

**13 December 2016**  
**[31–16]**

Approval report – Application A1117

## Extension of Use of L-Cysteine as a Food Additive

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Food Standards Australia New Zealand (FSANZ) has assessed an Application made by Link Trading (Qld) Pty Ltd to extend the use of the food additive, L-cysteine, to limit enzymatic browning of peeled and cut avocado and banana and so extend the shelf life.

On 29 June 2016, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received three submissions, along with one late submission which were supportive of the FSANZ's report and the draft variation.

FSANZ approved the draft variation on 6 December 2016. The Australia and New Zealand Ministerial Forum on Food Regulation (Forum) was notified of FSANZ's decision on 12 December 2016.

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

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### Supporting document

The [following document](#)<sup>1</sup> which informed the assessment of this Application is available on the FSANZ website:

SD1 Risk and Technical Assessment Report (at Approval)

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<sup>1</sup> <http://www.foodstandards.gov.au/code/applications/Pages/A1117-L-cysteineasaFA.aspx>

## Executive summary

Link Trading (Qld) Pty Ltd submitted an Application seeking to extend the permission for a currently permitted food additive, L-cysteine monohydrochloride, to treat peeled and/or cut avocados and bananas to control enzymatic browning and so extend their shelf life.

The table to section S15—5 in Schedule 15 – Substances that may be used as food additives in the *Australia New Zealand Food Standards Code* (the Code) contains permissions for food additives across different food categories.

L-Cysteine monohydrochloride is a permitted food additive for root and tuber vegetables (peeled, cut or both peeled and cut), but not for fruits.

L-Cysteine is an amino acid which occurs widely in dietary proteins. In a normal diet, amino acids are ingested as components of food proteins and not as free amino acids. Based on the amino acid composition of soy bean protein, an intake of 100 g protein per day is equivalent to an L-cysteine intake of 2.2 g/day. When given as a chronic nutritional supplement (in the form of N-acetyl cysteine), typical doses range from 300 to 600 mg/day, with up to 2400 mg/day used in the treatment of certain conditions. No evidence of adverse effects has been reported at these levels of supplementation. Any additional dietary exposure to L-cysteine resulting from the requested extension of use is expected to be negligible in comparison to L-cysteine intake from the consumption of dietary protein.

FSANZ's risk assessment concluded that there were no public health and safety concerns associated with the proposed extension of use of the food additive for the proposed purpose. The assessment also concluded that its use was technologically justified.

There is a primary source of specifications within Schedule 3 – Identity and Purity for L-cysteine monohydrochloride. The current labelling requirements in subsection 1.2.4—7 apply for ingredient labelling of products containing the food additive. L-cysteine is an amino acid and the analysis of amino acids is relatively well-developed, with well-established methods available.

FSANZ created a new sub subcategory of 4.1.3.3 (Avocados and bananas) which was added to the table to section S15—5 with a permission for L-cysteine monohydrochloride as a food additive for use in this food category at Good Manufacturing Practice (GMP).

# 1 Introduction

## 1.1 The Applicant

Link Trading (Qld) Pty Ltd is a supplier of raw materials to the food and beverage processing industry.

## 1.2 The Application

The Application sought to extend the permissions for a currently permitted food additive, L-cysteine monohydrochloride (hereafter referred to as L-cysteine unless reference is required to the monohydrochloride salt), to treat peeled and cut avocado and banana to control enzymatic browning and so extend their shelf life.

## 1.3 The current Standard

The table to section S15—5 in Schedule 15 – Substances that may be used as food additives contains permissions for food additives across different food categories.

Food category 4 (Fruits and vegetables (including fungi, nuts, seeds, herbs and spices)) contains subcategory 4.1.3 (fruits and vegetables that are peeled, cut, or both peeled and cut). All the additives permitted for use at GMP (Good Manufacturing Practice) (i.e. the food additives listed in the table to section S16—2) are permitted. In addition, sorbic acid and sodium, potassium and calcium sorbates, and ethyl lauroyl arginate are permitted to be added to these food products at various specified upper levels.

There are also further sub subcategories, being 4.1.3.1 (products for manufacturing purposes) which has permissions for sulphur dioxide and various sulphites, but only to treat processed apples and potatoes. The sub subcategory of root and tuber vegetables has permissions for sulphur dioxide and various sulphites and L-cysteine monohydrochloride.

The terms L-cysteine and L-cysteine monohydrochloride are used interchangeably throughout this report, as the monohydrochloride salt is the usual permitted form of L-cysteine.

Food additive permissions from the table to section S15—5 for subcategory 4.1.3 are:

<b>4.1.3</b>		<b>Fruits and vegetables that are peeled, cut, or both peeled and cut</b>	
		Additives permitted at GMP	
200 201 202 203	Sorbic acid and sodium, potassium and calcium sorbates	375	
243	Ethyl lauroyl arginate	200	
<b>4.1.3.1</b>		<b>Products for manufacturing purposes</b>	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	200	Only apples and potatoes
<b>4.1.3.2</b>		<b>Root and tuber vegetables</b>	
220 221 222 223 224 225 228	Sulphur dioxide and sodium and potassium sulphites	50	
920	L-cysteine monohydrochloride	GMP	

There are no permissions to use L-cysteine monohydrochloride as a food additive for peeled, cut, or both peeled and cut avocado and banana since neither fruit is a root or tuber vegetable.

L-cysteine (or the hydrochloride salt) is also a permitted processing aid used as a dough conditioner up to a maximum level of 75 mg/kg. This permission is listed in the table to section S18—9 (Permitted processing aids – various technological purposes) in Schedule 18 – Processing aids. The Code regulates the substance as a processing aid and not a food additive since it performs the technological purpose during the manufacture of the food. That is, it is used during the conditioning of the dough as part of the manufacturing process for bread and baked goods, and does not have a technological purpose in the final baked food.

This permission for dough conditioning is similar to that listed in Codex Alimentarius (see section 1.3.1 below), the United States of America (USA) (see section 1.3.1.1) and the European Union (EU) (section 1.3.1.3 below), except the other regulations permit the substance as a food additive not a processing aid.

### **1.3.1 International and National Standards**

There are limited international and national permissions for the use of L-cysteine monohydrochloride.

L-cysteine, and its hydrochloride and sodium and potassium salts, has the Codex Alimentarius International Number System (INS) of 920 and function class and technological purpose of flour treatment agent. This information is obtained from the Codex Standard CAC/GL 36-1989 (Class names and the international numbering system for food additives).

L-cysteine monohydrochloride has a specification in the Food Chemicals Codex (9<sup>th</sup> edition) but not in the Joint WHO/FAO Expert Committee for Food Additives (JECFA) Compendium of Food Additive Specifications.

#### **1.3.1.1 The USA**

L-cysteine as a nutrient amino acid is permitted to be added to foods in accordance with the conditions in section 172.320 of the Code of Federal Regulations (CFR), Title 21.

There is also permission in the CFR for the use of both L-cysteine (§184.1271) and L-cysteine monohydrochloride (§184.1272) as food additives with the technological purpose of dough strengthener in yeast-leavened baked goods and baking mixes. The permission is for 0.009 part of total L-cysteine per 100 parts of flour in dough (i.e. 90 mg/kg, parts per million (ppm)).

#### **1.3.1.2 Canada**

The Canadian Food and Drug Regulations Division 16, Table XI, Part IV permit the use of L-cysteine hydrochloride as a food additive sulphite replacement formulation for prepared fruits and vegetables consistent with Good Manufacturing Practice.

This use is similar to that proposed by the Application.

#### **1.3.1.3 EU**

L-Cysteine is permitted as a food additive in the EU for use in two types of food categories within the Commission Regulation (EU) No 1129/2011. They are:

- flours and other milled products and starches (category number 06.2.1) at level of *quantum satis* (comparable to GMP in the Code)

- processed cereal-based foods and baby foods for infants and young children as defined by Directive 2006/125/EC (food category 13.1.3). A maximum permitted limit of 1000 mg/kg applies for biscuits for infants and young children.

#### **1.3.1.4 Japan**

L-cysteine monohydrochloride is permitted as a food additive in Japan, as mentioned in Table 1 in Article 12 of the Food Sanitation Law Enforcement Regulations.

This listing does not detail how the food additive may be used.

#### **1.3.1.5 Singapore**

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

### **1.4 Reasons for accepting Application**

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that warranted the variation of a food regulatory measure.

### **1.5 Procedure for assessment**

The Application was assessed under the General Procedure.

## **2 Summary of the findings**

### **2.1 Summary of issues raised in submissions**

After assessing the Application, public submissions were sought from 29 June to 10 August 2016. Three submissions were received, with two from government agencies supporting the draft variation. One industry submission did not provide an opinion on whether it supported the progression of the Application or not; rather, it requested extending the use of L-cysteine to other food categories. The issues raised in submissions and how they have been addressed are provided in Table 1. Late comments were received after the closing date from an industry group which supported the Application, but raised one issue.

The outcome of assessing and addressing issues raised in submissions was to make a change to SD1 to correct an error pointed out by a submitter as noted in Table 1.

**Table 1: Summary of issues**

Issue	Raised by	FSANZ response
<p><b>Notes an error in SD1 in Table 2 of section 2.7.1 – Avocados. The results in the table do not accurately reflect the trial results presented in the Application.</b></p> <ul style="list-style-type: none"> <li><b>The trial used 2.5 – 5% w/v of the proprietary product, not L-cysteine as presented in Table 2</b></li> </ul>	<p>Victorian Department of Health and Human Services and the Victorian Department of Economic Development, Jobs, Transport &amp; Resources</p>	<p>FSANZ notes this comment which is correct. Changes have been made to the relevant section in SD1 to make it explicit that the data in Table 2 (taken from the Application) referred to the commercial preparation that contains L-cysteine and not L-cysteine itself.</p>
<p><b>Calls to extend the use of L-cysteine as a food additive in gels, gummies and liquid containing reducing sugars, protein and /or peptide.</b></p>	<p>Gelita Australia</p>	<p>This Application is not a vehicle to extend the use of L-cysteine in other food categories. If this is requested, a new application would be required.</p>

## 2.2 Risk assessment

FSANZ conducted a risk assessment on the extension of use of L-cysteine which is provided as SD1. The conclusions of this assessment are provided below.

L-cysteine is an amino acid which occurs widely in dietary proteins. In a normal diet, amino acids are ingested as components of food proteins and not as free amino acids. Based on the amino acid composition of soy bean protein, an intake of 100 g protein per day is equivalent to an L-cysteine intake of 2.2 g/day. When given as a chronic nutritional supplement (in the form of *N*-acetylcysteine), typical doses range from 300 to 600 mg/day, with up to 2400 mg/day used in the treatment of certain conditions. No evidence of adverse effects has been reported at these levels of supplementation. Any additional dietary exposure to L-cysteine resulting from the requested extension of use is expected to be negligible in comparison to L-cysteine intake from the consumption of dietary protein.

The food technology assessment concluded that L-cysteine performs the technological purpose of an antioxidant for the proposed purpose of treating peeled and cut avocado and banana pieces by reducing enzymatic browning. The fruit pieces are dipped into an aqueous solution containing L-cysteine, which extends the shelf life of such products stored at refrigeration temperature compared to untreated product.

## 2.3 Risk management

The conclusion of the risk assessment (section 2.2 and SD1) was that the extension of use of L-cysteine for the proposed purpose was both safe and technologically justified. There were, however, a number of risk management issues to consider; specifically how to add permissions into the Code, and labelling and specification aspects which are summarised below.

### 2.3.1 Amendments to the Code

The Application requested approval for L-cysteine monohydrochloride as a food additive to treat avocados and bananas that are peeled and/or cut. As noted in section 1.3, there is a food subcategory 4.1.3 (Fruits and vegetables that are peeled, cut, or both peeled and cut) within section S15—5 which details food additive permissions for different food categories.

There were two further sub subcategories being 4.1.3.1 (products for manufacturing purposes) and 4.1.3.2 (root and tuber vegetables) which were both not applicable for the requested products. The hierarchical nature of food additive permissions in Schedule 15 means that if permissions are provided for in subcategory 4.1.3 for these particular foods, even with a qualification statement, possible misinterpretations could be made that L-cysteine monohydrochloride is then also permitted to treat food in both sub subcategories 4.1.3.1 and 4.1.3.2. Therefore, it was decided to create a new sub subcategory called 4.1.3.3 (Avocados and bananas) and provide permission for L-cysteine at GMP.

### **2.3.2 Labelling requirements**

Substances used as food additives are required to be declared in the list of ingredients on the label of most packaged foods. Section 1.2.4—7 in Standard 1.2.4 – Information requirements – statement of ingredients requires food additives to be declared by their class name followed by the prescribed name, or code number in brackets.

Schedule 7 – Food additive class names (for statement of ingredients) provides the list of food additive class names for labelling purposes, while Schedule 8 – Food additive names and code numbers (for statement of ingredients) provides the lists of food additive names and code numbers. For the purposes proposed for this Application, FSANZ is proposing the class name ‘antioxidant’ be used for L-cysteine monohydrochloride, with either the prescribed food additive name ‘L-cysteine monohydrochloride’ or the code number ‘920’.

There are some exemptions to these requirements that apply to food for sale that is not required to bear a label. These exemptions are set out in Standard 1.2.1 – Requirements to have labels or otherwise provide information. The exemptions include whole or cut fresh fruit and vegetables (other than seed sprouts or similar products) in a package that does not obscure the nature or quality of the food, and food made and packaged on the premises from which it is sold. This means that L-cysteine monohydrochloride would not need to be declared if an exemption applies. This is consistent with the approach taken for other permitted food additives.

An issue was raised (in a late comment and so not a submission) that the term L-cysteine monohydrochloride is not consumer friendly as it is too technical. That is, it is of no relevance to a consumer if it is the monohydrochloride salt or not and so the simpler term for labelling purposes should be listed as L-cysteine in the list of food additives for labelling purposes in Schedule 8. However, FSANZ is unable to make this change to the Code as part of the assessment of this Application as it would have impact on current labelling of products that already use L-cysteine. Food manufacturers usually prefer to use the food additive number i.e. ‘920’ since it is shorter and less technical in the statement of ingredients.

### **2.3.3 Specifications**

Subsection 1.1.1—15(2) requires that a substance used as a food additive (paragraph 1.1.1—15(1)(a)) must comply with a relevant specification in Schedule 3 – Identity and purity. Food Chemicals Codex, which is a primary source of specifications under paragraph S3—2(1)(c), contains a specification for L-cysteine monohydrochloride. Therefore, no additional specification is required to be included in Schedule 3.

### **2.3.4 Analytical methods**

L-Cysteine is an amino acid and the analysis of amino acids is relatively well developed with well-established methods available to measure amino acids.



### **2.3.5 Cost benefit analysis**

The Office of Best Practice Regulation (OBPR), in a letter dated 24 November 2010 (reference 12065), granted a standing exemption from the need for the OBPR to assess if a Regulatory Impact Statement is required for the approval of applications relating to food additives. This standing exemption was provided as such changes are considered as minor, machinery and deregulatory in nature.

Notwithstanding the above exemption, FSANZ conducted a limited cost benefit analysis for this Application. That analysis found that extending the permission for the food additive L-cysteine to treat peeled and cut avocado and banana to limit enzymatic browning and so extend the shelf life had benefits to consumers and the cut fruit processors. No costs to different stakeholders were identified that overrode these benefits. Nor was any benefit in rejecting the Application identified.

FSANZ concluded that the direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the Application outweighed the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure. Therefore, the preferred option was to prepare a variation to the Code to permit the use of L-cysteine to treat peeled and cut avocado and banana.

## **3. Decision**

The draft variation as proposed following assessment was approved without change, and is at Attachment A. The variation takes effect on gazettal.

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

## **4 Risk communication**

### **4.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this Application. Every submission on the Application was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

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

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

The FSANZ Board considered the draft variation taking into account public comments received from the call for submissions.

The Applicant, individuals and organisations that made submissions on this Application will be notified at each stage of the assessment. Subscribers and interested parties were also notified via email about the availability of reports for public comment.

The FSANZ Board's decision has been notified to the Australia and New Zealand Ministerial Forum on Food Regulation. If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the Notification Circular and on the FSANZ website.

## **5 FSANZ Act assessment requirements**

### **5.1 Section 29**

#### **5.1.1 Consideration of costs and benefits**

As explained in section 2.3.5, FSANZ conducted a cost benefit analysis which concluded that the benefits that would arise from the proposed food regulatory measure outweigh the costs to the community, Government or industry that may arise from that measure.

#### **5.1.2 Other measures**

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

#### **5.1.3 Any relevant New Zealand standards**

Schedule 15 applies in both Australia and New Zealand.

#### **5.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **5.2. Subsection 18(1)**

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

#### **5.2.1 Protection of public health and safety**

FSANZ had undertaken a safety assessment (SD1) and concluded there were no public health and safety concerns with permitting L-cysteine as a food additive to treat peeled and cut avocado and banana.

#### **5.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

In accordance with existing labelling provisions for substances used as food additives, L-cysteine monohydrochloride would be required to be declared in the statement of ingredients on the label of most packaged foods, unless there is an exemption that applies for food for sale that is not required to bear a label.

#### **5.2.3 The prevention of misleading or deceptive conduct**

No issues were identified for this Application relevant to this objective.

### **5.3 Subsection 18(2) considerations**

FSANZ has also had regard to:

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

FSANZ used the best available scientific evidence to conduct the risk analysis which is provided in SD1. The Applicant submitted a dossier of scientific studies as part of their Application. Other technical information including scientific literature was also used in assessing the Application.

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

Section 1.3.1 details the current permissions for L-cysteine monohydrochloride in different countries. Permitting this Application ensures consistency between the Code and other international food standards.

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

Permitting L-cysteine monohydrochloride as a food additive to treat peeled and cut avocado and banana to extend the shelf life of such treated food products will improve and make such products more competitive and useful for consumers and so providing opportunities for interested companies.

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

No issues were identified for this Application relevant to this objective.

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

The Policy Guideline 'Addition to Food of Substances other than Vitamins and Minerals'<sup>2</sup> includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted 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')
- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ determined that permitting L-cysteine monohydrochloride to treat peeled and cut avocado and banana is consistent with these specific order policy principles.

## **Attachments**

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

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<sup>2</sup> <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

## **Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code***



### **Food Standards (Application A1117 – Extension of Use of L-cysteine as a Food Additive) Variation**

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

Dated [To be completed by Standards Management Officer]

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

**Note:**

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

**1 Name**

This instrument is the *Food Standards (Application A1117 – Extension of Use of L-cysteine as a Food Additive) Variation*.

**2 Variation to a standard in the *Australia New Zealand Food Standards Code***

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

**3 Commencement**

The variation commences on the date of gazettal.

**Schedule**

**[1] Schedule 15** is varied by adding the following to subcategory 4.1.3 in the table to section S15—5, in numerical order

<b>4.1.3.3</b>	<b>Avocados and bananas</b>	
920	L-cysteine monohydrochloride	GMP

## **Attachment B – Explanatory Statement**

### **1. Authority**

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

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

Application A1117 seeks to extend the permission of the food additive, L-cysteine, to permit its use for limiting enzymatic browning of peeled and cut avocado and banana and so extend the shelf life. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation.

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

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

### **2. Purpose**

The purpose of this variation is to permit the use of L-cysteine monohydrochloride to treat peeled, cut, or both peeled and cut avocado and banana. The food additive is used to prevent enzymatic browning of the cut surfaces (which is unacceptable to consumers) and so extend the shelf life of the treated food products.

### **3. Documents incorporated by reference**

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

### **4. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1117 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 29 June 2016 for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variations to Schedule 15 are likely to have a minor impact on business and individuals.

### **5. Statement of compatibility with human rights**

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

## **6. Variation**

The variation amends the table to section S15—5 in Schedule 15 by adding new food sub subcategory 4.1.3.3. The new food sub subcategory provides permission for the use of L-cysteine monohydrochloride (INS 920) in avocados and bananas subject to a maximum permitted level of GMP (Good Manufacturing Practice).