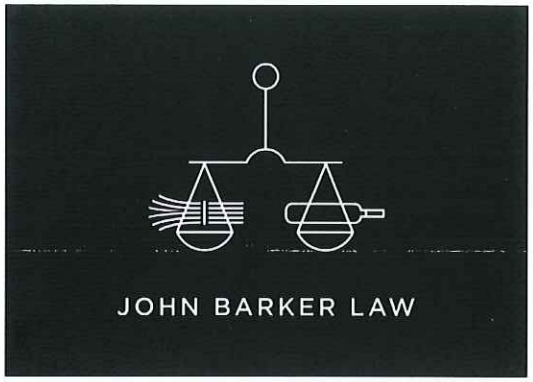


APPLICATION TO AMEND AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE: *INCLUSION OF CITRIC & LACTIC ACID AS ADDITIVES FOR BEER*

1 CONTENTS

PART 3.1 GENERAL REQUIREMENTS

PART 3.1.2 APPLICANT DETAILS

Applicant's name(s):
[redacted]

Company/Organisation name:
DB BREWERIES LIMITED

Address:

i. Street: 1 BAIRDS RD, OTAHUHU, AUCKLAND
ii. Postal: 1 BAIRDS RD, OTAHUHU, AUCKLAND

Telephone number:
[redacted]

Email address:
[redacted]

Nature of applicant's business:
Production and sale of alcoholic beverages (predominantly beer and cider).

Details of other individuals, companies or organisations associated with the application:
DB Breweries Ltd (the Applicant) is a wholly owned subsidiary company of Heineken N.V. The Applicant's related companies include Redwood Cider Company Limited (produces and sells cider) and Barworks Group Limited (on-premise hospitality company).

PART 3.1.3 PURPOSE OF THE APPLICATION

Purpose of application
The purpose of the Application is to allow the use of citric acid and lactic acid as food additives (acidity regulators) in beer under Standard 1.3.1: Schedule 1: Section 14.2.1 in order to facilitate the importation and production of lower-strength and flavoured beer styles.

Standard(s) requiring amendment
The Applicant requests that Standard 1.3.1: Schedule 1: Section 14.2.1 Beer and Related Products be amended by inclusion of the following:

- 330 Citric acid GMP
- 270 Lactic acid GMP

No amendments are requested to Standard 2.7.2 Beer.

PART 3.1.4 JUSTIFICATION FOR THE APPLICATION

(a) Need for the proposed change

This application requesting an amendment to the Australia New Zealand Food Standards Code (FSC) to permit the addition of citric acid and/or lactic acid to beer is for performance of an acidity regulator function.

The use of citric and lactic acid as food additives is necessary for the production of innovative beer styles, specifically lower-strength and flavoured beers.[1]

- Lower strength beers produced with a shorter fermentation may require acidity adjustment in order to counteract undesirable sensory characteristics from unfermented sugars or wort (the liquid used for beer fermentation).
- Flavoured beers may also require acidity adjustment in order to achieve a commercially acceptable pH balance.

In principle, both lower-strength and flavoured beer styles are within the scope of the definition of beer in Standard 2.7.2. No minimum strength is specified for beer and the addition of flavourings is permitted in beer. In practice however, because citric and lactic are not included as food additives for beer in Standard 1.3.1, Schedule 1: 14.2.1, most lower-strength and flavoured beer styles are excluded from being sold as "beer".

This means lower-strength or flavoured beers made with the use of citric or lactic acid as an additive are not standardized alcoholic beverages. They may only be sold provided that they are labelled as "beer product" or similar and they are also required to carry ingredient labelling and a nutritional information panel.

This situation has a number of consequences in relation to:

- product innovation, particularly the development of lower-strength and flavoured beers;
- consistency within the Food Standards Code; and
- consistency with the rules of trading partners and international obligations.

Product innovation

First, it limits the sales channels for such products which has a flow-on effect on the commercial viability of introducing new products of these types into the market. In New Zealand, section 58(1)(a) of the Sale and Supply of Alcohol Act 2012 permits only beer, wine, fruit and vegetable wine and mead as standardized in the FSC to be sold in supermarkets.

As a result, lower-strength and flavoured beers that fall outside those standards due solely to the use of citric as food additives are excluded from the most important sales channel in the New Zealand market. This has a material impact on the viability of producing and/or importing beer containing these substances as food additives.

Supermarket sales account for 60-70% of off-premise beer sales in New Zealand. If a lower-strength or flavoured beer cannot be sold in supermarkets it is often not viable to invest in product development (or

[1] Refer to pages 12-13 for further details.

in the case of imported products, the transport and labelling costs) to introduce a new product into the New Zealand market.

Consistency within the FSC

Second, it creates inconsistencies in the FSC regime regarding the addition of citric and lactic acids to standardized alcoholic beverages that are potentially misleading to consumers and unfair to producers. Standard beer styles will naturally contain citric and lactic acid. Citric and lactic acid may also be used as processing aids in the production of beer. Flavourings can also legally be added to "beer" that may contain far higher concentrations of citric or lactic acid than would be used to perform the acidity regulator function (e.g. addition of lemon juice).

However, as above, the current FSC regime only requires beer styles with citric or lactic acid used as a food additive in the production process include this information on the label. This creates the possibility that consumers may be given an incorrect impression that some beers contain citric and lactic acid while others do not.

Furthermore, other standardized fermented alcoholic beverages, such as grape, fruit and vegetable wines, are permitted to use citric and lactic acids as acidity regulators. There is no reason to exempt some standardized products containing citric and lactic acid from ingredient and nutritional information labelling and not others. Applying different rules for different products or different sources of these substances simply promotes consumer confusion.

Consistency with international obligations

Third, it creates inconsistency with the rules of international trading partners and international trade obligations. Citric and lactic acids are permitted additives in Codex Alimentarius and the beer standards of NZ's major trading partners including:

- European Union;
- USA;
- Canada.[2]

Products made in other countries where citric and lactic acid are used as permitted food additives must change their packaging in a significant way in order to be sold in Australia or New Zealand. In New Zealand such products are excluded from major sales channels. These effects could be construed as obstacles to trade.

New Zealand and Australia's obligations under the WTO Agreement on Technical Barriers to Trade require that technical regulations relating to product characteristics, processes and production and not related to human or plant health must not create unnecessary obstacles to trade. Such standards should be based where possible on existing international standards such as those set by Codex Alimentarius. Approval of this application would ensure that New Zealand and Australia are fully aligned with these obligations.

[2] See pages 9-10 for further detail.

(b) Advantages and disadvantages of proposed change over status quo

As above, this application enables the importation, production and sale of a greater range of beers in all distribution channels in New Zealand, including lower-strength beers, thereby giving consumers greater choice. It would also remove the requirement for imported beers made with the addition of citric/lactic acid in accordance with the beer standards in the country of origin to re-label as "beer products" for the Australian and New Zealand markets. Further, it would ensure that New Zealand and Australia are aligned with their international obligations and trading partners.

On the disadvantage side, there is only the possibility of the traditional understanding that the range of additives to beer should be kept to a minimum (as in Germany's historic "purity laws") being perceived to be diluted. In our view, this is significantly outweighed by the public interest in having a greater range of lower-strength beers widely available and in ensuring consistency with international obligations.

We further note the following points:

- citric and lactic acids are permitted additives to beer in many other jurisdictions (including the EU where the "purity" laws originate);
- citric acid and lactic already occur naturally in beer;
- both citric and lactic acid were previously permitted additives in beer in NZ prior to FSC implementation; and
- there is no minimum alcohol specified for beer so the facilitation of lower-strength styles is entirely consistent with the FSC;
- flavourings are permitted for beer so the facilitation of flavoured beer styles is entirely consistent with the FSC.

Effectively, the Applicant simply seeks to put NZ on a par with our major trading partners and re-instate the original position in NZ with the added advantage of allowing further development in lower-strength beers.

There is no question about the safety of citric and lactic acid as both are widely found in the food supply either as naturally occurring components of many products or as additives. They are permitted as additives according to Good Manufacturing Practices (GMP) in many processed foodstuffs in Australia and New Zealand as well as internationally (including wine and fruit wine). Citric acid and lactic acid are also permitted processing aids to GMP in beer under generally permitted food additive provisions.

(c) Status of similar applications made in other countries

No applications are being made by the Applicant to other national jurisdictions as these provisions already exist in the relevant countries national regulations.

3.1.4A REGULATORY IMPACT INFORMATION

1. Costs and benefits

(a) Costs and benefits to consumers

There are no costs to consumers. Citric acid and lactic acid are typically present in beer as a result of wort fermentation and production of alcohol. Additionally, citric acid and lactic acid can already be used in production of beer as processing aids.

The benefits to consumers are:

- the ability to offer a greater range of international beers; and
- the development of new and innovative New Zealand and Australian beers, including lower-strength beers; and
- for New Zealand consumers, the convenience of having a wider product range in supermarkets consistent with the Sale and Supply of Alcohol Act 2012.

In short, consumers get much greater variety, consistent with consumers from our major trading partners.

(b) Costs and benefits to industry and business in general

There are no costs to industry and business. The addition of citric and lactic acid is entirely voluntary. They will generally be used for lower-strength or flavoured beer styles due to the natural occurrence of these acids in more typical beer styles.

The benefits to producers include increased possibilities for innovation and development of commercially viable new beer styles, particularly lower-strength beers. For importers, there is the opportunity to import more international beer styles. For retailers, there is the opportunity to offer a wider range of products to their customers.

(c) Costs and benefits to government

There are no costs to Government. Benefits include increased trade and innovation, consistency with the rules of major trading partners, consistency with international obligations, and increased ability to develop lower-strength beer styles which supports public policy objective of reducing harmful consumption of alcohol.

2. Impact on International Trade

There would be a beneficial impact on beers imported into Australia and New Zealand. Beers containing citric and/or lactic acid in accordance with the beer standards in the country of origin would not need to be re-labeled as "beer product" but would instead be able to follow the same labelling rules as other beers.

There would also be an additional beneficial impact on beers imported into NZ as being able to sell these products in NZ supermarkets (where beer can generally be sold) which would improve the viability of importing new beers to NZ.

Encouraging the production of lower strength beers in New Zealand containing citric/lactic acids could also create an export market for these products as they will be produced in accordance with the

standards of New Zealand's major trading partners. Given New Zealand is already renowned for its malts and hops, and beer exports more than doubled between 2010 and 2012, this could enable a new export growth story.

PART 3.1.5 INFORMATION TO SUPPORT THE APPLICATION

(a) Public health and safety issues

The Applicant believes that the approval of this application is consistent with FSANZ's obligation to protect public health and safety.

Citric and lactic acids are found throughout the food supply both as naturally occurring substances and as food additives. As food additives they have been evaluated as safe by the Joint Expert Committee of Food Additives (JECFA) and other institutions.

They are generally permitted as food additives in a wide range of processed foods according to GMP (Standard 1.3.1: Schedule 2) and are also specifically permitted as food additives for other alcoholic beverages (wine and fruit wine – Standard 1.3.1: Schedule 1: Sections 14.2.2 and 14.2.4).

As permitted food additives (listed Standard 1.3.1, Schedule 2), citric acid and lactic acid may be used in the production of beer as generally permitted processing aids (Standard 1.3.3, clause 3(b)). Their function when used as processing aids in beer is the facilitation of fermentation.

Citric and lactic acid are also naturally present in beer by virtue of beer fermentation process. While permission to add citric or lactic acid as an acidity regulator may result in levels of these substances above those typically found in beer, they will still be at a comparatively low level overall.

(b) Consumer choice issues

The Applicant believes that the approval of this application is consistent with FSANZ's obligations to ensure the provision of adequate information relating to food to enable consumers to make informed choices and prevent misleading or deceptive conduct.

It will ensure that products sold in New Zealand and Australia are labeled consistently with other markets around the world. It will further benefit consumer choice by:

- facilitating the importation of different beer styles;
- facilitating the development of flavoured and lower-strength beer styles;
- making such styles more widely available in the New Zealand market.

The application will mean that some products will no longer be required to bear ingredient labelling and a nutritional information panel. However, this is consistent with the current regime for such labelling. As above, there is no reason to exempt some standardized products containing citric and lactic acid from ingredient and nutritional information labelling and not others. Applying different rules for different products or different sources of these substances simply promotes consumer confusion.

(c) Evidence of general food industry or specific company support

The Applicant's intention to seek application to amend the Food Standards Code Standard 1.3.1, Schedule 1 has been discussed at brewing industry association meetings. The majority of association brewers are Australia-based and do not experience the limitations on distribution experienced by New

Zealand brewers which are attributable to the New Zealand Sale and Supply of Alcohol Act 2012. However, no opposition was expressed at those meetings and the Applicant does not anticipate that other brewers will oppose this application.

PART 3.1.6 ASSESSMENT PROCEDURE

The Applicant's view is that the appropriate assessment procedure is **General Procedure, Level 1**.

The application extends the use of two common food additives to another product, in which the substances in question can be naturally present.

Because these additives have been assessed and classified as permitted for use according to GMP with no limit to Acceptable Daily Intake (ADI) and no new evidence of concern appears in the public domain that has warranted a recent evaluation, the application is likely to:

- involve an assessment of the risk to public health and safety of less than average complexity;
- have a limited, or no, social or economic impact;
- require a toxicological, nutritional, food technology, dietary modelling or microbiological assessment of less than average complexity;
- require an assessment of risk management measures of less than average complexity; and
- involve the development of no more than a basic community communications strategy to address public concern.

PART 3.1.7 CONFIDENTIAL COMMERCIAL INFORMATION

The Applicant consents to the application being non-confidential in its totality.

PART 3.1.8 EXCLUSIVE CAPTURABLE BENEFIT

There is no exclusive capturable benefit to the Applicant. Citric and lactic acid are widely available food additives that could be used by any beer producer.

PART 3.1.9 INTERNATIONAL AND OTHER NATIONAL STANDARDS

A. Codex Alimentarius

The addition of citric acid and lactic acids to beer is permitted 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)

B. Other National Standards or Regulations

USA, European Union and Canada all permit both citric acid and lactic acid to be added to "beer" as a food additive. Given the permissions in Codex, it is likely that these substances are permitted in other jurisdictions as well.

USA

The US Code of Federal Regulations Chapter 21, Title 3, affirms the GRAS status of citric and lactic acids and approves their use in all foods on a GMP basis (see links below). There is no limitation specified as to the use of such products in the corresponding beer standard (27 CRF Part 25).

Lactic acid: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1061
Citric acid: http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?fr=184.1033

European Union

Regulation (EC) 1333/08 specifies that E 270 lactic acid and E 330 citric acid are permitted additives for beer and malt beverages (see p254): http://eur-lex.europa.eu/legal-content/EN/TXT/?qid=1407036980848&uri=CELEX:02008R1333-20140414.

Canada

Canada's Food and Drug Regulations (C.R.C., c. 870) at B.02.130. [S]. "Beer" specify that pH adjusting and water correcting agents are permitted in the production of beer: http://laws-lois.justice.gc.ca/eng/regulations/C.R.C.,_c._870/page-65.html#h-63

Citric and lactic acid are both specified by Health Canada as permitted pH Adjusting Agents, Acid-Reacting Materials and Water Correcting Agents: http://www.hc-sc.gc.ca/fn-an/securit/addit/list/10-ph-eng.php

Other: New Zealand Food Regulations 1984

A consolidation of the NZ Department of Health Food Regulations 1984 incorporating Amendments 1 to 7 were valid up to promulgation of the Australia New Zealand Food Standards Code in 2000 and through the transition period to end 2002. Clause 218(g) permitted "Any food conditioner specified in clause 253(2) of these regulations"...to be added to beer. Both citric acid and lactic acid were permitted in clause 253(2)(c).

Before consolidation of both the New Zealand and Australian Beer Standards occurred, New Zealand brewers could add both citric acid and lactic acid to beer. A technical reason for its removal from the FSC could not be determined.

PART 3.1.10 STATUTORY DECLARATION

Refer attached document.

STATUTORY DECLARATION

Oaths and Declarations Act 1957

I, [redacted] Corporate Relations Manager, solemnly and sincerely declare that:

1. the information provided in this application fully sets out the matters required; and

2. the information is true to the best of my knowledge and belief; and

3. no information has been withheld which might prejudice this application to the best of my knowledge and belief.

And I make this solemn declaration conscientiously believing the same to be true and by virtue of the Oaths and Declarations Act 1957.

Declared at Auckland this 3rd day of SEPTEMBER 2014.

Signature: [redacted]

Declared before me: [redacted]

Solicitor
Auckland

PART 3.1.11 CHECKLIST

Refer attached document.

Checklist for General requirements

This Checklist will assist you in determining if you have met the information requirements as detailed in Section 3.1 – General Requirements. All applications must include this Checklist.

General requirements (3.1)

☐ 3.1.1 Form of application
- ☑ *Application, abstracts and other key documents in English*
- ☑ *Executive Summary (separated from main application electronically and in hard copy)*
- ☑ *Relevant sections of Part 3 clearly identified*
- ☑ *Pages sequentially numbered*
- ☑ *Electronic copy (searchable)*
- ☑ *1 hard copy*
- ☑ *Electronic and hard copy identical*
- ☑ *Hard copy capable of being laid flat*
- ☑ *All references provided (in electronic and hard copy)*

☑ 3.1.2 Applicant details

☑ 3.1.3 Purpose of the application

☑ 3.1.4 Justification for the application
- ☑ *Regulatory impact information*
- ☑ *Impact on international trade*

☑ 3.1.5 Information to support the application
- ☑ *Data requirements*

☑ 3.1.6 Assessment procedure
- ☑ *General*
- ☐ *Major*
- ☐ *Minor*
- ☐ *High level health claim variation*

☑ 3.1.7 Confidential Commercial Information
- ☐ *Confidential material separated in both electronic and hard copy* N/A
- ☐ *Formal request including reasons* N/A
- ☐ *Non-confidential summary provided* N/A

☑ 3.1.8 Exclusive Capturable Commercial Benefit
- ☐ *Justification provided* N/A

☑ 3.1.9 International and other national standards
- ☑ *International standards*
- ☑ *Other national standards*

☑ 3.1.10 Statutory Declaration

☑ 3.1.11 Checklist/s provided with application
- ☑ *3.1 Checklist*
- ☐ *Any other relevant checklists for Parts 3.2-3.7*

Checklist for Standards related to substances added to food

This Checklist is in addition to the Checklist for Section 3.1 and will assist you in determining if you have met the information requirements as specified in Sections 3.3.1-3.3.3.

Food Additives (3.3.1)

- ☑ A.1 Nature and technological function information
- ☑ A.2 Identification information
- ☑ A.3 Chemical and physical properties
- ☑ A.4 Impurity profile
- ☑ A.5 Manufacturing process
- ☑ A.6 Specifications
- ☑ A.7 Food labelling
- ☑ A.8 Analytical detection method
- ☑ A.9 Additional functions
- ☑ B.1 Toxicokinetics and metabolism information
- ☑ B.2 Toxicity information
- ☑ B.3 Safety assessments from international agencies
- ☑ C.1 List of foods likely to contain the food additive
- ☑ C.2 Proposed levels in foods
- ☑ C.3 Likely level of consumption
- ☑ C.4 Percentage of food group to contain the food additive
- ☑ C.5 Use in other countries (if applicable)
- ☑ C.6 Where consumption has changed, information on likely consumption

Processing Aids (3.3.2)

- ☐ A.1 Type of processing aid
- ☐ A.2 Identification information
- ☐ A.3 Chemical and physical properties
- ☐ A.4 Manufacturing process
- ☐ A.5 Specification information
- ☐ A.6 Analytical method for detection
- ☐ B.1 Industrial use information (chemical only)
- ☐ B.2 Information on use in other countries (chemical only)
- ☐ B.3 Toxicokinetics and metabolism information (chemical only)
- ☐ C.3. Allergenicity information of enzyme (enzyme only)
- ☐ C.4. Overseas safety Assessment Reports
- ☐ D.1 Information on source organism (enzyme from microorganism only)
- ☐ D.2 Pathogenicity and toxicity of source microorganism (enzyme from microorganism only)
- ☐ D.3 Genetic stability of source organism (enzyme from microorganism only)
- ☐ E.1 Nature of genetic modification of source organism (enzyme from GM source microorganism)
- ☐ F.1 List of foods likely to contain the processing aid
- ☐ F.2 Anticipated residue levels in foods
- ☐ F.3 Information on likely level of consumption

PART 3.3 STANDARDS RELATED TO SUBSTANCES ADDED TO FOOD

PART 3.3.1A FOOD ADDITIVES: TECHNICAL INFORMATION ON THE ADDITIVES

1. Nature and Technological Function of the Additives

(a) Technological functions listed in FSC 1.3.1 Schedule 5

This Application seeks the approval of citric acid and lactic acid to perform the technical function of acidity regulators.

It is noted that the acid content of beer generally can also have a preservative function in that many bacteria cannot grow at a lower pH, especially gram-negative bacteria likely to cause food poisoning. Consequently the use of citric and lactic acids could assist with this technical function. However, this is an incidental function and not an objective of this Application.

It is further noted that both lactic acid and citric acid are already permitted for use as processing aids. They are used in the preparation of wort by adjusting pH to allow malt enzymes to operate at their optimum. However, if lactic acid and/or citric acid are added post fermentation to further reduce the pH below that of the fermented beer, the Applicant's interpretation is that these acids may be construed as performing a technological function as an acidity regulator.

(b) Reason why food additive needed to fulfil these functions

Wort and beer contain soluble proteins and amino acids that buffer the pH fall during fermentation. During fermentation, yeast performs a number of functions including:

- removing amino acids (reduces buffering capacity),
- producing a spectrum of organic acids (including small amounts of both citric and lactic acids) and
- producing carbon dioxide.

All these changes serve to reduce the pH of the wort to give a final fermented beer pH typically between 3.8 and 4.6. The total acid content may include a number of organic acids, although lactic and citric acids are found in the highest concentrations.[3]

While the naturally occurring pH levels are generally adequate for standard beer styles, addition of citric and lactic is necessary for other beer styles, particularly lower-strength beers and/or flavoured beers. Lower-strength and flavoured beers fall within the scope of the definition of beer in Standard 2.7.2, unless a non-permitted additive is used such as citric and/or lactic acid.

The reasons why addition of citric and lactic acid may be needed for lower-strength beer styles is linked to the less extensive fermentation process used for such products. Shorter fermentation produces less alcohol. However, it also means that the pH reducing functions of the yeast during fermentation are not as extensive. The final pH of lower-strength beers can be higher than 4.6 and as high as slightly above 5.0. From a sensory standpoint, this can be unappealing to consumers as it does not give the sensory

[3] See for e.g. Pollock, J.R.A. ed. (1981), *Brewing Science Volume 2,* Academic Press, London at p. 239; Gerstenberg, H. (2000), On the natural citric acid content of beer, *Brauwelt*, 18 May 2000, 140(20), 856-857. (Refer Appendix 1).

profile they typically associate with beer. Consequently, addition of food acid is required to adjust the pH to within a range more typically associated with beer.

Shorter fermentation can also result in higher residual sugars as less sugar is consumed by the yeast in fermentation. The addition of citric and/or lactic acid can serve to counteract the perception of excessive sweetness in such products. (It also assists with microbiological stability in such products, slightly lowering pasteurisation times - although as above this is an incidental function).

Finally, shorter fermentation can leave a product with atypical sensory characteristics from the unfermented wort. These may need to be adjusted by the addition of flavourings (in accordance with the permissions in Standard 1.3.1, Schedule 1) which necessitate a consequent pH adjustment.

Products other than lower-strength beers made with the addition of flavourings may also require a pH adjustment as a consequence of the addition of such flavourings to adjust the pH to within a range more typically associated with beer. Fruit-flavoured beers are a particular case in point.

Fruit-flavoured beers have a long history in some parts of the world - such as Belgium's famous Kriek (cherry) and Framboise (raspberry) beer styles. While fruit-flavoured beers have not been commonly produced in New Zealand or Australia, the use of such flavourings is permitted in the Food Standards Code and offers a potential avenue for product innovation.

Standard beer typically has a pH in the range of 3.8 - 4.6. When fruit flavourings are added to beer, a pH within this range may be too high for optimal expression of the fruit characters. This may be due to an alteration in the balance of sugars and acids or simply because a higher or different acidity profile is associated by consumers with a particular fruit character. Fruits such as raspberry, strawberry, orange and lemon-lime are complemented by the addition of citric acid which offers the correct, lively form of acidity with a short temporal experience that optimises the organoleptic experience of their flavours.

Lactic acid offers a smooth 'dairy' form of acidity that can be used by itself or in combination with citric acid to enhance the flavours of peach, apricot and cherry which require a softer acidity of longer duration. The taste profile of the base beer characteristics can influence the final optimised taste profile, and final pH levels are usually determined empirically for that reason. In the above examples, lemon taste may be best expressed at around pH 3.3, whereas for raspberry and strawberry final product pH around 3.8 is optimal.

(c) Evidence that amounts to be added are consistent with the technological function

The proposed amount of addition is GMP. A GMP limit is consistent with the recommendation in the Codex General Standard for Food Additives.

Citric and lactic acid have almost identical properties in beer and may be used individually or in combination. In practice, the typical addition of citric and/or lactic acid would be approximately 1500 mg/L (total in combination). This will lower the pH of beer pH by 0.5 units. In some circumstances where the pH is exceptionally high an addition of up to 3000 mg/L may be necessary.

As above, the target range for beer pH is between 3.8 and 4.6 (or, as above, slightly lower in the case of certain fruit-flavoured beer styles). In this respect, the amount of citric or lactic acid is self-limiting. Products with a pH much lower that this range will be commercially unacceptable, thereby defeating the purpose of the pH addition.

CITRIC ACID

2. Information to Enable Identification of the Additive

(a) Chemical name

i. Chemical Abstracts (CAS)

Anhydrous
anhydrous citric acid
beta-Hydroxytricarballylic acid
Monohydrate
citric acid monohydrate

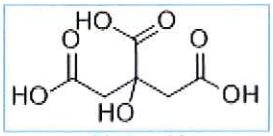
ii. International Union of Pure and Applied Chemistry (IUPAC)

Anhydrous
2-hydroxy-1,2,3-propanetricarboxylic acid
Monohydrate
2-hydroxy-1,2,3-propanetricarboxylic acid monohydrate

(b) Chemical formula

Anhydrous: $C_5H_8O_7$
Monohydrate: $C_5H_8O_7.H_2O$

(c) Structural formula



Citric acid

(d) Common name and synonyms

Citric acid

(e) Manufacturer's code

Not relevant

(f) Marketing name

Citric acid anhydrous or
Citric acid monohydrate

(g) Chemical Abstract Service (CAS) registry number

a. Anhydrous 77-92-9
b. Monohydrate 5949-29-1

3. Information on the Chemical and Physical Properties of the Additive

(a) Information to characterise technological properties in a food matrix

Citric acid is readily soluble in aqueous solutions. Its primary effect is to lower pH or increase acidity of a food or beverage. Its role in beer is primarily to regulate acidity but it will also contribute to flavour profile. The degree of dissociation of citric acid depends on the pH of the food system in relation to citric acid isoelectric point.

(b) Interaction with other foods

Citric acid may associate with cations (Na, Ca, Mg, and K) in a food or beverage to form a citrate salt which may have a buffering effect.

(c) Metabolic fate of food additive after consumption

Citric acid is naturally occurring in a wide range of foods and a natural constituent of the diet. Intake of citric acid to the diet from consumption of foods where citric acid is used as a food additive is expected to be low in comparison with intake from natural sources.

Citric acid and citrates have a well-established and recognised role as an intermediate metabolite of the citric acid cycle.

4. Information on the Impurity Profile

(a) Nature and amounts of all impurities

Impurities are indicated in the attached JECFA specification.
These are:

- Sulphated ash not more than 0.05 %
- Oxalate not more than 100 mg/kg
- Sulphates not more than 150 mg/kg
- Lead not more than 0.5 mg/kg

(b) Impurity identification by CA or IUPAC names

As above.

5. Manufacturing Process

Refer Appendix 2.

6. Specification for Identity and Purity

(a) Specification from one of published sources in FSC Standard 1.3.4

JECFA Specification: Citric Acid. (See Appendix 3)

(b) Presence of known allergens

None known

7. Information for Food Labelling

Functional class: Acidity regulator
Code number: 330

8. Analytical Method for Detection

(a) Analytical method capable of detecting and quantifying food additive in foods for which use being sought

There are widely available methods of analysis capable of detecting and quantifying lactic and citric acid in beer. For example: Floridi, S., Perretti, G., Montanari, L. and Fantozzi, P., "Determination of Organic Acids in Italian Beer by HPLC", *Ind. Bevande, Dec. 2002, 31(182), 546-549;*

There are also several reverse phase HPLC methods for determining citric acid and lactic acid in wine, ciders and fruit juices that can be sourced and adapted.

Below are links to further quantification methods:

http://www.dionex.com/en-us/webdocs/4760-AN46_IC_beer_03May95_LPN0661-01.pdf

http://www.phenomenex.com/application/print/14171

http://www.shodex.com/en/dc/03/08/13.html

An analytical method used to quantify citric acid and/or lactic acid will quantify both the food additive proportion and that derived from wort fermentation in the final beer.

(b) Consideration to quantifying degradation products

The Applicant considers that quantification of degradation products in a food system is not required for citric acid or lactic acid.

9. Potential Additional Functions of the Food Additive when Added to Food

(a) Nutritive function

Other than contribution to energy as required in Nutrition Information Requirements, FSC Standard 1.2.8 Table to clause 2(2)[4] citric acid and lactic acid have no nutritive function in foods. The expected level of citric acid and/or lactic acid in beer will not materially contribute to the energy value of beer.

(b) Health related function

Not relevant. Foods with alcohol content greater than 1.15% are excluded from provisions for nutrition and health related claims

LACTIC ACID

2. Information to Enable Identification of the Additive

(a) Chemical name

i. Chemical Abstracts (CAS)
Lactic acid

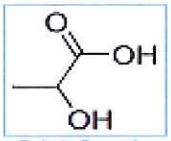
ii. International Union of Pure and Applied Chemistry (IUPAC)
2-hydroxypropanoic acid
2-hydroxyproprionic acid

[4] energy factor for organic acids = 13 kJ/g

(a) *Chemical formula*

$C_3H_6O_3$

(b) *Structural formula*



L(+)-Lactic acid

(c) *Common name and synonyms*

Lactic acid

May indicate form e.g. L-lactic acid, D-Lactic acid, DL-Lactic acid or lactic acid content for aqueous solutions

(d) *Manufacturer's code*

Not relevant

(e) *Marketing name*

Lactic acid

Some suppliers sell by Brand name e.g. Purac

(f) *Chemical Abstract Service (CAS) registry number*

a. All forms 50-21-5
b. L-Lactic acid 79-33-4
c. D-Lactic acid 10326-41-7
d. DL-Lactic acid 598-82-3

3. Information on the Chemical and Physical Properties of the Additive

(a) *Information to characterise technological properties in a food matrix*

Lactic acid is readily soluble in aqueous solutions. It is the predominant organic acid in milk and milk products. Lactic acid's primary function is to lower pH or increase acidity of a food or beverage. Its role in beer is to regulate acidity and contribute to flavour. The degree of dissociation of an acid depends on the pH of the food system in relation to its isoelectric point.

(b) *Interaction with other foods*

Lactic acid may associate with cations (Na, Ca, Mg, and K) in a food or beverage to form a lactate salt which may have a buffering effect.

(c) Likely metabolic fate of food additive after consumption

Lactic acid is normal intermediary compound of mammalian metabolism in the L(+)-lactate form. It can also arise in the body from glycogen, amino acids and dicarboxylic acids breakdown. Lactic acid is produced by muscular contractile activity, liver and blood metabolism. It may be produced by some microorganisms specifically *Lactobacilli spp.* Lactic acid is excreted in urine.

4. Information on the Impurity Profile

(a) Nature and amounts of all impurities

Impurities are indicated in the attached JECFA specification.

These are:

- Sulphated ash not more than 0.1 %
- Chloride not more than 0.2 %
- Sulphate not more than 0.25 %
- Iron not more than 10 mg/kg
- Lead not more than 2 mg/kg
- Other acids[5] not present

Impurity identification by CA or IUPAC names

As above.

5. Manufacturing Process

Refer Appendix 4.

6. Specification for Identity and Purity

(a) Specification from one of published sources in FSC Standard 1.3.4

JECFA Monograph: Lactic Acid. (Refer Appendix 5)

(b) Presence of known allergens

None

7. Information for Food Labelling

Functional class: Acidity regulator
Code number: 270

8. Analytical Method for Detection

As for citric acid above.

9. Potential Additional Functions of the Food Additive when Added to Food

As for citric acid above.

[5] Citric acid, phosphoric acid or tartaric acid

B. Information Related to the Safety of the Food Additives

In relation to matters 1-3 under this sub-heading of the Handbook, the Applicant refers to the evaluations conducted by the JECFA and other authorities set out below.

Citric acid

- The most recent JECFA evaluation for citric acid was in 1973: http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=3594. The ADI "not limited" is as assessed by JECFA in 1973. It includes citric acid and its calcium, potassium, sodium and ammonium salts.
- US Food and Drug Administration Select Committee on GRAS substances (SCOGS) reviewed citric acid in 1977: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogsListing&id=82
- In 2001, the OECD SIDS initial assessment of citric acid recommended that no further work was required on citric acid and noted that the sheer volume and high congruence of data on citric acid give a uniform picture even if individual results may sometimes be difficult to assess: www.chem.unep.ch/irptc/sids/OECDSIDS/77929.pdf.
- In 2006, European Food Safety Authority (EFSA) prepared a scientific opinion for magnesium potassium citrate as a source of magnesium and potassium in food for particular nutritional uses: http://www.efsa.europa.eu/en/scdocs/doc/afc_op_ej392_potassium%20magnesium%20citrate_op_en,3.pdf. In assessing the toxicological data for citric acid EFSA referred to JECFA's 1973 evaluation above.
- Given the widespread use of citric acid as an additive, the longstanding nature of the JECFA evaluation and its comparatively recent citation by EFSA, a comprehensive literature review was not considered necessary. However, a search of the TOXLINE>TOXNET database using the search term "citric acid" and a search of the MEDLINE>Pubmed database using the search term "citric AND acid AND toxic*" did not reveal new studies of significance or toxicology effects relating to the use of citric acid as a food additive.[6]

Lactic acid

- The most recent JECFA evaluation for lactic acid is as a flavouring agent in 2001. The ADI "not limited" is as assessed by JECFA in 1973. (http://apps.who.int/food-additives-contaminants-jecfa-database/chemical.aspx?chemID=3367)
- US Food and Drug Administration Select Committee on GRAS substances (SCOGS) reviewed lactic acid in 1978: http://www.accessdata.fda.gov/scripts/fcn/fcnDetailNavigation.cfm?rpt=scogslisting&id=180.
- In 1991, the European Commission's Scientific Committee for Food supported the view of the JEFCA (ec.europa.eu/food/fs/scf/reports/scf_reports_25.pdf) and this view was re-asserted in the 2011

[6]A very recent safety assessment of citric acid, inorganic citrate salts and alkyl citrate esters as used in cosmetics concluded that they were safe in the present practices of use and concentration. While the focus of the study was on dermal exposure, the recognition of citric acid and the other substances as safe direct food additives was acknowledged. (Fiume MM et al. *Safety Assessment of Citric Acid, Inorganic Citric Salts and Alkyl Citric Esters Used in Cosmetics*, Int. J. Toxicol. 2014 May 26;33(2 suppl):16S-46S). We also note for completeness a recent study into in vitro adverse effects of citric and benzoic acid on human etrythrocytes as mediated by quercetin, which found incomplete protective action by quercetin in relation to higher doses of citric acid against oxidative stress induction in human erythrocytes. (Bas H et al. *In vitro effects of quercetin on oxidative stress in human erythrocytes by benzoic acid and citric acid*, Folia Biol (Krakow) 2014;62(1): 59-66).

Scientific Opinion of EFSA evaluating the use of lactic acid as an anti-microbial treatment for beef carcasses: www.efsa.europa.eu/en/efsajournal/doc/2317.pdf.

- Given the widespread use of lactic acid as an additive, the longstanding nature of the JECFA evaluation and its comparatively recent citation by EFSA, a comprehensive literature review was not considered necessary. However, a search of the TOXLINE>TOXNET database using the search term "lactic acid" and a search of the MEDLINE>PubMed database using the search term "lactic AND acid AND toxic*" did not reveal new studies of significance or toxicology effects relating to the use of lactic acid as a food additive.

PART C INFORMATION RELATING TO DIETARY EXPOSURE TO THE FOOD ADDITIVE

1. List of food groups or foods proposed to contain the food additive

Based on FSC 1.3.1 food group classification: Section 14.2.1 Beer and related products.

2. Maximum proposed level and/or the concentration range of the food additive

The maximum proposed level of use of citric and lactic acid is GMP. The typical addition of citric and/or lactic acid would be approximately 1500 mg/L (total in combination). In some circumstances where the pH is exceptionally high an addition of up to 3000 mg/L may be necessary.

Given the pH of beer the quantity of citric and or lactic acid added is low and insignificant given the naturally occurring levels in a wide range of foods.

3. Information on the likely level of consumption

The Applicant recommends that the most recent NNS survey be used for modelling intake for age groups above minimum age for alcohol consumption.

The latest NNS' 2011 - 2013 survey classifies beer products as follows:

2011-13 Sub-major food group code	2011-13 Sub-major food group name	1995 Food group code or food Code	1995 Food Group Name or food name
291	Beers	2811	Beers, > 3.5% alcohol
291	Beers	2812	Beers, 1.15 — 3.5% alcohol, reduced alcohol / light
291	Beers	2813	Beers, <1.15% alcohol, ultra / special / extra light

The Applicant anticipates that citric acid and/or lactic acid would most likely be used in lower-strength (reduced alcohol and light) beers. Flavored beers may also use these additives, although these are a small sub-set of the overall beer market that is not disaggregated within the NNS.

4. Percentage of the food group/market for which the food additive is proposed to be used

As above, the Applicant anticipates that it will be predominantly lower-strength beers and, to a lesser extent, flavoured beers in which these additives will be used. The current market share for these styles in New Zealand is estimated at (1.7%). These styles are growing in popularity and the Applicant anticipates that overall market share for these products could grow to an estimated (5%+). In volume terms, 2014 full year estimates for lower strength beers are around 50,000 hectolitres, whereas annual

beer volumes are around 2.85 million hectolitres and carbonated soft drinks around 1.96m hectoliters, so there is plenty of room for growth in this category.

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

As above, citric and lactic acid are permitted additives for beer in many international markets. Both citric acid and lactic acid are also naturally occurring in a wide range of foods and may be added to an extensive range of processed foods in international markets. The range and scope of use for both compounds is extensive and limited by the buffering capacity of a food and the accepted acidic/sour taste.

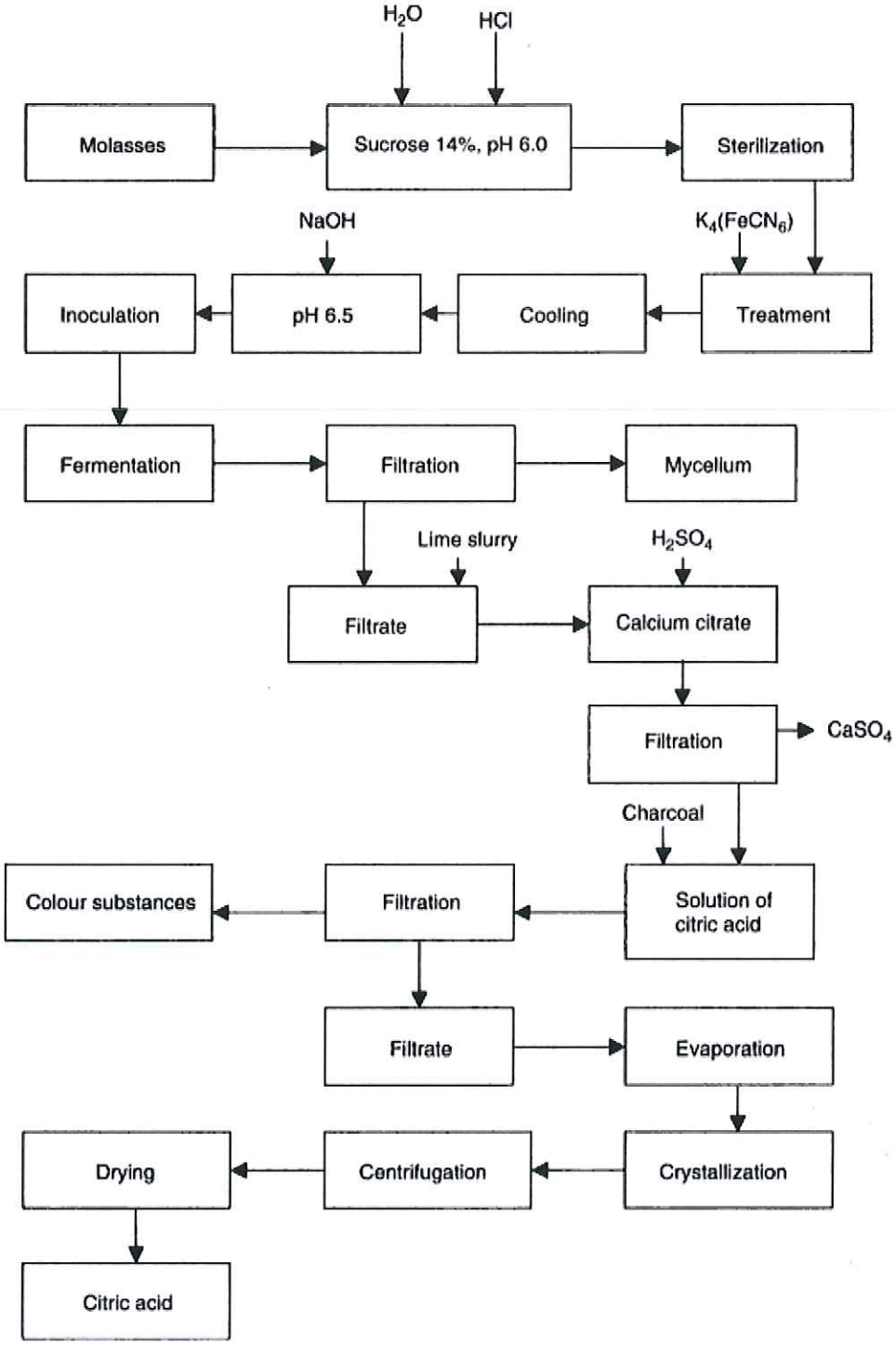
6. Information on likely current consumption

The latest NNS provides the most up to date data on consumption of beers and other alcoholic beverages.

APPENDIX 1: REFERENCES REGARDING ORGANIC ACIDS IN BEER

APPENDIX 2: CITRIC ACID PRODUCTION

Citric acid is typically obtained from a biochemical process involving fermentation and extraction steps.



APPENDIX 3: JECFA SPECIFICATION: CITRIC ACID

CITRIC ACID

Prepared at the 53rd JECFA (1999) and published in FNP 52 Add 7 (1999), superseding specifications prepared at the 51st JECFA (1998), published in FNP 52 Add 6 (1998). Group ADI "Not limited" for citric acid and its calcium, potassium, sodium and ammonium salts established at the 17th JECFA in 1973.

SYNONYMS INS No. 330

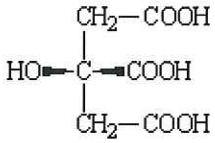
DEFINITION Citric acid may be produced by recovery from sources such as lemon or pineapple juice or fermentation of carbohydrate solutions or other suitable media using *Candida* spp. or non-toxicogenic strains of *Aspergillus niger*

Chemical names 2-hydroxy-1,2,3-propanetricarboxylic acid

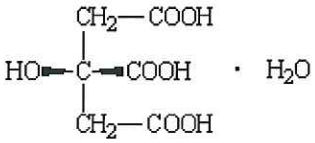
C.A.S. number 77-92-9 (anhydrous)
5949-29-1 (monohydrate)

Chemical formula $C_6H_8O_7$ (anhydrous)
$C_6H_8O_7 \cdot H_2O$ (monohydrate)

Structural formula



Anhydrous



Monohydrate

Formula weight 192.13 (anhydrous)
210.14 (monohydrate)

Assay Not less than 99.5% and not more than 100.5% on the anhydrous basis

DESCRIPTION White or colourless, odourless, crystalline solid; the monohydrate form effloresces in dry air

FUNCTIONAL USES Acidulant; sequestrant; antioxidant synergist; flavouring agent (see "Flavouring agents" monograph)

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol.4) Very soluble in water; freely soluble in ethanol; slightly soluble in ether

Test for citrate (Vol. 4) Passes test

PURITY

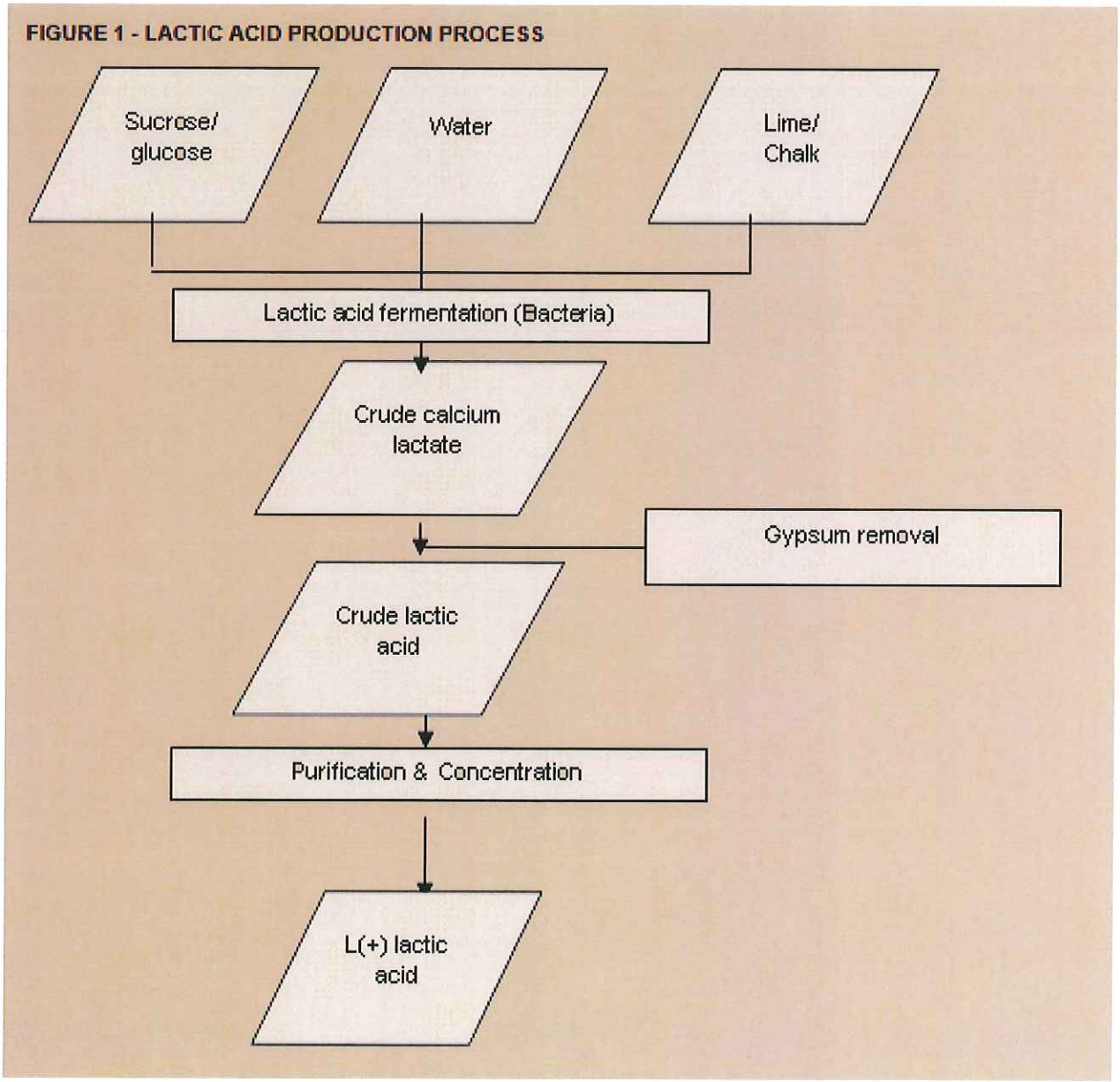
Water (Vol. 4) Anhydrous: Not more than 0.5% (Karl Fischer Method)
Monohydrate: Not less than 7.5% and not more than 8.8% (Karl Fischer

	Method)
Sulfated ash (Vol. 4)	Not more than 0.05%
Oxalate (Vol. 4)	Not more than 100 mg/kg Test 1.0 g of the sample by the Oxalate Limit Test (Volume 4). Measure absorbance at 520 nm in a 10 mm cell. The test solution should have less than 0.023 absorbance units.
Sulfates (Vol. 4)	Not more than 150 mg/kg Test 20 g of the sample by the Sulfates Limit Test (Volume 4) using 6.0 ml of 0.01N sulfuric acid in the standard
Readily carbonizable substances	Heat 1.0 g of sample with 10 ml of 98% sulfuric acid in a water bath at 90±1° for 60 min. No colour darker than *MatchingFluid K* (25°) should be produced (not more than 0.5 absorbance units at 470 nm in a 10 mm cell).
Lead (Vol. 4)	Not more than 0.5 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."
METHOD OF ASSAY	Weigh, to the nearest mg, 2.5 g of the sample and place in a tared flask. Dissolve in 40 ml of water and titrate with 1 N sodium hydroxide, using phenolphthalein TS as the indicator. Each ml of 1 N sodium hydroxide is equivalent to 64.04 mg of $C_6H_8O_7$.

APPENDIX 4: LACTIC ACID PRODUCTION

Lactic acid is typically obtained from a biochemical process involving fermentation and extraction steps.

FIGURE 1 - LACTIC ACID PRODUCTION PROCESS



APPENDIX 5: JECFA SPECIFICATION: LACTIC ACID

LACTIC ACID

Prepared at the 46th JECFA (1996), published in FNP 52 Add 4 (1996) superseding specifications prepared at the 21st JECFA (1977), published in NMRS 57 (1977) and in FNP 52 (1992). Metals and arsenic specifications revised at the 63rd JECFA (2004). An ADI 'not limited' for lactic acid and its salts was established at the 23rd JECFA (1979)

SYNONYMS INS No. 270

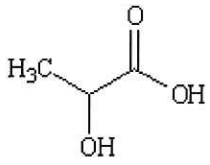
DEFINITION Obtained by the lactic fermentation of sugars or is prepared synthetically; may contain condensation products such as lactic acid, lactate and dilactide. Common products of commerce are 50-90% solutions. Solid products containing about 100-125% of titratable lactic acid also exist. (Note: Lactic acid is hygroscopic and when concentrated by boiling or by distillation it forms condensation products which hydrolyze to lactic acid on dilution and heating in water).

Chemical names: Lactic acid, 2-hydroxypropanoic acid, 2-hydroxypropionic acid

C.A.S. number: 50-21-5 (L-: 79-33-4; D-: 10326-41-7; DL-: 598-82-3)

Chemical formula: $C_3H_6O_3$

Structural formula:



Formula weight: 90.08

Assay: Not less than 95.0% and not more than 105.0% of the labelled concentration. For the purity tests, prepare an aqueous solution containing 40% of lactic acid, using the labelled concentration. To dissolve the sample, use warming if necessary. When the labelled concentration is less than 40%, use the product for the test without dilution. The amount of sample to be tested in the tests is the amount of lactic acid calculated from the labelled concentration of the products, except in the tests for "sugars" and for "readily carbonizable substances". In the latter two tests, the term "sample" refers to the 40% solution of lactic acid. The limit of the tests is based on the amount of lactic acid, calculated from the labelled concentration.

DESCRIPTION Colourless, syrupy liquid or white to light yellow solid or powder

FUNCTIONAL USES Acid, acidifier

CHARACTERISTICS

IDENTIFICATION

Solubility (Vol. 4): Liquid: Soluble in water and in ethanol

	Solid: Sparingly soluble in water, soluble in acetone
Test for acid	A 1 in 10 solution or dispersion of the sample is acid to litmus paper
Test for lactate (Vol. 4)	Passes test
PURITY	
Sulfated ash (Vol. 4)	Not more than 0.1% Test 2 g of the sample (Method I). Retain the ash for use in the test for iron.
Chloride	Not more than 0.2% Weigh accurately a portion of the sample solution equivalent to about 5 g of lactic acid, dissolve in 50 ml of water, and neutralize to litmus with sodium hydroxide solution (1 in 4). Add 2 ml of potassium chromate TS and titrate with 0.1N silver nitrate to the first appearance of a red tinge. Each ml of 0.1N silver nitrate is equivalent to 3.545 mg of Cl.
Sulfate	Not more than 0.25% Weigh accurately a portion of the sample solution equivalent to about 50 g of lactic acid, transfer into a 600-ml beaker, dissolve in 200 ml of water, and neutralize to between pH 4.5 and 6.5 with sodium hydroxide solution (1 in 2), making the final adjustment with a more dilute alkali solution. Filter, if necessary, and heat the filtrate or clear solution to just below the boiling point. Add 10 ml of barium chloride TS, stirring vigorously, boil the mixture gently for 5 min, and allow to stand for at least 2 h, or preferably overnight. Collect the precipitate of barium sulfate in a tared Gooch crucible, wash until free from chloride, dry, and ignite at 600° to constant weight. The weight of barium sulfate so obtained, multiplied by 0.412, represents the weight of SO_4 in the sample taken.
Iron	Not more than 10 mg/kg To the ash obtained in the test for Sulfated ash add 2 ml of dilute hydrochloric acid (1 in 2), and evaporate to dryness on a steam bath. Dissolve the residue in 1 ml of hydrochloric acid, dilute to 40 ml with water, and add 40 mg of ammonium persulfate crystals and 10 ml of ammonium thiocyanate TS. Any red or pink colour does not exceed that produced by 2.0 ml of Iron Standard Solution (20 µg Fe) in an equal volume of solution containing the quantities of reagents used in the test.
Cyanide	To 0.1 g of the sample add 3 ml of a 20% of sodium hydroxide solution and heat on a water bath for 10 min. After cooling, add 1 drop of phenolphthalein TS and add dropwise dilute acetic acid TS until the pink colour has disappeared. Add 3 drops of dilute acetic acid TS and water to make 40 ml. Add 0.6 ml of chloramine-T solution (dissolve 1 g of chloramine-T ($C_7H_7NNaO_2SCl \cdot 3H_2O$) in water to make 100 ml; prepare freshly before use) and allow to stand for 3 min. Add 10 ml of pyridine-pyrazolone (dissolve 0.5 g of 1-phenyl-3-methyl-5-pyrazolone in 100 ml of hot water at 75° and cool to room temperature; mix with 20 ml of pyridine containing 0.025 g of bis-(1-phenyl-3-methyl-5-pyrazolone); prepare freshly before use) and allow to stand for 25 min. No blue colour is produced (limit approx. 1 mg/kg).

Citric, oxalic, phosphoric or tartaric acid	Dilute 1 g of the sample to 10 ml with water, add 40 ml of calcium hydroxide TS, and boil for 2 min. No turbidity is produced
Sugars	Add 5 drops of the sample solution to 10 ml of hot alkaline cupric tartrate TS. No red precipitate is formed.
Readily carbonizable substances	Superimpose carefully 5 ml of the sample solution kept at 15° on 5 ml of sulfuric acid TS kept at 15°. No deep grey colour is produced within 15 min at the contact zone of the two liquids.
Lead (Vol. 4)	Not more than 2 mg/kg Determine using an atomic absorption technique appropriate to the specified level. The selection of sample size and method of sample preparation may be based on the principles of the method described in Volume 4, "Instrumental Methods."
METHOD OF ASSAY	Weigh accurately a portion of the sample equivalent to about 3 g of lactic acid, transfer to a 250-ml flask, add 50 ml of 1N sodium hydroxide, mix, and boil for 20 min. Add phenolphthalein TS, titrate the excess alkali in the hot solution with 1N sulfuric acid, and perform a blank determination. Each ml of 1N sodium hydroxide is equivalent to 90.08 mg of $C_3H_6O_3$.