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Approval report – A1124

Alternative DHA-rich Algal Oil for Infant Formula Products

Food Standards Australia New Zealand (FSANZ) assessed an application made by DSM Nutritional Products to permit an additional, replacement or alternative oil source of docosahexaenoic acid (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-9695. The oil is referred to as DHA-B throughout this report.

On 1 November 2016 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received four submissions.

FSANZ approved the draft variation on 9 March 2017. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 22 March 2017.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION	3
1.1 THE APPLICANT	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.3.1 <i>Australia New Zealand</i>	3
1.3.2 <i>Current proposals to amend the Code</i>	4
1.3.3 <i>International and overseas regulations</i>	4
1.4 REASONS FOR ACCEPTING APPLICATION	5
1.5 PROCEDURE FOR ASSESSMENT	5
1.6 DECISION	5
2 SUMMARY OF THE FINDINGS	5
2.1 SUMMARY OF ISSUES RAISED IN SUBMISSIONS	6
2.2 RISK ASSESSMENT	6
2.3 RISK MANAGEMENT	7
2.4 RISK COMMUNICATION.....	8
2.4.1 <i>Consultation</i>	8
2.5 FSANZ ACT ASSESSMENT REQUIREMENTS	8
2.5.1 <i>Section 29</i>	8
2.5.2 <i>Subsection 18(1)</i>	9
2.5.3 <i>Subsection 18(2) considerations</i>	9
6 REFERENCES	10
ATTACHMENT A – APPROVED DRAFT VARIATION TO THE <i>AUSTRALIA NEW ZEALAND FOOD STANDARDS</i> <i>CODE</i>	11
ATTACHMENT B – EXPLANATORY STATEMENT	13

Supporting documents

The [following 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/A1124DHAAIlgalOilinInfantFormula.aspx>

Executive summary

FSANZ assessed an Application from DSM Nutritional Products that sought approval of an additional, replacement or alternative oil source of docosahexaenoic acid (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-9695. For ease of reading, the oil is referred to as DHA-B throughout this report.

DHA-B was proposed to be added to infant formula products at levels consistent with the current uses of DHA oils; and within the 1% maximum level of omega-3 long chain polyunsaturated fatty acids (n-3 LC-PUFAs) permitted in Standard 2.9.1 in the *Australia New Zealand Food Standards Code*. Several novel oils derived from marine micro-algae are already permitted as optional ingredients in infant formula products. Thus, FSANZ had 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 therefore considered that guidance as part of the assessment of this Application.

FSANZ 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 prescribed levels in infant formula products only. The risk and technical assessment identified no risk to infant health and safety from the use of DHA-B oil as an alternative to other approved sources of DHA oil in infant formula products, noting the maximum level of n-3 LC-PUFA permitted in Standard 2.9.1.

FSANZ concluded that DHA-B is suitable as an additional or alternative source of DHA-rich algal oils for use in infant formula products. Therefore, FSANZ approved the use of DHA-B. Schedule 25 – Permitted novel foods and Schedule 3 – Identity and purity will be amended to include:

- 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-PUFA) are permitted as novel foods in the Australia New Zealand Food Standards Code (the Code). Oils containing docosahexaenoic acid (DHA) have been used in the manufacture of infant formula products since the mid-1990s. FSANZ had 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 sought permission for a DHA-rich marine micro-algal oil derived from a new production strain of *Schizochytrium* sp. known as American Type Cell Culture (ATCC) PTA-9695. The Applicant advised that this strain is more productive than other marine algal DHA-rich oils currently in the market². The Applicant also advised that the oil will be sold under the trade names DHASCO-B or DHA-B. For ease of reading, the oil is referred to as DHA-B throughout this report.

1.3 The current Standard

1.3.1 Australia New Zealand

In the Code, 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. Several DHA-rich oils derived from different marine micro-algae species are permitted for use 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. Although specifications for oil derived from the algae *Cryptocodinium cohnii* are listed in Schedule 3, they are not included in a specific standard in the Code.

Schedule 29 – Special purpose foods (section S29—8) sets a limit 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 n-3 LC-PUFA fatty acids 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

[Proposal 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 [Proposal P1028](#)⁴. Stakeholders' submissions to P1028 have highlighted a current lack of clarity on the use of oil ingredients that contribute to the LC-PUFA component of infant formula. This issue was discussed in the 2016 Consultation Paper and will be further considered.

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 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 purposes. However, DHA is listed 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 the 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). However, several sources of DHA have been accorded a status as GRAS for use in infant formula.

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

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

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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with one minor amendment. This was to renumber the new specification inserted into Schedule 3 to reflect new specifications inserted into Schedule 3 as a result of other approved applications.

The variation takes effect on gazettal. The approved draft standard is at Attachment A.

The related 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.

2 Summary of the findings

Four submissions were received; all supported the proposed variation to the Code, but with one subject to further information on product stability (see section 2.1).

2.1 Summary of issues raised in submissions

Table 1: Summary of issues

Issue	Raised by	FSANZ response
<p>The stability of DHA-B within powdered infant formula products (the most common variety in Australia) has not been demonstrated.</p> <p>The manufacturer is responsible for assuring the product is stable throughout its shelf life; however, the Applicant should provide information on the stability in all types of infant formula (powdered and liquid).</p>	<p>Victorian Departments of Economic Development, Jobs, Transport and Resources; and Health and Human Services.</p>	<p>FSANZ re-contacted the Applicant to request information specific to powdered infant formula products. Commercially confidential information was provided which FSANZ considered demonstrated acceptable stability of DHA-B in these products.</p>
<p>DHA-B is proposed for permission in infant formula products only, whereas other DHA sources are permitted in all foods.</p> <p>Suggests a clear explanation of this difference, and requests the reasoning behind this limited permission.</p>	<p>New Zealand Ministry for Primary Industries (MPI)</p>	<p>The Applicant sought permission for DHA-B only in infant formula products. Therefore the Assessment focussed on this specific request, as required in specific policy principle (i) in the infant formula products policy guideline.</p> <p>Broadening permissions to all other foods would require significant risk assessment for population groups other than infants, and dietary modelling which was considered out of scope for this Application.</p> <p>Also, previous Applications (e.g. A522) did not specifically request permission for infant formula products and/or other foods so were considered more broadly at that time.</p>
<p>Not all sources of DHA oils are listed as novel foods under Standard 1.5.1 – Schedule 25-2 i.e. <i>Cryptocodinium cohnii</i>, although specifications are provided in section S3-19 for this oil.</p>	<p>MPI</p>	<p>This lack of clarity in the Code is acknowledged and will be dealt with elsewhere e.g. under a relevant proposal such as P1028 or P1024, as it is out of scope of this Application.</p>

2.2 Risk assessment

FSANZ has previously assessed several marine micro-algal DHA-rich oils for use in infant formula products e.g. DHASCO and ARASCO oils were assessed under [Proposal P93](#)⁵ – Review of Infant formula, and determined to be “a safe source of LCPUFAs for supplementation of infant formula”. The composition of the new strain of *Schizochytrium* sp. micro-algae and its oil are comparable to other currently permitted sources of DHA.

⁵<http://www.foodstandards.gov.au/code/proposals/Pages/proposalp93reviewofinfantformula/Default.aspx>

Therefore, the objective of this risk and technical assessment was to evaluate the safety of this new production strain of *Schizochytrium* species algae, as an additional or alternative source of DHA oil for use in infant formula products. A wider assessment of the use of DHA-B in other foods was not undertaken as it was considered to be out of scope for this Application.

FSANZ's risk and technical assessment conclusions (see SD1) are summarised as follows:

- The Applicant provided sufficient technical data to demonstrate that DHA-B is suitable as an additional or alternative source of DHA oil for use in infant formula products. The submitted data were considered adequate to define the hazard of DHA-B; define the nutritional adequacy of DHA-B; and to support the conclusion that DHA-B is a safe source of DHA for supplementation of infant formula products.
- No evidence was found of reproductive or developmental toxicity, or toxicity as a consequence of subchronic dietary consumption of either dried *Schizochytrium* or DHA-B by experimental animals. The weight of evidence indicates that DHA-B is unlikely to be genotoxic.
- 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 found in a range of other 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.
- The oil was found to be bioequivalent to other DHA rich oils in the diet of piglets and human 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.

2.3 Risk management

As 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 demonstrate that they provide a nutritional or health benefit for formula-fed infants.

The risk and technical assessment (SD1) identified no public health and safety concern if DHA-B oil is used as an additional or alternative source of DHA in infant formula products, noting there is a set maximum level of n-3 LC-PUFA of 1% of total fatty acids in Standard 2.9.1. Therefore, permission for the use of oil derived from *Schizochytrium* sp. (ATCC PTA-9695) as a novel food, in infant formula products only, is included in Schedule 25.

This permission has not been extended to all other food categories as the risk assessment focussed specifically on infant formula products, as requested by the Application.

Section 1.1.1—15 requires that when a novel food is added to food in accordance with the Code, or sold for use in food, the novel food must comply with any relevant specification set out in Schedule 3. 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 for inclusion. As discussed in the 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.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. The process is open, accountable, consultative and transparent.

FSANZ applied a basic communication strategy to this Application. Public submissions were called for to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

All submissions have been considered by the FSANZ Board and contributed to the rigour of our assessment. The Applicant, individuals and organisations that made submissions on this Application were notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

A regulation impact statement was not required as the Application sought permission for the voluntary addition of an additional or alternative source of DHA-rich algal oil. FSANZ has a standing exemption from the OBPR from undertaking a RIS (Reference No. 14943) for amendments that permit voluntary addition of a nutritive substance to foods (which, in this case, has been more appropriately listed as a novel substance, for consistency with other DHA oils permitted in the Code).

Affected parties include infant formula companies (industry) and government enforcement agencies. The direct and indirect benefits that would arise from varying the food regulation as a result of this Application outweigh any costs to the Government, industry or community.

Permitting this new oil derived from *Schizochytrium* sp. (ATCC PTA-9695) will provide an additional or alternative source of DHA oil in infant formula products. Because the organism used to manufacture DHA-B is more productive when compared to the production of other DHA-rich algal oils, the new oil provides a lower cost source of DHA to infant formula manufacturers who use 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 reducing costs.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant standards in the Code apply in both Australia and New Zealand; and there are no related New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2. Subsection 18(1)

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

2.5.2.1 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 concluded that oil derived from *Schizochytrium* sp. (ATCC PTA-9695) is as safe as other n-3 LC-PUFA oils derived from micro-algal sources that are already permitted for use in infant formula products.

2.5.2.2 The provision of adequate information to enable consumers to make informed food 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 is no change to the level or type of information required for carers when compared to the current labelling of infant formula products.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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 for use in 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 proposed regulatory approach supports an internationally competitive food industry by permitting the optional addition of oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695). This permission will be available to all manufacturers, allows for innovation, and is consistent with international and overseas regulations.

- **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) is equitable for all infant formula products, and allows 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**

Two Ministerial Policy Guidelines apply to this Application. 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 – Assessment against the Policy Guidelines.

FSANZ considered that the [Ministerial Policy Guideline on the Regulation of Infant Formula Products](#)⁶ 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). These are further discussed in Table 1 of SD2. Specific policy principles (a), (b), (f) and (g) are not applicable to this Application.

FSANZ considered that the [Ministerial Policy Guideline on Novel Foods](#)⁷ 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 is consistent with international approaches for these types of oils and infant formula products. It also provides a timely and cost effective response to the Applicant and industry more broadly which encourages industry growth, innovation and international trade.

6 References

[ANZFA \(2002\) Supplementary Final Assessment Report. Proposal P93 – Infant Formula](#). Australia New Zealand Food Authority, Canberra

Attachments

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

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

⁷ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

Attachment A – Approved 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—36
<i>Schizochytrium</i> sp. (American Type Culture Collection (ATCC) PTA-9695)	

[1.2] adding the following after section S3—35

S3—36 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 – 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 additional or alternative source of DHA 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.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the Legislation Act 2003.

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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 1 November 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the variations proposed are voluntary and likely to have a minor impact on business and individuals.

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

Subitem [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—36.

Subitem [1.2] amends Schedule 3 by inserting new section S3—36 in that Schedule. The new section provides a specification for oil derived from marine micro-algae *Schizochytrium* sp. (ATCC PTA-9695).

Item [2] amends Schedule 25 by inserting a reference into the table to section 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.