

15 December 2010

[25-10]

APPLICATION A1030 CALCIUM LIGNOSULPHONATE (40-65) AS A FOOD ADDITIVE ASSESSMENT REPORT

Executive Summary

Purpose

On 26 June 2009, FSANZ received an Application from DSM Nutritional Products Australia Pty Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of calcium lignosulphonate (40-65). The Application seeks permission to use calcium lignosulphonate (40-65) as a carrier for fat-soluble vitamins (A, D, E and K) and carotenoids (e.g. β -carotene, carotenal, β -apo-8', lutein, lycopene, etc) in preparations of food additives and nutrients to facilitate their introduction into water-based foods (foods, including drinks, that contain water as an ingredient or component, or as part of their production). The purpose of using calcium lignosulphonate (40-65) is to assist in ensuring uniform dispersal and distribution of water insoluble vitamins and carotenoids into water based foods and beverages.

The Applicant proposes calcium lignosulphonate (40-65) as an alternative substance to commonly used substances for this purpose, such as gelatines, gum arabic (also called gum acacia), soy protein hydrolysate or starches. For some food manufacturers the use of these materials can cause difficulties. In particular gelatines potentially have allergen labelling requirements, and may have kosher/halal problems. The use of some hydrolysate or starches derived from soy may give rise to concerns due to supply from genetically modified sources. The Applicant claims that calcium lignosulphonate (40-65) does not have these drawbacks.

The Applicant requested FSANZ to assess and permit calcium lignosulphonate (40-65) as a processing aid (with a function as a carrier). However FSANZ considers the substance functions as a food additive (as an emulsifier and stabiliser) for the purpose proposed in the Application. Therefore, a change to Standard 1.3.1 – Food Additives of the Code would be required if the Application is accepted.

Prior to any approval being granted to a substance as a food additive a pre-market assessment is required.

The Application is being assessed under the General Procedure.

Risk Assessment

A risk assessment has been performed as part of the assessment of the Application. This risk assessment was undertaken to establish the technological aspects and properties of how the substance performs the role requested by the Application. The risk assessment also investigated any risks to public health and safety, including nutritional risk.

The evidence presented in support of the Application provides adequate assurance that calcium lignosulphonate (40-65) is technologically justified, as an emulsifier and stabiliser in the addition of encapsulated fat-soluble active ingredients to aqueous foods.

Setting an acceptable daily intake (ADI) is necessary based on the available toxicological data. An ADI of 0-20 mg/kg bodyweight (bw) (rounded value) for calcium lignosulphonate (40-65) has been established based on a 13-week dietary study in rats that obtained a NOAEL of 1978 mg/kg bw/day for males and 2040 mg/kg bw/day for females. This ADI includes 10-fold safety factors for both intra- and inter-species variability giving an overall 100-fold safety factor. An additional safety factor for the absence of a chronic toxicity study of calcium lignosulphonate (40-65) was not considered to be necessary because of the poor absorption of calcium lignosulphonate (40-65) and the absence of any adverse effects in a 13-week study.

This approach differs from the conclusion of the European Food Safety Authority (EFSA). They assessed calcium lignosulphonate (40-65) for use as a carrier for vitamins and carotenoids in 2010. However, the EFSA scientific opinion concluded that the safety of use of the substance as a carrier for vitamins and carotenoids intended to be added to foods could not be assessed due to a lack of suitable animal studies. The EFSA Panel considered that the available studies are insufficient to establish an ADI.

Predicted dietary exposures to calcium lignosulphonate (40-65) were assessed as low, using the proposed food groups and concentration data provided by the Applicant, and the best available consumption data for the Australian and New Zealand populations. Predicted mean dietary exposures were less than 20% of the reference health standard (ADI) of 20 mg/kg bw/day for all population groups assessed, while 90th percentile exposures were less than 30% of the reference health standard for all population groups assessed. These estimates were based on very conservative assumptions so as not to underestimate the potential exposure.

Given the conservative nature of this dietary exposure assessment, and the low exposures that have been obtained, FSANZ does not expect that intakes will exceed the ADI for calcium lignosulphonate (40-65).

Data from a suitable animal model show that the use of calcium lignosulphonate (40-65) as a carrier of fat-soluble nutrients is likely to result in the same gastrointestinal absorption of these nutrients as occurs with the use of another common carrier agent. There is also indirect evidence suggesting that calcium lignosulphonate (40-65) presents fat-soluble nutrients to the gastrointestinal system in an arrangement that allows for normal digestion and absorption of these nutrients.

The use of calcium lignosulphonate (40-65) could result in the capture of fat-soluble nutrients from other dietary sources into a calcium lignosulphonate (40-65) oil mixture. However, this scenario is unlikely to result in any interference with the normal digestion and absorption of these nutrients.

To summarise, FSANZ concludes that calcium lignosulphonate (40-65) is technologically justified for the purpose proposed by the Applicant as a food additive to assist the incorporation of oil soluble vitamins and carotenoids to aqueous foods. There are no public health and safety concerns with approving the substance as a food additive.

Risk Management

When the proposed purpose of the Application is considered, the risk assessment concludes that calcium lignosulphonate (40-65) acts as a food additive and not as a processing aid. The reason for this conclusion is that calcium lignosulphonate (40-65) performs a technological function as a food additive in the final food, not just during the processing of the food (further explained in section 2.2). The risk assessment further concluded that use of the substance as proposed by the Applicant for the highest consumers of the substance from dietary modelling produced exposures 30% or less than the determined reference health standard (i.e. the ADI). FSANZ therefore determined that it is appropriate to permit calcium lignosulphonate (40-65) as a generally permitted food additive that can be used under conditions of Good Manufacturing Practice (GMP) in appropriate processed foods. Therefore, the substance is proposed to be added to Schedule 2 of Standard 1.3.1. The proposed permission would be comparable to those permitted for alternative food additives used for the same purpose. This permission also requires consequential changes to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients.

Food additives are required to be labelled when they are added to processed foods, which will be the case for calcium lignosulphonate (40-65). In contrast processing aids are exempted from labelling. Therefore, there are labelling implications from FSANZ's proposed approach to permit the substance as a food additive and not a processing aid.

Assessing the Application

In assessing the Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters as prescribed in section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act):

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the Application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure to permit calcium lignosulphonate (40-65) as a carrier to add fat-soluble vitamins and carotenoids to water based food.
- Whether other measures (available to the Authority or not) would be more cost-effective than a variation to Standard 1.3.1 that could achieve the same end.
- Any relevant New Zealand standards.
- Any other relevant matters.

Preferred Approach

To prepare draft variations to Standards 1.2.4 and 1.3.1 to allow the use of calcium lignosulphonate (40-65) as a GMP food additive to assist in adding fat soluble vitamins and carotenoids to water-based foods.

Reasons for Preferred Approach

- The Risk Assessment Report concludes that for the purpose proposed by the Applicant, the substance has a technological function as a food additive and not as a processing aid as requested by the Applicant.
- The risk assessment concluded that there is a need to establish an ADI for the substance but the dietary exposure assessment concluded that it is safe to be added to water based foods in accordance with GMP. This is because there would not be any risk of exceeding this reference health standard for the Australia and New Zealand populations.
- The risk assessment concludes that there are no detrimental nutritional outcomes from adding the substance to food.
- Permitting use of the substance would not impose significant costs for government agencies, consumers or manufacturers.
- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards.

Consultation

Public submissions are now invited on this Assessment Report. Comments are specifically requested on the scientific aspects of this Application, in particular on the technological function of calcium lignosulphonate (40-65) to incorporate fat-soluble vitamins and carotenoids to be added to water based foods. FSANZ also seeks comments on the Risk Assessment Report dealing with the safety assessment of the substance and the dietary exposure to consumers of the substance when used as proposed in the Application.

As this Application is being assessed as a general procedure, there will be one round of public comment. Submissions to this Assessment Report will be considered in developing the Approval Report.

Invitation for Submissions

FSANZ invites public comment on this Report and the draft variations to the Code based on regulation impact principles for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in further considering this Application. Submissions should, where possible, address the objectives of FSANZ as set out in section 18 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information, separate it from your submission and provide justification for treating it as confidential commercial material.

Section 114 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Changing the Code](#) tab and then through [Documents for Public Comment](#). Alternatively, you may email your submission directly to the Standards Management Officer at submissions@foodstandards.gov.au. There is no need to send a hard copy of your submission if you have submitted it by email or the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR PUBLIC SUBMISSIONS: 6pm (Canberra time) 9 February 2011

SUBMISSIONS RECEIVED AFTER THIS DEADLINE WILL NOT BE CONSIDERED

Submissions received after this date will only be considered if agreement for an extension has been given prior to this closing date. Agreement to an extension of time will only be given if extraordinary circumstances warrant an extension to the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions relating to making submissions or the application process can be directed to the Standards Management Officer at standards.management@foodstandards.gov.au.

If you are unable to submit your submission electronically, hard copy submissions may be sent to one of the following addresses:

**Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222**

**Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 978 5636**

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Assessment Report, is available on the FSANZ website at:

<http://www.foodstandards.gov.au/foodstandards/applications/applicationa1030calc4429.cfm>

SD1 Risk Assessment Report

Introduction

On 26 June 2009, FSANZ received an Application from DSM Nutritional Products Australia Pty Ltd to amend the *Australia New Zealand Food Standards Code* (the Code) to permit the use of calcium lignosulphonate (40-65) as a carrier. The carrier was proposed to be used to add fat-soluble vitamins (A, D, E and K) and carotenoids (e.g. β -carotene; carotenal, β -apo-8'; lutein; lycopene; etc) in preparations of food additives and nutrients to facilitate their introduction into water-based foods (foods, including drinks, that contain water as an ingredient or component, or as part of their production). The Applicant claims calcium lignosulphonate (40-65) acts as a processing aid when it is used as a carrier for the proposed purpose of the Application and so requested that Standard 1.3.3 – Processing Aids be amended if the Application is accepted and permission for use is approved.

FSANZ accepted the Application on 17 July 2009 after an Administrative Assessment. FSANZ commenced its assessment of the Application in the first quarter of 2010.

Fat soluble vitamins (also called lipophilic vitamins) and various carotenoids are often susceptible to light and oxidation, as well as being difficult to disperse uniformly in water based foods including drinks. These nutrients are not naturally readily soluble or able to be evenly and uniformly dispersed in aqueous foods and beverages. To overcome these food manufacturing difficulties the vitamins and carotenoid colours are often encapsulated so they are suitable to be incorporated into water-based processed foods. Encapsulation means ensuring the active ingredient (e.g. the vitamin or carotenoid) is finely dispersed and embedded in a matrix which has a protective, stabilising and bulking effect to assist in uniformly dispersing the active ingredient within the water-based food matrix.

There are a number of encapsulating agents (commonly called carriers) that food manufacturers can use to protect and aid in incorporating nutrients that are normally poorly soluble in water into water-based foods. A number of commonly used carriers are gelatines, gum arabic (also called gum acacia), soy protein hydrolysate or starches. For some food manufacturers the use of these carriers can cause difficulties. The Applicant argues that gelatines, being of animal origin, have disadvantages in not being kosher or halal, have perceived BSE issues if from bovine sources and potential allergen labelling issues if sourced from fish. Soy protein hydrolysate or starches may have genetically modified (GM) labelling issues (if sourced from soy that may include GM soy). The Applicant claims that calcium lignosulphonate (40-65) does not have these potential disadvantages.

1. The Issue / Problem

Processing aids and food additives are not permitted to be used in the manufacture of food unless there is a specific permission for their use in Standard 1.3.3 and Standard 1.3.1 respectively. There is currently no permission for the use of calcium lignosulphonate (40-65) in the Code. FSANZ is therefore required to make an assessment of the Application to determine whether permission for the use of calcium lignosulphonate (40-65) for the proposed purpose as outlined in the Application can be granted.

In order to determine whether calcium lignosulphonate (40-65) is more appropriately considered to be a processing aid or a food additive the technological function it performs requires investigation i.e. whether it is a processing aid carrier as the Applicant claims or whether the substance is better described as a food additive having one of the technological functions in Schedule 5 of Standard 1.3.1 – Food Additives, in the final food. Schedule 5 does not define 'carrier' as a technological function for a food additive.

2. Background

2.1 Technological background of how calcium lignosulphonate (40-65) functions

The purpose of the use of calcium lignosulphonate (40-65) is to incorporate fat soluble vitamins and carotenoids that are not water soluble or easily able to be uniformly dispersed in the aqueous phase of water-based foods. The technology has been used in the food industry for many years.

Currently the food manufacturing industry uses different types of materials to ensure uniform dispersal and distribution of water insoluble vitamins and carotenoids into water based foods and beverages. The specific vitamins are vitamin A, D, E and K that are soluble in oil (therefore being termed lipophilic) while carotenoids are not really oil soluble but are able to be dispersed in oil. These vitamins and carotenoids are sensitive to light and oxidation and are difficult to uniformly disperse into water based foods.

To help protect them and to assist in being able to incorporate them into water based foods the active nutrients are first dissolved or dispersed in oil, with added antioxidant (for example, tocopherol) in fine oil droplets (0.2-0.4 µm diameter). These oil droplets are treated so they are coated by water soluble material (such as gelatine, gum acacia (gum arabic), soy protein hydrolysate or starches, such as octenylsuccinate starch), and embedded in a particle of this material or another material. This occurs as an emulsification of oil droplets (lipophilic phase) with a hydrophilic phase followed by processes that produce small dry particles of the emulsion which contains the embedded oil droplets. This is where the term encapsulation is used; the small oil droplets containing the nutrients are embedded or encapsulated in a larger particle (100 µm).

When the particles containing the oil droplets are dissolved in water or aqueous solution the surrounding matrix is dissolved releasing the oil droplets. The small oil droplets are coated by a thin layer that acts as an emulsifier to assist in dispersing the oil phase in the immiscible aqueous phase. The thin coating and the small size of the droplets also ensure uniform dispersal and prevent aggregation of the droplets to form either an oil film on the surface or large oil drops. The surface coating may have lipophilic (oil loving) sections, to assist in solubilising in the oil and hydrophilic (water loving) sections to solubilise the droplets in water. By performing this function the coating material acts as an emulsifier. Having surface charges on the coatings repels the droplets so assisting in stabilising the emulsion, and ensuring uniform dispersal.

The Applicant provided information in the Application, and review references, explaining how calcium lignosulphonate (40-65) performs its technological function to assist in protecting and presenting fat soluble vitamins and carotenoids to water based foods and beverages. A more detailed discussion of the technical aspects is provided in section 4.1 of the Risk Assessment Report (Supporting Document 1). The function is loosely described as encapsulation though this term does not fully explain the function calcium lignosulphonate (40-65) has for adding nutrients to food during food manufacturing and in the final food that is consumed.

The Applicant proposes using calcium lignosulphonate (40-65) to act as the coating material.

Calcium lignosulphonate (40-65) is proposed by the Applicant as an alternative to the hydrophilic phase, such as gelatine, gum acacia, starches etc. It is suggested as an alternative since it has good technical advantages to produce particles of embedded oil droplets of the appropriate size.

2.2 Does calcium lignosulphonate (40-65) function as a processing aid or food additive?

FSANZ has assessed the function of the substance as described and explained by the Applicant, in the Application and in extra information and references provided by the Applicant. The conclusion from this assessment is that for the purpose proposed by the Applicant, in the final food calcium lignosulphonate (40-65) functions as a food additive and not a processing aid. The reason for this conclusion is that the substance maintains its technological function in the final food and not just during the production and manufacture of the food. This function can be variously described as an emulsifier and stabiliser to ensure stable incorporation and emulsion of water insoluble phases in an aqueous media and their uniform dispersal by preventing aggregation of the small particles and droplets. Emulsifier and stabiliser are two technological functions of food additives listed in Schedule 5 (Technological functions which may be performed by food additives) in Standard 1.3.1.

As explained in section 2.3 the Codex Committee on Food Additives (CCFA) determined that calcium lignosulfonate (note alternative spelling) (40-65) was a food additive with a food additive INS number of 1522, and functional class as carrier and encapsulating agent (which are not food additive technological functions in the Code).

2.3 International permissions

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed calcium lignosulfonate (40-65) in 2008 and assigned an acceptable daily intake (ADI) of the substance of 0-20 mg/kg bodyweight per day (WHO, 2009). From this analysis JECFA also performed a dietary exposure of the substance and concluded that it was below the ADI even at extreme consumption levels when used as a carrier for fat-soluble vitamins and carotenoids in both food and supplements.

JECFA also wrote specifications (JECFA 2009) and a Chemical and Technical assessment for calcium lignosulfonate (40-65) (JECFA 2008).

The Codex Committee on Food Additives (CCFA) assigned calcium lignosulfonate (40-65) a food additive INS number of 1522 and functional class as carrier and encapsulating agent at the 41st session in March 2009 (CCFA, 2009). The CCFA did not take any further action relating to calcium lignosulfonate (40-65) at the 42nd session in March 2010, since no proposals for use of the substance for inclusion in the Codex General Standard for Food Additives (GSFA) had been forwarded in response to a request for information on uses and use levels of the substance sent to the members of the CCFA.

In Europe the European Food Safety Authority (EFSA) assessed calcium lignosulphonate (40-65) for use as a carrier for vitamins and carotenoids in 2010. The EFSA scientific opinion (EFSA, 2010) concluded that the safety of use of the substance as a carrier for vitamins and carotenoids intended to be added to foods could not be assessed due to a lack of suitable animal studies. The EFSA Panel considered that the available studies were insufficient to establish an ADI.

Lignosulphonates are approved generically as feed additives in the European Community in the European Commission Directive 70/524/EEC.

In the United States, calcium lignosulfonate is approved as a dispersion agent and stabiliser in pesticides for preharvest or postharvest applications to bananas (Title 21, Code of Federal Regulations section 172.715).

However, the Applicant notes that their more specific calcium lignosulphonate (40-65) substance has higher purity, lower content of reducing sugars and a higher degree of polymerisation than the more generic substance calcium lignosulfonate which has a purity specification in the Food Chemicals Codex VI, 2008.

3. Current Standard

The use of food additives in food is regulated by Standard 1.3.1. A food additive may only be added to food where it performs an identified technological function as listed in Schedule 5 of Standard 1.3.1. Permissions to add food additives to food are listed in Schedules 1-4 of Standard 1.3.1.

There is no permission for calcium lignosulphonate (40-65) or any other form of calcium lignosulphonate as a food additive in the Code. There are also no permissions for calcium lignosulphonate (40-65) as a processing aid or calcium lignosulphonate anywhere else in the Code.

Processing aids used in food manufacture are regulated under Standard 1.3.3.

4. Objectives

The objective of this Assessment is to determine whether it is appropriate to amend the Code to permit the use of calcium lignosulphonate (40-65) to be used to incorporate oil-soluble vitamins and carotenoids into water-based foods.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 18 of the FSANZ Act. These are:

- the protection of public health and safety; and
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

The Ministerial Council Policy Guideline, *Addition to Food of Substances other than Vitamins and Minerals*, includes specific order policy principles for substances added to achieve a solely technological function, such as food additives and processing aids. These specific order policy principles state that permission should be permitted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose'); and
- the addition of the substance to food is safe for human consumption; and
- the amounts added are consistent with achieving the technological function; and
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and
- no nutrition, health or related claims are to be made in regard to the substance.

5. Questions to be answered

For this Application, FSANZ has considered the following risk assessment questions.

1. Is the substance (in the quantity and form proposed by the Applicant) able to achieve the stated purpose; that is, is its use technologically justified?
2. Is there a need to establish a reference health standard for calcium lignosulphonate (40-65) in order to protect public health and safety? If so, what should this be?
3. If a reference health standard is established for calcium lignosulphonate (40-65), then the following questions also apply:
 - What is the estimated dietary exposure to calcium lignosulphonate (40-65) for the Australian and New Zealand populations?
 - Will Australian and New Zealand population intakes of calcium lignosulphonate (40-65) exceed the reference health standard as a result of this Application?
4. Are there any adverse nutritional outcomes associated with the Applicant's proposed use of calcium lignosulphonate (40-65) as a carrier of fat-soluble nutrients?
 - Does calcium lignosulphonate (40-65) release the carried fat-soluble nutrient for use by the human body?
 - Will calcium lignosulphonate (40-65) encapsulate and decrease the availability of free nutrients in the food matrix once the carried fat-soluble nutrient has been delivered into the food?
 - Will the gastrointestinal absorption of fat-soluble nutrients be impaired by the use of calcium lignosulphonate (40-65) as their carrier?

RISK ASSESSMENT

The Risk Assessment Report (**SD1**) provides the detailed technical assessment used to produce the summary and conclusions to address the questions written in the section above.

6. Risk Assessment Summary

6.1 Technological Function

6.1.1 *Is the substance (in the quantity and form proposed by the Applicant) able to achieve the stated purpose; that is, is its use technologically justified?*

The evidence presented in support of the Application provides adequate assurance that calcium lignosulphonate (40-65) is technologically justified, as an emulsifier and stabiliser in the addition of encapsulated fat-soluble active ingredients to water-based foods.

6.2 Safety Assessment

6.2.1 *Is there a need to establish a reference health standard for calcium lignosulphonate (40-65) in order to protect public health and safety? If so, what should this be?*

An acceptable daily intake (ADI) is necessary based on the available toxicological data. An ADI of 0-20 mg/kg bw (rounded value) for calcium lignosulphonate (40-65) has been established based on a 13-week dietary study in rats that obtained a NOAEL of 1978 mg/kg bw/day for males and 2040 mg/kg bw/day for females. This ADI includes 10-fold safety factors for both intra- and inter-species variability giving an overall 100-fold safety factor. An additional safety factor for the absence of a chronic toxicity study of calcium lignosulphonate (40-65) was not considered to be necessary because of the poor absorption of calcium lignosulphonate (40-65) and the absence of any adverse effects in a 13-week study.

6.3 Dietary Exposure Assessment

6.3.1 *If a reference health standard is established for calcium lignosulphonate (40-65), then the following questions also apply:*

- *What is the estimated dietary exposure to calcium lignosulphonate (40-65) for the Australian and New Zealand populations?*
- *Will Australian and New Zealand population intakes of calcium lignosulphonate (40-65) exceed the reference health standard as a result of this Application?*

Predicted dietary exposures to calcium lignosulphonate (40-65) were low using the proposed food groups and concentration data provided by the Applicant, and the best available consumption data for the Australian and New Zealand populations. Predicted mean dietary exposures were less than 20% of the reference health standard, while 90th percentile exposures were less than 30% of the reference health standard for all population groups assessed. These estimates were based on very conservative assumptions so as not to underestimate the potential exposures.

Given the conservative nature of this dietary exposure assessment, and the low exposures that have been obtained, FSANZ does not expect that intakes will exceed the ADI for calcium lignosulphonate (40-65).

6.4 Nutritional Assessment

6.4.1 *Are there any adverse nutritional outcomes associated with the Applicant's proposed use of calcium lignosulphonate (40-65) as a carrier of fat-soluble nutrients?*

Data from a suitable animal model show that the use of calcium lignosulphonate (40-65) as a carrier of fat-soluble nutrients is likely to result in the same gastrointestinal absorption of these nutrients as occurs with the use of another common carrier agent. There is also indirect evidence suggesting that calcium lignosulphonate (40-65) presents fat-soluble nutrients to the gastrointestinal system such that normal digestion and absorption of these nutrients can occur.

The use of calcium lignosulphonate (40-65) could result in the capture of fat-soluble nutrients from other dietary sources into a calcium lignosulphonate (40-65) oil mixture. However, this scenario is unlikely to result in any interference with the normal digestion and absorption of these nutrients.

On the basis of this evidence, FSANZ concludes that the use of calcium lignosulphonate (40-65) as a carrier of fat-soluble nutrients is unlikely to result in any adverse nutritional outcomes.

Risk Management

7. Issues raised

7.1 Risk Management Strategy

As explained in section 2.2 of the Report and in section 4.2 of **SD1**, FSANZ concludes that calcium lignosulphonate (40-65) acts as a food additive and not as a processing aid for the purpose proposed in the Application. That is, to assist to incorporate oil soluble vitamins and carotenoids in water based foods.

Based on the outcome of the risk assessment FSANZ concludes that it is appropriate to permit calcium lignosulphonate (40-65) as a generally permitted food additive that can be used under conditions of Good Manufacturing Practice (GMP) in appropriate processed foods. That is, the substance can be added to Schedule 2 (Miscellaneous additives permitted to GMP in processed foods specified in Schedule 1) of Standard 1.3.1. Permitting calcium lignosulphonate (40-65) to be used at GMP means food manufacturers need to use the minimum amount necessary to achieve the desired purpose. Some of the currently used substances that perform the same function as calcium lignosulphonate (40-65) are also permitted in Schedule 2 of Standard 1.3.1. These are gum arabic (also called acacia gum) with INS 414 and various starches with INS numbers of 1400s.

The proposed drafting, to permit calcium lignosulphonate (40-65) as a food additive permitted at GMP, in Schedule 2 of Standard 1.3.1 and the consequential changes to Schedule 2 of Standard 1.2.4 – Labelling of Ingredients is provided in **Attachment 1**.

7.2 Labelling implications

The Applicant sought approval for the use of calcium lignosulphonate (40-65) as a processing aid. Under paragraph 3(d) of Standard 1.2.4, processing aids are exempt from ingredient labelling.

However, based on the information provided by the Applicant, FSANZ considers that calcium lignosulphonate (40-65) functions as a food additive rather than a processing aid (see section 3.2). Food additives must be labelled in accordance with clause 8 of Standard 1.2.4. Under this clause, where a food additive can be classified in one of the classes of additives listed in Schedule 1 of the Standard, the additive must be declared in the statement of ingredient by the name of that class followed by the additive's specific name or code number in brackets. Therefore calcium lignosulphonate (40-65) would be declared as either [class](calcium lignosulphonate (40-65)) or [class](1522).

7.3 Analytical methods for determining presence of calcium lignosulphonate (40-65) in food

The Applicant states in their Application that there is no analytical method available that quantifies the amount of calcium lignosulphonate (40-65) that would be present in the final food. The Chemical and Technical Assessment Report written by JECFA on calcium lignosulphonate (40-65) makes the same statement.

The Applicant further argues that there will only be small amounts of the substance in the final food. An analytical method has not been developed due to the difficulties inherent in detecting a complex polymer of varying size, in low concentrations, within complex and varying food matrices.

FSANZ agrees that an analytical method to determine the presence of the substance in the final food is neither appropriate nor necessary. Various analytical methods are however available to determine the presence of the active ingredient (e.g. the fat soluble vitamin or carotenoid) encapsulated using calcium lignosulphonate (40-65). It is possible that the analytical methods to check for compliance with the JECFA specification could be adapted to check for the presence of the substance in the food, but this seems unlikely to be a practical method to discriminate the substance from the complex food matrix

FSANZ concludes that an analytical method to determine the presence (or to quantify the amount) of the substance in the final food is neither appropriate nor necessary.

8. Options

Food additives require a pre-market approval under Standard 1.3.1 before they can be used in food manufacture. Therefore, it is not appropriate to consider non-regulatory options. Consequently, two regulatory options are considered for this Application. They are:

Option 1 Reject the Application

Option 2 Accept the Application and permit the use of calcium lignosulphonate (40-65) as a food additive

9. Impact Analysis (RIS ID: 11376)

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The benefits and costs associated with the proposed amendments to the Code have been analysed using regulatory impact principles.

In accordance with the Best Practice Regulation Guidelines, completion of a preliminary assessment for this Application indicated a low or negligible impact.

The Office of Best Practice Regulation has advised that the Application appears to have no to low regulatory impacts on business and individuals and no further regulatory impact analysis, in the form of a Business Cost Calculator or Regulation Impact Statement, is required.

9.1 Affected Parties

The affected parties for this Application may include:

- those sectors of the food manufacturing industry who wish to use calcium lignosulphonate (40-65) to incorporate oil-soluble vitamins and carotenoids to water based foods
- consumers of food produced using calcium lignosulphonate (40-65) as a food additive
- Government agencies with responsibility for compliance and enforcement of the Code.

9.2 Benefit Cost Analysis

OBPR has deemed that a cost benefit analysis for this Application is not required.

However, FSANZ notes that the permission of calcium lignosulphonate (40-65) proposed as a food additive is as an alternative to currently permitted and used substances for the same proposed purpose. That indicates that use of calcium lignosulphonate (40-65) for the proposed purpose is voluntary. Food manufacturers will use a range of factors to determine which substance they use for the purpose. Such factors will include cost, suitability for the desired purpose, any labelling requirements and the benefit of adding the nutrients to the food product. The potential benefit for consumers are that nutrients are added to the food product that may otherwise not be.

Approving a new food additive may impose an added modest cost to government enforcement agencies, to widen the scope of their activities.

On balance there is expected to be a net benefit to stakeholders from approving calcium lignosulphonate (40-65) as a new food additive.

9.3 Comparison of Options

Given that the acceptance of this Application imposes no financial burden on any sector of the community, and given that the use of this substance raises no public health and safety issues, option 2 is the preferred option.

Communication and Consultation Strategy

10. Communication

FSANZ has developed and will apply a basic communication strategy to this Application. The strategy involves notifying subscribers and any interested parties of the availability of the assessment reports for public comment and placing the reports on the FSANZ website.

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

The issues raised in the public submissions are evaluated and addressed in the subsequent Approval Report.

The Applicant, individuals and organisations making submissions on this Application will be notified at each stage of the consideration of the Application. If the FSANZ Board approves the draft variations to the Code, FSANZ will notify its decision to the Ministerial Council. The Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

11. Consultation

FSANZ is seeking comment from the public and other interested stakeholders to assist in assessing this Application. Once the public comment period has closed there will be no further round of public comment.

FSANZ seeks comments in relation to the scientific aspects of the Application as well as the proposed drafting to the Code. In particular these are the questions detailed in section 5 of this Report. In summary they relate to the:

- Technological function of calcium lignosulphonate (40-65) as it is proposed to be used for the stated purpose explained by the Application. For this stated purpose does it function as a processing aid (carrier) or a food additive? If as a food additive, is it appropriate for the substance to be added to Schedule 2 of Standard 1.3.1 as a GMP food additive as permitted by Schedule 1.
- Hazard assessment. Are there any safety concerns with using calcium lignosulphonate (40-65) in the manufacture of food?
- Dietary exposure assessment. If a reference health standard is required does dietary modelling indicate there are any public health and safety concerns with any consumers exceeding such a reference health standard?
- Nutrition assessment. Does the addition of calcium lignosulphonate (40-65) to food for the proposed stated purpose cause any nutritional issues for consumers? In particular are there likely to be bioavailability concerns for added vitamins and carotenoids, or other nutrients in the food and gastrointestinal tract?

11.1 World Trade Organization (WTO)

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

There are no relevant international standards directly related to calcium lignosulphonate (40-65) use in food. Amending the Code to allow calcium lignosulphonate (40-65) to be used to incorporate oil-soluble vitamins and carotenoids to water based foods is unlikely to have a significant effect on international trade. Calcium lignosulphonate (40-65) is not permitted as a food additive in the Codex General Standard for Food Additives, but it has been assessed and approved as a food additive by the Codex Committee on Food Additives and assigned a food additive number. Therefore, notification to WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreements is not considered necessary.

Conclusion

12. Conclusion and Preferred Option

This Application has been assessed against the requirements of section 29 of the FSANZ Act with FSANZ recommending the proposed draft variations to Standard 1.3.1 (and the consequential amendments to Standard 1.2.4 – Labelling of Ingredients).

The Assessment Report concludes that calcium lignosulphonate (40-65) is technologically justified as a food additive for the purpose of incorporating oil soluble and dispersible nutrients (fat soluble vitamins and carotenoids) in aqueous based foods. Use of calcium lignosulphonate (40-65) for this purpose does not pose a public health and safety risk.

Therefore the preferred option, based on the available scientific information, is to prepare draft variations to the Code giving permission for calcium lignosulphonate (40-65) as a Schedule 2 food additive in Standard 1.3.1.

The proposed draft variations are provided in **Attachment 1**.

Preferred Approach

To prepare draft variations to Standards 1.2.4 and 1.3.1 to allow the use of calcium lignosulphonate (40-65) as a GMP food additive to assist in adding fat soluble vitamins and carotenoids to water-based foods.

Reasons for Preferred Approach

- The risk assessment concludes that the substance has a technological function as a food additive for the purpose as proposed by the Applicant and not as a processing aid as requested by the Applicant.
- The risk assessment concluded that there is a need to establish an ADI but the dietary exposure assessment concluded that it is safe to be added to water based foods in accordance with GMP, since there would not be any risk of exceeding this reference health standard for the Australia and New Zealand populations.
- The nutritional assessment concludes that there are no detrimental nutritional impacts of adding the substance to food.
- Permitting use of the substance would not impose significant costs for government agencies, consumers or manufacturers.
- The proposed draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.
- There are no relevant New Zealand standards

13. Implementation and Review

Following the consultation period for this Assessment Report an Approval Report will be completed and the draft variations will be considered for approval by the FSANZ Board. The FSANZ Board's decision will then be notified to the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council).

Following notification, the proposed draft variations to the Code are expected to come into effect on gazettal, subject to any request from the Ministerial Council for a review of FSANZ's decision.

References

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ATTACHMENT

1. Draft variations to the *Australia New Zealand Food Standards Code*

Attachment 1

Draft variations to the *Australia New Zealand Food Standards Code*

Subsection 94 of the FSANZ Act provides that standards or variations to standards are legislative instruments, but are not subject to disallowance or sunseting

[1] **Standard 1.2.4** of the *Australia New Zealand Food Standards Code* is varied by –

[1.1] *inserting the following entry in alphabetical order into Part 1 of Schedule 2 –*

| | |
|---------------------------------|------|
| Calcium lignosulphonate (40-65) | 1522 |
|---------------------------------|------|

[1.2] *inserting the following entry in numerical order into Part 2 of Schedule 2 –*

| | |
|---------------------------------|------|
| Calcium lignosulphonate (40-65) | 1522 |
|---------------------------------|------|

[2] **Standard 1.3.1** of the *Australia New Zealand Food Standards Code* is varied by *inserting in column 1 and 2 respectively in each of the listings in Schedule 2 (Alphabetical Order and Numeric Order) –*

| | |
|------|---------------------------------|
| 1522 | Calcium lignosulphonate (40-65) |
|------|---------------------------------|