

APPLICATION

JULY 2015

TO:

FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

IN RELATION TO:

APPLICATION FOR EXTENSION OF USE OF L-CYSTEINE
MONOHYDROCHLORIDE AS A FOOD ADDITIVE IN
STANDARD 1.3.1 – FOOD ADDITIVES.

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ADMINISTRATIVE INFORMATION

Applicant Details

(As per section 3.1.2 of the Application Handbook 1 September 2013)

Applicant: [REDACTED]
Organisation: Link Trading (Qld) Pty Ltd (hereafter Link Trading)
Address: 1/52 Fulcrum Street, Richlands, Queensland 4077
Telephone: [REDACTED]
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Nature of Business

(As per section 3.1.2(f) of the Application Handbook 1 September 2013)

Link Trading is a supplier of raw materials to the food and beverage processing industry. Established in 1978 and with its headquarters in Brisbane, Link Trading is the Agent/Distributor for National and Multi-National raw material manufacturers whose focus is on quality and technology.

Details of Other Parties Associated with the Application

(As per section 3.1.2(g) of the Application Handbook 1 September 2013)

The following Scientific and Regulatory Consultants are involved in the preparation, submission and stewardship of this application:

[REDACTED] Brooke-Taylor & Co Pty Ltd

[REDACTED] FJ Fleming Food Consulting Pty Ltd

1. APPLICATION INFORMATION

Assessment Procedure

(As per section 3.1.6 of the Application Handbook 1 September 2013)

Link Trading seeks to proceed with an **unpaid** application for consideration as a General Procedure, Level 1 (maximum of 350 hours).

Confidential commercial information

(As per section 3.1.7 of the Application Handbook 1 September 2013)

This application **does contain** information that is confidential commercial information (CCI).

Link Trading requests the information contained within **Appendices 9 and 10** be considered CCI.

The CCI information and letter of request for CCI has been submitted to FSANZ separately to this Application document.

Exclusive capturable commercial benefit

(As per section 3.1.8 of the Application Handbook 1 September 2013)

This application will **not** confer an exclusive capturable commercial benefit for Link Trading or any other individual company.

Status of Similar Applications

(As per Section 3.1.4 of the Application Handbook 1 September 2013)

The Applicant is not aware of any similar applications to extend the use of L-cysteine as a food additive to fruits and vegetables.

2 PURPOSE OF THE APPLICATION

(As per section 3.1.3 of the Application Handbook 1 September 2013)

2.1 Purpose

The purpose of this application is to request an amendment to Schedule 1 of Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (hereafter the Code) to extend the use of L-cysteine monohydrochloride (hereafter referred to as L-cysteine) as a food additive.

The Applicant is seeking approval for the use of L-cysteine in avocado and banana (fruits and vegetables that are peeled, cut or both peeled and cut) at GMP levels.

L-cysteine is intended for use in controlling enzymatic browning of fresh cut avocado and banana to extend their shelf life.

2.2 Proposed Amendment

The Applicant is requesting an addition to the permissions in Schedule 1 of Standard 1.3.1 – permitted use of food additives by food type to allow for the use of L-cysteine in fruits and vegetables that are peeled, cut or both peeled and cut – avocado and banana.

The Applicant notes that FSANZ prefers that the proposed amendment is kept general and suggested drafting is not provided in the application.

3 JUSTIFICATION FOR THE APPLICATION

(As per section 3.1.4 of the Application Handbook 1 September 2013)

3.1 Need for the Proposed Change

(As per section 3.14(a) of the Application Handbook 1 September 2013)

3.1.1 Purpose of using the Food Additive

The purpose of using L-cysteine is to control enzymatic browning of fresh-cut (minimally processed) avocado and banana. Avocado and banana treated with L-cysteine can be maintained as fresh cut for 5-7 days when stored at 5°C.

The use of L-cysteine provides an alternative to the currently available options discussed below to control enzymic browning (Section 3.1.1.1) which are not suitable for minimally processed avocado and banana.

In a product intended to be marketed by the Applicant, L-cysteine is used in conjunction with calcium chloride which assists in maintenance of the firmness of the fruit. Calcium chloride is currently permitted to be used on fruits and vegetables that are peeled, cut, or both peeled and cut. The action of L-cysteine is not dependent on the presence of calcium chloride.

3.1.1.1 Enzymatic Browning of Fruit and Vegetables

A major hurdle to the successful marketing of fresh-cut fruit is the short shelf life caused by browning and softening. Preservation of colour is, after safety, the most important attribute to be preserved since frequently a fruit product is selected for its appearance, particularly its colour (Garcia and Barrett 2002).

Enzymic browning is the discolouration which results from the action of a group of enzymes called polyphenol oxidases (PPO) which exist in high amounts in banana, avocado, apple, pear, peach potato and mushroom (Garcia and Barrett 2002). Oxidative reactions such as enzymic browning are the second most important cause of food deterioration after that induced by microbiological contamination (Ioannou and Ghoul 2013).

Enzymic browning involves two oxidoreductases enzymes:

- Polyphenoloxidase (PPO); and
- Peroxidase (POD)

Polyphenyl oxidase (PPO) is a naturally occurring enzyme - it catalyses two oxidation reactions at the beginning of the enzymatic browning process, PPO-1 and PPO-2. In oxygen, PPO will conduct the transformation of phenols to diphenols and on to o-quinones. o-Quinones are reactive compounds that polymerise to form complex brown pigments of high molecular weight (melanin).

PPO is unchanged by the reaction, and retains the ability to catalyse the oxidation of unlimited amounts of substrate. The substrates for the enzymatic part of the reaction, phenols and diphenols, are also naturally occurring compounds present inside the cell structure of fruit. When the cells are damaged

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(during processing) the cell contents are exposed to the oxygen in the atmosphere and enzymatic browning begins. This reaction is shown in **Figure 1** below.

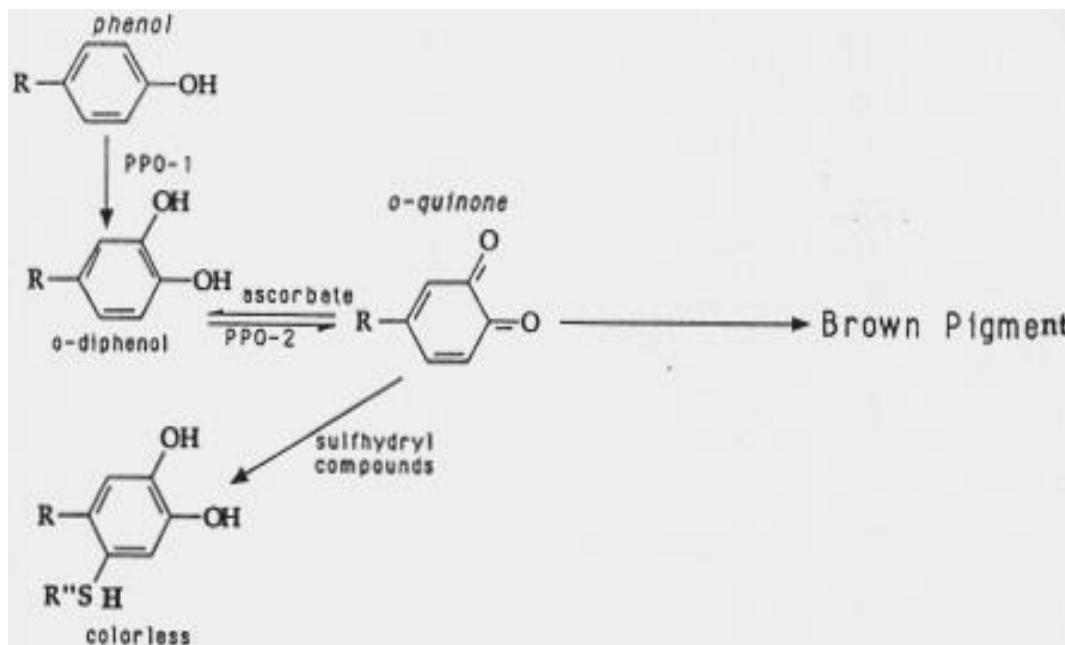


Figure 1: Reaction scheme for enzymatic browning (Laurila, 1998)

Control of enzymic browning

Processes such as peeling and cutting lead to the start of browning reactions - to reduce the impact there are a number of methods which can be used to either inactivate the PPO or to avoid contact between the enzyme and its substrate.

Enzymic browning may be controlled through the use of both physical methods and chemical treatments. Physical treatments either modify the temperature of the product or decrease the availability of oxygen. Chemical treatment agents can be classified according to their action – antioxidant, chelating, firmness or acidifying.

A summary of the physical and chemical methods available to control enzymic browning in fresh-cut fruit is provided in **Appendix 1**.

The disadvantages of these methods, which make them unsuitable for use in the treatment of fresh-cut avocado and banana, are also summarised in **Appendix 1**.

In general, chemical treatments are used to treat fresh-cut foods (Ioannou and Ghoul 2013).

The extension of approval for L-cysteine to control enzymatic browning of fresh-cut avocado and banana will provide manufacturers in Australia and New Zealand with an alternative to the options summarised in **Appendix 1**.

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3.1.1.2 Application of L-cysteine to fresh-cut Avocado & Banana

The Applicant is proposing to apply the L-cysteine to fresh-cut avocado and banana in solution. The L-cysteine is present in a dipping solution product marketed by the Applicant - NatureSeal®BAS6. A specification for this product is provided in **Appendix 2**.

The dipping solution contains L-cysteine as the antioxidant and calcium chloride as the firming agent. Calcium chloride is currently permitted to be used on fruits and vegetables that are peeled, cut, or both peeled and cut. The action of L-cysteine is not dependent on the presence of calcium chloride.

L-cysteine (a naturally occurring amino acid) reacts with o-quinones intermediates to form new molecules that are not subject to oxidation, and remain unpigmented.

The process followed for treatment of fresh-cut banana and avocado is set out in **Appendix 3**.

3.2 Advantages of the Proposed Change

(As per Section 3.1.4(b) of the Application Handbook 1 September 2013)

The Applicant proposes that extended use of L-cysteine has the following advantages:

- opportunity for manufacturers to produce fresh-cut avocado and banana products with an extended shelf life over untreated products;
- increase choice and convenience for consumers who will have access to pre-prepared fresh-cut avocado and banana products which retain flavour and freshness; and
- provides an alternative to current treatments available.

Examples of fresh-cut avocado products currently on the market in the UK and fresh-cut banana products are provided in **Appendix 4**.

3.2.1 Fresh-Cut Fruit and Vegetables

The International Fresh-cut Produce Association (IFPA) defines fresh-cut products as fruit or vegetables that have been trimmed and/or peeled and/or cut into 100% usable product that is bagged or pre-packaged to offer consumers high nutrition, convenience, and flavour while still maintaining its freshness.¹

Minimal processing gives additional value to fresh-cut fruits in terms of:

- Convenience;
- Reduce meal preparation time;
- Uniform and consistent quality;
- Less storage space and easy to store packages; and
- Reduced waste and handling (Stanley 2010)

¹ <http://www.creativew.com/sites/ifpa/about.html>, accessed 26.10.14 & 12.07.2015 to confirm link

Fresh-cut sliced apples have been on the market in Australia for approximately 8 years. Based on ABS figures the per capita consumption of fresh apple in 2013/14 was 8.43kg². Fresh-cut sliced apple represents approximately 0.31% of fresh apple consumption in Australia (Link Trading, pers comm).

The use of L-cysteine for avocado and banana will allow the industry to offer fresh-cut products such as those shown in **Appendix 4**.

3.2.2 Fruit and Vegetable Consumption - Australia

The 2011–13 Australian Health Survey (AHS) reported that in 2011-12, fruit products and dishes were consumed by six out of ten people (Australians 2 years and over) (60%) overall on the day before interview. Based on self-reported usual serves of fruit eaten per day, just over half (54%) met the recommendations for usual serves of fruit.

Apples were the most commonly consumed fruit type with 23% of people consuming apple on the day before interview. Bananas were the second most popular (18% of people consuming), followed by mandarins (7.8%), oranges (6.8%) berry fruit (6.1%) and peaches and nectarines (4.7%).³

An alternative method to produce fresh-cut banana products could provide opportunities to develop products which could assist to increase fruit consumption in Australia.

Wansink et al (2013) reported that children will eat up to 70% more fruit when it is offered as “fresh sliced” compared to whole fruit.

For example, the Fresh for Kids website (www.freshforkids.com.au) which is a part of the Fresh for Kids program has suggestions for including fresh fruit in children’s school lunches which include ideas for sliced banana and avocado⁴ (**Appendix 4**). Fresh-cut banana and avocado available pre-prepared could provide a time-saving alternative to preparing the cut fruit at home.

According to Avocados Australia (2011-2016), avocados in Australia are typically consumed in salads, as a sandwich filling, as an accompaniment to meals or as guacamole. Research shows that avocados are consumed throughout the day. Most avocados are marketed as fresh whole fruit however consumers are becoming more discerning and demanding. New technology is facilitating the development of improved products that are better meeting consumer needs – including fresh-cut/preserved products. The approval of L-cysteine for use on fresh-cut avocado would assist with the development of products to fulfil these consumer needs.

The benefit to consumers will be that they have a wider choice of fresh-cut fruit and vegetables. It will give parents the opportunity to put small packs of cut fruits and vegetables into school lunch boxes with the expectation that children will consume them compared to whole fruit/vegetables. This is aligned with the Government’s and the community’s desire to increase the consumption of fruit and vegetables.

² <http://apal.org.au/statistics/>, accessed 26.10.14 & 12.07.2015 to confirm link

³ Australian Health Survey: Nutrition First Results - Foods and Nutrients, 2011-12, Fruit Products and Dishes, accessed 18.10.2014

⁴ Fresh for kids Recipe Ideas http://www.freshforkids.com.au/lunch_box/pdf/recipe4.pdf, accessed 18.10.14 & 12.07.2015 to confirm link

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3.2.3 Alternative to current treatments available

A summary of current treatments for control of enzymic browning in fresh-cut fruit is provided in **Appendix 1**. There are a number of physical and chemical treatment options however most are unsuitable due to the high cost or effect on the “fresh-like” characteristics of the product. Some of the chemical treatments are not suitable for fresh-cut avocado or banana or their use is not approved.

The use of acids to lower the pH to effectively control enzymatic browning makes the product unpalatable. The amount of ascorbic acid required to prevent pigmentation in bananas for even a few hours is so great that the bananas taste unacceptably acid.

Sulphur dioxide is not permitted to be added to products under 4.1.3 – fruits and vegetables that are peeled, cut or both peeled and cut.

Due to adverse health effects, the WHO has recommended limiting the use of sulphiting agents as much as possible in the treatment of foods (Queiroz et al 2008).

3.3 Disadvantages of the Proposed Change

The Applicant has not identified any disadvantages for the proposed change.

Products containing L-cysteine as a food additive will be required to be labelled to indicate the presence of the food additive.

4 REGULATORY IMPACT INFORMATION

(As per section 3.1.4 A of the Application Handbook 1 September 2013)

4.1 Costs and Benefits – Consumer

The proposed amendment places no additional economic cost on consumers – L-cysteine will be labelled and consumers can choose if they wish to purchase a product containing this food additive.

The benefits to consumers could be time savings and reduced wastage with pre-packaged fresh-cut fruits available.

4.2 Costs and Benefits - Industry and Business

Use of L-cysteine will be at the discretion of business, therefore there are no direct costs imposed on industry.

Where a business chooses to use L-cysteine there will be the cost involved in:

- cost of L-cysteine dipping solution;
- labelling the product to indicate the presence of L-cysteine; and
- analysis to ensure compliance with GMP usage.

The potential benefit to industry is the opportunity to develop new product formats to provide fresh-cut avocado and banana ready prepared for consumer use.

One of the key objectives of Avocados Australia is to increase demand for Australian avocados with the outcome to:

In the next 5 years, to increase the per capita consumption of Australian avocados in line with increasing supply and at a rate of return equivalent or better than 2011 farm gate prices.

A sub-strategy is to:

Track new technologies, research and trends in relation to fresh and value added products to support the development of new products that meet market/consumer needs.

4.3 Costs and Benefits – Government

The proposed amendment places no additional regulatory costs on government beyond the initial regulatory cost of approving the extension of use of L-cysteine as a food additive.

4.4 Impact on International Trade

The Applicant notes that, in developing food standards, FSANZ must have regard to its WTO obligations; the promotion of consistency between domestic and international food standards; and the promotion of fair trading in food. These matters encompass consideration of international standards and trade issues.

The Applicant is not aware of fresh-cut avocado and banana products currently being imported into Australia however; under this proposal products currently manufactured in other markets will be permitted to be imported into Australia and New Zealand which will reduce potential barriers to entry for these products.

Businesses in Australia and New Zealand will have access to L-cysteine to enable them to develop and manufacture products to compete with imported products and to explore the opportunities to export products.

5 INFORMATION TO SUPPORT THE APPLICATION

(As per section 3.1.5 of the Application Handbook 1 September 2013)

5.1 FSANZ Act Objectives

Information is provided in this application to enable the objectives specified in Section 18 of the FSANZ Act to be addressed as follows:

- (a) The protection of public health and safety: information to support objective (a) is provided in Sections 7.1 (Technical Information on the food additive); 7.2 (Information related to the safety of the food additive) and 7.3 (Information related to the dietary exposure to the food additive) of the Application.
- (b) The provision of adequate information relating to food to enable consumers to make informed choices: provided in Section 5.3; and
- (c) the prevention of misleading or deceptive conduct: provided in Section 5.3.

Food products will be labelled and consumers can choose if they wish to purchase a product containing L-cysteine.

5.2 Public Health and Safety Issues

This is addressed under Section 7.2 of this application.

L-cysteine is a non-essential amino acid which occurs widely in protein in a normal diet. Estimates by EFSA suggest that exposure to L-cysteine through the diet may typically reach or exceed 2200mg per day. Consumption at these levels is not associated with any evidence of toxicity. Exposure from the requested extension of use in accordance with GMP is unlikely to result in a significant increase in daily L-cysteine intake and does not therefore present a risk to consumer safety.

The treated cut fruit products will carry a date mark and storage instructions to ensure that consumers are aware of the shelf life of these product ensuring that potential health risks will be managed. The shelf life and storage conditions will be determined by the manufacturer of the cut fruit products as is the case for other pre-packaged ready to eat products.

5.3 Consumer Choice

L-cysteine will be required to be labelled enabling consumers to choose if they wish to purchase a product containing this food additive.

This application does not present any consumer choice issues – food products will be labelled and consumers can choose if they wish to purchase a product containing L-cysteine.

For unpackaged fresh-cut avocado and banana, retailers would be required to provide this information on request.

5.4 Support for the Proposed Change

Letters of support for the application will be provided by the applicant with the formal submission of the application.

6 INTERNATIONAL AND OTHER NATIONAL STANDARDS

(As per section 3.1.9 of the Application Handbook 1 September 2013)

The status of L-cysteine with respect to other national standards or regulations is discussed under this section of the Application.

6.1 International Standards

Food Chemicals Codex (FCC) has published a monograph on L-Cysteine Monohydrochloride. This is provided as **Appendix 5**.

The L-cysteine present in the dipping solution product marketed by the Applicant - NatureSeal®BAS6 meets the requirements of the FCC specification provided as Appendix 5.

6.2 Other National Standards or Regulations

6.2.1 Australia/New Zealand

Current Permissions for L-cysteine

L-cysteine monohydrate is currently permitted to be added to food in Australia and New Zealand under the following Standards of the Australian New Zealand Food Standards Code (the Code).

Standard	Permitted Products	Level permitted	Form
1.3.1 – Food Additives	in peeled, cut or both peeled and cut - root and tuber vegetables (4.1.3)	GMP	L-cysteine monohydrochloride
1.3.3 – Processing Aids Table to clause 14 – Permitted processing aids with miscellaneous functions	Dough conditioner	to a maximum level of 75 mg/kg	L-Cysteine or [HCl salt]).
2.9.1 - Infant Formula Products Table to clause 22	Required to be added to infant formula and follow-on formula	minimum level of 19mg per 100kJ, and must provide no less than 6 mg of cysteine, cystine or combined cysteine and cystine per 100 kJ.	cysteine, cystine and methionine
2.9.4 - Formulated Supplementary Sports Foods - Table to paragraph 2(b)	formulated supplementary sports food	maximum amount added per one-day quantity – 440mg	Amino Acid - Cysteine

6.2.2 United States of America

L-cysteine, a food additive amino acid may be safely used as a nutrient added to foods in accordance with the conditions set out in the Code of Federal Regulations, Title 21, Volume 3 (Cite: 21CFR172.320).⁵

The amount of the additive added for nutritive purposes plus the amount naturally present in free and combined (as protein) form does not exceed the following levels of amino acids expressed as percent by weight of the total protein of the finished food:

	Percent by weight of total protein (expressed as free amino acid)
L-Cystine (including L-cysteine)	2.3

A copy of 21CFR172.320 is provided as **Appendix A6.1**.

6.2.3 Canada

The Canadian Food and Drug Regulations Division 16, Table XI, Part IV, allows the use of L-cysteine hydrochloride as a sulphite replacement formulation for prepared fruits and vegetables. It may be used in quantities consistent with Good Manufacturing Practice.⁶

A copy of the relevant section of Table XI, Part IV is provided as **Appendix A6.2**.

6.2.4 Europe

L-cysteine is authorised to be used in the following categories:

- Flours and other milled products and starches (06.2.1) – quantum satis (EU) No 1129/2011, application as from 01/06/2013.⁷
- Processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (13.1.3). (EU) No 1129/2011, applicable as from 01/06/2013. A maximum limit of 1000mg/kg applies, only for biscuits for infants and young children

A copy of the relevant section of Table XI, Part IV is provided as **Appendix A6.3**.

Note: The term “quantum satis” is applied to usage for a large number of additives. “Quantum satis” indicates that no maximum level is specified. However, additives must be used in accordance with good manufacturing practice, at a level not higher than is necessary to achieve the intended purpose and provided that they do not mislead the consumer.⁸

⁵ <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?fr=172.320>, accessed 06.12.2014

⁶ http://laws-lois.justice.gc.ca/eng/regulations/c.r.c.,_c._870/page-160.html, accessed 06.12.2014

⁷ https://webgate.ec.europa.eu/sanco_foods/main/?event=substance.view&identifier=301, accessed 06.12.2014

⁸ https://www.fsai.ie/faqs/additives/food_additive_legislation.html#quantum, accessed 06.12.2014

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6.2.5 Japan

L-Cysteine Monohydrochloride is permitted for use in Japan as a designated additive appearing in Table 1 as mentioned in Article 12 of the Food Sanitation Law Enforcement Regulations.⁹

A copy of the relevant section of the legislation is provided as **Appendix A6.4**.

6.2.6 Singapore

L-cysteine is permitted as a flavour enhancer under paragraph 23 – (2)(d) of the Food Regulations¹⁰ of the Agri-Food & Veterinary Authority of Singapore.

A copy of the relevant section of the legislation is provided as **Appendix A6.5**.

⁹ <http://www.itp.gob.pe/normatividad/demos/doc/Normas%20Internacionales/OTROS/Japn/RegulaciJapn.pdf>, p57, accessed 17.11.2014

¹⁰ http://www.ava.gov.sg/NR/rdonlyres/0CA18578-7610-4917-BB67-C7DF4B96504B/26630/2web_FoodRegulations_1August2013.pdf, accessed 17.11.2014

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7 L-CYSTEINE AS A FOOD ADDITIVE

(As per section 3.3.1 of the Application Handbook 1 September 2013)

7.1 Technical Information on the food additive

(As per section 3.3.1A of the Application Handbook 1 September 2013)

7.1.1 Policy Guidelines

Information is provided in this section to address the Policy Guideline - Addition to Food of Substances other than Vitamins and Minerals¹¹.

Specific Order Policy Principles – Technological Function

The addition of substances other than vitamins and minerals to food where the purpose of the addition is to achieve a solely technological function should be permitted where:

Specific Order Policy Principles – Technological Function	Section of Application
a) the purpose for adding the substance can be articulated clearly by the manufacturer (i.e. the 'stated purpose'); and	2.1; 3.1
b) the addition of the substance to food is safe for human consumption; and	7.2
c) the amounts added are consistent with achieving the technological function; and	7.1.2 & Appendix 7
d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose; and	7.1.2 & Appendix 7
e) no nutrition, health or related claims are to be made in regard to the substance	N/A

7.1.2 Nature and technical function of the additive

This part includes information related to the technological function of the food additive and includes the following specific information.

- a) *For the purpose of this application, L-cysteine will perform the technological function listed in Schedule 5 of Standard 1.3.1 – Food Additives:*
- Antioxidant – retards or prevents the oxidative deterioration of a food
- b) L-cysteine is required to fulfil this function in peeled, cut or both peeled and cut fruits and vegetables – avocado and banana, to prevent enzymic browning which reduces the shelf life of these products.

¹¹<http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf>

c) Evidence that the amounts proposed to be added is consistent with achieving the technological function.

The thiol containing amino acid cysteine has been reported to effectively inhibit PPO-mediated enzymatic browning of fruit and vegetables. Kahn (1985) reported that L-cysteine was shown to be the most effective inhibitor of browning in banana and avocado tissues.

Bico et al (2010) studied the effect of chemical dips combined with edible coatings to maintain the fresh-like quality (colour and firmness) of fresh-cut slices of Cavendish banana from Madeira Island at 5°C. The chemical dips used in the experiment were: 1% (w/v) calcium chloride, 0.5% (w/v) ascorbic acid and 0.75% (w/v) cysteine, and 2% calcium lactate, 0.5% ascorbic acid and 0.75% cysteine.

Dip with 1% (w/v) CaCl₂, 0.50% (w/v) ascorbic acid and 0.75% (w/v) cysteine was the most efficient treatment in retarding softening and browning of this produce. According to sensory analysis, the edible shelf life of banana slices dipped in such solution was the longest: five days at 5°C.

The use of antioxidants such as cysteine to prevent browning of fresh-cut fruit has been reported to extend the shelf life for up to 7 days at 5°C:

A 2 minute dip in a mixture of 1% (w/v) calcium chloride + 1% (w/v) ascorbic acid + 0.5% (w/v) cysteine was found to effectively prevent browning and softening of banana slices for 6 days at 5°C. Dips in less than 0.5% cysteine promoted pinking of fresh-cut banana slices, while concentrations between 0.5% and 1.0% delayed browning and maintained higher visual quality, extending the post cutting life up to 7 days at 5°C (Vilas-Boas & Kader 2006).

The level of L-cysteine used ranged from 0.5 – 1.0% (w/v).

7.1.2.1 Application of NatureSeal® BAS6

Information provided by the Applicant to demonstrate the effectiveness of BAS6 to extend the shelf life of fresh-cut avocado and banana is provided in **Appendix 7**.

L-cysteine is not a preservative for the purpose of this application.

Avocado

The trial results set out in the report provided as **Appendix A7.1** show that BAS6 does have considerable ability to extend the shelf life of fresh-cut avocado portions, particularly when used at the manufacturer's higher recommendation rate of 5% w/v.

The lower recommended rate of 2.5% w/v extended the marketable shelf life (the point at which the product is deemed unsaleable) significantly, as shown in Table 1.

BAS6 containing L-cysteine extended the shelf life of fresh-cut avocado by 3-11 days depending on the concentration of dipping solution used and the method of processing the avocado – halves, slices, dice based on assessment of enzymic browning activity. The results are summarised in Tables 1 and 2 below.

Table 1: Shelf Life Expectancy for 2.5% BAS6

	Shelf Life Expectancy*		
	Not Treated (days)	2.5% BAS6 (days)	Extension (days)
Halves (skin off)	4	11	7
Halves (skin on)	4	11	7
Slices (5mm)	4	9	5
Diced (15mm)	3	6	3

* To the point at which the product is deemed unsaleable

The higher recommended rate of 5% extended the shelf life of each cut style even further than the 2.5% rate, as shown in Table 2.

Table 2: Shelf Life Expectancy for 5% BAS6

	Shelf Life Expectancy*		
	Not Treated (days)	5% BAS6 (days)	Extension (days)
Halves (skin off)	4	13 days	9
Halves (skin on)	4	13 days	9
Slices (5mm)	4	15 days	11
Diced (15mm)	3	14 days	11

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* To the point at which the product is deemed unsaleable

Banana

The Applicant is proposing to apply L-cysteine to fresh-cut avocado and banana at the level of 1.25 – 3.0% BAS6.

The trial results set out in the report provided as **Appendix A7.2** show that BAS6 does have considerable ability to extend the shelf life of fresh-cut banana.

7.1.3 Information to enable identification of the additive

L-cysteine monohydrochloride occurs as a white crystalline powder. It is freely soluble in water and in alcohol.

Property	Description
Common or usual name	L-Cysteine Monohydrochloride
Chemical name	L-2-Amino-3-mercaptopropaniic Acid Monohydrochloride
CAS Register Number	7048-04-6
Molecular Formula	$C_3H_7NO_2S.HClH_2O$
Molecular Weight	175.63

7.1.4 Information on the chemical and physical properties of the additive

L-Cysteine has a monograph published in *Food Chemicals Codex* (8th Edition) published by United States Pharmacopoeia (2012). This is provided as **Appendix 5**.

7.1.5 Information on the impurity profile for a typical preparation

Table 2: Impurities and by products present

Impurity	Acceptance Criteria
Lead	5mg/kg

7.1.6 Manufacturing process

L-Cysteine has a monograph published in *Food Chemicals Codex* (8th Edition) published by United States Pharmacopoeia (2012). This is provided as **Appendix 5**.

7.1.7 Specification for identity and purity

L-Cysteine has a monograph published in *Food Chemicals Codex* (8th Edition) published by United States Pharmacopoeia (2012). This is provided as **Appendix 5**.

7.1.8 Information for food labelling

L-cysteine monohydrochloride has the additive number 920.

Products containing L-cysteine monohydrochloride will be labelled to meet the requirements of clause 8 of Standard 1.2.4 – Labelling of Ingredients.

7.1.9 Analytical method for detection

As set out in FCC monograph for L-Cysteine which is provided as **Appendix 5**.

7.1.10 Potential additional functions of the food additive when added to food

L-cysteine will not have any other functions in the fresh-cut avocado and banana products.

7.2 Information related to the safety of the food additive

(As per section 3.3.1B of the Application Handbook 1 September 2013)

There is no ADI set for L-cysteine - the various committees who have reviewed it for various uses in food, have taken the view that there is no safety concern at levels of intake when used as a food additive.

It is a macronutrient and a normal component of protein and, as such, human exposure through food is orders of magnitude higher than the anticipated level of exposure from use as a food additive.

7.2.1 Information on the toxicokinetics and metabolism of the food additive and, if necessary, its degradation products and/or major metabolites

As outlined in the JECFA 2004 evaluation of various amino acids as flavourings (see section 7.2.3), cysteine is degraded to acetyl-CoA via pyruvate in two steps, the first being removal of sulphur and the second transamination to remove the amino group.

7.2.2 Information on the toxicity of the food additive and, if necessary, its degradation products and major metabolites

A literature search of Medline, TOXNET and PubMed using the keywords “Cysteine” and “Toxicology” or “Toxicity”, undertaken 17 October 2013 and again on 18 September 2014, identified no new oral toxicity studies. One recent repeat dose intravenous toxicity study with L-Cysteine was identified:

Sawamoto et al., Four-week intravenous repeated dose toxicity study of L-cysteine in male rats. J Toxicol Sci. 2003 May;28(2):95-107.

In this 4-week repeated dose toxicity study male Sprague-Dawley rats randomly allocated to 4 groups received L-cysteine by intravenous administration at dosages of 0, 100, 300, and 1,000 mg/kg body weight/day. Suppressed weight gain, slight anaemia, and histopathological changes, including neuronal death in the cerebellum, tubular basophilia in the kidney and sperm granuloma in the epididymis, were observed in the 1,000-mg/kg group. Slight renal tubular basophilia was observed in the 300mg/kg. No adverse effects were observed in the 100 mg/kg group. Given the route of administration, this study demonstrates that there is a large margin of safety for L-cysteine at levels of exposure consistent with normal dietary intake.

7.2.3 Safety assessment reports prepared by international agencies or other national government agencies, if available.

JECFA

(Report: TRS 928-JECFA 63/98, Tox monograph: FAS 54-JECFA 63/435)

The 63rd meeting of JECFA (June 2004) evaluated the safety of L-amino acids, including L-cysteine, as food flavourings. The Committee concluded that these amino acids are macronutrients and normal components of protein, and therefore their use as flavouring agents did not raise any safety concerns at estimated current intakes. In regard to potential intake from this use, JECFA noted that:

The total annual volume of production for use as flavouring agents of the group of 20 amino acids and related substances evaluated was reported to be approximately 11 200 kg and 21 100 kg in Europe and the USA, respectively. On the basis that L-cysteine accounts for approximately 30% of the total annual volume of production in Europe and approximately 9% in the USA, the estimated daily per capita intake of L-cysteine from use as a flavour was estimated by JECFA at 642µg and 293µg for Europe and the USA respectively.

EC Scientific Committee for Food (SCF)

(SCF (1991). First series of food additives of various technological functions. Opinion expressed on 18th May 1990. Reports from the Scientific Committee for Food (25th series). European Commission, Luxembourg.)

The SCF noted the established history of use of cysteine monohydrochloride as a dough conditioner in baked goods and that L-cysteine is a non-essential amino acid which occurs widely in the diet, especially in cereals. The Committee concluded that the contribution to total dietary intake from L-cysteine monohydrate used as a dough conditioner was insignificant.

EFSA

1. (Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of L-cysteine in foods intended for infants and young children. The EFSA Journal (2006) 390, 1-7)

This evaluation was undertaken in response to an application for use of L-cysteine and its hydrochloride as flour treatment agent in biscuits for infants and young children, at a level of 1 g/kg. Biscuits for infants and young children are required to have a suitable composition, including a controlled content of sugar and fat. However biscuit recipes with a low fat content have increased brittleness, with an associated risk of choking and/or suffocation due to breakage of the biscuit in the child's mouth. The function of L-cysteine in the intended application is to act as a dough improver to control the texture of the final product.

The estimated intake of L-cysteine by infants aged 3 – 12 months as a result of the consumption of 1-3 biscuits potentially containing the amino acid is considered to be very low in comparison with the intake provided by the remainder of the child's diet. The intake of 6 mg L-cysteine from one baby biscuit baked from dough containing the amino acid represents 2 % of the estimated total intake of 296 mg cysteine per day from a typical varied infant diet. Two biscuits per day will, proportionately, represent 4% of the total intake, while three biscuits will represent 6%.

2. *(Amino acids from chemical group 34, Flavouring Group Evaluation 26, Revision 1 Scientific Opinion of the Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Food (AFC). The EFSA Journal (2008) 790, 1-51)*

The AFC noted that comprehensive information on metabolism of amino acids arising from dietary protein is available. In the normal diet, the amino acids are ingested as components of food proteins and not as free acids. An intake of 100 g protein per day is not an unusual intake for an adult European individual. Based on the amount of individual amino acids from soy bean protein, an intake of 100 g protein would lead to a daily intake of 2.2g cysteine

The Committee concluded that the human exposures to L-cysteine and L-cysteine hydrochloride through food are orders of magnitude higher than the anticipated levels of exposure from the use as the flavouring substances. Therefore, the Panel concluded that the use of L-cysteine and L-cysteine hydrochloride as flavouring substances are not of safety concern at their estimated levels of intake.

The Committee identified one oral toxicity test undertaken with L-cysteine: A single dose level of 3500 ppm L-cysteine in the diet of rats, equivalent to approximately 175mg/kg bw/day, did not result in any adverse effects over six generations (Frape et al., 1971).

Conclusion

L-cysteine is a non-essential amino acid which occurs widely in protein in a normal diet. Estimates by EFSA suggest that exposure to cysteine through the diet may typically reach or exceed 2200mg per day. Consumption at these levels is not associated with any evidence of toxicity. Exposure from the requested extension of use to peeled and or cut avocado and banana, in accordance with GMP is unlikely to result in a significant increase in daily cysteine intake and does not therefore present a risk to consumer safety.

7.3 Information related to the dietary exposure to the food additive

(As per section 3.3.1C of the Application Handbook 1 September 2013)

7.3.1 A list of the food groups or foods proposed to contain the food additive, or changes to currently permitted foods

The individual proposed food-uses of L-cysteine are set out in **Appendix 8**, following the categories set out in Schedule 1 to Standard 1.3.1 (Food Additives).

7.3.2 The maximum proposed level and/or the concentration range of the food additive for each food group or food, or the proposed changes to the currently permitted levels

The individual proposed use-levels of L-cysteine are set out in **Appendix 8**, following the categories set out in Schedule 1 to Standard 1.3.1 (Food Additives).

7.3.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

The Applicant is applying for extension of use of L-cysteine in avocado and banana – fruit is listed in the most recent Australian and New Zealand National Nutrition surveys.

7.3.4 The percentage of the food group in which the food additive is proposed to be used or the percentage of the market likely to use the food additive

The Applicant estimates that 0.3% of fresh-cut avocado and banana consumed in Australia will be treated with L-cysteine. The information supporting this is set out in **Appendix 9**.

7.3.5 Information relating to the use of the food additive in other countries, if applicable

This information has been addressed under Section 6.2.

7.3.6 For foods where consumption has changed in recent years, information on likely current food consumption

Fresh **avocado** consumption per person in Australia was reported as 2.7kg per person in 2010 (Avocados Australia).

Consumption of **banana** for 2012/13 is reported as 15.1kg/person (Australian Bananas Growers Council Inc).

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1. (*Opinion of the Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Food on a request from the Commission related to the use of L-cysteine in foods intended for infants and young children. The EFSA Journal (2006) 390, 1-7*)

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