applicant has submitted detailed toxicological studies to support the safety of DHA-rich *Schizochytrium sp.* micro-algae at the proposed level. There are no specific studies available on the DHA-rich oil extracted from *Schizochytrium sp.* micro-algae, but the safety of DHA-rich oil of similar composition from other sources has been documented and the studies on the DHA- rich micro algae can be used to support the safety of the extracted oil.

Technological justification

The dried micro-algae are produced by a controlled fermentation process, and have a minimum DHA content of 20%. DHA itself is a highly unsaturated fatty acid and susceptible to oxidative degeneration, however, encapsulation of the DHA by the dried micro-algae provides stability and it can then be effectively used in various food products for DHA enrichment.

The proposed name of the dried micro-algae product is DHA Gold. The applicant has provided detailed product specifications for DHA-rich oil derived from dried micro-algae.

The applicant claims that the dried micro-algae product (DHA Gold) is very stable and provides food manufacturers with the opportunity to enrich a range of foods with DHA and thus provide consumers with greater choice and ability to increase their sources of omega-3 fatty acids.

Standard A19 and Standard 1.5.1

Standard A19 - Novel Foods came into effect in Volume 1 of the *Food Standards Code* on 16 December 1999. It was replicated in volume 2 of the *Food Standards Code* as Standard 1.5.1. The Standard prohibits the sale of novel foods unless they are listed in the Table to clause 2 and comply with any special conditions in that Table. The specific permission may impose conditions relating to matters such as the need for preparation or cooking instructions, a warning statement or other advice, or the need to meet specific requirements of composition or purity.

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

The Authority will assess the safety for human consumption of each novel food in accordance with the Authority's safety assessment guidelines.

In order to allow a period of time to assess any foods currently on the market that are deemed to be novel, clause 2 of the Standard, which prohibits the sale of novel foods does not come into force until 16 June 2001 (18 months after gazettal of the Standard).

OBJECTIVE:

The objective of the application is to seek permission to use DHA- rich dried marine microalgae (*Schizochytrium sp.*) and DHA-rich oil derived from the same source as novel food ingredients in various food products.

CONSIDERATION OF ISSUES UNDER SECTION 13

This application does relate to a matter that warrants a variation of a food regulatory measure, and is not so similar to a previous application that it ought not be accepted.

Costs and benefits arising for any food regulatory measure or other measures developed or varied as a result of this application are considered below.

REGULATORY IMPACT ASSESSMENT

The regulatory impact assessment is preliminary only and based on available information provided by the applicant. The assessment is designed to assist in identifying the affected parties, any alternative regulatory options, and the potential impacts of any regulatory or non-regulatory provisions. The information needed to make an assessment of this application will include information from public submissions. This preliminary assessment invites public comment on these areas.

Objective of the regulatory impact assessment

To assess the risks and benefits associated with adopting the proposed regulatory change to permit the use of DHA- rich oil and DHA- rich dried marine micro-algae (*Schizochytrium sp.*) as novel food ingredients.

Potential regulatory impacts

The potential impact of the various regulatory options is as follows:

Option 1. Not approve the use of DHA- rich oil and DHA- rich dried marine micro-algae (*Schizochytrium sp.*) as novel foods.

Option 2. Approve the use of DHA- rich oil and DHA- rich dried marine micro-algae (*Schizochytrium sp.*) as novel foods.

Identification of affected parties

Parties affected by the options outlined above include:

1. Food industry wishing to promote food products with DHA.
2. Consumers who may benefit from the use of DHA-containing products.
3. Government agencies enforcing the food regulations.

Costs

Government

- There may be some enforcement costs in regulating these new novel foods.
- There may be a health care cost to the government by not allowing the use of these novel food ingredients which have reported health benefits.

Industry

- The cost to industry is the loss of a potential markets for new products should approval not be granted.

Consumers

- There may be a cost to consumers of not permitting these novel food ingredients which have reported health benefits.

Benefits

Government

- Approval for food use may lower health expenditure in the long term given the reported health benefits of DHA.

Industry

- The benefit to industry is the opportunity to market DHA in a range of food products.

Consumers

- These products may offer long-term health benefits to consumers.
- Approval will provide consumers with an alternative dietary source of DHA.

These costs and benefits will be further considered at full assessment.

OTHER RELEVANT MATTERS

Codex

There are no Codex standards in relation to DHA- rich oil or in relation to DHA- rich dried marine micro-algae derived from *Schizochytrium sp.*

Approval in other Countries

USA

DHA-rich oil extracted from *Schizochytrium sp.* is sold in the USA as a dietary supplement and as a nutritional ingredient in food as a Generally Recognised As Safe (GRAS) ingredient.

EU

DHA- rich oil is being considered for approval as a novel food under EU regulations by virtue of the source organism (*Schizochytrium sp.*) from which it is derived.

Commercial-in-Confidence (CIC) data

The applicant requested that details of the manufacturing and fermentation processes be treated as commercial-in-confidence.

ANZFA agreed with this and granted CIC status for this data on 26 March 2001.

Workplan Classification

ANZFA's initial assessment of this application for placement on the Work-Plan was Group 3, Category 3¹. This classification has been confirmed following preliminary assessment.

WTO IMPLICATIONS

As a member of the World Trade Organisation (WTO) Australia is 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.

The Australia New Zealand Food Standards Code is mandatory legislation applying to both domestic and imported food products. Suppliers of food products are not required to take up permissions granted through amendments to the Code however food products not complying with the Code can not legally be supplied in Australia.

¹ For a detailed explanation of these terms, refer to details of the Workplan on ANZFA's website: www.anzfa.gov.au.

Amending the Code to allow the use of DHA-rich oil extracted from *Schizochytrium sp.* or the use of DHA- rich dried micro algae (*Schizochytrium sp.*) as novel food ingredients is unlikely to significantly affect trade, however this issue will be fully considered in the context of the Regulatory Impact Statement at full 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.

CONCLUSIONS

This application warrants a variation of a food regulatory measure, as provided for in section 13 of the *ANZFA Act 1991*. Costs and benefits arising from any variation to a food regulatory measure so developed will be further assessed at Full Assessment.

Accordingly the Authority has decided to accept the application and will now make a full assessment of it.

If subsequently recommended by the Authority and agreed to by the Australia New Zealand Food Standards Council, an amendment to Volume 2 of the *Food Standards Code* would allow the addition of DHA- rich oil derived from *Schizochytrium sp.* and DHA rich dried marine micro algae (*Schizochytrium sp.*) to food products. Conditions of use such as a requirement to comply with specifications for identity and purity, and to comply with a maximum percentage addition to specific foods may be required.

FOOD STANDARDS SETTING IN AUSTRALIA AND NEW ZEALAND

The Governments of Australia and New Zealand entered an Agreement in December 1995 establishing a system for the development of joint food standards. On 24 November 2000, Health Ministers in the Australia New Zealand Food Standards Council (ANZFSC) agreed to adopt the new *Australian New Zealand Food Standards Code*. The new Code was gazetted on 20 December 2000 in both Australia and New Zealand as an alternate to existing food regulations until December 2002 when it will become the sole food code for both countries. It aims to reduce the prescription of existing food regulations in both countries and lead to greater industry innovation, competition and trade.

Until the joint *Australia New Zealand Food Standards Code* is finalised the following arrangements for the two countries apply:

- **Food imported into New Zealand other than from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, as gazetted in New Zealand, or the *New Zealand Food Regulations 1984*, but not a combination thereof. However, in all cases maximum residue limits for agricultural and veterinary chemicals must comply solely with those limits specified in the *New Zealand (Maximum Residue Limits of Agricultural Compounds) Mandatory Food Standard 1999*.
- **Food imported into Australia other than from New Zealand** must comply solely with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as the joint *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two.

- **Food imported into New Zealand from Australia** must comply with either Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* as gazetted in New Zealand, but not a combination thereof. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.
- **Food imported into Australia from New Zealand** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code*, but not a combination of the two. However, under the provisions of the Trans-Tasman Mutual Recognition Arrangement, food may **also** be imported into Australia from New Zealand provided it complies with the *New Zealand Food Regulations 1984*.
- **Food manufactured in Australia and sold in Australia** must comply with Volume 1 (known as *Australian Food Standards Code*) or Volume 2 (known as *Australia New Zealand Food Standards Code*) of the *Australian Food Standards Code* but not a combination of the two. Certain foods listed in Standard T1 in Volume 1 may be manufactured in Australia to equivalent provisions in the *New Zealand Food Regulations 1984*.

In addition to the above, all food sold in New Zealand must comply with the *New Zealand Fair Trading Act 1986* and all food sold in Australia must comply with the *Australian Trade Practices Act 1974*, and the respective Australian State and Territory *Fair Trading Acts*.

Any person or organisation may apply to ANZFA to have the *Food Standards Code* amended. In addition, ANZFA may develop proposals to amend the *Australian Food Standards Code* or to develop joint Australia New Zealand food standards. ANZFA can provide advice on the requirements for applications to amend the *Food Standards Code*.

INVITATION FOR PUBLIC SUBMISSIONS

Written submissions containing technical or other relevant information which will assist the Authority in undertaking a full assessment on matters relevant to the application, including consideration of its regulatory impact, are invited from interested individuals and organisations. Technical information presented should be in sufficient detail to allow independent scientific assessment.

Submissions providing more general comment and opinion are also invited. The Authority's policy on the management of submissions is available from the Standards Liaison Officer upon request.

The processes of the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any confidential information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it in confidence. The *Australia New Zealand Food Authority Act 1991* requires the Authority 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.

Following its full assessment of the application the Authority may prepare a draft standard or draft variation to a standard (and supporting draft regulatory impact statement), or decide to reject the application. If a draft standard or draft variation is prepared, it is then circulated to interested parties, including those from whom submissions were received, with a further invitation to make written submissions on the draft. Any such submissions will then be taken into consideration during the inquiry which the Authority will hold to consider the draft standard or draft variation to a standard.

All correspondence and submissions on this matter should be addressed to the **Project Manager - Application A435** at one of the following addresses:

Australia New Zealand Food Authority
PO Box 7186
Canberra Mail Centre ACT 2610
AUSTRALIA
Tel (02) 6271 2222 Fax (02) 6271 2278

Australia New Zealand Food Authority
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Fax (04) 473 9942 Fax (04) 473 9855

Submissions should be received by the Authority by **20 June 2001**.

Submissions may be sent by Email to slo@anzfa.gov.au. However, ANZFA cannot guarantee accurate transmission and it is suggested that you also forward a hard copy by mail.

Queries regarding procedural aspects of this matter can be directed to the Standards Liaison Officer at the above address or by Email on slo@anzfa.gov.au. Requests for more general information on ANZFA can be directed to the Information Officer at the above address or by Email on info@anzfa.gov.au.