FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

13 May 2011
[9-11]

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

Executive Summary

Purpose

The purpose of the Application is to seek permission to use calcium lignosulphonate (40-65) as a food additive in order to incorporate fat-soluble vitamins (A, D, E and K) and carotenoids (e.g. β-carotene, carotenal, β-apo-8', lutein, lycopene, etc) into water-based foods (foods, including drinks, that contain water as an ingredient or component). Calcium lignosulphonate (40-65) assists in ensuring uniform dispersal and distribution of water insoluble vitamins and carotenoids into water-based foods. The suffix (40-65) is used to distinguish that the product has a more defined range of weight-average molecular weights to other calcium lignosulphonates.

Background

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) to incorporate fat-soluble vitamins and carotenoids into water-based foods.

The Applicant proposed calcium lignosulphonate (40-65) as an alternative substance to commonly used substances, 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 limitations. The use of some hydrolysate or starches derived from soy may give rise to concerns due to ensuring supply from non-genetically modified sources, as well as allergen labelling requirements. 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 is required; rather than Standard 1.3.3 – Processing Aids.

A pre-market assessment is required prior to any approval being granted to a new substance for use as a food additive.

The Application was assessed under the General Procedure.

Risk Assessment

A risk assessment was performed as part of the assessment of the Application. This risk assessment considered the technological aspects and properties of the substance in performing its role in foods. 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 for use as an emulsifier and stabiliser in order to incorporate fat-soluble active ingredients into aqueous foods.

The available toxicological data indicates that setting an acceptable daily intake (ADI) is necessary. An ADI of 0-20 mg/kg bodyweight (bw) per day (rounded value) for calcium lignosulphonate (40-65) has been established based on a 13-week dietary study in rats. This study obtained a NOAEL (no observable adverse effect limit) 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.

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 dietary exposures to calcium lignosulphonate (40-65) were assessed as low. 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) to incorporate fat-soluble nutrients is likely to result in the same gastrointestinal absorption of these nutrients as occurs with the use of another common substance (gelatine). 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 use of calcium lignosulphonate (40-65) as a food additive to assist the incorporation of oil soluble and dispersible vitamins and carotenoids to aqueous foods is technologically justified and is consistent with the purpose proposed by the Applicant.

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[1] and not as a processing aid[2]. The reason for this conclusion is that calcium lignosulphonate (40-65) performs a technological function in the final food, not just during the processing of the food (further explained in Section 2.2). The risk assessment further concluded that when used as proposed by the Applicant, dietary modelling produced exposures for the highest consumers of the substance that were less than 30% of 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 certain processed foods. Accordingly, it is appropriate the substance is added to Schedule 2 of Standard 1.3.1. The permission is 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 decision to permit the substance as a food additive and not as 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 food additive 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.

Decision

To approve 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.

[1] Purpose statement for food additive in Standard 1.3.1 is: A food additive is ... intentionally added to a food to achieve one or more of the technological functions specified in Schedule 5.
[2] Processing aid definition from Standard 1.3.3 contains the following: to fulfil a technological purpose relating to treatment or processing, but does not perform a technological function in the final food.

Reasons for Decision

- 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 while there is a need to establish an ADI for the substance, 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 the 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 draft variations to the Code are consistent with the section 18 objectives of the FSANZ Act.

- There are no relevant New Zealand standards.

Consultation

As this Application was assessed under the General Procedure, there was one round of public comment following the preparation of the Assessment Report. The Assessment Report was available for public comment between 15 December 2010 and 9 February 2011. Five comments were received, which have been summarised in **Attachment 2**, while issues raised have been addressed and used to finalise this Approval Report.

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SUPPORTING DOCUMENT

The following material, which was used in the preparation of this Approval Report, is available on the FSANZ website at
http://www.foodstandards.gov.au/foodstandards/applications/applicationa1030calc4429.cfm.

SD1 Risk Assessment Report (Approval)

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) to incorporate fat-soluble vitamins and carotenoids into water-based foods. The fat-soluble vitamins are vitamin A, D, E and K and the carotenoids include β-carotene; carotenal, β-apo-8'; lutein and lycopene.

The Applicant claimed calcium lignosulphonate (40-65) acts as a processing aid when it is used 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 substances 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 substances are gelatines, gum arabic (also called gum acacia), soy protein hydrolysate or starches. For some food manufacturers, the use of these substances can cause difficulties. The Applicant argues that gelatines, being of animal origin, have disadvantages in not being kosher or halal, have perceived Bovine Spongiform Encephalopathy (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) as well as allergen labelling requirements. The Applicant claims that calcium lignosulphonate (40-65) does not have these potential disadvantages.

The Applicant, along with Codex Committee on Food Additives and the Joint FAO/WHO Expert Committee on Food Additives (JECFA) uses the suffix (40-65) to calcium lignosulphonate to distinguish its more defined form of the substance from other calcium lignosulphonates. The term (40-65) refers to the range of weight-average molecular weights of the polymers; being in the range of 40 to 65 kDa.

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 as a processing aid or a food additive the technological function it performs required investigation. That is, whether it is a processing aid 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 and dispersible 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 to achieve this 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 (A, D, E and K) 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 disperse uniformly into water-based foods.

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, **SD1**).

In summary, calcium lignosulphonate (40-65) coated small oil droplets (containing the fat-soluble and dispersible vitamins and carotenoids) are embedded in a slightly larger particle of a water soluble matrix. These particles are produced by spray drying or powder catch technologies. Calcium lignosulphonate (40-65) acts as an emulsifier by stabilising oil soluble or dispersible nutrients in a water soluble matrix during production of the particles. When the small particles containing the embedded oil droplets are added to aqueous solutions the matrix dissolves, releasing the small oil droplets that still have a coating of calcium lignosulphonate (40-65). The calcium lignosulphonate (40-65) layer acts as an emulsifier by forming an emulsion between the two immiscible phases (oil and water). The small oil droplets are dispersed and do not aggregate together to form larger oil drops or films in the aqueous media due to electronic repulsions caused by the surface charges on the calcium lignosulphonate (40-65) coating.

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 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, calcium lignosulphonate (40-65) functions as a food additive in the final food and not as 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 used 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. It should be noted that carrier and encapsulating agent are not food additive technological functions in the Code.

Because FSANZ assessed the technological function of calcium lignosulphonate (40-65) as being different from that requested in the Application, FSANZ was required by section 30 of the FSANZ Act to notify the Applicant and to delay releasing the Report for 10 business days. The Applicant subsequently agreed with FSANZ's position.

2.3 International permissions

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 food additive for fat-soluble vitamins and carotenoids in both food and supplements.

JECFA established 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.

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 additives for animal feed in the European Community in the European Commission Directive 70/524/EEC. However, this Application relates to calcium lignosulphonate (40-65); a more defined form of the substance from other calcium lignosulphonates.

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 by 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 fat-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.

FSANZ has determined that the primary objective relevant to the assessment of this Application is the first one; the other two have less direct relevance. FSANZ performed a risk assessment to determine if there are any public health and safety concerns with approving the use of the substance.

The risk assessment performed has been based on the best available scientific evidence. Other relevant matters for this assessment are to seek consistency with international food standards and the desirability of an efficient food industry, since calcium lignosulphonate (40-65) has been assessed by other international agencies.

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.

FSANZ has addressed the relevant policy guidelines as part of the assessment of the Application. The technological function and the safety of adding calcium lignosulphonate (40-65) to food are important risk assessment issues addressed in this assessment.

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 means of incorporating fat-soluble nutrients into water-based foods?

    - Does calcium lignosulphonate (40-65) release the 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)?

RISK ASSESSMENT

The Risk Assessment Report (**SD1**) (amended from that used for the Assessment Report) 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 ADI is necessary based on the available toxicological data. An ADI of 0-20 mg/kg bw per day (rounded value) for calcium lignosulphonate (40-65) has been established based on a 13-week dietary study in rats that obtained a NOAEL (no observable adverse effect level) 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.

FSANZ's determination of an ADI is consistent with that of JECFA. But FSANZ notes that EFSA did not establish an ADI. Consequently, FSANZ had its safety assessment peer reviewed by an external expert toxicologist, who agreed with FSANZ's conclusion.

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 assessed as low when dietary exposure was determined using a) the proposed food groups and concentration data provided by the Applicant and b) 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 means of incorporating fat-soluble nutrients into water-based foods?

Data from a suitable animal model show that the use of calcium lignosulphonate (40-65) as a means of incorporating fat-soluble nutrients into water-based foods will likely result in the same gastrointestinal absorption of these nutrients as occurs with the use of another common substance (gelatine). 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 means of incorporating fat-soluble nutrients into water-based foods 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) is a food additive and not a processing aid for the purpose proposed in the Application. That is, to assist to incorporate oil-soluble and dispersible 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 permitted 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 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 2.2). 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 argues that there will only be small amounts of the substance in the final food. An analytical method has not been able to be developed due to the difficulties inherent in detecting a complex polymer of varying size, in low concentrations, within complex and varying food matrices. The Applicant also uses calcium lignosulphonate (40-65) in animal feed preparations. They investigated developing analytical methods for determining the presence of, or quantifying, the amount of calcium lignosulphonate (40-65) in animal feed but could not develop an analytical method.

FSANZ sought further information and justification for why an analytical method was not possible to be developed from the Applicant. The summary of the reasons are essentially as noted above. Food matrices are variable and usually complex. Phenolic compounds are ubiquitous in food, especially plant derived and their presence interferes with the detection of a specific form, being calcium lignosulphonate (40-65). Even detecting lignosulphonate and lignin in the wood pulp and paper pulp industry is complicated. This is the case even when the substance occurs in relatively high levels and the matrix is relatively simple compared to the complexity in food.

Since the permission for calcium lignosulphonate (40-65) is as a GMP food additive, there is no maximum permitted level to check compliance against.

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 it may not be a practical method to discriminate the substance from a 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 not currently available. However, FSANZ does not believe this issue is a concern since other analytical methods exist to check for the presence of the active nutrients, and the safety assessment for calcium lignosulphonate (40-65) indicates there are no safety concerns with adding the substance to food.

More detail is supplied in section 11.2.4 where FSANZ addresses a submitter's issue over concern that no analytical method is available for the presence of calcium lignosulphonate (40-65) in treated food.

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 Approve the draft variations 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 (OBPR) 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 purposed purpose is voluntary. Food manufacturers will use a range of factors to determine which substance they use. Such factors will include cost, suitability for the desired purpose, any labelling requirements and the benefit of adding the nutrients to the food product.

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 applied a basic communication strategy to this Application. The strategy involved 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 to the Assessment Report were evaluated and addressed in Section 11.2 of this Approval Report.

The Applicant, individuals and organisations making submissions on this Application were notified at each stage of the consideration of the Application. The FSANZ Board's decision to approve the draft variations has been notified 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

11.1 Public Consultation

The Assessment Report for this Application was released for public comment between 15 December 2010 and 9 February 2011. Comments were specifically sought on the scientific and technical aspects of the assessment, as well as the proposed drafting to the Code. In particular, these related to the risk assessment questions contained in Section 5 of the Report in regard to the technological function of the substance as proposed to be used by the Applicant, any safety or nutrition concerns over its use and the dietary exposure assessment performed. As this Application was assessed under a General Procedure, only one round of public comment was applicable.

Five submissions were received during the public consultation period. A summary of these submissions is provided in Attachment 2. Four submissions were received from jurisdictions while one was received from an industry association. Four submissions supported approving the Application. One submission did not express any explicit decision though it indicated that if the substance is to be approved as a food additive then an analytical method for the presence of the substance in food is highly appropriate and necessary, which is different to the position of FSANZ (issue addressed in Section 11.2.4).

One submitter has a different view to that of FSANZ, where they concluded that the technological function of the calcium lignosulphonate (40-65) as proposed by the Applicant was as a processing aid and not as a food additive.

FSANZ has taken submitters' comments into account in finalising this Approval Report.

FSANZ's responses to issues raised in submissions are provided in the following section.

11.2 Issues raised in Submissions

11.2.1 Technological function

One submitter disagreed with FSANZ's conclusion that the technological function of calcium lignosulphonate (40-65) as proposed to be used to incorporate fat-soluble vitamins and carotenoids in water-based foods is as a food additive. The submitter believed it is more appropriate to be considered as a processing aid and thus regulated in Standard 1.3.3.

Schedule 5 of Standard 1.3.1 defines the function of an emulsifier food additive that 'facilitates the formation or maintenance of an emulsion between two or more immiscible phases'. The submitter disagrees that using calcium lignosulphonate (40-65) for the stated purpose of the Application would meet this definition.

11.2.1.1 FSANZ Response

FSANZ notes the different view of a submitter regarding the technological function of calcium lignosulphonate (40-65) for the purpose as proposed by the Applicant.

FSANZ has detailed how calcium lignosulphonate (40-65) functions for the proposed purpose in Section 4.1 of the Risk Assessment Report (SD1). Understanding the technological function was important for FSANZ to determine whether calcium lignosulphonate (40-65) should be regulated as a food additive or a processing aid, if it was approved for the purpose requested. This consideration is explained in Section 4.2 of SD1.

Calcium lignosulphonate (40-65) has a function of an emulsifier since it ensures the incorporated oil droplets containing the added nutrients are emulsified in the final water-based foods. That is, it ensures an emulsion between water insoluble nutrients and the water-based food is formed and maintained so it directly meets the technological function of an emulsifier in Schedule 5 of Standard 1.3.1. This technological function continues in the final food, so the substance acts as a food additive; not just during the production of the food, which is the function of a processing aid.

Both the Applicant's explanation and various sections in the relevant literature use the term 'emulsifier' to explain the function of calcium lignosulphonate (40-65) and other comparable substances for the proposed purpose.

The Applicant's explanation of how calcium lignosulphonate (40-65) is used for the purpose explains that the usual process involves a fat-soluble substance (e.g. corn oil), water soluble substance and emulsifiers. It lists a range of suitable emulsifiers, such as smaller molecules being Tween (commercial type of detergent emulsifier), lipids (diacylglycerols), proteins (e.g. gelatine, casein) and polysaccharides such as gum arabic, agar and calcium lignosulphonate (40-65).

The Applicant also explains that calcium lignosulphonate (40-65) also acts as a stabiliser to prevent the small oil droplets from aggregating or coagulating to produce larger droplets or films of oil on the water surface.

It is important that the small oil droplets remain uniformly distributed throughout the water-based food.

FSANZ concludes that both the food additive technological functions of emulsifier and stabiliser are appropriate as the functions performed by calcium lignosulphonate (40-65) for the purpose proposed by the Applicant. Which technological function is the most appropriate for individual food manufacturers for their products, is a decision they need to make and be able to explain and justify.

11.2.2 Labelling

One submitter questioned the name of the substance to be used on labels should it be classified as a food additive by FSANZ. The submitter believes the numbers at the end of the name of the substance proposed by FSANZ (calcium lignosulphonate (40-65)) may be misread as a food additive INS number. The submitter proposes that it would be simpler to use the term 'calcium lignosulphonate' for labelling purposes.

11.2.2.1 FSANZ Response

The numbers (40-65) refer to the range of weight-average molecular weight (being between 40 to 65 kDa) of the specific calcium lignosulphonate considered in this Application. This molecular weight range is the key differentiator between this substance and other food-grade calcium lignosulphonates. As explained in the Introduction of this Report and in Section 2.2 (chemical identification) of the Risk Assessment Report (SD1), the name 'calcium lignosulphonate (40-65)' has been used by JECFA and Codex. JECFA established specifications for this specific product; namely, calcium lignosulphonate (40-65). The Codex Committee on Food Additives (CCFA) assigned the food additive INS number of 1522 to this specific food additive. Therefore, FSANZ has used the name calcium lignosulphonate (40-65) to maintain the differentiation between this substance and other food-grade calcium lignosulphonates and to be consistent with the approach taken internationally.

Food suppliers have the option of declaring this food additive on the label of the treated food as [class](calcium lignosulphonate (40-65)) or use the INS number to declare it as [class](1522).

11.2.3 Nutritional matters

One submitter noted FSANZ's nutritional assessment conclusion (Section 6.4 of the Assessment Report, and Section 7 of SD1) that the use of calcium lignosulphonate (40-65) for the stated purpose is likely to result in the same gastrointestinal absorption of nutrients as for other comparable food additives. However, the submitter commented that there could be a risk from increasing fat-soluble vitamins (in particular vitamin A/carotenoids) in the diet, which FSANZ has interpreted to mean that there would be increased gastrointestinal absorption of these vitamins. The submitter further commented that this situation could potentially increase the risk of vitamin A toxicity for vulnerable consumers.

11.2.3.1 FSANZ Response

FSANZ previously reported that data from a suitable animal model showed that the use of calcium lignosulphonate (40-65) to incorporate fat-soluble nutrients was likely to result in the same gastrointestinal absorption of these nutrients as occurs with the use of gelatine (commonly used to incorporate colours and vitamins). Because of the similarities in gastrointestinal absorption, FSANZ previously concluded that the use of calcium lignosulphonate (40-65) to incorporate fat-soluble nutrients would be unlikely to result in any adverse nutritional outcomes.

FSANZ reaffirms this conclusion. We expect that the consumption of fat-soluble vitamins from foods with added calcium lignosulphonate (40-65) will have the same effect on circulating vitamin biomarkers and storage levels as the consumption of these vitamins from other sources, because of the similarities in gastrointestinal absorption that were previously identified.

11.2.4 Analytical method

One submitter expressed its concern with FSANZ's conclusion (in Section 7.3 of the Assessment Report) that an analytical method to determine the presence of the substance in the final food is neither appropriate nor necessary. The submitter commented that it is never inappropriate to have an analytical method for a food additive available.

11.2.4.1 FSANZ Response

FSANZ addressed this issue in the Assessment Report and also in this Approval Report in Section 7.3.

FSANZ has agreed at a recent meeting of the Implementation Sub-Committee[3] (ISC), to be more stringent on the requirement for an appropriate method of analysis for new substances, ensuring that the method of analysis section is adequately addressed in all new applications.

Where applications do not adequately address this requirement, FSANZ will either request additional information from the applicant to ensure this is addressed within the administrative assessment period of 15 working days, or reject the application. This decision will be made on a case-by-case basis and remains at the discretion of FSANZ.

However, it should be noted that the provision of an analytical method may not be required in all circumstances. For example, where processing aids and food additives are requested to be permitted according to good manufacturing practice (GMP) and therefore there is no maximum limit to measure compliance against, the provision of an analytical method may not be deemed necessary. In these cases, a short explanation or statement from the applicant regarding this is sufficient.

ISC is currently considering the establishment of an Expert Advisory Group (EAG) to provide expert advice on analytical methodology as required during the standards development process. It is envisaged that the EAG would work alongside the standards development process to provide any expert advice on analytical methodology as required. This advice could then be incorporated into the assessment reports so it is clear to jurisdictions what methods are fit-for-purpose and are available for enforcement purposes. If needed, this may be an area where advice is sought from the EAG by FSANZ, if and when the ISC EAG is established.

In light of the above, FSANZ communicated with the Applicant with respect to the submitter's comment and concern that no analytical method is available to determine the presence of calcium lignosulphonate (40-65) in any treated food.

FSANZ is of the understanding that it is not practical to require an analytical method for determining the presence of calcium lignosulphonate (40-65) for the following reasons:

- the relatively low concentration of the substance in the final treated food
- the complex nature of the calcium lignosulphonate (40-65) polymer which has varying composition and size
- as well as the complex nature of the differing food matrices.

[3] http://www.health.gov.au/internet/main/publishing.nsf/content/foodsecretariat-isc.htm

Other reasons why FSANZ does not believe an analytical method is required for this Application are:

- calcium lignosulphonate (40-65) is a safe food additive that is relatively inert in the final food and also once the food has been consumed
- permissions for calcium lignosulphonate is at GMP; hence there is no permitted level to measure compliance against.

However, FSANZ notes that the JECFA specification for calcium lignosulphonate (40-65) contains a number of analytical tests to determine the purity of the substance itself. These identification tests are used to determine weight-average molecular weight, degree of sulphonation, determination of inorganic sulphur and organic sulphur, reducing sugars, sulphite and total ash. It is possible, although not specifically clear, that these analytical methods could be modified and used as a method to test for the presence of calcium lignosulphonate (40-65) in the final treated food, should there be a need by enforcement agencies.

In conclusion, FSANZ believes there are appropriate reasons why no analytical method for the presence of calcium lignosulphonate (40-65) in food is required. However, if there are any enforcement concerns about the presence of calcium lignosulphonate (40-65) added to food, it may be more appropriate and practical to analyse for the actual active nutrient, being either the fat-soluble vitamin or carotenoid, for which there are currently available analytical methods.

11.3 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 and dispersible 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 was not considered necessary.

Conclusion

12. Conclusion and Decision

This Application has been assessed against the requirements of section 29 of the FSANZ Act.

The Approval 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 water-based foods. Use of calcium lignosulphonate (40-65) for this purpose does not pose a public health and safety risk.

Approving the substance as a food additive requires the presence of the substance to be listed in ingredient lists on food packages. This labelling requirement enables consumers to have adequate information to make informed purchase choices.

FSANZ has concluded there are no misleading or deceptive conduct aspects to this assessment.

The Ministerial Council Policy Guidelines have been addressed in this assessment. The technological function of using the substance has been articulated and assessed as being met. Its use as proposed has been assessed as being safe and suitable.

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, and consequential draft variations to Standard 1.2.4.

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

Because FSANZ had assessed the technological function of calcium lignosulphonate (40-65) as being different from that requested in the Application, FSANZ was required by section 30 of the FSANZ Act to notify the Applicant of this conclusion. The Applicant had 10 working days to decide whether to accept the decision, which it did.

Decision

To approve 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.

Reasons for Decision

- 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 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

If no review of the Board's decision is requested by the Ministerial Council, the draft variations to the Code will come into effect on gazettal.

References

CCFA (2009), Report of the 41st Session of the Codex Committee on Food Additives. ALINORM 09/32/12. March 2009. http://www.codexalimentarius.net/download/report/721/al32_12e.pdf Accessed on 31 March 2011.

EFSA (2010) Panel on Food Additives and Nutrient Sources added to Food (ANS); Scientific Opinion on the use of calcium lignosulphonate (40-65) as a carrier for vitamins and carotenoids on request of the European Commission. EFSA Journal 2010;8(3):1525. http://www.efsa.europa.eu/en/scdocs/scdoc/1525.htm Accessed on 31 March 2011.

JECFA (2008) Joint FAO/WHO Expert Committee on Food Additives (JECFA), 2008 Calcium lignosulfonate (40-65) Chemical and Technical Assessment Prepared by Toledo MCF and Kuznesof PM http://www.fao.org/ag/agn/agns/jecfa/cta/69/Calcium_Lignosulfonate%20_40_65_CTA_69.pdf Accessed on 31 March 2011.

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Saariaho A-M (2004) Resonance Raman spectroscopy in the analysis of residual lignin and other unsaturated structures in chemical pulps. Doctor of Science (Technology), Helsinki University of Technology, Laboratory of Forest Products Chemistry, Reports, Series A 20 (received from the Applicant)

WHO (2009) Safety evaluation of certain food additives WHO Food Additives Series No. 60 Calcium Lignosulfonate (40-65) – Toxicological Monographs. Report prepared by Munro IC and Baines J. For the 69th JECFA meeting. pp15-37 http://whqlibdoc.who.int/publications/2009/9789241660600_eng.pdf Accessed on 31 March 2011

ATTACHMENTS

1. Draft variations to the *Australia New Zealand Food Standards Code*
2. Summary of public submissions on the Assessment Report

Attachment 1

Draft variation 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 sunsetting

To commence: on gazettal

[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)

Attachment 2

Summary of Public Submissions on the Assessment Report

Five submissions were received during the public consultation period for the Assessment Report. Four submissions were received from jurisdictions, while one was received from an industry association.

A summary of the submissions is provided in the Table below, noting that the two options are:

Option 1 Reject the Application

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

Table: Summary of Submissions

Submitter	Comments
Food Technology Association of Australia	Supports option 2.
The Ministry of Agriculture and Forestry (MAF) (New Zealand)	Supports option 2. It is satisfied use of the substance is technologically justified and no public health or safety concerns (including nutritional) were identified.
South Australia Health	Supports option 2. However, it has some queries. *Technological Function* It questions whether the substance should be more appropriately classified (and hence regulated) as a processing aid (as a carrier) than as a food additive. The Codex Committee on Food Additives classifies the substance as a food additive with functional class of carrier and encapsulating agent. The Code does not have a food additive functional class of carrier and hence carriers are regulated in the Code as processing aids. It states that the function the substance performs does not meet the technological function of an emulsifier (Schedule 5 of Standard 1.3.1) nor does it have any technological function in the final food as required for a food additive. *Labelling* If FSANZ concludes it is a food additive it would be required to be listed in the label of foods. It suggests adding the number (40-65) at the end of the name could be confusing for consumers as it could be misinterpreted as a food additive number. It suggests a simpler name would be 'calcium lignosulphonate'. *Nutritional Issues* It notes that the nutritional section of the Report concludes there will be the same gastrointestinal absorption of nutrients (in particular vitamin A) as other delivery agents. However, it questions whether use of the substance increases the absorption of these vitamins, which potentially raises the possibility of vitamin A toxicity in vulnerable consumers.

Submitter	Comments
Queensland Health	No option indicated. It disagrees with FSANZ's assessment, indicating it is highly appropriate and necessary that an analytical method is available for the presence of the food additive in food. It notes that there does not appear to be any current approval for the use of the food additive in any other country.
Victorian Department of Health	Supports option 2.