

24 April 2012
[8-12]

Call for submissions – Application A1068

Hydrogen Peroxide as a Processing Aid

FSANZ has assessed an Application made by Fonterra Co-operative Group Ltd (Fonterra), to permit the use of hydrogen peroxide as a processing aid to control the population of lactic acid producing microorganisms, and in so doing, stabilise the pH during the production of dairy products manufactured using lactic acid producing microorganisms. FSANZ 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 its consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

Under the Information Publication Scheme all submissions on applications and proposals will be published on our website. We will not publish any material provided in-confidence. 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 [information for submitters](#).

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 [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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) 5 June 2012

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:

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Supporting document

The following document which informed the assessment of this Application is available on the FSANZ website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1068hydr5375.cfm>.

SD1 Risk and Technical Assessment

1. Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Fonterra Co-operative Group Ltd on 18 October 2011 to approve an additional use of hydrogen peroxide as a processing aid. The Applicant requested a variation to Standard 1.3.3 – Processing Aids, to permit the use of hydrogen peroxide to control the population of lactic acid producing microorganisms, and in so doing, stabilise the pH during the production of dairy products manufactured using lactic acid producing microorganisms. The Applicant has proposed a maximum permissible limit (MPL) for residual hydrogen peroxide of 5 mg/kg in the final food.

As part of its assessment and the subsequent development of a food regulatory measure, FSANZ has had regard to section 29 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ has also addressed the objectives set out in section 18 of the FSANZ Act.

FSANZ has assessed the technological suitability of hydrogen peroxide as a food processing aid and its potential risks to public health and safety when used as proposed. It has been determined that hydrogen peroxide fulfils its intended technological function. That is, it is effective as a processing aid for controlling the population of lactic acid producing microorganisms during the production of dairy products manufactured using lactic acid producing microorganisms. No public health and safety concerns have been identified with the use of hydrogen peroxide and an MPL of 5 mg/kg as proposed.

FSANZ has also determined that the use of hydrogen peroxide as a processing aid in the manufacture of these products is consistent with the specific order policy principles for 'Technological Function' under the Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*.

FSANZ proposes to approve the draft variation to Standard 1.3.3 to permit the use of hydrogen peroxide as a processing aid in the manufacture of:

- fermented milk
- fermented milk products
- cheese made using lactic acid producing microorganisms
- cheese products made using lactic acid producing microorganisms.

The proposed variation is not intended to permit the use of hydrogen peroxide as an alternative to good hygienic practice during the manufacture of dairy products, nor to permit its use to stabilise deteriorating milk.

2. Introduction

2.1 The Applicant

Fonterra Co-operative Group Ltd (Fonterra) is a New Zealand-based multinational dairy company cooperatively owned by 11,000 New Zealand dairy farmers. It claims to be the world's leading exporter of dairy products and the largest diversified milk processing company globally.

2.2 The Application

Application A1068 – Hydrogen peroxide as a processing aid was submitted by Fonterra on 18 October 2011. It sought approval to extend the use of hydrogen peroxide as a processing aid, to the production of dairy products manufactured using lactic acid producing microorganisms.

2.3 The current Standard

Food processing aids are regulated under Standard 1.3.3. This Standard currently permits the use of hydrogen peroxide as a processing aid for a number of scenarios:

- Table to clause 11, to treat packaged water and water used as an ingredient in other foods
- Table to clause 12, as a bleaching agent, washing and peeling agent to treat all foods
- Table to clause 14, miscellaneous uses:
 - inhibiting agent for dried vine fruits, fruit and vegetable juices, sugar, vinegar and yeast autolysate
 - removal of glucose from egg products
 - removal of sulphur dioxide.

The maximum permissible level (MPL) of residual hydrogen peroxide in the final food for the above permitted uses is 5 mg/kg.

Currently, there is no permission to use hydrogen peroxide as a processing aid in the production of dairy products manufactured using lactic acid producing microorganisms.

2.4 Reasons for accepting Application

The Application was accepted for assessment because:

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

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Technical and safety risk assessment

FSANZ has assessed the technological justification for the proposed use of hydrogen peroxide and the potential risks to consumer health and safety of foods manufactured as proposed by the Applicant. Details on the assessment are available in Supporting Document 1 (SD1).

The conclusions from the technical and risk assessment are as follows:

- The proposed use of hydrogen peroxide as a processing aid in the manufacture of the following products is technologically justified:
 - fermented milk
 - fermented milk products
 - cheese made using lactic acid producing microorganisms
 - cheese products made using lactic acid producing microorganisms.

These products are collectively referred to as 'dairy products manufactured using lactic acid producing microorganisms' in the rest of this document.

- Hydrogen peroxide fulfils the stated technological function at the proposed level of use i.e. it is effective for maintaining a stable pH in the production of dairy products manufactured using lactic acid producing microorganisms
- A suitable specification for hydrogen peroxide used in food already exists in the Food Chemicals Codex (2010)
- There are effective processes to control the level of hydrogen peroxide in the final food so it does not exceed the proposed maximum permitted level of 5 mg/kg
- There are suitable detection methods available to measure the amount of hydrogen peroxide in the final food
- Alternative methods of pH control such as refrigeration and heat treatment are costly, less effective and may result in poorer quality products
- Hydrogen peroxide has a long history of safe use as a food processing aid
- Hydrogen peroxide is a product of normal mammalian metabolism produced in gram quantities by the body daily. Therefore, the body has inbuilt mechanisms to detoxify it
- An Acceptable Daily Intake (ADI) for hydrogen peroxide has not been established by FSANZ or any other regulatory body and is not considered necessary
- Estimates of dietary exposure to hydrogen peroxide, from that naturally occurring in food and/or present in food due to use during manufacturing indicate negligible exposure relative to amounts produced by the body during normal metabolism, and
- The proposed use of hydrogen peroxide as a processing aid with a maximum permitted level of 5 mg/kg in the finished product raises no public health and safety concerns.

3.2 Risk Management

When hydrogen peroxide is present in dairy products manufactured as proposed in this Application at or below the requested MPL of 5 mg/kg, there is no evidence of risk to public health and safety. Therefore, no other specific risk management measures are needed besides specifying this MPL in the Standard.

3.2.1 Limitations on permitted uses

As hydrogen peroxide could be misused in the manufacture of dairy foods, it is considered prudent to provide clarity on the use proposed in this Application.

The Applicant has requested permission for hydrogen peroxide to be used as a processing aid to control the population of lactic acid producing microorganisms and in so doing stabilise the pH in the production of dairy products manufactured using lactic acid producing microorganisms.

The use of hydrogen peroxide proposed in this Application is limited to stabilising pH only and excludes its use to stabilise deteriorating milk, and use as a sanitiser i.e. use as an alternative to good hygienic practices.

3.3 Regulatory options and impacts

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:

- whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure,
- whether other measures (available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the Application,
- any relevant New Zealand standards, and
- any other relevant matters.

3.3.1 Cost/benefit analysis

Under subsection 30(1) of the FSANZ Act, FSANZ must either:

- (1) prepare a draft variation to Standard 1.3.3 to permit the use of hydrogen peroxide as a processing aid in the production of dairy products manufactured using lactic acid producing microorganisms; or
- (2) reject the Application.

Although the Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), has provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to processing aids as they are machinery in nature, FSANZ has performed an impact assessment.

A consideration of the cost/benefit of the regulatory options is not intended to be an exhaustive, quantitative financial analysis of the options and, in fact, most of the impacts that are considered cannot be assigned a dollar value. Rather, the analysis seeks to highlight the qualitative impacts of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Develop a draft variation to Standard 1.3.3

Sector	Costs or benefits to sector
Consumers	Varying Standard 1.3.3 to permit the use of hydrogen peroxide as proposed by the Applicant may bring advantages to consumers by expanding the range of dairy products available to them. There are no disadvantages to consumers associated with this option.
Industry	This option would benefit industry by widening the range of dairy products they can manufacture. The Applicant also states that using hydrogen peroxide as proposed would enable them to be more competitive on the international stage as they will be making products under similar cost structures to manufacturers in the United States and Canada, where hydrogen peroxide is approved for this use.
Governments	There are no costs or benefits to governments associated with this option .

Option 2 – Reject the Application

Sector	Costs or benefits to sector
Consumers	There are no benefits or costs to consumers from this option.
Industry	There are no benefits or costs to industry from this option.
Governments	There are no benefits to governments from this option. Declining the Application may be seen as stifling industry innovation.

3.3.2 Other measures

There are no other measures that could achieve the same result other than an amendment to Standard 1.3.3.

3.3.3 Relevant New Zealand Standards

Standard 1.3.3 applies to New Zealand. There are no relevant New Zealand-only standards.

3.3.4 Any other relevant matters

None identified.

3.3.5 Addressing FSANZ's objectives for standards-setting

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

3.3.5.1 Protection of public health and safety

The consumption of dairy products manufactured using hydrogen peroxide as a processing aid as proposed in this Application does not raise any public health or safety concerns.

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

There are no specific labelling requirements for hydrogen peroxide when used as proposed in this Application. Under clause 3 of Standard 1.2.4 – Labelling of Ingredients, substances used as processing aids in accordance with Standard 1.3.3 are not subject to ingredient labelling in the final food.

3.3.5.3 The prevention of misleading or deceptive conduct

There is potential for hydrogen peroxide to be misused during the manufacture of dairy foods, therefore it is considered prudent to provide clarity on the use proposed in this Application. The proposed use is limited to controlling the population of lactic acid producing microorganisms and, in so doing, stabilise the pH during the production of dairy products manufactured using lactic acid producing microorganisms.

The proposed variation does not permit the use of hydrogen peroxide as a sanitiser (thus replacing good hygienic practice) in the manufacture of these products. Hydrogen peroxide is also not intended to be used to stabilise deteriorating milk.

3.3.5.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2):

- *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 their Application. Other resource material including published scientific literature and general technical information was also used in assessing this Application.

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

The proposed variation is consistent with international food standards. Hydrogen peroxide is currently used in the United States and Canada in the production of fermented dairy products.

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

The proposed variation is expected to have a positive impact on competitiveness of the food industry. The proposed use of hydrogen peroxide may allow Australian and New Zealand food industries to manufacture new innovative products and to compete with international manufacturers under similar cost structures.

- *the promotion of fair trading in food*

The proposed variation is not expected to have any impact on fair trading in food.

- *any written policy guidelines formulated by the Ministerial Council¹.*

The *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 processing aids. 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; and

¹ Now known as the COAG Legislative and Governance Forum on Food Regulation (the Forum).

- the substance is added in a quantity and a form which is consistent with delivering the stated purpose, and
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of hydrogen peroxide as a processing aid in the production of dairy products manufactured using lactic acid producing microorganisms is consistent with the specific order policy principles for 'Technological Function'.

3.4 Decision

FSANZ recommends the extension of the use of hydrogen peroxide as a processing aid to the production of dairy products manufactured using lactic acid producing microorganisms based on technological justification for the proposed use, potential benefits to industry and consumers, and because there are no public health or safety issues arising from the consumption of foods manufactured as proposed.

3.5 Risk communication

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ's social media tools and *Food Standards News*.

Subscribers and interested parties are also notified via email about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options. Documents relating to A1068 are available on the website at <http://www.foodstandards.gov.au/foodstandards/applications/applicationa1068hydr5375.cfm>.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions.

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

If the draft variation to the Code is approved by the FSANZ Board, that decision will be notified to COAG Legislative and Governance Forum on Food Regulation (the 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.

3.5.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards. Amending the Code to permit the use of hydrogen peroxide as a processing aid in the production of dairy products manufactured using lactic acid producing microorganisms is unlikely to have a negative effect on

international trade because the proposed variation introduces a new permission for foods produced in, or imported into Australia and New Zealand. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variation

The draft variation to Standard 1.3.3 is at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variation will take effect on gazettal.

5. References

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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 A1068 – Hydrogen Peroxide as a Processing Aid) 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

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

1 Name

This instrument is the *Food Standards (Application A1068 – Hydrogen Peroxide as a Processing Aid) Variation*.

2 Variation to Standards in the Australia New Zealand Food Standards Code

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

3 Commencement

This variation commences **on the date of gazettal**.

SCHEDULE

[1] **Standard 1.3.3** is varied by inserting in columns 2 (Function) and 3 (Maximum permitted level) of the Table to clause 14, for the processing aid Hydrogen peroxide –

Control of lactic acid producing microorganisms to stabilise the pH during the manufacture of – (a) fermented milk; (b) fermented milk products; (c) cheese made using lactic acid producing microorganisms; and (d) cheese products made using lactic acid producing microorganisms.	5
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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.

FSANZ accepted Application A1068 which seeks permission to extend the use of hydrogen peroxide as a processing aid to the production of dairy products manufactured using lactic acid producing microorganisms. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation.

2. Purpose and operation

Currently, there is no permission to use hydrogen peroxide as a processing aid in the production of dairy products manufactured using lactic acid producing microorganisms.

The variation is intended to permit the use of hydrogen peroxide as a processing aid to control the population of lactic acid producing microorganisms, and in so doing, stabilise the pH during the manufacture of:

- fermented milk
- fermented milk products
- cheese made using lactic acid producing microorganisms
- cheese products made using lactic acid producing microorganisms.

The variation is not intended to allow the use of hydrogen peroxide as an alternative to good hygienic practices during the manufacture of dairy products. Neither is it intended to permit the use of hydrogen peroxide to stabilise deteriorating milk.

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 A1068 will include one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (which includes the draft variation) will be released for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Standard 1.3.3 is 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

This variation permits the use of hydrogen peroxide as a processing aid to control the population of lactic acid producing microorganisms during the manufacture of:

- fermented milk
- fermented milk products
- cheese made using lactic acid producing microorganisms
- cheese products made using lactic acid producing microorganisms.