HYDROGEN PEROXIDE AS A PROCESSING AID TO CONTROL pH IN FERMENTED DAIRY INGREDIENTS

1. EXECUTIVE SUMMARY

Fonterra Co-operative Group Ltd (Fonterra), seeks to extend the approval of hydrogen peroxide as a processing aid as allowed in Standard 1.3.3 (Clause 14). We request approval to use hydrogen peroxide to control and maintain viable populations of starter bacteria, allowing the maintenance of a stable pH in fermented dairy processes using pasteurised (or equivalent) milk or dairy material. We propose that a maximum permitted residual level of 5 mg/kg be allowed which matches currently permitted use levels for many food and drinking water applications, as well as the permitted residual levels of hydrogen peroxide when used as a bleaching agent.

The ability to use hydrogen peroxide to control the pH of pasteurised (or equivalent), fermented dairy ingredients at the finished, set value, yet retain starter population viability enhances the processing options that may be used in food manufacture. The acceptance as hydrogen peroxide as a processing aid for the control of pH in fermented dairy products will expand range of potential dairy ingredients, thereby significantly enhancing earning potential. Approval of this application allows Australian and New Zealand dairy manufacturers and exporters to produce and market fermented dairy produces under equivalent processing conditions and cost structures as used by dairy manufacturers in other countries (e.g. USA and Canada). As such, the acceptance of this application more closely aligns New Zealand and Australia with the USFDA standards.

Hydrogen peroxide does not pose a food safety risk when used as a processing aid in the manufacture of dairy ingredients and components. Indeed, hydrogen peroxide is already permitted a processing aid in Standard 1.3.3 (e.g. bleaching agent).

CONTENTS

2. GENERAL REQUIREMENTS

1. APPLICANT DETAILS

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Nature of business: Dairy Manufacturer

2. PURPOSE OF THE APPLICATION

The purpose of the application is to vary Standard 1.3.3 of the Australia New Zealand Food Standards Code on Processing Aids by expanding the permitted use of hydrogen peroxide as an approved processing aid (Clause 14) for the manufacture of fermented dairy products and ingredients*. We seek approval to use hydrogen peroxide as a processing aid to control and maintain, viable populations of starter bacteria, allowing the maintenance of a stable pH in fermented dairy processes using pasteurised (or equivalent) milk or dairy material. We propose a maximum permitted residue level of 5 mg/kg in accordance with the currently permitted levels of residual levels of hydrogen peroxide when used as a bleaching agent (Standard 1.3.3).

Fonterra recognises that hydrogen peroxide may have been seen in the past as an alternative to good hygienic practices. We wish to stress that we acknowledge that the use of hydrogen peroxide is not a substitute for good hygienic practice and that such a purpose is not within the scope of this application. Indeed, Fonterra maintains that the use of hydrogen peroxide envisioned in this application is solely intended to control viable starter metabolism, thereby holding the pH of a fermented dairy ingredient at a set, finished value that enables further processing. Addition of hydrogen peroxide is not intended to destroy the starter organisms.

* Hence forth referred to in this document as "dairy ingredients and products"

Fonterra affirms that processors employing hydrogen peroxide to control the pH of fermented dairy ingredients must also fully abide with all required elements of good manufacturing practice (GMP) etc.

3. JUSTIFICATION FOR THE APPLICATION

A. Regulatory impact information

1. Costs and benefits

Fermented dairy ingredients are widely used as essential components in the formulations of many other dairy and food products. For example, the manufacture of frozen yoghurt requires the fermentation of prepared milk to create the yoghurt that subsequently is used as an ingredient. Fermented dairy ingredients initially are made from pasteurised milk, whey, or related dairy material(s) that are inoculated with suitable dairy starter microorganisms. Fermentation by the starter organisms produces acid, which reduces the pH of the dairy ingredient to the desired level. The pH of fermentation significantly affects the quality and functionality of the finished dairy product or ingredient. Optimum functionality and quality typically occur at a specific pH for each fermented dairy ingredient or product and for each application. However, once the fermentation has reduced the pH to the desired value, subsequent starter activity, which continues to lower pH levels compromises the functionality and quality of the ingredient or food product. Therefore a reliable means to control acid production by the starter and maintain a viable starter population is required to stabilise the pH of the fermented dairy ingredient or product.

Alternative pH control options, such as heat treatments, will halt pH production by destroying the starter organisms. However, heat does not allow the retention of viable starter bacteria required for final product functionality, and in some cases product identity (e.g. yoghurt). Furthermore, heating fermented dairy products at low pH will denature the whey proteins and coagulate any available casein, as occurs in the manufacture of Ricotta cheese (Walstra and Jenness, 1984; Kosikowski and Mistry, 1997). Heat treatments that coagulate casein and denature the whey proteins inherently destroy the functionality of fermented dairy ingredient, ruining the finished product quality.

Hydrogen peroxide (molecular formulation H_2O_2; CAS-No: 7722-84-1) is widely used in many food and industrial applications (European Chemicals Bureau (ECB), 2003; European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), 1993; International Agency for Research on Cancer (IARC), 1999). The major advantages of hydrogen peroxide when used for ingredient or product manufacture as compared to other options is that hydrogen peroxide breaks down rapidly into only water and oxygen, which are essential, innocuous compounds (Select Committee on GRAS Substances (SCOGS), 1979). Hydrogen peroxide also lacks of allergenicity (Pumphrey, 2000). Treating the fermented dairy ingredient with sub-lethal concentrations of hydrogen peroxide effectively prohibits further acid production by the starter without adversely affecting the functionality and finished product quality. Indeed, Canada

expressly allows the use of hydrogen peroxide for this purpose in the manufacture of dry whey products (Department of Justice Canada, 2011b).

Hydrogen peroxide is readily available and relatively inexpensive. It is safe when handled properly and has numerous approvals for its use in foods (as shown in section B.8.b). Because hydrogen peroxide is widely used in many food and industrial applications, the proper procedures for transporting, storing, and handling hydrogen peroxide have been determined and are readily available (ECETOC, 1993). Hydrogen peroxide readily decomposes into oxygen and water, particularly in the presence of catalase (EC 1.11.1.6). Catalase (International Union of Biochemistry and Molecular Biology (IUBMB), 1999) is also widely available, relatively inexpensive, accepted as Generally Recognised as Safe (GRAS) (21 Code of Federal Regulations (CFR) § 184.1034), and approved for food use. Permitted microbial sources of catalase in the Food Standards Code are, *Aspergillus niger* and *Micrococcus luteus* (Table to clause 17, Standard 1.3.3). Fonterra requires the use catalase from an approved microbial source. The presence and removal of hydrogen peroxide in the fermented dairy ingredient is quickly identified by relatively inexpensive test strips (Marks et al., 2001; Merck, 2009), as well as by established analytical procedures (International Dairy Federation (IDF), 2006; Association of Official Analytical Chemists (AOAC), 2005; Lück, 1956; Lück, 1962).

The approval of this application would more closely align New Zealand and Australia with the regulatory requirements of the United States, a major trading partner. Such approval would allow Australia and New Zealand dairy manufacturers to quickly and economically produce innovative of dairy products to maintain a competitive edge over other major dairy manufacturing regions.

a) Consumer benefits

Using hydrogen peroxide to control the pH of fermented dairy products benefits consumers by effectively and inexpensively creating superior quality finished food products. Maintaining the functionality of the dairy ingredient with an inexpensive treatment allows the manufacturer to provide the consumer with the greatest variety of the highest quality finished products without added expense. The consumer is not exposed to hydrogen peroxide in the food, as catalase addition decomposes residual hydrogen peroxide into oxygen and water. Hydrogen peroxide minimally affects the nutritional quality of the dairy ingredient, only destroying ascorbic acid (vitamin C), and possibly a small amount of the amino acids methionine and cystine. Nutrition experts worldwide regard this effect as insignificant (SCOGS, 1979).

Nutritional issues

Hydrogen peroxide does not significantly reduce the nutritional quality of dairy ingredients and products such as milk and cheese (SCOGS, 1979). Hydrogen peroxide destroys ascorbic acid (vitamin C) and a portion of the amino acids methionine, and cystine in treated milk (Koning and Rooijen, 1972; Teply et al. 1958). However, dairy ingredients are not a major source of ascorbic acid, and pasteurisation at the specified heat treatments destroys virtually

all of the available ascorbic acid and similar amounts of the methionine and cystine in milk. Hence, the effect of hydrogen peroxide upon the nutritional quality of dairy ingredients greatly resembles the similar destruction of these nutrients by the heat treatment required for pasteurisation (Lück, 1956, 1962). Therefore, the SCOGS report states that:

> *"The Select Committee believes their loss* (ascorbic acid, methionine, and cystine) *to be nutritionally insignificant."* (SCOGS, 1979).

Public health and safety issues

The addition of hydrogen peroxide during the fermentation process is not considered to be a processing Critical Control Point (CCP). Rather, the microbiological safety of the finished product is maintained by the pasteurisation (or equivalent) of the milk or dairy material used to produce the fermented dairy ingredient, as combined with the appropriate product composition, handling, storage, and subsequent Good Manufacturing Practice (GMP).

The proper handling of hydrogen peroxide creates no known safety issues associated as evidenced by the fact Food Standards Australia New Zealand (FSANZ) already recognises hydrogen peroxide as a safe substance through its recognition as a permitted processing aid for other specified purposes (FSANZ, 2000a). Additionally, the U.S. Food and Drug Administration (USFDA) classifies hydrogen peroxide as GRAS in 21 CFR § 184.1366 (Hydrogen peroxide); (Federal Register, 1983; SCOGS, 1979).

All cells, except anaerobic bacteria, produce hydrogen peroxide as a metabolic by-product. Cells use catalase and/or glutathione peroxidise (EC 1.11.1.9) to decompose hydrogen peroxide into oxygen and water to prevent cellular damage.

b) Industry benefits

The approval of this application proportionally enhances the ability of Australian and New Zealand manufacturers to produce a greater variety of products within the fermented milks category, particularly where other forms of pH control are less effective. Such approval greatly facilitates the development of many more innovative fermented dairy products and allows Australian and New Zealand manufacturers to compete in the US market.

c) Government benefits

As previously noted, the use of hydrogen peroxide as described in this application, is not an alternative to pasteurisation or GMP.

The use of hydrogen peroxide to control the pH of fermented, pasteurised (or equivalent) dairy products benefits the government by allowing food manufacturers to provide consumers with the greatest number of the highest quality products at minimal expense. Hydrogen peroxide decomposition creates only oxygen and water, which are not toxic compounds or pollutants. The hydrogen peroxide treatment does not significantly reduce the nutritional value of the food.

We believe that the use and subsequent decomposition of hydrogen peroxide into water and oxygen as requested in this petition does not create any environmental impact.

Fonterra recognises that hydrogen peroxide may have been seen in the past as an alternative to good hygienic practices. We wish to stress that we acknowledge that the use of hydrogen peroxide is not a substitute for good hygienic practice and that such a purpose is not within the scope of this application.

2. Impact on international trade

We the applicant are in the food industry and if hydrogen peroxide is approved as a processing aid to control and maintain, viable populations of starter bacteria, allowing the maintenance of a stable pH in fermented dairy processes using pasteurised (or equivalent) milk or dairy material.

Fonterra has not solicited food industry support for this application. However, we are unaware of any opposition to this proposed change. We do not anticipate that approval of this application confers upon Fonterra any competitive advantage over other domestic companies, as all companies will operate within the same regulatory parameters.

The acceptance of hydrogen peroxide as a processing aid for controlling the pH of fermented dairy products greatly expands the variety and improves the quality of dairy ingredients Australian and New Zealand dairy manufacturers may produce. Acceptance of this petition thereby significantly enhances the competitive ability and earning potential for the Australian and New Zealand dairy and food industries. Inversely, we do not believe approval of this application adversely affects the importation of dairy products into either Australia and/or New Zealand. This process maintains the competiveness of the inherently viable dairy industry. Rather, allowing Australia and New Zealand dairy manufacturers and exporters to produce and market fermented dairy products under equivalent processing conditions and cost structures used in other countries (e.g. United States of America) restores and enhances their competitiveness. Acceptance of this application, therefore more closely aligns New Zealand and Australia with the USFDA standards and manufacturing opportunities.

4. INFORMATION TO SUPPORT APPLICATION

This application contains sufficient supporting information as detailed in Section 3, to address the objectives specified in section 18 of the FSANZ Act. References are provided for all information that has been sourced externally to Fonterra Co-operative Group Limited.

5. ASSESSMENT PROCEDURE

This application is for the extended use of a processing aid and therefore should be assessed as a general level procedure up to 600 hours.

6. CONFIDENTIAL COMMERICAL INFORMATION (CCI)

This application does not contain any confidential commercial information.

7. EXCLUSIVE CAPTURABLE COMMERICAL BENEFIT (ECCB)

The applicant does not expect to realise any Exclusive Capturable Commercial Benefit (ECCB) upon approval of this application, because:

1. All essential elements of the proposed process are well established within the public domain (Goor et al. 1989; Hess, 1995). The usage of hydrogen peroxide to control the pH of fermented dairy ingredients is not novel and cannot be patented or claimed as Intellectual Property (Campos-Martin et al., 2006). Therefore, no individual or organisation can use any aspect of this process to establish a viable proprietary position; and
2. The Fonterra Co-operative Group, Ltd. currently does not own, or contemplate acquiring a proprietary position for either:
   a. the manufacture of hydrogen peroxide, or
   b. the use of hydrogen peroxide as a pH control processing aid in the manufacture of fermented dairy product or ingredients.

8. INTERNATIONAL AND OTHER NATIONAL STANDARDS

A. International Standards

CODEX

The Codex Alimentarius includes hydrogen peroxide in the List of Codex Specifications for Food Additives (Codex Alimentarius, 2010a). The specification for hydrogen peroxide is presented in the 63rd Joint FAO/WHO Expert Committee on Food Additives (JECFA) (2004) and published in FP 52 DD 12 (2004). However, hydrogen peroxide has not been assigned an INS number, and currently is not approved as a food additive. However, the Codex Alimentarius describes the importance of hydrogen peroxide in preserving milk in Guidelines for the preservation of raw milk by use of the lactoperoxidase system (Codex Alimentarius, 1991; IDF. 1988).

Hydrogen Peroxide is listed in the Inventory of Processing Aids, a working document used by the Codex Committee on Food Additives (Codex Alimentarius, 2010b). Uses noted in this document include microbiological control in sugar manufacture and for washing and peeling uses.

B. Other National Standards or Regulations

US Food and Drug Administration

The USFDA affirms that hydrogen peroxide is GRAS in 21 CFR § 184.1366 hydrogen peroxide, permitting usage in the following applications:

- Milk intended for use during cheese making process as permitted in the appropriate standards of identify for cheese and related cheese products (21 CFR § 133 Cheese and cheese related products). Appropriate individual standards of identity include:

- Cheddar cheese:	21 CFR § 133.113
- Cheddar cheese for manufacturing	21 CFR § 133.114
- Low sodium Cheddar cheese	21 CFR § 133.116
- Colby cheese	21 CFR § 133.118
- Colby cheese for manufacturing	21 CFR § 133.119
- Low sodium Colby cheese	21 CFR § 133.121
- Washed curd and soaked cheese	21 CFR § 133.136
- Granular and stirred curd cheese	21 CFR § 133.144
- Granular and stirred curd cheese for manufacturing	21 CFR § 133.145
- Swiss and emmentaller cheese	21 CFR § 133.195
- Swiss and emmentaller cheese for manufacturing.	21 CFR § 133.196

These standards allow the addition of up to 0.05% hydrogen peroxide followed by treatment with a sufficient quantity of catalase preparation to eliminate the hydrogen peroxide in the designated cheese variety.

- Whey, during the preparation of modified whey by electrodialysis methods,
- Note: in a final rule: the USFDA is amending 21 CFR § 173 to include § 173.356 hydrogen peroxide, permitting the use of hydrogen peroxide as an antimicrobial agent in the production of modified whey (including, but not limited to, whey protein concentrate and whey protein isolates) by ultrafiltration methods (Federal Register, 2011; Fonterra, 2010).
- Dried egg products including

- Dried eggs	21 CFR § 160.105
- Dried egg whites	21 CFR § 160.145
- Dried egg yolks	21 CFR § 160.185

21 CFR § 184.1366 also allows the use of hydrogen peroxide in the following products for a variety of purposes, including use as an oxidising, bleaching, antimicrobial, and sulphur removing agent.

- Tripe,
- Beef feet,
- Herring,
- Wine,
- Starch,
- Instant tea,
- Corn syrup,
- Colored (annatto) cheese whey,
- Wine vinegar, and
- Emulsifiers containing fatty acid esters,

The USFDA accepts hydrogen peroxide as an indirect food additive in 21 CFR § 178.1005(b) Hydrogen peroxide solution; substances utilised to control the growth of microorganisms (when applied to specified food contact surfaces).

3. Food Standards Australia New Zealand

The FSANZ allows the use of hydrogen peroxide as a permitted processing aid in the following applications:

- Packaged water and in water used as an ingredient in other foods (FSANZ, 2000b),
- Bleaching agent, washing and peeling agent in all foods to a maximum permitted level of 5mg/kg (FSANZ, 2000c),
- Permitted processing aid with miscellaneous functions (FSANZ, 2000a), including Inhibiting agent for dried vine fruits, fruit and vegetable juices, sugar, vinegar and yeast autoylysate,
- Removal of glucose from egg products, and
- Removal of sulphur dioxide.

<u>Japan</u>

The Japanese Specifications and Standards for Foods, Food Additives etc. Under the Food Sanitation Act allows for hydrogen peroxide to be used as a sterilising agent with a condition that it must be decomposed or removed prior to preparation of the final food (Japan External Trade Organisation, 2011).

Canada

Canadian food regulations allow for the use of hydrogen peroxide as a food additive in the following applications:

- Brewers mash as a clarification aid at a maximum addition rate of 135 p.p.m. in the mash
- Liquid whey destined for the manufacture of dried whey products to decolourize and maintain pH. The maximum addition rate of hydrogen peroxide is 100 p.p.m.
- Oat hulls used in the manufacture of oat hull fibre as a bleaching agent in an amount consistent with good manufacturing practice.

(Department of Justice Canada, 2011b).

The use of catalase to eliminate any residual hydrogen peroxide in the treated whey is also allowed (Department of Justice Canada, 20011a).

8. Statutory declaration

STATUTORY DECLARATION

Oaths and Declarations Act 1957

I, Dianne Lillian Schumacher of Fonterra Co-operative Group 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 14th October 2011

Signature 

Declared before me 

Daniel Eli Porus
Solicitor
AUCKLAND

9. Checklist

General Requirements (3.1)

- ☑ Form of application
  - ☑*Executive Summary*
  - ☑*Relevant sections of part 3 identified*
  - ☑*Pages sequentially numbered*
  - ☑*Electronic + 2 hard copies*
  - ☑*Electronic and hard copies identical*
  - ☑*Hard copies capable of being laid flat*
  - ☑*All references provided*
- ☑ Applicant details
- ☑ Purpose of the application
- ☑ Justification for the application
- ☑ Information to support the application
- ☑ Assessment procedures
  - ☑*General*
  - ☑*Major*
  - ☑*Minor*
- ☑ Confidential Commercial Information
  - ☐*Confidential material separated in both electronic and hard copy*
  - *NO CONFIDENTIAL INFORMATION*
- ☑ Exclusive Capturable Commercial Benefit
- ☑ International and Other National standards
- ☑ Statutory Declaration
- ☑ Checklist/s provided with Application
  - ☑*Checklist*
  - ☑*Any other relevant checklists for Sections 3.2 – 3.7*

Processing Aids (3.3.2)

- ☑ Type of processing aid
- ☑ Identification information
- ☑ Chemical and physical properties
- ☑ Manufacturing process
- ☑ Specification information
- ☑ Analytical method for detection
- ☑ Industrial use information (chemical only)
- ☑ Information on use in other countries (chemical only)
- ☑ Toxicokinetics and metabolism information (chemical only)
- ☑ Toxicity information (chemical only)
- ☑ Safety assessments from international agencies (chemical only)
- ☑ Overseas safety assessment reports
- ☑ List of foods likely to contain the processing aid
- ☑ Anticipated residue levels in foods
- ☑ Information on likely level of consumption
- ☑ Percentage of food group to use processing aid
- ☑ Information on residues in foods in other countries (if available)
- ☑ Where consumption has changed information on likely consumption

3. PROCESSING AIDS

A. TECHNICAL INFORMATION ON HYDROGEN PEROXIDE AS A PROCESSING AID

1. Type of processing aid

Hydrogen peroxide falls under Standard 1.3.3 processing aid category under clause 14 – Permitted processing aids with miscellaneous functions. We apply to have the table to clause 14 amended to include the following function for hydrogen peroxide:

Table 1. Proposed change to table to clause 14.

Substance	Function	Maximum permitted level (mg/kg)
Hydrogen Peroxide	To control and maintain, viable populations of starter bacteria, allowing the maintenance of a stable pH in fermented dairy processes using pasteurised (or equivalent) milk or dairy material	5

2. Identity of the proposed processing aid

Chemical name: Hydrogen Peroxide (IUPAC, CA)

Other names: Hydrogen Dioxide

Dihydrogen dioxide

Hydroperoxide

Dioxidane

Albone

Hioxyl

Marketing names: Hydrogen Peroxide, Aqueous Solution

CAS registry no: 7722-84-1

EINECS-No: 231-765-0

ChemSpider ID 763

Molecular formula: H_2O_2

Structural formula: H-O-O-H

Molecular weight: 34.0147 g/mol

3. Chemical & physical properties of the proposed processing aid[1]

Hydrogen peroxide is a colourless to very light blue liquid at ambient temperature

Melting point:	-0.43°C @ 1 atmosphere; typically -0.40 to -0.43°C
Boiling point:	150.2°C at 1 atmosphere
Colour:	Colourless to very light blue liquid that appears colourless in dilute solution
Density:	1.4425 g/cm^3 25°C
Vapour pressure	3 hPa (25°C)
pK_a	11.62 (25°C)
Dipole moment	2.26 D
Standard enthalpy of formation ($\Delta_f H^{\ominus}_{298}$)	-4.007 kJ/g
Odour:	Hydrogen peroxide (detectable at 0.33 ppm)
Flavour	Bitter
Oxidation stability (in air)	Autoignition temperature in air = 350°C
	Flash point = Non-flammable
Oxidising agent potential	$H_2O_2 + 2H^+ + 2e^- \Rightarrow 2H_2O$ Eo = +1.763 V at pH 0
	$HO_2^- + H_2O + 2e^- \Rightarrow 3OH^-$ Eo = + 0.878 V at pH 14
Reducing agent potential	$H_2O_2 \Rightarrow O_2 + 2H^+ + 2e^-$ Eo = -0.66 V at pH 0
	$HO_2^- + OH^- \Rightarrow O_2 + H_2O + 2e^-$ Eo = +0.08 V at pH 14
Refractive index (n_D)	1.32
Specific Heat Capacity	1.267 J/gK (gas)
	2.619 J/gK (liquid)
Solubility	Miscible in water and soluble in ether
	Insoluble in petroleum ether
	Decomposes in many solvents
Viscosity	1.245 cP (20°C)
Thermal stability	Thermally stable under inert gas atmosphere, at less than 400°C. Does not form measurable levels of peroxides under storage temperatures up to 353K. Stable in neutral and dilute acidic and alkaline solutions.
Stability in water	Henry's Law constant 7.5×10^{-4} Pa m^3/mol (20°C) measured
LD_{50}*	1.518mg/kg

Vapour pressure	4450 mmHg (593 kPa) @ 25°C
Bio-concentration	BCF 0.70 Method: The estimated value was calculated using a log KOW Reliability: Estimated value based on accepted Model

[1]Sources ECB, (2003); ECETOC, (1993); Goor et al. (1989); Hess, (1995); Lide, (2009); O'neil, (2001); Perry et al. (1997); US Department of Labor (1996).

*References Goor et al., (1989); SCOGS (1979); and ECETOC (1993) provide additional LD_{50} values for specific species (see Table 11 in SCOGS (1979) and Table 21 in ECETOC (1993)).

4. Manufacturing process

Goor, et al. (1989) and Hess (1995) review in detail the major commercial procedures used to produce hydrogen peroxide worldwide. The most widely used manufacturing method proceeds by the autoxidation of 2-alkyl anthrahydroquinone (Riedl and Pfeiderer, 1939). This method is frequently called the anthraquinone process (Campos-Martin et al., 2006). Alternative procedures include the electrolytic oxidation of sulphuric acid or a sulphate to form persulfuric acid or a persulfuric acid salt. Hydrolysing the persulfuric acid or persulfuric acid salt subsequently creates hydrogen peroxide. Alternatively, hydrogen peroxide is produced by decomposing barium peroxide with sulphuric or phosphoric acid, or by discharging an appropriate electrical current through a mixture of hydrogen, oxygen, and water vapour (ECB. 2003). Crude aqueous hydrogen peroxide produced by any process subsequently is concentrated and purified by distillation, diluted to the desired strength (typically ranging from 3 to 90%), and stabilised (Goor et al., 1989; Hess, 1995).

All major toxicity and allergy reviews fail to identify hydrogen peroxide as an allergen (Pumphrey, 2000). Food grade hydrogen peroxide has been used worldwide for many years without providing any evidence of allergencity.

5. Specification for identity & purity

The Food Chemicals Codex (FCC), 3rd ed. (FCC, 2010) publishes the for specification hydrogen peroxide purity recognised by Standard 1.3.4 of the Australia New Zealand Food Standards Code. The proposed application specifically requires food grade hydrogen peroxide meeting this specification.

6. Analytical Methods for Detecting Hydrogen Peroxide in Foods

Most methods used to detect the presence of hydrogen peroxide in foods depend upon the ability of hydrogen peroxide to react with compounds that readily oxidise to release a coloured or observable component. The presence of hydrogen peroxide is confirmed upon formation of the defined colour or observable compound in the tested food or milk sample (Lück. 1956). Quantitative analysis for hydrogen peroxide usually requires the coagulation and removal of any protein in the sample prior to testing (Lück. 1962). The supernatant prepared from the sample after protein removal subsequently is analysed by the selected method, and the amount of hydrogen peroxide present quantatively determined by either titration or by spectrophotometric analysis (Amin and Olson, 1967; Ovenston and Rees, 1950; Patrick and Wagner, 1949). Alternative test methods include refractometry or electrical conductivity (Toyoda et al, 1982).

The Ministry of Agriculture and Forestry (MAF) approved the International Dairy Federation (IDF) Provisional Standard 74A:1991: Anhydrous Milk fat Determination of Peroxide Value as the official method for detecting hydrogen peroxide in milk and anhydrous milk fat (AMF), as shown in Table 2 (See also IDF, 2006).

The official procedure for detecting hydrogen peroxide in milk used in the United States is AOAC Official Method 957.08 Hydrogen Peroxide in Milk (AOAC, 2005). This procedure proceeds by adding a solution of vanadium pentoxide (V_2O_5) dissolved in sulphuric acid (H_2SO_4) to the milk sample. Formation of a pink or red colour in the milk indicates the presence of hydrogen peroxide. The results of this method as described are subjective, only showing the presence, but not the amount of hydrogen peroxide present in the sample. However, the original method claims a sensitivity of 0.008% by weight H_2O_2 (Munday, 1957).

Table 2. MAF approved dairy test methods is for peroxide in AMF, Milk fat etc (MAF, 2011)

Test	Designation	Reference	Products
Peroxide Value	NZTM 3.7.5 Peroxide Value for Anhydrous Fat Products, Hydrous Fat Products and Butter Issue 10.1: September 2003	IDF Provisional Standard 74A:1991 - Anhydrous Milkfat - Determination of Peroxide Value	*Anhydrous Milkfat, Hydrous Milkfat, Butter*

Lück (1956, 1962) reviews additional analytical procedures for detecting hydrogen peroxide in milk, which are listed with several additional methods in Table 3.

Table 3. Analytical procedures for determining the presence of hydrogen peroxide in milk.

Test Reagent	Indicative Colour	Sensitivity	Inhibitory Substances	Reference:
Potassium Iodide (KI) dissolved in Sulphuric acid. Quantitative analysis requires Titratation with sodium thiosulphate ($Na_2S_2O_3$)	Yellow	3 mg H_2O_2/L	Formaldehyde and dichromate	Ovenston & Rees, 1950 Patrick & Wagner, 1949 Pien et al., 1953
Potassium Iodide-Starch paper	Blue or violet	0.001% (by weight H_2O_2) following ppt of milk protein		Luck, 1962
In milk containing dichromate Ether + Sulphuric acid	Blue			Rouquette, 1955
Skopoletin (6-methyl-7-oxy-1,2-benzojpjyone)	Skopoletin-fluorescence	≈ 10^{-10}%	Ascorbic acid, glutathione and Mn^{++}ions	Andreae, 1955
Benzidine in alcohol solution	Blue			Funk, 1949
Aminophthalic acid with sodium hydroxide (NaOH)	Yellow-green luminescence	10^{-9}%		Funk, 1949
Potassium iodide (KI).	Canary yellow			Kosikowski and Mistry 1997
Peroxidase (horseradish) and *o*-dianisidine (in methanol)	Colour component formed but not identified	<1 µg/ml	Enzymatic activity following heat treatments to 100°C	Gilliland 1969
Nitroprusside in an alkaline	Light orange, (untreated	0.02 to 0.05%		Barone and Krett, 1969

Test Reagent	Indicative Colour	Sensitivity	Inhibitory Substances	Reference:
solution, treatment of ppt casein	sample is red)			
Titanium tetrachloride	Turbidity, absorbance determined at 415 nm	2 to 3 µg/ml		Ferrier et al., 1970
Ferric Tyiocyanate				Hills and Thiel, 1946
Non-fluorescent coumarin is oxidized to fluorescent 7-hydroxycoumarin	Fluorometric			Abbas et al., 2010

Several manufacturers sell hydrogen peroxide “test strips” to detect the presence of hydrogen peroxide in various samples, particularly liquids. Such strips are widely available, relatively inexpensive, and easily used to test for the presence of hydrogen peroxide in liquids and foods (Marks et al. 2001). A fresh, clean strip is immersed into the sample, possibly incubated at a defined temperature for a set time, and compared to a standard colour chart. The formation of an indicative colour on the strip shows the presence of hydrogen peroxide. Colour intensity may approximate the quantity of hydrogen peroxide present in the sample. Commercially available test strips include RM Quant peroxide testing strips (EMD Chemicals Inc., Gibbstown, NJ, USA) and Merckoquant™ (Merck, 2009).

B. INFORMATION RELATED TO THE SAFETY OF HYDROGEN PEROXIDE AS A PROCESSING AID

A. General information on the industrial use of the hydrogen peroxide

Hydrogen peroxide is used in numerous industrial, food, and consumer applications (ECETOC, 1993). The European Union Risk Assessment Report (ECB, 2003) states that European, utilisation of hydrogen peroxide exceeded 670,000 tonnes in 1997. Bleaching cellulose pulp for paper manufacture constitutes the largest single use of hydrogen peroxide in Europe (48%), and is a major application worldwide (29%) (ECB, 2003). The IARC (1999) review notes the production capacity of hydrogen peroxide in North America in 1995 of 547 thousand tonnes, and a world-wide manufacturing capacity of 1800-1900 thousand tonnes. This review reports hydrogen peroxide use in the US divided between the following uses: pulp and paper (50%), environmental uses including water treatment (17%), chemical manufacture (15%), textile production (9%) and the combination of mining, electronic, food, cosmetic etc. applications (9%) (IARC, 1999).

Chemical manufacture utilised 38% of the available hydrogen peroxide in Europe, mainly facilitating the manufacture of sodium perborate, sodium percarbonate, epoxidised soybean oil, cathecol, hydroquinone, hydrazine, organic peroxides, peracetic acid, caprolatone, and fatty amine oxides (ECB, 2003). Non-food uses consuming the remaining hydrogen peroxide in European manufacturing include bleaching textiles, treating wastewater and waste gas, sanitising surfaces and instruments, etching and cleaning metal surfaces for printed circuit board and semiconductor manufacture, and treating drinking water (ECB, 2003). Other uses in the US include the removal of hydrogen sulphide from steam produced by geothermal power plants, the mining of uranium, pickling of copper and copper alloys, and cleaning metals (IARC, 1999).

Consumer applications for hydrogen peroxide include bleaching, dyeing, fixing hair perms, disinfecting wounds, removing stains on teeth in dentistry, and cleaning and disinfecting contact lenses (ECB, 2003). Various cosmetics, toothpastes, and deodorants contain prescribed amounts of hydrogen peroxide (ECETOC, 1993).

B. General information on the use of the hydrogen peroxide as a food processing aid in other countries

Food processing uses for hydrogen peroxide include antimicrobial, bleaching, and oxidising or reducing applications. (ECB, 2003) Various reviews (ECETOC, 1993; US Department of Labor, 1996)report that hydrogen peroxide is frequently used to:

- clean and sanitise processing equipment and processing surfaces experiencing direct product contact, especially in the meat industry,
- sterilise food contact areas of packaging materials, especially for aseptic processes,

- treat milk used for cheese manufacture, whey and related whey products, starch products, and corn syrup as an antimicrobial agent,
- bleach various food products, including whey [especially whey containing annatto colouring (Croissant et al., 2009; Fonterra, 2010; Kang et al. 2010)], tripe, beef feet, herring, tea, and emulsifying agents,
- oxidise and reducing applications, including dried egg and wine processing,
- remove of sulphur dioxide from starch and from wine subsequently fermented to produce wine vinegar

C.Data on the toxicogenetics and metabolism of the processing aid

Environmental Sources and Exposure

Selected conditions spontaneously promote hydrogen peroxide synthesis, creating trace amounts of hydrogen peroxide in the atmosphere, water, and soil as an endogenous environmental component (ECETOC, 1993). Levels of endogenous hydrogen peroxide depend upon many factors including location, altitude, time of day, season, decomposition of organic materials (especially the decomposition of sewage), pH, and the amount and type of pollution (ECETOC, 1993).

The photolysis of ozone (O_3) in the atmosphere produces free radicals that may ultimately react to form hydrogen peroxide. The greater intensity of solar radiation occurring at higher altitudes and specific types of air pollution typically enhances hydrogen peroxide production. Precipitation carries atmospheric hydrogen peroxide to the earth's surface and surface water. Various reactions in soil and water sources produce additional hydrogen peroxide, particularly the oxidation of organic material. However, the extreme reactivity of hydrogen peroxide combined with the sensitivity to enzymes, such as catalase, usually promote rapid decomposition in water and soil to trace levels (ECETOC, 1993).

The Joint Assessment of Commodity Chemicals (JACC) Report No. 22 (ECETOC, 1993) records that atmospheric hydrogen peroxide concentrations during daylight typically range between 0.3 to 3 ppb for rural air. Hydrogen peroxide usually is not detected in air at night, because photolysis ceases without solar radiation, while decomposition eliminates the existing hydrogen peroxide. Atmospheric concentrations of hydrogen peroxide typically increase at higher altitudes, and with pollution or smog to levels of 40 to 2,200 ppb, during summer months, and in more highly populated areas. Hydrogen peroxide levels in surface waters generally range between 0.35 to 8 ppb, but may exceed 58 to 109 ppb for certain heavily used, highly polluted reservoirs sampled in summer months (ECETOC, 1993). The JACC Report No. 22 (ECETOC, 1993) reviews the environmental production of hydrogen peroxide.

Toxicogenetics and Carcinogenicity

The JACC Report No. 22 (ECETOC, 1993) reviews the toxicogenetics and carcinogenicity of hydrogen peroxide concluding that only the hydroxyl radical and free oxygen produced upon

the decomposition of hydrogen peroxide can directly damage DNA. (Note: some reviews refer to toxicogenetics by using the terms mutagengenic or genotoxicity). The JACC Report No. 22 (ECETOC, 1993) concludes that the ability of these compounds to affect mutagenesis (toxicogenetics) depends upon access to the target DNA. DeSesso et al. (2000) notes that eukaryotic cells provide extensive protection from hydrogen peroxide by:

1. locating the cellular DNA within a double membrane in a nuclear envelope,
2. protecting the histone proteins binding to the DNA, and
3. positioning numerous peroxisomes containing large amounts of catalase and peroxidise in the cytoplasm surrounding the nucleus.

The high reactivity of the hydroxyl radicals and the presence of specific exogenous metabolic agents and/or catalase significantly reduce the bioavailability of hydrogen peroxide for mutagenesis. Desesso et al. (2000) report that biological fluids typically eliminate hydroxyl radicals within one millionth of a second. The SCOGS select committee therefore concludes that:

> *"There is no evidence that hydrogen peroxide is carcinogenic, teratogenic, or mutagenic at levels present in foods treated with hydrogen peroxide during processing."* (SCOGS, 1979)

Additionaly, the IARC (1999) review concludes as follows:

> *"For all types of cancer examined (oesophagus, stomach, colon, rectum, pancreas, lung, prostate, bladder, kidney, skin melanoma, lymphoma) there was no indication of an excess risk due to hydrogen peroxide exposure."* IRAC, (1999).

Metabolism

Mammalian tissues decompose hydrogen peroxide into water and oxygen, almost immediately upon contact (ECETOC, 1993). Yet, all aerobic cells also produce hydrogen peroxide during respiration by several chemical reactions and metabolic pathways. Liver cells particularly generate large amounts of hydrogen peroxide. Major metabolic pathways producing hydrogen peroxide, include oxidase-catalysed reactions in mitochondria, microsomes, peroxisomes and ctytosol; as reviewed in detail in JACC Report No. 22 (ECETOC, 1993). A USFDA review (Federal Register, 1983, 1993) cites independent calculations by Sies (1974) and by Boveris et al. (1972) indicating that rat liver cells produce either 1.7 or 3.1 µg of hydrogen peroxide/g of rat liver tissue per minute. The JACC Report No. 22 (ECETOC, 1993) sites a typical hydrogen peroxide concentration in liver cells of approximately 90 nmol/min/g liver tissue. Extrapolation of these calculations predicts that human liver cells typically produce between 150 to 270 mg of hydrogen peroxide per hour (Federal Register, 1983; SCOGS, 1979). Liver tissues presumably generate larger amounts of hydrogen peroxide when stimulated by appropriate substrates.

Damaged tissues may release hydrogen peroxide at injury sites, to combat microbial infection. Niethammer et al. (2009) reports that damaged tissues in zebra fish release hydrogen peroxide, possibly to destroy invading microorganisms and to direct leukocytes to wound sites. These researchers postulate that a similar release of hydrogen peroxide occurs at injury sites in other species. Additionally, the USFDA reports that hydrogen peroxide may initiate an insulin-like effect in fatty tissues. The review reports the activation of glycogen synthase I in rat adicoytes incubated with hydrogen peroxide and glucose (Federal Register, 1983).

The viability of all cells, and particularly aerobic cells, depends upon their ability to rapidly detoxify environmental and/or endogenously produced hydrogen peroxide. Aerobic cells typically concentrate catalase and/or glutathione peroxidise (peroxidise) in specialised vesicles or organelles, called peroxisomes, to decompose hydrogen peroxide. The Life Sciences Research Office (LSRO) review cites Sies (1974), who found that peroxisomes comprise about 2 percent of liver volume which are particularly rich in catalase for decomposing hydrogen peroxide into oxygen and water (SCOGO, 1979). Glutathione peroxidise reduces hydrogen peroxide to water during the transformation of glutathione into glutathione disulfide. The highest catalase concentrations typically occur in the duodenum, liver, spleen, kidney, blood, mucous membrane and other highly vascularised tissues (ECETOC, 1993). The catalase concentration in liver cells limits the steady-state concentration of hydrogen peroxide to 10^{-9} molar, or to 30 ng hydrogen peroxide/kg liver tissue (Federal Register, 1993; SCOGS, 1979). The ability of liver cells to decompose hydrogen peroxide prevents the concentration of hydrogen peroxide from exceeding 10^{-7} molar (3 µg/kg liver tissue) under conditions maximising hydrogen peroxide production (Federal Register, 1993; SCOGS, 1979). The JACC Report No. 22 (ECETOC, 1993) states that hydrogen peroxide concentrations in various tissues under normal physiological conditions range from 1 to 100 nmol/l, depending upon organ, cell type, oxygen pressure and cell metabolic activity. The JACC Report No. 22 (ECETOC, 1993) reviews in detail the enzymatic systems present in different tissues for decomposing hydrogen peroxide.

In conclusion, environmental and metabolic conditions inherently produce trace amounts of hydrogen peroxide as an endogenous environmental and cellular component, particularly in aerobic tissues. Viable cells therefore must maintain extensive systems for rapidly decomposing hydrogen peroxide. Such systems are well established and depend upon catalase and/or glutathione peroxidise to decompose hydrogen peroxide into oxygen and water.

D.Information on the toxicity of the processing aid

Several reviews extensively evaluate hydrogen peroxide toxicity (ECETOC, 1993; ECB, 2003; Fonterra, 2010; IARC, 1999; SCOGS, 1979; Watt et al., 2004). The following survey summarises key findings and conclusions, referring to the relevant reviews for specific details in the studies.

Hydrogen peroxide toxicity occurs upon direct tissue contact, which may include vapour inhalation and ingestion (Watt et al., 2004). Hydrogen peroxide toxicity occurring with direct contact and inhalation pose risks to personnel manufacturing the food. Hydrogen peroxide toxicity from ingestion relates to consumption of treated food.

Hydrogen peroxide rapidly oxidises upon direct tissue contact to produce burns (ECETOC, 1993). The severity of the burn progresses from a mild irritation-to-extreme corrosion depending upon the strength of the hydrogen peroxide, the length of contact, the presence of neutralising agents, and to the type of tissue affected. Additionally, hydrogen peroxide decomposition releases large amounts of oxygen (Watt et al., 2004). The rapid release of exceptionally large amounts of oxygen may saturate tissues and the vascular network, creating oxygen bubbles acting as microemboli. The microemboli may produce the characteristic whitening of the skin occurring upon direct contact with hydrogen peroxide (SCOGS, 1979). Exposing skin to hydrogen peroxide concentrations exceeding 35% causes epidermanl necrosis, producing at least brown or grey burns (ECETOC, 1993). Application of stronger hydrogen peroxide solutions proportionally produces burns of greater severity (ECETOC, 1993).

Hydrogen peroxide quickly and extensively damages eye tissue. Applications of 2 to 5% hydrogen peroxide solutions clouded the cornea and inflamed the conjuctiva of rabbit's eyes. Applying 6 to 8% hydrogen peroxide solutions to the eyes of rabbits caused irreversible damage (ECEROC, 1993). The relevant reviews cite the results of major studies (ECETOC, 1993, ECB, 2003; Fonterra, 2010; SCOGS, 1979; Watt et al., 2004).

Inhalation

Inhaling hydrogen peroxide vapours promotes direct contact with the surfaces of respiratory tract organs, including the nasal cavity, larynx, and lungs (ECB, 2003). Hydroxide vapours also facilitate direct contact with surface organs, including the eyes and skin. The severity of the exposure depends upon the strength of the hydrogen peroxide vapour, sometimes present as an aerosol, and length of exposure (Watt et al., 2004). However, respiratory organs, such as the mucous membrane, contain many peroxisomes with large amounts of catalase, which minimises the corrosiveness of inhaled hydrogen peroxide (ECEROC, 1993). Studies cited by the (ECEROC, 1993) detail the exposure of rats to highly concentrated hydrogen peroxide vapours and aerosols. Only 10 to 50% of the animals died in one study, after exposure to 9,400 mg of 90% hydrogen peroxide/m^3 (6,645 ppm) for 5 to 15 min. Exposing test animals to hydrogen peroxide concentrations of 5,000 mg/m^3 (3,676 ppm) for 5 minutes only resulted in

mild nasal irritation, blinking, and slight gasping. The saturation concentration for gaseous hydrogen peroxide is 4,670 mg/m^3 (3,300 ppm). Dogs exposed to hydrogen peroxide vapours of 10 mg/m^3 (7 ppm) for 6 hr/day, 5 days/week, for 6 months (126 treatments) developed patchy areas of atelectasis and emphysema in the lungs. Red circular clots of collagen, occasional muscle cells, and strands of elastic tissue appeared in the alveolar wall of the lungs. The treated dogs also developed a thicker skin and showed extensive hair loss. However, the exposure did not destroy the dog's hair follicles (ECB, 2003).

A 41 year old man exposed to hydrogen peroxide vapours for several years at his job station gradually developed eye and throat irritation, combined with the bleaching of his hair. Clinical diagnosis revealed the development of progressive dyspnoea and bilateral diffuse nodular infiltrates in this man's lungs. This man also smoked 2 packages of cigarettes/day for 25 years, which possibly enhanced and/or confounded the effect of hydrogen peroxide exposure. The patient's condition progressively improved without treatment upon eliminating the occupational exposure to hydrogen peroxide. The man no longer experienced dyspnoea within one and a half months, while his test radiograph and lung function tests normalised with the subsequent application of oral corticosteroid medication (ECB, 2003). Improvements in the operating and environmental conditions at the man's original working area at the manufacturing plant reduced hydrogen peroxide vapours to levels ranging from non-detectable to 0.79 mg/m^3. Employees working in this area subsequently registered only a few complaints of hair bleaching, nose bleeds, and eye or respiratory irritation (ECB, 2003).

Ingestion

Acute toxicity occurs with the ingestion of relatively large amounts of concentrated hydrogen peroxide solutions (Watt et al., 2004). The JACC review (ECETOC, 1993) cites reports listing the separate deaths of two infants upon consuming unknown quantities of 30% and 40% hydrogen peroxide. Respiratory failure usually is listed as the cause of death in these cases (Watt et al., 2004). The JACC review cites (ECETOC, 1993) complete recovery for victims in other nearly fatal incidents involving infants and adults consuming hydrogen peroxide of various concentrations. One incident involved the consumption of the contents of a pint bottle containing 35% hydrogen peroxide by a 33 year old woman. Although seriously affected, the woman recovered completely following treatment (ECETOC, 1993).

Mice consuming at least 1 g hydrogen peroxide/kg body weight/day as drinking water experienced pronounced weight loss and death within 2 weeks. Three-week old mice consuming 0.15% hydrogen peroxide in drinking water (150 mg hydrogen peroxide/kg body weight/day) developed no visible abnormalities during a 35 week test. Necropsy of the treated mice showed some degenerative changes in the liver, kidney, stomach, and lymphatic small intestinal wall tissues (ECETOC, 1993).

The catalase in the mucus membranes and gastrointestinal tract decomposes hydrogen peroxide upon ingestion (ECETOC, 1993). Hydrogen peroxide decomposition following the ingestion of concentrated doses rapidly releases large amounts of oxygen that may diffuse

into tissues and blood to form pulmonary gas embolisms. The formation of pulmonary gas embolisms may be the primary cause of death in acute hydrogen peroxide toxicity (Watt et al., 2004).

The hydrogen peroxide dose required to produce enough oxygen to form a pulmonary gas embolism is much, much greater than the residual amount of hydrogen peroxide remaining in a fermented dairy ingredient.

Summary and Conclusions

Hydrogen peroxide certainly is a hazardous reagent that demands appropriate, carefully executed handling procedures to protect workers utilising the compound in commercial applications. However, the proper handling procedures for commercial applications are well established and readily available (ECETOC, 1993; Watt et al., 2004). Large amounts of hydrogen peroxide are continually used worldwide in numerous applications ranging from rocket fuel to toothpaste (ECB, 2003; ECETOC, 1993; SCOGS, 1979). The commercial handling of hydrogen peroxide therefore is no more hazardous than incurred for many other commercially essential compounds. Proper management and handling eliminate potential risks to workers exposed to hydrogen peroxide in the execution of the use of hydrogen peroxide in the processing of fermented dairy ingredients envisioned in this application (Goor et al., 1989; Hess, 1995).

Simultaneously, consumers consuming foods prepared using hydrogen peroxide as described in this application are exposed to no safety risks whatsoever. The catalase treatment decomposes any residual hydrogen peroxide to oxygen and water (SCOGS, 1979). Both oxygen and water are essential to life and non-polluting. The approval of this application greatly enhances the competitiveness of the Australian and New Zealand dairy and food industries, facilitating the production of a larger variety of fermented dairy products.

E. Safety assessment reports prepared by international agencies or other national government agencies

The EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing aids (CEF) has published a recommendation on the use of hydrogen peroxide. This document is attached to the application (ECB, 2003).

C. INFORMATION RELATED TO THE DIETARY EXPOSURE TO HYDROGEN PEROXIDE

1. Foods or food groups likely to contain the processing aid

Approval of this application would extend hydrogen peroxide use in the following categories:

Table 4. Food groups likely to contain material processed using the processing aid

Food group	Examples of food products
Dairy products	Fermented milk products (e.g. yoghurt, fermented milk drinks), other nutritional dairy beverages (e.g. fruit milk drinks), cheese and cheese products

2. Proposed levels of residues of the processing aid for ingredients and foods

Fermented dairy ingredients and products manufactured using hydrogen peroxide will contain less than or equal to 5 ppm hydrogen peroxide.

3. Percentage of the food group in which the processing aid is likely to be found or the percentage of the market likely to use the processing aid

Approval of this application would extend hydrogen peroxide use in the following dairy products.

Table 5. Maximum percentage of each food group likely to contain a hydrogen peroxide processed ingredient.

Food group	Max percentage likely to contain hydrogen peroxide-processed ingredient (wt %)	Expected level of hydrogen peroxide - processed ingredient in food product (ppm)
Dairy products		
Fermented milk products	10	< 5
Cheese and cheese products	10	< 5

4. Levels of processing aid residues in foods in other countries

- FSANZ accepted max level 5ppm
- USFDA accepted max level 0.05%

4. REFERENCES

Abbas, M. E., W. Luo, L. Zhu, J. Zou, and H. Tang. 2010. Fluorometric determination of hydrogen peroxide in milk by using a Fenton reaction system. Food Chemistry 120:327-331.

Amin, V. M., and N. F. Olson. 1967. Spectrophotometric determination of hydrogen peroxide in milk. Journal of Dairy Science. 50:461-464.

Andreae, W. A. 1955. A sensitive method for the examination of hydrogen peroxide in biological materials. Nature. 175:859-860.

AOAC. 2006. Hydrogen Peroxide in Milk Official Method 957.08. Official Methods of Analysis of the AOAC18th ed. Association of Official Analytical Chemists, Inc. Arlington, VA.

Barone, W. B., and O. J. Krett. 1969. M 17 Rapid procedure for the detection of hydrogen peroxide-catalase treated milk. [Abst.] Journal of Dairy Science. 52:882.

Boveris, A., N. Oshino, and B. Chance. 1972. The cellular production of hydrogen peroxide. Biochem. Journal. 128:617-630.

Campos-Martin, J. M., G. Blanco-Brieva, and J.L.G Fierro. 2006. Hydrogen peroxide synthesis: An outlook beyond the anthraquinone process. Angewandte Chemie. International Ed. 45:6962-6984.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.113 Cheddar cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.114 Cheddar cheese for manufacturing. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.116 Low sodium Cheddar cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.118 Colby cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.119 Colby cheese for manufacturing. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.121 Low sodium Colby cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.136 Washed curd and soaked cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C

Code of Federal Regulations. Title 21. Food and Drugs. § 133.144 Granular and stirred curd cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C

Code of Federal Regulations. Title 21. Food and Drugs. § 133.145 Granular and stirred curd cheese for manufacturing. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.195 Swiss and emmentaler cheese. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 133.196 Swiss and emmentaler cheese for manufacturing. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 173. Secondary direct food additives permitted in food for human consumption. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 160.145. Dried egg whites. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 160.185. Dried egg yolks. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 160.185. Dried egg yolks. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 178.1005. Hydrogen peroxide solution Indirect food additives: Adjutants, production aids, and sanitizers. Subpart B. Substances utilised to control the growth of microorganisms. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 184.1034 Catalase (bovine liver). Direct food substances affirmed as generally recognized as safe. Subpart B. Listing of specific Substances Affirmed as GRAS.. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Code of Federal Regulations. Title 21. Food and Drugs. § 184.1366 Hydrogen peroxide. Direct food substances affirmed as generally recognized as safe. Subpart B. Listing of specific Substances Affirmed as GRAS.. Revised as of April 1, 2010. U. S. Government Printing Office, Washington, D.C.

Codex Alimentarius. (2010a). *List of Codex specifications for food additives* (CAC/MISC 6-2010).

Codex Alimentarius (2010b). Inventory of Substances used as Processing Aids (IPA), Updated List (FA/43/INF/03)

Codex Alimentarius. (1991). *Guidelines for the preservation of raw milk by use of the Lactoperoxidase system* (CAC/GL 13-1991).

Croissant, A. E., E. J. Kang, R. E. Campbell, E. Bastian, and M. A. Drake. 2009. The effect of bleaching agent on the flavour of liquid whey and whey protein concentrate. Journal of Dairy Science. 92:5917-5927.

Das, H., S. Jayaraman, M. Naika, and A. S. Bawa. 2006. Effect of chemical contaminants on preservation of milk – a comparative study. Journal of Food Science and Technology. 43:425-429.

Department of Justice Canada. 2011a. Food and Drug Regulations (C.R.C., c. 870) Division 16. Food Additives. Table V. Food additives that may be used as food enzymes. C.1 Catalase. Regulations current to 2011-06-15 and last amended on 2011-04-01.

Department of Justice Canada. 2011b. Food and Drug Regulations (C.R.C., c. 870) Division 16. Food Additives. Table VIII. Miscellaneous food additives. H.1. Hydrogen peroxide.

Desesso, J. M., A. L. Lavin, S. M. Hsia, and R. D. Mavis. 2000. Assessment of the carcinogenicity associated with oral exposures to hydrogen peroxide. Food and Chemical Toxicology 38:1021-1041.

European Chemicals Bureau (ECB). 2003. European Union Risk Assessment Report, Hydrogen peroxide. Final report. 2nd Priority List. Vol. 38. European Chemicals Bureau (ECB), Report Number: EUR 20844 EN. P. 1-243.

European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). 1993. Joint Assessment of Commodity Chemicals (JACC) No. 22, Hydrogen peroxide. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). Report Number: 22.

Federal Register. (March 2) 2011. Food and Drug Administration. 21 CFR Parts 173. Secondary Direct Food Additives Permitted in Food for Human Consumption. Final Rule. 72(41):11328-11330.

Federal Register. (Nov. 7) 1983. Food and Drug Administration. 21 CFR Parts 182 and 184. Hydrogen peroxide. Proposed Affirmation of Gras Status as a direct human food ingredient with specific limitations. 48(223):52323-52333.

Ferrier, L. K., N. F. Olson, and T. Richardson. 1970. Analysis of hydrogen peroxide in milk using titanium tetrachloride. Journal of Diary Science. 53:598-599.

Food Chemical Codex (FCC). 2010. Hydrogen peroxide. In Food Chemicals Codex. 3rd ed. National Academy Press, Washington, DC p 146-147.

Fonterra Co-operative Group, Ltd. 2010. Food additive petition for the use of hydrogen peroxide in the manufacture of whey protein concentrates. G. A. Burdock, ed. Burdock Group. Orlando, FL. [Docket No. FDA-2010-0200].

Food Standards Code of Australia and New Zealand. (2000a). *Clause 14: Permitted processing aids with miscellaneous functions. Standard 1.3.3: Processing Aids*. (Standard 1.3.3: Processing Aids). Commonwealth of Australia Gazette, Canberra, Australia.

Food Standards Code of Australia and New Zealand. (2000b). *Clause 11, permitted processing aids used in packaged water and in water used as an ingredient in other foods*. (Standard 1.3.3: Processing Aids). Commonwealth of Australia Gazette, Canberra, Australia.

Food Standards Code of Australia and New Zealand. (2000c). *Clause 12: Permitted bleaching agents, washing and peeling agents*. (Standard 1.3.3: Processing Aids). Commonwealth of Australia Gazette, Canberra, Australia.

Funk, E. 1949. Uber den nachweis von wasserstoffsuperoxyd in der molke. [The measurement of hydrogen peroxide in whey]. Molkereiztg. Hildesh. 3:129-130. *Cited in* Lück. H. 1962. The use of hydrogen peroxide in milk and dairy products. WHO/FAO In Milk Hygiene. Hygiene in milk production, processing and distribution. World Health Organisation Monograph Series No. 48. pp. 423-447. World Health Organisation. Geneva.

Gilliland, S. E. 1969. Enzymatic determination of residual hydrogen peroxide in milk. Journal of Dairy Science. 52:321-324.

Goor, G., W. Kunkul, O. Weiburg, and A. G. Degussa. 1989. Hydrogen peroxide. In Ullmann's Encyclopaedia of Industrial Chemistry, 5th completely revised edition, Supp. Vol. A13. Eds. B. Elvers, VCH, Weinheim.

Hess, W. T. 1995. Hydrogen Peroxide, *in* Kirk-Othmer Encyclopaedia of Chemical Technology, 4th ed. Wiley, New York, Volume 13. pp 961-995.

Hills, G. L., and C. C. Thiel. 1946. The ferric tyiocyanate method of estimating peroxide in the fat of butter, milk and dried milk. Journal of Dairy Research. 14:340-353.

International Agency for Research on Cancer (IARC).1999. Hydrogen peroxide IARC monographs on the evaluation of carcinogenic risk of chemicals to humans. International Agency for Research on Cancer. World Health Organization. Lyon, France Vol. 71:29: 671-689.

International Diary Federation (IDF) Provisional Standard 74A:1991 - Milkfat – Determination

of Peroxide Value of the International Dairy Federation N° 234/1988. Brussels

International Diary Federation (IDF). 2006. International Standard 74. Milk fat – Determination of peroxide value. International Dairy Federation. Brussels.

International Diary Federation (IDF). 1988. Code of practice for the preservation of raw milk by the lactoperoxidase system. Bulletin of the International Dairy Federation N° 234/1988. Brussels.

International Union of Biochemistry and Molecular Biology (IUBMB) Enzyme Nomenclature. 1999. *Catalase: EC 1.11.1.6*. Retrieved from http://www.chem.qmul.ac.uk/iubmb/enzyme/EC1/11/1/6.html

Japan External Trade Organisation, 2011. Specifications and Standards for Foods, Food Additives etc. Under the Food Sanitation Act. p145

Joint FAO/WHO Expert Committee on Food Additives (JECFA). 2004. Hydrogen peroxide. FNP 52 ADD 12.

Kang, E. J., R. E. Campbell, E. Bastian, and M. A. Drake. 2010. Invited review: Annatto usage and bleaching in dairy foods. Journal of Dairy Science. 93:3891-3901.

Koning, P. J., and P. J. van Rooijen. 1972. Effect of hydrogen peroxide on the amino acid composition of the proteins from cheese whey and evaporated milk. Netherlands Milk and Dairy Journal. 26:41-45.

Kosikowski, F. V., and V. V. Mistry, 1997. Cheese and fermented milk foods. 3rd ed. F. V. Kosikowski, L.L.C. Westport, CT. Hydrogen peroxide analysis in milk: Vol. I. pp. 256-257 and 562; Vol. II. P 119; Heat coagulation of acidified milk: Vol. I. p 187..

Lide, D. R. (Ed.). (2009). CRC Handbook of Chemistry & Physics (90th ed.). CRC Press. Boca Raton, FL

Lück, H. 1956. The use of hydrogen peroxide as a dairy preservative. Review article No. 48. Dairy Science Abstracts. 18(5): 363-386.

Lück. H. 1962. The use of hydrogen peroxide in milk and dairy products. WHO/FAO In Milk Hygiene. Hygiene in milk production, processing and distribution. World Health Organisation Monograph Series No. 48. pp. 423-447. World Health Organisation. Geneva.

Marks, N. E., A. S. Grandison, and M. J. Lewis. 2001. Use of hydrogen peroxide detection strips to determine the extent of pasteurization in whole milk. International Journal of Dairy Technology. 54:20-22.

Merck 2009. Merckoquant® 110011 Peroxide Test Colometric. Merck. Sarmstadt, Germany.

Ministry of Agriculture and Forestry (MAF). 2011. Approved test method: peroxide value. http://www.foodsafety.govt.nz/registers-lists/

Munday, W. H. 1957. Report on hydrogen peroxide. Journal of Association of Official Agricultural Chemists. 40:789-792.

Niethammer, P., C. Grabher, A. T. Look, and T. J. Mitchison. 2009. A tissue-scale gradient of hydrogen peroxide mediates rapid wound detection in zebrafish. Nature. 459:996-999.

O'neil, M. J.. et al. (2001). The Merck index: an encyclopaedia of chemicals, drugs, and biologicals (13th ed.). Merck & Co., Inc. Whitehouse Station, NJ.

Ovenston, T.C.J, and W. T. Rees. 1950. The spectrophotometric determination of small amounts of hydrogen peroxide in aqueous solutions. Analyst 75:204-208.

Patrick, W. A., and H. B. Wagner. 1949. Determination of hydrogen peroxide in small concentrations. Analy. Chem. 21:1279-1280.

Perry, J.H., D. W. Green, and J. O. Maloney, ed. 1997. Chemical Engineers Handbook, 7th ed. McGraw-Hill New York.

Pien, J., J. Desirant, and D. Lafontaine. 1953. Ann. Falsif., Paris, 46:416, *as Referenced in* Lück. H. 1962. The use of hydrogen peroxide in milk and dairy products. WHO/FAO In Milk Hygiene. Hygiene in milk production, processing and distribution. World Health Organisation Monograph Series No. 48. pp. 423-447. World Health Organisation. Geneva.

Pumphrey, R.S.H. 2000. Lessons for management of anaphylaxis from a study of fatal reactions. Clinical and Experimental Allergy. 30:1144-1150.

Riedl, H-J., and G. Pfleiderer [Inventors]. May 16, 1939. Production of hydrogen peroxide. United States Patent 2,158,525. Ludwigshafen-on-the-Rhine assignee.

Rouquette, R. 1955. La recherché de l'eau oxygénée dans le lait bichromaté [The detection of hydrogen peroxide in dichromate-preserved milk]. Ann. Faksuf, Fraydesm Oarus 48:4-8. *Cited in* Lück. H. 1962. The use of hydrogen peroxide in milk and dairy products. WHO/FAO In Milk Hygiene. Hygiene in milk production, processing and distribution. World Health Organisation Monograph Series No. 48. pp. 423-447. World Health Organisation. Geneva.

See also: Dairy Science Abstracts. 1955. 17(5)435 for translated abstract.

Select Committee on GRAS Substances (SCOGS). 1979. Evaluation of the health aspects of hydrogen peroxide as a food ingredient. Prepared by the Select Committee of GRAS Substances (SCOGS). Life Sciences Research Office (LSRO), Bethesda, MD. Report Number . PS80104607.

Sies, H. 1974. Biochemistry of the peroxisome in the liver cell. Angew. Chem. Int. Ed. Eng. 13:706-718.

Teply, L. J., P. H. Derse, and W. V. Price. 1958. Composition and nutritive value of cheese produced from milk treated with hydrogen peroxide and catalase. Journal of Dairy Science. 41:593-605.

Toyoda, M., Y. Ito, M. Iwaida, and M. Fujii. 1982. Rapid procedure for the determiniation of minute quantities of residual hydrogen peroxide in food by using a sensitive oxygen electrode. Journal of Agricultural and Food Chemistry 30:346-349.

US Department of Labor. 1996. Occupational Safety and Health Guideline for Hydrogen Peroxide:
http://www.osha.gov/SLTC/healthguidelines/hydrogenperoxide/recognition.html

Walstra, P. and R. Jenness. 1984. Dairy Chemistry and Physics. John Wiley & Sons. New York. pp. 234 -237, 245-246, 248-253.

Watt, B. E., A. T. Proudfoot, and J. A. Vale. 2004. Hydrogen peroxide poisoning. Toxicological Reviews. 23:51-57.