26 September 2012
[22-12]

Approval Report – Application A1068

Hydrogen Peroxide as a Processing Aid

Food Standards Australia New Zealand (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.

On 24 April 2012, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received seven submissions.

FSANZ approved the draft variation on 20 September 2012. The COAG Legislative and Governance Forum on Food Regulation[1] (Forum) was notified of FSANZ's decision on 25 September 2012.

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

[1] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting document

The following document used to prepare this Report is available on the FSANZ website at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1068hydr5375.cfm

SD1 Risk and technical assessment report (Approval)

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 in the *Australia New Zealand Food Standards Code* (the Code), to permit the use of hydrogen peroxide to control the population of lactic acid producing microorganisms in order to stabilise pH during production of dairy products manufactured using these microorganisms. The Applicant proposed a maximum permitted level (MPL) for residual hydrogen peroxide of 5 mg/kg in the final food.

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

FSANZ 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 Ministerial Council Policy Guideline on the *Addition to Food of Substances other than Vitamins and Minerals.*

FSANZ has approved the 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 variation does not permit the use of hydrogen peroxide as an alternative to good hygienic practice during the manufacture of dairy products, nor 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

A1068 was lodged by Fonterra on 18 October 2011. It sought approval to extend the use of hydrogen peroxide as a processing aid for 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 purposes:

- To treat packaged water and water used as an ingredient in other foods (Table to clause 11)
- As a bleaching agent, washing and peeling agent to treat all foods (Table to clause 12)
- Miscellaneous uses (Table to clause 14):
  - 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 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 the Application

The Application was accepted for assessment because:

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

2.5 Procedure for assessment

The Application was assessed under the General Procedure.

2.6 Decision

The draft variation as proposed following assessment was approved without change.

The draft variation is at Attachment A.

3. Summary of the findings

3.1 Risk assessment

FSANZ 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 were:

- Using hydrogen peroxide as a processing aid for the proposed purpose in manufacturing 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. The conclusions of this report do not apply to dairy products made using other methods.

- 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), which is one of the primary sources of specifications in Standard 1.3.4 – Identity and Purity.

- There are effective processes to control the level of hydrogen peroxide in the final food so it does not exceed the proposed MPL of 5 mg/kg.

- There are suitable analytical methods for verifying whether products manufactured as proposed comply with the MPL.

- 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.

- The proposed use of hydrogen peroxide as a processing aid with a MPL 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, and providing limits on its use as noted below. No separate specifications need be written for hydrogen peroxide because a suitable specification already exists in the Food Chemicals Codex (2010), which is one of the primary sources of specifications in Standard 1.3.4.

3.2.1 Limitations on permitted uses

Hydrogen peroxide could be misused in the manufacture of dairy foods; hence it is necessary to clarify the uses permitted via this Application.

The permission granted via this Application is for hydrogen peroxide to be used as a processing aid to control the population of lactic acid producing microorganisms in order to stabilise the pH in the production of dairy products manufactured using these microorganisms.

The permission does not apply to products made using methods other than lactic acid producing microorganisms. Neither does it allow the use of hydrogen peroxide to stabilise deteriorating milk, and as a sanitiser i.e. as an alternative to good hygienic practices.

3.2.2 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. While not all comments and recommendations are upheld, they are valued and all contribute to the rigour of our assessment.

Submissions were received from the Australian Food and Grocery Council (AFGC), Food Technology Association of Australia, New South Wales Food Authority (NSWFA), New Zealand Food and Grocery Council, New Zealand Ministry of Primary Industries (MPI), Queensland Health and Victoria Department of Health.

All submitters supported varying Standard 1.3.3 to permit the use of hydrogen peroxide as proposed by the Applicant. However, the AFGC, NSWFA, MPI, Queensland Health and Victorian Department of Health raised issues as summarised with FSANZ's response provided in Table 1.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
FSANZ acknowledged that varying Standard 1.3.3 as proposed may advantage consumers by expanding the range of available products, but did not point out the corresponding disadvantage if the proposed variation is declined (production of a narrower range of products). FSANZ also identified that approving the variation would enable industry to manufacture a wider range of dairy products, but did not identify the associated disadvantage to industry if the variation is declined.	AFGC	FSANZ cited the advantage to consumers and industry of approving the variation as proposed. This acknowledgement implies that if the variation was not approved, then consumers and industry would lose the advantage i.e. the disadvantage associated with not approving the proposed variation is that the range of products that can be manufactured will not expand. Consequently, FSANZ considers it inappropriate to cite the advantage as a basis for supporting the proposed variation, and then also cite potential absence of that advantage (i.e. the corresponding disadvantage) as further support for the variation.
The proposed technological function has not been demonstrated and only partially explained	NSWFA	FSANZ is of the view that the Applicant has provided sufficient information regarding the technological function of hydrogen peroxide, and that the proposed use is not 'novel'. The actual mechanism for the action of hydrogen peroxide is not required. FSANZ recognises that hydrogen peroxide has a history of use as an anti-bacterial agent during processing.
The proposed use is broader than existing overseas permissions, without adequate explanation for the extended use		FSANZ acknowledges that the permissions in USA and Canada relate to cheese making and whey, and to that extent the proposed amendment to the Code is equivalent, including having a maximum level in the final product. However, there is no safety or technological reason to not permit the use of hydrogen peroxide, under conditions as described, to other fermented dairy products that may not meet the definition of "cheese".
It is not clear what effect the addition of sub-lethal doses of hydrogen peroxide has on the starter culture viability and functionality in the final product		The Applicant has provided data in support of their conclusion that addition of sub lethal concentrations of hydrogen peroxide reduces but does not eliminate viable counts of starter bacteria, see document titled "A1068 Additional Info – Viable Starter Bacteria Counts before and after hydrogen peroxide" under "Application" at http://www.foodstandards.gov.au/foodstandards/applications/applicationa1068hydr5375.cfm. If there are no other steps, then the starter culture is able to continue its growth. Therefore, FSANZ concludes that fermented milks produced using hydrogen peroxide as proposed in this Application can still comply with the minimum level of starter culture bacteria for fermented milks as specified in the Code.

Issue	Raised by	FSANZ Response (including any amendments to drafting)
While 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, further consideration is needed on how this can be enforced, particularly when techniques to reduce levels of hydrogen peroxide are used.	MPI	FSANZ notes the issue raised and considers that there are suitable methods for detecting the presence of hydrogen peroxide in milk. Therefore, the presence of hydrogen peroxide in unapproved products can be detected, which is the same situation that existed before this Application.
There is insufficient evidence in SD1 to show that a reliable quantitative method exists for enforcing the proposed standard with respect to the relevant foods.	Queensland Health	FSANZ considers there are suitable analytical methods for verifying whether products manufactured as proposed comply with the proposed MPL, and has amended SD1 to reflect this.
The methods of analysis provided by the Applicant determine the total 'peroxides' in a product, not just added hydrogen peroxide. Consider setting an MPL of 5 mg/kg *total peroxides* expressed as hydrogen peroxide instead.	Victorian Department of Health and Dairy Food Safety Victoria	FSANZ considers the current approach is sufficient for monitoring the presence of hydrogen peroxide in finished products. An overestimation of hydrogen peroxide levels because it is also detecting some other peroxides is unlikely to be a concern for this Application. The Applicant is aware of the potential for this to occur and indicated they are able to meet an MPL of 5 mg/kg.
The term 'lactic acid producing microorganisms' does not differentiate between lactic acid bacteria that may be naturally present and those deliberately added. Consider using *'lactic acid producing starter cultures*' instead.		FSANZ has decided to retain the term "lactic acid producing microorganisms" rather than changing it to "lactic acid producing starter cultures" because: • The products will be made from pasteurised (or equivalent) milk, so the concentration of "naturally present" lactic acid producing microorganisms will be low • The added lactic acid producing microorganisms will be present at concentrations at the start of the fermentation far in excess of the naturally occurring microorganisms • The addition of hydrogen peroxide will influence the behaviour of both the added and naturally present lactic acid producing microorganisms.

3.3 Risk communication

FSANZ applied a basic communication strategy to this Application. This involved using the media, website and Facebook and Twitter sites to encourage people to comment. Email alerts were sent to more than 4500 subscribers to the FSANZ Notification Circular and to interested parties, including the Applicant.

The process by which FSANZ considers standard matters is open, accountable, consultative and transparent. The purpose of inviting public submissions is to obtain the views of interested parties on the issues raised by the Application and the impacts of regulatory options. The issues raised in the public submissions were evaluated and addressed in this Report.

The Applicant and organisations who made submissions on this Application are notified at each stage of the Application.

The FSANZ Board's decision has been notified to the Forum. If no request for a review of the decision is made by the Forum, the Applicant and stakeholders, including the public, will be notified of the gazetted changes to the Code in the national press and on the FSANZ website.

4. Reasons for decision

The draft variation to Standard 1.3.3, as proposed following assessment, was approved without change on the basis of the available evidence for the following reasons:

- The use of hydrogen peroxide as a processing aid for food manufacture does not raise any public health and safety concerns.
- The use of hydrogen peroxide as proposed is technologically justified and may provide benefits to manufacturers of dairy products and consumers.
- Permitting the use of hydrogen peroxide is consistent with the requirements of sections 18 and 29 of the FSANZ Act as described below.

FSANZ 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
- any other relevant matters.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), 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. However, FSANZ has performed an impact assessment and determined that varying Standard 1.3.3 to permit the use of hydrogen peroxide as proposed by the Applicant may confer net benefits on industry and consumers.

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

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

4.1 Addressing FSANZ's objectives for standards-setting

FSANZ considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.1.1 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.

4.1.2 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.

4.1.3 The prevention of misleading or deceptive conduct

There is potential for hydrogen peroxide to be misused during the manufacture of dairy foods such as being used to stabilise deteriorating milk or as an alternative to good hygienic practices. This risk is limited by specifying the permission is only for controlling the population of lactic acid producing microorganisms and, in so doing, stabilising the pH during the production of dairy products manufactured using lactic acid producing microorganisms.

The 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.

4.1.4 Subsection 18(2) considerations

FSANZ 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 to support their Application. Other resource material including published scientific literature and general technical information was also used.

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

  The variation is consistent with international food standards. Hydrogen peroxide is currently used in the United States of America and Canada to produce similar products.

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

  The variation is expected to have a positive impact on competitiveness of the food industry. It 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 Council*[2]*.*

  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.

[2] Now known as the COAG Legislative and Governance Forum on Food Regulation (the Forum).

FSANZ determined that permitting the use of hydrogen peroxide as proposed by the Applicant is consistent with the specific order policy principles for 'Technological Function'.

4.2 Implementation

The variation will come into effect on gazettal.

Attachments

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

Attachment A – Approved 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

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	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 – 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 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. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to Standard 1.3.3.

Following consideration by COAG Legislative and Governance Forum on Food Regulation[3], section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

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

2. Purpose and operation

The Authority has approved a variation to Standard 1.3.3 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 does not permit the use of hydrogen peroxide:

- as a processing aid in the manufacture of cheese and cheese products made otherwise than with lactic acid producing microorganisms;
- as an alternative to good hygienic practices during the manufacture of dairy products; or
- to stabilise deteriorating milk.

3. Documents incorporated by reference

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

[3] Previously known as the Australia and New Zealand Food Regulation Ministerial Council

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1068 has included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 24 April 2012 for a six-week consultation period.

A Regulation Impact Statement (RIS) was not required because the proposed variations to Standard 1.3.3 are likely to have only 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; and
- cheese products made using lactic acid producing microorganisms.