

1 November 2016
[27–16]

Call for submissions – Application A1124

Alternative DHA-rich Algal Oil for Infant Formula Products

FSANZ has assessed an Application made by DSM Nutritional Products to permit the addition of DHA-rich algal oil from *Schizochytrium sp.* American Type Culture Collection (ATCC) PTA-9695 as an alternative or replacement oil for other currently permitted DHA-rich algal oils added to infant formula products; and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 13 December 2016

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following [supporting documents](#)¹ which informed the assessment of this Application are available on the FSANZ website:

- SD1 Risk and technical assessment
- SD2 Assessment against the Policy Guidelines

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1124DHAAlgalOilinInfantFormula.aspx>

Executive summary

FSANZ has assessed an Application from DSM Nutritional Products that seeks approval of an additional, replacement or alternative oil source of DHA for use in infant formula products. The DHA oil is derived from a new production strain of *Schizochytrium* sp. known as American Type Cell Culture (ATCC) PTA-9655. For ease of reading, throughout this report the oil is referred to as DHA-B.

DHA-B is proposed to be added to infant formula products at levels consistent with the current uses of DHA oils and within the 1% maximum permitted level of omega-3 long chain polyunsaturated fatty acids (n-3 LC-PUFAs) in Standard 2.9.1 in the *Australia New Zealand Food Standards Code* (the Code). Several novel oils derived from marine micro-algae are already permitted as an optional ingredient in infant formula products. Thus, FSANZ has previously concluded that the composition of oil derived from *Schizochytrium* sp. is comparable to other traditional sources of DHA. However, since then, the Forum on Food Regulation has issued the *Ministerial Policy Guideline on the Regulation of Infant Formula Products*. FSANZ has had regard to that guidance as part of the assessment of this Application.

FSANZ has assessed the equivalence of the composition of the new strain of *Schizochytrium* sp. micro-algae and the DHA-B oil in the context of current use levels in infant formula products only. The risk and technical assessment identifies no risk to infant health and safety in relation to the use of DHA-B oil as an alternative to other approved sources of DHA in infant formula products, noting the maximum level of n-3 LC-PUFA permitted in Standard 2.9.1.

FSANZ concludes that DHA-B is suitable as an alternative, replacement or substitute source of DHA-rich algal oils for use in infant formula products. Therefore, FSANZ proposes to permit the use of DHA-B. The draft variations to Schedule 25 – Permitted novel foods and Schedule 3 – Identity and purity, propose including:

- oil derived from *Schizochytrium* sp. (ATCC PTA-9695) as a permitted novel food for use in infant formula products only
- a specification for oil derived from *Schizochytrium* sp. (ATCC PTA-9695).

1 Introduction

Several micro-algal oils that are sources of omega-3 long chain polyunsaturated fatty acids (n-3 LC-PUFAs) are permitted as novel foods in the Australia New Zealand Food Standards Code (the Code). Oils containing DHA have been used in the manufacture of infant formula products since the mid-1990s. FSANZ has previously concluded that the composition of oil derived from *Schizochytrium* sp. is comparable to other traditional sources of DHA (ANZFA, 2002).

1.1 The Applicant

This Application was lodged by DSM Nutritional Products.

1.2 The Application

In November 2015, DSM Nutritional Products submitted an Application requesting approval of an additional, replacement or alternative oil source of DHA for infant formula products. Specifically, the Application is for a DHA-rich oil marine micro-algal oil derived from a new production strain of *Schizochytrium* sp. known as American Type Cell Culture (ATCC) PTA-9695. The Applicant has advised that this strain is more productive than other marine algal DHA-rich oils currently in the market². The Applicant has advised that the oil will be sold under the trade names DHASCO-B or DHA-B. For ease of reading, DHA-B is used throughout this report to refer to this oil.

1.3 Current standards

1.3.1 Australia New Zealand

Standard 1.5.1 – Novel foods and Schedule 25 – Permitted novel foods contain permissions for the sale of novel foods that have been assessed and approved by FSANZ. These include several DHA-rich oils derived from different marine micro-algae species that are permitted in all foods.

Schedule 3 – Identity and purity includes specifications for the following oils derived from marine micro-algae species and fungi rich in DHA:

- oil derived from the algae *Cryptocodinium cohnii* rich in docosahexaenoic acid (DHA)
- oil derived from marine micro-algae (*Schizochytrium* sp.) rich in docosahexaenoic acid (DHA)
- oil derived from marine micro-algae (*Ulkenia* sp.) rich in docosahexaenoic acid (DHA)

All of these specifications refer to only the fatty acids DHA and trans fatty acids.

Schedule 29 – Special purpose foods (section S29—8) sets limits on the n-3 LC-PUFA content that may be present in infant formula products at a maximum of 1% total fatty acid content.

Standard 2.9.1 – Infant formula products controls the relative proportions of the specific LC-PUFA DHA and eicosapentaenoic acid (EPA).

² Productivity refers to how quickly the organisms grow and the cell densities.

1.3.2 Current proposals to amend the Code

The following two Proposals are currently reviewing the regulation of novel foods and nutritive substances, and infant formula. They intend to consider the broader issues relating to the regulation of micro-algal oils in infant formula products.

P1024 – Revision of the Regulation of Nutritive Substances & Novel Foods

[P1024](#)³ seeks to improve the regulation of novel foods and nutritive substances to ensure appropriate pre-market safety assessment of these foods before they are sold in Australia and New Zealand. The recent 1st call for submissions considered how to develop an alternative framework for the regulation of nutritive substances and novel foods in the Code. Although the approach implemented under P1024 for general foods may be able to be considered for infant formula products, FSANZ will consider infant formula products separately given the vulnerability of formula-fed infants and the current regulatory environment.

P1028 – Review of the Regulation of Infant formula

FSANZ is currently reviewing the fatty acid composition of infant formula and the regulatory approach for the addition of new substances to infant formula in [P1028](#)⁴. Submissions from stakeholders as part of this work have highlighted that there is currently a lack of clarity on the use of oil ingredients that contribute to the LC-PUFA component of infant formula. This issue has been discussed in the 2016 Consultation Paper and will be further considered in the next paper.

1.3.3 International and overseas regulations

This section covers regulation of both marine micro-algal oils and DHA in infant formula products. Several DHA-rich oils and other products derived from marine micro-algae species are permitted as novel foods and for use in infant formula products in many countries around the world. DHA permissions for infant formula products vary. Some countries permit the voluntary addition and some have a mandatory requirement.

1.3.3.1 Codex Alimentarius

The Codex Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants (Codex Standard 72-1981) does not contain specific provisions for marine micro-algal oils in infant formula and infant formula for special medical uses. However, it does list DHA as an optional ingredient with a guidance upper level GUL of 0.5% total fatty acids. The Codex standard also contains provisions for ‘optional ingredients’, which apply to the inclusion of substances such as DHA-rich algal oils. The Standard requires that the suitability of ‘optional ingredients’ must be “scientifically demonstrated; the formula must contain sufficient amounts of these substances to achieve intended effect, taking into account levels in human milk”.

1.3.3.2 North America

In 2015, the US Food and Drug Administration (USFDA) issued a letter stating that “the FDA has no questions at this time” regarding DSM’s conclusion that this particular algal oil is Generally Recognised as Safe (GRAS) under the intended conditions of use in infant formula. DHA is not listed as a required nutrient in infant formula in the Federal Food, Drug and Cosmetic Act (FFDCA) or the USFDA’s implementing regulations in Title 21 of the Code of Federal Regulations (21 CFR).

³ <http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1024revisio5756.aspx>

⁴ <http://www.foodstandards.gov.au/code/proposals/Pages/P1028.aspx>

However, several sources of DHA have been accorded a status as GRAS for use in infant formula.

In 2015, Health Canada issued a letter of no objection to “the sale of DHASCO-B to be added as a source of DHA to infant formula and follow-on formula”. DHA is not specifically listed in the Divisions B.25 (Infant formula) of the Canadian Food and Drug Regulations.

However, ‘nutritive substances normally contained in human milk’ are permitted to be added to infant formula if the amount of the substance in the product is equal to the amount present (per 100 available kilocalories) in human milk (section B.25.056 (a)).

1.3.3.3 European Union

Oil from the micro-algae *Schizochytrium* sp. (ATCC PTA-9695) has been authorised for use as a novel food ingredient for use in various food categories, including infant formula and follow-on formula in alignment with Directive 2006/141/EC and Commission Delegated Regulation (EU) 2016/127.

Directive 2006/141/EC allows for the addition of DHA on a voluntary basis. The recent Commission Delegated Regulation (EU) 2016/127 specifies mandatory addition of DHA to infant and follow-on formula within the range of 4.8 mg/100 kJ to 12 mg/100 kJ.

1.4 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure
- a pre-market safety assessment is required for any substance proposed to be used in infant formula products that does not have a history of safe use at the proposed level in these products in Australia and New Zealand.

1.5 Procedure for assessment

The Application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ has previously assessed several marine micro-algal DHA-rich oils for use in infant formula products. This alternative DHA-rich algal oil is proposed to be added to infant formula products at levels consistent with the current use of DHA oils and within the maximum 1% level of n-3 LC-PUFAs permitted in Standard 2.9.1.

The composition of the new strain of *Schizochytrium* sp. micro-algae and its oil are comparable to other currently permitted sources of DHA. Therefore the objective of this risk and technical assessment is to evaluate the safety of this new production strain of *Schizochytrium* species algae and the safety and suitability of DHA-B as an additional, replacement or alternative DHA oil source for infant formula products.

The risk and technical assessment conclusions (see SD1) can be summarised as follows:

- FSANZ concludes that the Applicant has provided sufficient technical data to ensure that DHA-B is suitable as an additional, alternative or replacement DHA oil source in infant formula products. The submitted data are considered adequate to define the hazard of DHA-B; define the nutritional adequacy of DHA-B and support the conclusion that DHA-B is a safe source of DHA for supplementation of infant formula products.
- No evidence was found of risk of genotoxicity, reproductive or developmental toxicity, or toxicity as a consequence of subchronic dietary consumption of either dried *Schizochytrium* or DHA-B by experimental animals. DHA-B was found to be bioequivalent to DHASCO[®] and to have no adverse effects in baby piglets at consumption levels higher than those likely to occur in formula-fed infants.
- There is no evidence to suggest that absorption, distribution, metabolism and excretion of DHA-B would be different to that of the other marine micro-algae oils.
- The fatty acids in DHA-B are normal components of edible oils.
- In general, the fatty acid composition of DHA-B is comparable to that of other micro-algal oils on the market. The DHA component is similar; the main difference between the products is the ratio of DHA to EPA. Any differences are nutritionally insignificant because the maximum amount of n-3 LC-PUFA that can be added to infant formula products is less than 14 mg/100 kJ.
- DHA-B was found to be bioequivalent to another micro-algal DHA-rich oil in piglets and infants.
- An analytical method (AOCS Ce 1b-89) is available for compliance of DHA oils against specifications contained within section S3—21 of the Code. The stability of DHA-B within a food matrix such as infant formula products is assured.

2.2 Risk management

Because infants are a vulnerable population group, infant formula products are regulated by highly prescriptive provisions for the composition and labelling of these products. Prior to being permitted for use in infant formula products, nutritive substances and novel foods need to be established as safe and to demonstrate that they provide a nutritive or health benefit for formula-fed infants.

The risk and technical assessment (SD1) identifies no public health and safety concern in relation to the use of DHA-B oil as an alternative to other approved sources of DHA in infant formula products, noting the maximum level of n-3 LC-PUFA of 1% of total fatty acids permitted in Standard 2.9.1. Therefore, permission for the use of oil derived from *Schizochytrium* sp. (ATCC PTA-9695) as a novel food for use in infant formula products only has been drafted in Schedule 25.

Standard 1.1.1–5(d) requires that specifications be included in Schedule 3 if a novel food is added to food or sold for use in food. Since no specifications exist in the primary sources listed in Schedule 3, a specification for oil derived from *Schizochytrium* sp. (ATCC PTA-9695) has been drafted. As discussed in the technical assessment (SD1), the fatty acid profile differs slightly from the generic specification already given for oil from *Schizochytrium* sp. In addition to limiting the DHA and trans fatty acid content, the specification includes a maximum for EPA as both DHA and EPA are regulated by Standard 2.9.1.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options.

Every submission on an application is considered the FSANZ Board. All comments are valued and all contribute to the rigour of our assessment. The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties are also notified via email about the availability of reports for public comment.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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.

At this stage, FSANZ considers that amending the Code to include permission for DHA-rich algal oil derived from *Schizochytrium* sp. (ATCC PTA-9695) as a novel food will have a trade enabling effect in Australia and New Zealand, but may have minimal adverse effects on international companies. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement is not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act.

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure.

A regulation impact statement (RIS) was not required as the Application is seeking permission for the voluntary addition of a replacement or alternative DHA-rich algal oil. FSANZ has a standing exemption from the OBPR from undertaking a RIS (Reference No. 14943) for amendments relating to voluntary requirements.

Affected parties include infant formula companies (industry) and government enforcement agencies. This is because permitting this new oil derived from *Schizochytrium* sp. (ATCC PTA-9695) will provide an alternative/additional source of DHA in infant formula products. Because the organism used to manufacture DHA-B is more productive when compared to other DHA-rich algal oils, the new oil provides a lower cost alternative source of DHA to infant formula manufacturers using DHA-rich algal oil as an ingredient.

In addition, there is likely to be a positive impact on trade as closer alignment with international regulations may allow for a single formulation and manufacturing of infant formula products for both local and overseas markets thereby potentially minimising production costs and reducing trade barriers.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

These standards apply in New Zealand and there are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a Risk and Technical Assessment (SD1) which considered the best available evidence. Based on this assessment, FSANZ has concluded that oil derived from *Schizochytrium* sp. (ATCC PTA-9695) is as safe as other LC-PUFA oils derived from micro-algal sources that are already permitted to be added to infant formula products.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The current provisions within the Code relating to the inclusion of micro-algal DHA-rich oils in the ingredient list on labels of infant formula products would also apply to DHA-B. Therefore, there would be no change to the level or type of information that would be required and available to carers when compared to the current labelling requirements.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, which aim to prevent misleading or deceptive conduct, would apply to the proposed amendment.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has applied a risk analysis approach to the consideration of this assessment which considered the best available evidence. Based on the risk and technical assessment (SD1), FSANZ has concluded that oil derived from *Schizochytrium* sp. (ATCC PTA-9695) is as safe as other n-3 LC-PUFA oils derived from micro-algae already permitted to be added to infant formula products.

- **the promotion of consistency between domestic and international food standards**

FSANZ has reviewed the relevant overseas regulations for infant formula products summarised in section 1.3.3. The proposed regulatory approach is in line with international guidelines and permissions and will promote consistency between domestic and international food standards.

- **the desirability of an efficient and internationally competitive food industry**

The preferred option is to permit the optional addition of oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695). This permission would be available to all manufacturers, allow for innovation, and is consistent with international and overseas regulations. This approach therefore supports an internationally competitive food industry.

- **the promotion of fair trading in food**

Several novel oils derived from marine micro-algae are already permitted as an optional ingredient in infant formula products. Extending the permission to include oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695) will be equitable for infant formula products, and allow infant formula products manufacturers to use alternative formulations that will continue to promote fair trade.

- **any written policy guidelines formulated by the Forum on Food Regulation**

A summary of FSANZ's consideration of this Application against the specific policy principles in the Ministerial Policy Guideline on the Regulation of Infant Formula Products is at SD2. The Ministerial Policy Guidelines that apply to this Application are listed below.

Ministerial Policy Guideline on the Regulation of Infant Formula Products

FSANZ considers that the [Ministerial Policy Guideline on the Regulation of Infant Formula Products](http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx)⁵ would be met if DHA-rich oil derived from *Schizochytrium* sp. (ATCC PTA-9695) were to be permitted as a source of oil in infant formula products. The relevant specific policy principles for composition are: (d), (e) (h) (i) and (j). Specific policy principles (a), (b), (f) and (g) are not applicable to this Application. These are further discussed in Table 1 of SD2.

Ministerial Council Policy Guidelines on Novel foods

FSANZ considers that the [Ministerial Policy Guideline on Novel Foods](http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx)⁶ has been met. As discussed above in relation to the Section 18(2) objectives, listing DHA-rich oil derived from *Schizochytrium* sp. (ATCC PTA-9695) as an alternative to permitted DHA-rich algal oils will be consistent with international approaches for these types of oils and infant formula products.

⁵ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

⁶ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

It will also provide a timely and cost effective response to the Applicant and industry more broadly which encourages industry growth, innovation and international trade.

3 Draft variation

The draft variation to the revised Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

4 References

ANZFA (2002) Supplementary Final Assessment Report. Proposal P93 – Infant Formula. Australia New Zealand Food Authority, Canberra
<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp93reviewofinfantformula/Default.aspx>

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1124 – Alternative DHA-rich Algal Oil for Infant Formula Products) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1124 – Alternative DHA-rich Algal Oil for Infant Formula Products) Variation*.

2 Variation to standards in the Australia New Zealand Food Standards Code

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] Schedule 3 is varied by

[1.1] inserting into the table to subsection S3—2(2), in alphabetical order

oil derived from marine micro-algae section S3—35
Schizochytrium sp. (American Type Culture
Collection (ATCC) PTA-9695)

[1.2] adding the following after section S3—34

S3—35 Specification for oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)

For oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695), the specifications are the following:

- (a) full chemical name—4,7,10,13,16,19-docosahexaenoic acid (22:6n-3 DHA);
- (b) DHA (%)—minimum 35;
- (c) EPA (%)—maximum 10;
- (d) *trans fatty acids (%)—maximum 2.0;
- (e) lead (mg/kg)—maximum 0.1;
- (f) arsenic (mg/kg)—maximum 0.1;
- (g) mercury (mg/kg)—maximum 0.1;
- (h) hexane (mg/kg)—maximum 0.3.

[2] Schedule 25 is varied by inserting into the table to section S25—2, in alphabetical order

Oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695)

- 1. May only be added to infant formula products in accordance with Standard 2.9.1.

Attachment B – Draft Explanatory Statement

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

FSANZ accepted Application A1124 which seeks to permit the addition of DHA-rich algal oil from *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) as an alternative or replacement oil for other currently permitted DHA-rich algal oils added to infant formula products.

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation setting out amendments to Schedule 3 and Schedule 25.

2. Purpose

The purpose of the draft variation is to permit the voluntary use of oil derived from marine micro-algae *Schizochytrium* sp. (American Type Culture Collection (ATCC) PTA-9695) as a source of DHA in infant formula products.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1124 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated assessment summary.

A Regulation Impact Statement was not required because the proposed variation is likely to have a minor impact on business and individuals, as the permission is for permission for the voluntary addition of a replacement or alternative DHA-rich algal oil.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1]

Item [1.1] amends Schedule 3 by inserting a reference into the table to subsection S3—2(2) to oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695) and to section S3—35.

Item [1.2] amends Schedule 3 by inserting new section S3—35 in that Schedule. The new section provides a specification for oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695).

Item [2]

Item [2] amends Schedule 25 by inserting a reference into the table to subsection S25—2 to oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695). The new reference contains a condition that the oil may only be added to infant formula products in accordance with Standard 2.9.1. The effect of the amendment is to provide a novel food permission for the use of the oil in only infant formula products.