

16 January 2015 [01–15]

Call for submissions – Application A1103

Citric and Lactic Acids in Beer and related products

FSANZ has assessed an Application made by DB Breweries Limited – New Zealand requesting permission to add citric and lactic acid as food additives to beer and related products under Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standard Code*, and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act* 1991 (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at information for submitters.

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at <u>information for submitters</u>.

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on <u>documents for public comment</u>. You can also email your submission directly to <u>submissions@foodstandards.gov.au</u>.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 27 February 2015

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au. Hard copy submissions may be sent to one of the

following addresses: Food Standards Australia New Zealand PO Box 7186 CANBERRA BC ACT 2610 AUSTRALIA Tel +61 2 6271 2222

Food Standards Australia New Zealand PO Box 10559 The Terrace WELLINGTON 6143 NEW ZEALAND Tel +64 4 978 5630

Table of Contents

E,	EXECUTIVE SUMMARY2				
1	INTRODUCTION	3			
	1.1 THE APPLICANT	3 3 4			
2	SUMMARY OF THE ASSESSMENT	4			
	2.1 RISK ASSESSMENT 2.2 RISK MANAGEMENT 2.2.1 Levels of addition 2.2.2 Labelling 2.3 RISK COMMUNICATION 2.3.1 Consultation 2.3.2 World Trade Organization (WTO) 2.4 FSANZ ACT ASSESSMENT REQUIREMENTS 2.4.1 Section 29 2.4.2 Subsection 18(1) 2.4.3 Subsection 18(2) considerations	5 5 5 6 6 6			
3	DRAFT VARIATION	9			
	3.1 TRANSITIONAL ARRANGEMENTS	9 10 11			
	ATTACHMENT B – DRAFT EXPLANATORY STATEMENT	13			

Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at

 $\underline{\text{http://www.foodstandards.gov.au/code/applications/Pages/A1103CitricandLacticAcidsFAinBe} \\ \underline{\text{er.aspx}}$

SD1 Risk and Technical Assessment Report

Executive summary

Application A1103 seeks permission to add citric and lactic acid as food additives (acidity regulators) to beer and related products under Standard 1.3.1 – Food Additives of the Australia New Zealand Food Standard Code (the Code). A food additive may only be added to food if it is expressly permitted in Standard 1.3.1. Additives can only be added to food in order to achieve an identified technological function and according to Good Manufacturing Practice (GMP).

Currently, citric acid and lactic acid are not listed for use in the food category 'beer or related products' in Standard 1.3.1. However, they are permitted to be added as food additives to other alcoholic beverages (wine, fruit and vegetable wines, and spirits) and a large range of foods, at levels consistent with Good Manufacturing Practice (GMP).

The purpose of adding these food acids in beer production is to reduce the pH for lower strength and flavoured beers. Such acidity adjustment can improve the flavour profile of these types of beer.

Citric acid and lactic acid are substances of very low toxicity and occur in many foods e.g. in lemon/orange juice and cheese/yoghurt respectively. FSANZ's risk assessment concluded that adding citric and lactic acid to beer and related products is technologically justified and safe. As there is no risk to health and safety from their use under GMP, it is not considered necessary to set maximum levels for citric and lactic acid in these products.

Citric and lactic acids are permitted to be added (at GMP) to beers and related food categories in the food regulations of other countries (USA, Canada and Europe), and in the Codex Alimentarius General Standard for Food Additives (GSFA). Permission in the Code would provide consistency with international regulations and trading partners.

FSANZ has prepared a draft variation to permit the food additives citric and lactic acids to be added to beer and related products according to GMP.

1 Introduction

1.1 The Applicant

The Applicant is DB Breweries Limited – Auckland, New Zealand.

1.2 The Application

This Application seeks permission to use citric acid and lactic acid as food additives (acidity regulators) in beer through an amendment to food category 14.2.1 - Beer and related products, in Schedule 1 of Standard 1.3.1 – Food Additives. This category may include a range of beer products such as stout, light beer, lager, ale, Pilsener and draught beer.

The addition of citric and lactic acids enables a reduction in the pH for lower strength and flavoured beers. These types of beers can require acidity adjustment to improve their flavour profile. Detail is provided in the Food Technology section of Supporting Document 1(SD1).

The Applicant has requested that Standard 1.3.1 Schedule 1, food category 14.2.1 – Beer and related products be amended to include:

- INS 330 Citric Acid at GMP (Good Manufacturing Practice)
- INS 270 Lactic acid at GMP

The Applicant notes that, both lower strength and flavoured beers styles are within the scope of the definition of beer in Standard 2.7.2 - Beer. No amendments are requested to Standard 2.7.2.

If approved, the proposed permission would facilitate the production and importation of lower strength and flavoured beer styles in Australia and New Zealand. The Applicant also notes that the permission would provide consistency with the permissions and labelling requirements for citric and lactic acid in beer of international trading partners (see 1.3.1 below).

1.3 The current Standard

Standard 1.3.1 regulates the use of food additives in the production and processing of food. A food additive may only be added to food if it is expressly permitted in Standard 1.3.1. Additives can only be added to food in order to achieve an identified technological function according to GMP and to a maximum permitted level specified in the standard.

Schedule 1 of Standard 1.3.1 lists the permitted use of food additives in specified food types. Currently citric acid and lactic acid are not listed in Schedule 1 under food category 14.2.1 for use in beer and related products.

Standard 2.7.2 defines the term 'beer' and permits the addition of specified foods during its manufacture.

1.3.1 International Regulations

Codex Alimentarius permits the addition of citric acid and lactic acid to beer under GMP conditions in the General Standard on Food Additives, Table 3 provisions:

Beer and malt beverages (14.2.1):

- 330 Citric Acid (http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=173)
- 270 Lactic acid, L-, D- and DL-(http://www.codexalimentarius.net/gsfaonline/additives/details.html?id=169)

Citric and lactic acids are also permitted to be added to beers and various related products (at GMP) in the food regulations of the following other countries:

- European Union: E270 lactic acid and E330 citric acid are permitted additives for beer and malt beverages under Regulation (EC) 1333/08.
- USA: The US Code of Federal Regulations Chapter 21, Title 3, affirms the GRAS
 (Generally Recognized as Safe) status of citric acid and lactic acids and approves their
 use in all foods on a GMP basis. There is no limitation on the use of such products
 specified in the beer standard (27 CRF Part 25).
- Canada: Canada's Food and Drug Regulations (C.R.C., c. 870) at B.02.130 (S) Beer, permit pH adjusting and water correcting agents in the production of beer. Health Canada permits both citric and lactic acid as pH adjusting agents.

These overseas standards do not contain a food category specifically for 'beer and related products' as in the Code. However, both Codex and EU permit citric and lactic acid in beer and 'malt beverages' and Canadian regulations specifically permit citric and lactic acid as pH adjusting agents in ale, stout, porter or malt liquor under B.02.132 [S] (C.R.C., c. 870), as well as in beer.

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 might be developed as a food regulatory measure.

Currently citric acid and lactic acid are not listed in Schedule 1 under food category 14.2.1 for use in beer and related products. This affects the production and importation of lower strength and flavoured beer styles in Australia and New Zealand. Therefore, the Application warrants assessment and consideration of a variation to a food regulatory measure.

1.5 Procedure for assessment

The Application is being assessed as a General Procedure.

2 Summary of the assessment

2.1 Risk assessment

FSANZ's risk assessment is provided in SD1. In summary, citric acid and lactic acid are substances of very low toxicity. Citric acid occurs in many foods, with levels of approximately 10–50 g/L in orange juice and lemon juice, respectively. Lactic acid levels are highest in foods produced by fermentation, with levels of approximately 10 g/kg reported for cheese and yogurt.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) concluded that establishing an Acceptable Daily Intake (ADI) expressed in numerical terms was unnecessary for either substance. Citric and lactic acids are currently permitted as food additives in a large range of foods at levels consistent with GMP.

The food technology assessment concluded that certain types of beers exhibit improved flavour profiles due to pH reduction achieved by the addition of citric and lactic acids. Maximum levels of addition are expected to be approximately 3 g per litre of beer (total of citric acid plus lactic acid).

FSANZ concluded that the use of citric and lactic acids as food additives in beer and related products is technologically justified and presents no public health and safety issues.

2.2 Risk management

2.2.1 Levels of addition

Additives are permitted in the Code with maximum permitted levels in some cases, or for use under GMP.

Citric and lactic acids are currently permitted as food additives in a large range of foods at levels consistent with GMP. The Application requests GMP permission for the proposed use of citric and lactic acids in beer and related products and no specific level has been requested.

As the addition of citric and lactic acids to beer is not expected to pose a risk to public health and safety, it is not considered necessary to set specific maximum levels in the Code. Therefore, it is proposed that the addition of citric and lactic acid to beer and related products would be permitted according to GMP.

2.2.2 Labelling

Existing generic and specific labelling requirements in the Code apply to beer and related products e.g. the name of the food (Standard 1.2.2 – Food Identification Requirements) and the declaration of the alcohol content and number of standard drinks (Standard 2.7.1 – Labelling of Alcoholic Beverages and Food containing Alcohol).

However, beer that is standardised in Standard 2.7.2 is exempt from ingredient labelling under Standard 1.2.4 – Labelling of Ingredients. This exemption includes the requirement to declare food additives.

Based on the risk assessment conclusion, FSANZ considers current labelling provisions are appropriate for standardised beer with citric and lactic acid added. Citric acid and lactic acid will not be required to be declared on the label of standardised beer. This is the case with any other food additive (that is not allergenic, or that meets the labelling requirements in Standard 1.5.2 – Food produced using Gene Technology), that is permitted to be added to beer standardised under Standard 2.7.2.

2.3 Risk communication

FSANZ has developed a basic communication strategy for this Application.

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. Public submissions are called for to obtain the views of interested parties on the Application and the impacts of the regulatory options. All calls for submissions are notified via the FSANZ Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

Following consultation, the FSANZ Board will consider the proposed variation taking into account comments received through submissions. If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to the Australia and New Zealand Ministerial Forum on Food Regulation¹ (Forum). 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 national press and on the FSANZ website.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members 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 relevant international standards. Amending the Code to permit the use of citric and lactic acids as food additives for producing of beer and related products is not expected to have any adverse effect on international trade as these food acids are permitted food additives in the production of beer and related products in most countries in the world. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this Application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Cost benefit analysis

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders. The benefits and costs associated with the proposed amendments to Standard 1.3.1 have been considered based on regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to determine whether a Regulation Impact Statement is required for applications relating to food additives, as they are machinery in nature and their use is voluntary.

¹ convening as the Australia and New Zealand Food Regulation Ministerial Council

However, FSANZ has undertaken a limited qualitative impact analysis.

Two regulatory options have been considered:

- (1) amend Standard 1.3.1 to permit the addition of citric and lactic acids as food additives, to beer and related products; and
- (2) reject the Application.

The likely impacts of these options were considered but this is not intended to be an exhaustive, quantitative economic analysis. Rather, the qualitative effects of each option are described below, and are deliberately limited to broad areas such as trade and consumer choice.

Option 1 – Amend Standard 1.3.1 to permit the addition of citric and lactic acids as food additives to beer and related products

Sector	Costs or benefits
Consumers	Consumer choice would increase as a greater variety of beers or related products would be available, specifically lower strength and flavoured beers, with improved taste. This may include international beers imported into Australia and New Zealand. While these beers may cost more to a consumer, standard beers will continue to be available, providing choice.
Industry	The brewing industry would have the opportunity to develop and market a wider variety of beer types or related products. Importers would be able to sell imported beers that use citric and lactic acid. Retailers, including supermarkets, could stock a greater variety of beers.
Governments	There are not likely to be any specific costs as a result of this option. It is possible that greater availability of new lower alcohol beers may support the public policy objective of reducing harm from alcohol.

Option 2 – Reject the Application

Sector	Costs or benefits
Consumers	This option does not provide a benefit for consumers. This option would limit the availability of new, innovative beers or related products which would limit consumers'
	choice of lower alcohol and flavoured beers.
Industry	There would be an opportunity cost for beer producers, importers and retailers. Companies are less likely to develop innovative products. Also, this option would limit importing these types of innovative beer products. Re-labelling or re-branding of beer products may not be commercially viable or attractive.
Governments	There would be no direct impacts on Government agencies.

FSANZ considered that Option 1 to permit the use of citric and lactic acids in the production of beer and related products is the preferred option and has prepared a draft variation to the Code. Beer producers and retailers would be able to produce and market new lower alcohol and flavoured beers; consumers' choice would expand; harmonisation would benefit trade; and there should not be costs to governments.

The benefits resulting from this Application outweigh the costs to the community, industry or Government agencies.

2.4.1.2 Other measures

FSANZ is not aware of any other measures (whether available to FSANZ or not) that would be more cost-effective than a variation to the Code, as a result of the Application.

2.4.1.3 Any relevant New Zealand standards

There are no New Zealand only Standards; Standards 1.3.1 and 2.7.2 apply to both Australia and New Zealand.

2.4.1.4 Any other relevant matters

There are no other relevant matters.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

Citric acid and lactic acid are currently permitted as food additives in certain food categories in Standard 1.3.1 under GMP conditions. FSANZ has undertaken a safety assessment (see SD1 and Section 2.1 above) and concluded that there are no public health and safety concerns from extending their use to the production of beer and related products.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The generic labelling requirements will apply for beer and related products, to provide information for consumers i.e. the name of the food, the alcohol content and the number of standard drinks. Section 2.2.1 above provides further details.

2.4.2.3 The prevention of misleading or deceptive conduct

FSANZ has not identified any relevant issues relating to the prevention of misleading or deceptive conduct for this Application.

2.4.3 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

This Application was assessed using the best available scientific evidence. The Applicant submitted a dossier of scientific studies in support of the Application. Other resource material including published scientific literature and general technical information was also used to assess this Application.

the promotion of consistency between domestic and international food standards

The proposed amendments (food additive permissions) make the Australian and New Zealand regulations for production of beer and related products consistent with food standards in other countries (see section 1.3.1).

the desirability of an efficient and internationally competitive food industry

The draft variation is expected to have a positive effect on the local beer industry as it will allow the development of innovative lower alcohol and flavoured beers, and related products. Such products would also meet international regulations and so could compete on their merits and not be at a disadvantage due to different regulations.

the promotion of fair trading in food

The proposed food additive permissions would facilitate the production, importation and sale of lower strength and flavoured beer styles in Australia and New Zealand, which would support fair trading for manufacturers and retailers.

• any written policy guidelines formulated by the Ministerial Council²

The 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. 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 has determined that permitting citric and lactic acids as food additives for use in beer production, is consistent with these specific order policy principles.

3 Draft variation

The draft variation is at Attachment A. The proposed variation to Standard 1.3.1 is intended to take effect on the date of gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislative Instruments.

3.1 Transitional arrangements

3.1.1 Transitional arrangements for Code Revision

FSANZ has reviewed the Code in order to improve its clarity and legal efficacy. This review was undertaken through Proposal P1025 – details of which are on the FSANZ website⁴. The FSANZ Board has approved the draft revision of the Code and the decision has been notified to Ministers. It is expected that the new Code will commence on 1 March 2016 and will repeal and replace the current Code.

² Now known as the Australia and New Zealand Ministerial Forum on Food Regulation (convening as the Australia and New Zealand Food Regulation Ministerial Council)

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

⁴ http://www.foodstandards.gov.au/code/proposals/Pages/proposalp1025coderev5755.aspx

The new Code will then need to be amended to incorporate any outstanding changes made to the current Code, including the draft variation at Attachment A.

3.2 Implementation

If approved, implementation of the proposed amendments to the Code would occur from the date of gazettal.

Attachments

- A. Draft variation to the Australia New Zealand Food Standards Code
- B. Draft Explanatory Statement

Attachment A – Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1103 - Citric & Lactic Acids as Food Additives in Beer) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard 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 A1103 – Citric & Lactic Acids as Food Additives in Beer) Variation.

2 Variation to Standards 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] Standard 1.3.1 is varied by inserting under item 14.2.1 Beer and related products in Schedule 1 each of the following in numerical order

270 Lactic acid GMP 330 Citric acid GMP

Attachment B - Draft 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.

The Authority accepted Application A1103 which seeks to amend Standard 1.3.1 of the Code to allow the use of citric and lactic acid as food additives (acidity regulators) in beer and related products under Schedule 1 (food category 14.2.1). The Authority considered the Application in accordance with Division 1 of Part 3 and has drafted a variation to Standard 1.3.1.

2. Purpose

The Authority has approved a draft variation to Standard 1.3.1 which would allow the use of citric and lactic acid as food additives (acidity regulators) in beer and related products. Permitting these two food additives in beer and related products would enable manufacturers to reduce the pH for the production of lower strength and flavoured beers which can improve the flavour profile of these types of beer.

The draft variation would provide consistency with international regulations and trading partners, and facilitate the production and importation of lower strength and flavoured beer products in Australia and New Zealand.

3. Documents incorporated by reference

The draft variation to Standard 1.3.1 Food Additives does 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 A1103 includes one round of public consultation following an assessment and the preparation of a draft Standard and associated report.

A Regulation Impact Statement (RIS) was not required because the proposed variation to Standard 1.3.1are likely to have a minor impact on business and individuals. The Office of Best Practice Regulation has exempted the need for a RIS for applications relating to food additives, as they are machinery in nature and their use is voluntary.

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

Item 1 of the draft variation amends Standard 1.3.1 Food Additives by inserting Lactic acid (INS number 270) and Citric acid (INS number 330) in numerical order in item 14.2.1 Beer and related products in Schedule 1 of the Standard.

The draft variation commences on the date of gazettal.