

Guide on Cleaners and Sanitisers that may have Incidental Contact with Food



November 2019

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Preface

This Guide has been prepared by Accord as a resource for the food cleaning and sanitising products industry.

This version replaces the previous publication which was issued in May 2010.

Important Notice

This Guide is intended to provide a summary overview only with links to important information and organisations. This is not meant to be an exhaustive review, rather, it is offered to readers by way of general information and should not be taken as legal advice. Where necessary, direct reference to relevant legislation may be required, and specialist regulatory or legal advice may need to be sought to address specific circumstances.

Skill, care and judgement should be used before relying on this information in any important matter.

Management of the Guide

Accord will review and update this document from time to time, so it is recommended that companies check the [Accord website](#) regularly for updated versions.

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Terms and Definitions

Throughout this document, various terms are used. The meanings and definitions of these terms are given in [Section 5 – Glossary](#).

Foreword to the Accord Guide

Cleaning and sanitising products play an important public health role in establishments and industries that prepare food for human consumption. Additionally, it is important to recognise that the requirements of food legislation also apply to meals provided by caterers and food service businesses, in institutions such as schools, childcare centres and hospitals or at exhibitions and events and even to food given away as a prize (e.g. in a raffle) or a promotion.

Australia's outcomes-based risk assessment approach to food regulation sets standards for food products rather than products such as cleaners and sanitisers that may be used on surfaces, equipment or other places where food is manufactured or prepared.

The purpose of this Guide is to:

- assist Accord member companies in ensuring suitability of their products for their intended purpose
- assist with enquiries from customers, and
- ensure a common understanding of requirements, for cleaners and sanitisers that may have incidental contact with food, throughout the industry.

This Guide was originally produced by ACSPA in September 2004, with the cooperation of Food Standards Australia New Zealand (FSANZ) and the NSW Food Authority. In 2010 the Guide was substantially reviewed to address regulatory changes in Australia and overseas. In 2019, the Guide has been reviewed to ensure it remains up to date and reflects current legislation and practices.

Bronwyn Capanna
Executive Director

November 2019

1. Introduction and Scope

Australian food legislation establishes outcomes-based measures for food production which set minimum requirements for the processing and handling of food, as well as setting standards for the final (finished) product. As a result, there is no system for positive regulation of cleaners and sanitisers that may be used in food manufacturing establishments. Nonetheless, companies supplying these materials to the food industry are frequently requested to provide assurances that their chemicals are 'food grade' or suitable for food use.

This Guide has been prepared to assist the manufacturers and distributors of cleaning and sanitising products to source data to demonstrate their products are suitable for food use and enable them to provide assurances to their customers in the food industry.

When considering the suitability of cleaning and sanitising chemicals that may come into incidental contact with food, suppliers should be aware that this is not limited to their use in food manufacturing and preparation - the requirements of food legislation also apply to meals provided by caterers and food service businesses, institutions such as schools, childcare centres and hospitals or at exhibitions and events and even to food given away as a prize (e.g. in a raffle) or a promotion.

Resources that can provide evidence that a cleaner or sanitiser is suitable for food use include the [Australia New Zealand Food Standards Code](#) (the Code) as well as registrations and listings by non-food regulatory agencies in Australia and New Zealand or by overseas food regulatory agencies.

This Guide does not address the use of chemicals intended to be applied directly to foods e.g. surface washing of fruit or rinsing of poultry carcasses (classified as food processing aids) or for veterinary purposes, e.g. application of sanitisers to the udders of dairy animals. Such products may require registration by the Australian Pesticides and Veterinary Medicines Authority (APVMA) if used on farm. Information on current registration requirements is available on the [APVMA website](#).

2. Australian and New Zealand Food Legislation

For Australia and New Zealand, Food Standards Australia New Zealand (FSANZ) develops food standards relating to the manufacture and sale of food. These food standards are subsequently enacted and enforced by the jurisdiction(s) in which the activity takes place – States, Territories and New Zealand. New Zealand also has some food standards that are specific to New Zealand.¹

The responsibilities of the Australian Commonwealth Government and the NZ Government with respect to food are largely restricted to biosecurity controls for imports and exports under the Department of Agriculture and Water Resources (DAWR) and the NZ Ministry for Primary Industries (MPI) and the management of coordinated food standards development for food safety, composition and labelling through FSANZ.

Under a unique agreement between the Australian Commonwealth, State and Territory governments and the New Zealand Government a single set of food standards has been

¹ <https://www.mpi.govt.nz/law-and-policy/requirements/food-standards/>

adopted. These standards, which are developed by FSANZ through a consultative process, are published in the [Australia New Zealand Food Standards Code](#) (hereafter the Code).

Australian state and territory governments and the New Zealand government implement and enforce the food standards developed by FSANZ through their respective laws. DAWR enforces the Code at the Australian border in relation to imported food through the Imported Food Control Act 1992. MPI sets minimum regulatory requirements for the safety of food entering NZ.

Food standards developed by FSANZ are enacted by the jurisdictions through their respective Food Acts (Table 1). As a result, the provisions relevant to materials such as cleaners and sanitisers having incidental contact with food are effectively harmonised across all jurisdictions.

Cooperation between the jurisdictions works to encourage harmonised interpretation of legislation across the jurisdictions. Therefore, if a cleaning/sanitising protocol is found to be acceptable by one jurisdiction it is likely to also be acceptable to others.

Table 1: Australian and New Zealand Food Acts (as at May 2019)

Jurisdiction	Food Act/Regulation ²
New Zealand	Food Act 2014
Queensland	Food Act 2006
New South Wales	Food Act 2003
Australian Capital Territory	Food Act 2001
Victoria	Food Act 1984
Tasmania	Food Act 2003
South Australia	Food Act 2001
Western Australia	Food Act 2008
Northern Territory	Food Act 2004
Imported Food	Imported Food Control Act 1992

2.1 Scope of Food Legislation

2.1.1 Australia

The State/Territory Food Acts apply to all food offered for sale, under a definition of ‘Sell’ that includes not only the wholesale and retail supply of unpackaged and packaged foods but also the supply of prepared food and meals throughout the restaurant, catering and service industries, including hospitals and nursing homes (Figure 1).

Consequently, any requirements to provide appropriate cleaners and sanitisers for incidental or indirect contact with food apply not only to manufacturers but also to commercial kitchens and any establishments in which food is assembled or served.

2.1.2 New Zealand

The New Zealand Food Act 2014 defines ‘Sale’ (Figure 2) covering a range of activities related to processing and handling of food for human consumption.

² <http://www.foodstandards.gov.au/about/foodlawandtreaties/Pages/default.aspx>, May 2019

Figure 1: 'Sell' in relation to the supply of food – Australia³

- (a) barter, offer or attempt to sell; or
- (b) receive for sale; or
- (c) have in possession for sale; or
- (d) display for sale; or
- (e) cause or permit to be sold or offered for sale; or
- (f) send, forward or deliver for sale; or
- (g) dispose of by any method for valuable consideration; or
- (h) dispose of to an agent for sale on consignment; or
- (i) provide under a contract of service; or
- (j) supply food as a meal or part of a meal to an employee, in Accordance with a term of an award governing the employment of the employee or a term of the employee's contract of service, for consumption by the employee at the employee's place of work; or
- (k) dispose of by way of raffle, lottery or other game of chance; or
- (l) offer as a prize or reward; or
- (m) give away for the purpose of advertisement or in furtherance of trade or business; or
- (n) supply food under a contract (whether or not the contract is made with the consumer of the food), together with accommodation, service or entertainment, in consideration of an inclusive charge for the food supplied and the accommodation, service or entertainment; or
- (o) supply food (whether or not for consideration) in the course of providing services to patients or inmates in public institutions; or
- (p) sell for the purpose of resale.

³ Food Regulation Agreement (FRA) – [Model Food Provisions – Annex A](#)

Figure 2: ‘Sale’ in relation to the supply of food – New Zealand⁴

13 Meaning of sale

- (1) In this Act, unless the context otherwise requires, sale, in relation to food,—
- (a) means selling food for processing and handling or for human consumption; and
 - (b) includes reselling food for processing and handling or for human consumption; and
 - (c) includes the following activities relating to food for human consumption
 - (i) offering food for sale or attempting to sell food, or receiving or having food in possession for sale, or exposing food for sale, or sending or delivering food for sale, or causing or permitting food to be sold, offered for sale, or exposed for sale:
 - (ii) bartering food:
 - (iii) selling, or offering to sell, any thing of which any food forms a part:
 - (iv) supplying food, together with any accommodation, service, or entertainment, as part of an inclusive charge:
 - (v) supplying food in exchange for payment or in relation to which payment is to be made in a shop, hotel, or restaurant, at a stall, in or on a craft or vehicle, or in any other place:
 - (vi) supplying food to an employee or other person in accordance with an employment agreement or an agreement for services:
 - (vii) for the purpose of advertisement or to promote any trade or business, giving away food or, whether or not on payment of money, offering food as a prize or reward to the public:
 - (viii) exporting food:
 - (ix) every other method of disposition of food for valuable consideration; but
 - (d) does not include—
 - (i) exchanging food for food or other goods or services as part of a personal relationship between individuals that is not commercial in nature; or
 - (ii) supplying food together with accommodation to a person residing at a private dwelling or farm in exchange for services or labour by the person; or
 - (iii) supplying food together with accommodation to a person residing for more than 2 weeks at a private dwelling or farm in exchange for payment; or
 - (iv) supplying drinking water by network reticulation to the point of supply of any dwellinghouse or commercial premises.

2.2 Safe and Suitable Food

2.2.1 Australia

The food acts in Australia all contain provisions that define unsafe and unsuitable food (Figures 3 & 4). The handling of food in a manner that will render it unsafe and/or unsuitable and the sale of unsafe and/or unsuitable food are all offences under food law. These practices could include contact with and/or residues in the food of an unsuitable cleaner or sanitiser.

⁴

http://www.legislation.govt.nz/act/public/2014/0032/latest/DLM2996092.html?search=ts_act%40bill%40regulation%40deemedreg_food+act_resel_25_a&p=1

2.2.2 New Zealand

The New Zealand Food Act 2014 defines 'safety and suitability' (Figure 5).

Figure 3: Definition of unsafe food - Australia⁵

<p>6 Meaning of 'unsafe' food</p> <p>(1) For the purposes of this Act, food is unsafe at a particular time if it would be likely to cause physical harm to a person who might later consume it, assuming:</p> <ul style="list-style-type: none"> (a) it was, after that particular time and before being consumed by the person, properly subjected to all processes (if any) that are relevant to its reasonable intended use, and (b) nothing happened to it after that particular time and before being consumed by the person that would prevent its being used for its reasonable intended use, and (c) it was consumed by the person According to its reasonable intended use. <p>(2) However, food is not unsafe for the purposes of this Act merely because its inherent nutritional or chemical properties cause, or its inherent nature causes, adverse reactions only in persons with allergies or sensitivities that are not common to the majority of persons.</p> <p>(3) In subsection (1), processes include processes involving storage and preparation.</p>

Figure 4: Definition of unsuitable food - Australia⁶

<p>7 Meaning of 'unsuitable' food</p> <p>(1) For the purposes of this Act, food is unsuitable if it is food that:</p> <ul style="list-style-type: none"> (a) is damaged, deteriorated or perished to an extent that affects its reasonable intended use, or (b) contains any damaged, deteriorated or perished substance that affects its reasonable intended use, or (c) is the product of a diseased animal, or an animal that has died otherwise than by slaughter, and has not been declared by or under another Act to be safe for human consumption, or (d) contains a biological or chemical agent, or other matter or substance, that is foreign to the nature of the food. <p>(2) However, food is not unsuitable for the purposes of this Act merely because:</p> <ul style="list-style-type: none"> (a) at any particular time before it is sold for human consumption it contains an agricultural or veterinary chemical, or (b) when it is sold for human consumption it contains an agricultural or veterinary chemical, so long as it does not contain the chemical in an amount that contravenes the Food Standards Code, or (c) it contains a metal or non-metal contaminant (within the meaning of the Food Standards Code) in an amount that does not contravene the permitted level for the contaminant as specified in the Food Standards Code, or (d) it contains any matter or substance that is permitted by the Food Standards Code. <p>(3) In this section, slaughter of an animal includes the killing of an animal in the process of capturing, taking or harvesting it for the purposes of preparing it for use as food.</p>

⁵ Food Regulation Agreement (FRA) – [Model Food Provisions – Annex A](#)

⁶ Food Regulation Agreement (FRA) – [Model Food Provisions – Annex A](#)

Figure 5: Definition of safety and suitability – New Zealand⁷

12 Meaning of safety and suitability

- (1) In this Act, unless the context otherwise requires, safety and suitability, in relation to food, have the meanings set out in subsections (2) and (3) respectively.
- (2) Safety means a condition in which food, in terms of its intended use, is unlikely to cause or lead to illness or injury to human life or public health.
- (3) Suitability means a condition in which the matters specified in—
 - (a) subsection (4) are appropriate to food in terms of its intended use; and
 - (b) subsection (5) do not apply.
- (4) The matters referred to in subsection (3)(a)—
 - (a) include the composition, labelling, identification, and condition of the food; but
 - (b) do not include—
 - (i) matters that are directly related to the food's safety; or
 - (ii) matters of quality or presentation of the food that relate to a purely commercial decision by the person trading in the food.
- (5) Food is unsuitable if it—
 - (a) is in a condition that is offensive:
 - (b) is damaged, deteriorated, or perished to the extent of affecting its reasonable intended use:
 - (c) contains, or has attached to it or enclosed with it, any damaged, deteriorated, perished, or contaminated substance or thing to the extent of affecting its reasonable intended use:
 - (d) contains a biological or chemical agent, or other substance or thing, that is foreign to the nature of the food and the presence of which would be unexpected and unreasonable in food prepared or packed for sale in accordance with good trade practice:
 - (e) has packaging that is damaged, deteriorated, perished, or contaminated to the extent of affecting the food's reasonable intended use.
- (6) Food is not unsafe or unsuitable merely because—
 - (a) any part of the community objects to it on moral, ethical, cultural, spiritual, or religious grounds; or
 - (b) any person objects to it because of personal preference; or
 - (c) its consumption in inappropriate quantities may damage a person's health; or
 - (d) its presence or consumption is unhealthy for any person who has an allergy or other personal health condition.

⁷

http://www.legislation.govt.nz/act/public/2014/0032/latest/DLM2996083.html?search=ts_act%40bill%40regulation%40deemedreg_food+act_resel_25_a&p=1

Due to the ‘outcomes-based’ nature of the Food Acts the legislation does not contain black and white answers regarding what constitutes a safe cleaner or sanitiser or suitable residue limits. The onus is on the food manufacturer to apply the requirements to their specific process and food to produce a product that is fit for consumption as ‘safe and suitable’ food.

A key consideration in the legislation relates to the term ‘foreign to the nature of the food’ and how this is to be interpreted. It is generally understood that this phrase is to be taken to refer to the food in the context in which it is presented. In this case, residues of chemicals that were consistent with sanitary preparation of the food in a manner consistent with Good Manufacturing Practice (GMP) would not generally be considered to be foreign to the nature of the food.

2.2.3 Offences relating to Food

The regulations in both Australia and New Zealand contain provisions for offences relating to handling of food in a manner which endangers consumers or creates risk to consumers.

In Australia these offences are set out in State and Territory Food Acts.

In New Zealand these offences are set out in the Food Act 2014.

In both countries, the penalties can be imprisonment and/or fines for a company or an individual.

2.3 The Australia New Zealand Food Standards Code (the Code)

The State and Territory Food Acts require that where a relevant food standard exists then food must comply with it. The Code⁸ contains a number of standards that may have a direct or indirect bearing on the choice of cleaners and sanitisers which may come into contact with foods as set out in Table 2.

Table 2: Standards in the Code relevant to cleaners and sanitisers which may come into contact with foods

Standard Name	Standard Number	Section of Guide
Structure of the Code and General Provisions [Materials in contact with food]	Standard 1.1.1 [1.1.1 – 10 (11)]	2.3.1
Processing Aids	Standard 1.3.3 Schedule 18	2.3.2
Identity and Purity	Schedule 3	2.3.3
Food Safety Practices and General Requirements (Australia only)	Standard 3.2.2	2.3.5
Microbiological Limits for Food	Standard 1.6.1 Schedule 27	2.3.6
Primary Production Standards	Standards 4.2.1 – 4.2.6	2.3.6

2.3.1 Materials in Contact with Food [Standard 1.1.1]

Clause 1.1.1-10(11) specifies requirements for any packaging and any article or material in the packaging or in contact with the food. Although primarily aimed at equipment surfaces, packaging materials and package inserts, this clause can also apply to residues of

⁸ <http://www.foodstandards.gov.au/code/Pages/default.aspx>

cleaners/sanitiser that may be on surfaces on which food is manufactured, prepared or served.

This effectively allows the presence of residues of cleaners and sanitiser that have been used to clean and disinfect food contact surfaces, whether during manufacturing or in preparation and serving, provided that the any material transferred to the food will not be likely to cause harm, distress or discomfort to the consumer (Figure 6).

Figure 6: Articles and Materials in Contact with Food [1.1.1 – 10 (11)]

<p>11) Any packaging, and any article or material in the packaging or in contact with the food, must not, if taken into the mouth:</p> <ul style="list-style-type: none"> (a) be capable of being swallowed or obstructing any alimentary or respiratory passage; or (b) be otherwise likely to cause bodily harm, distress or discomfort. <p>Example Articles or materials include any materials in contact with food, including packaging materials that contain other items such as moisture absorbers, mould inhibitors, oxygen absorbers, promotional materials, writing or other graphics.</p>

2.3.2 Processing Aids [Standard 1.3.3 & Schedule 18]

Processing aids are substances intentionally added to food to fulfil a technological purpose in the course of processing but not performing a technological function in the food for sale. Schedule 18 – Processing aids includes a number of cleaners, e.g. sodium hydroxide, as a generally permitted processing aid. While not directly applicable to cleaners and sanitiser for incidental food contact use, Schedule 18 contains a list of permitted bleaching agents, washing and peeling agents that may be used directly on food, together with permitted maximum residue limits in food (Table 3). Many of these chemicals also have applications as cleaners and sanitiser in food manufacturing and preparation.

Table 3: Schedule 18⁹ – Clause S18-7 Permitted bleaching agents, washing and peeling agents – various foods

Substance	Food	Maximum permitted level (mg/kg)
Benzoyl peroxide	All foods	40 (measured as benzoic acid)
Bromo-chloro-dimethylhydantoin	All foods	1.0 (available chlorine) 1.0 (inorganic bromide) 2.0 (dimethylhydantoin)
Calcium hypochlorite	All foods	1.0 (available chlorine)
Chlorine	All foods	1.0 (available chlorine)
Chlorine dioxide	All foods	1.0 (available chlorine)
Diammonium hydrogen orthophosphate	All foods	GMP
Dibromo-dimethylhydantoin	All foods	2.0 (inorganic bromide) 2.0 (dimethylhydantoin)

⁹ Up to Amendment No. 184, 28 February 2019

Substance	Food	Maximum permitted level (mg/kg)
2-Ethylhexyl sodium sulphate	All foods	0.7
Hydrogen peroxide	All foods	5
Iodine	Fruits, vegetables and eggs	GMP
Oxides of nitrogen	All foods	GMP
Ozone	All foods	GMP
Peracetic acid	All foods	GMP
Sodium chlorite	All foods	1.0 (available chlorine)
Sodium dodecylbenzene sulphonate	All foods	0.7
Sodium hypochlorite	All foods	1.0 (available chlorine)
Sodium laurate	All foods	GMP
Sodium metabisulphite	Root and tuber vegetables	25
Sodium peroxide	All foods	5
Sodium persulphate	All foods	GMP
Triethanolamine	Dried vine fruit	GMP

2.3.3 Identity and Purity [Schedule 3]

This Schedule lists the reference sources of monographs to be used to identify suitable/food grade additives and processing aids. In addition, where no relevant monograph is identified, the Standard establishes minimum contaminant levels with which added substances must comply:

- (a) 2 mg/kg* of lead; or
- (b) 1 mg/kg* of arsenic; or
- (c) 1 mg/kg* of cadmium; or
- (d) 1mg/kg* of mercury

* on a dry weight basis

There is no requirement in the Code for a cleaning or sanitising chemical that may come into incidental contact with food, such as sodium hydroxide, to be prepared to the Standard prescribed for the same chemical when intended for direct addition to food. Nonetheless, where a specification exists, any product that complies with it could be considered 'Food Grade'. Where this is not achievable, or no specification exists then the general contaminant levels also provide a benchmark that may be useful in determining whether a chemical is suitable for indirect food contact use or if a cleaned surface holding residue of that chemical is acceptable for food preparation.

2.3.4 Agvet Chemicals [Standard 1.4.2 and Schedules 20 & 21]

This Standard and the associated Schedules set out the maximum residue limits and extraneous residue limits for agricultural or veterinary chemicals that are permitted in foods for sale.

If an agricultural or veterinary chemical is not listed in the Schedule in relation to a food, there must be no detectable residue of that agvet chemical and no detectable residue of any metabolites of that agvet chemical in food. For some agvet chemicals FSANZ has also established 'all other foods except animal food commodities' MRLs.

Whilst not applicable to the majority of cleaners/sanitiser, this may work to prohibit residues arising from indirect incidental food contact use as a cleaner/sanitiser for a chemical which is also registered as the active constituent in an agricultural or veterinary chemical, but not including adjuncts such as solvents, sequestrants, wetting agents etc. In practice this is only likely to be an issue where there is potential for confusion about the purpose for which the chemical has been used.

2.3.5 Food Safety Practices and General Requirements [Standard 3.2.2] – AUSTRALIA ONLY

Standard 3.2.2 mandates the use of cleaners/sanitiser, and effectively recognises their residues, are an integral part of Good Manufacturing Practice by requiring that food businesses must ensure that food preparation and handling equipment is kept in a clean and sanitary condition (Figure 7).

Furthermore, the Standard specifically mentions the use of chemicals on food surfaces and utensils as one of the accepted ways of reducing microbial numbers. This effectively recognises the use of cleaners and sanitiser as being consistent with GMP in food manufacturing. Residues arising from their appropriate use should not therefore be considered foreign to the nature of a food.

Figure 7: Standard 3.2.2 Food Safety Practices and General Requirements

Division 5 - Cleaning, sanitising and maintenance	
19	Cleanliness
(1)	A food business must maintain food premises to a standard of cleanliness where there is no accumulation of – <ul style="list-style-type: none"> (a) garbage, except in garbage containers; (b) recycled matter, except in containers; (c) food waste; (d) dirt; (e) grease; or (f) other visible matter.
(2)	A food business must maintain all fixtures, fittings and equipment, having regard to its use, and those parts of vehicles that are used to transport food, and other items provided by the business to purchasers to transport food, to a standard of cleanliness where there is no accumulation of – <ul style="list-style-type: none"> (a) food waste; (b) dirt; (c) grease; or (d) other visible matter.
20	Cleaning and sanitising of specific equipment
(1)	A food business must ensure the following equipment is in a clean and sanitary condition in the circumstances set out below – <ul style="list-style-type: none"> (a) eating and drinking utensils - immediately before each use; and (b) the food contact surfaces of equipment - whenever food that will come into contact with the surface is likely to be contaminated.
(2)	In subclause (1), a 'clean and sanitary condition' means, in relation to a surface or utensil, the condition of a surface or utensil where it – <ul style="list-style-type: none"> (a) is clean; and (b) has had applied to it heat or chemicals, heat and chemicals, or other processes, so that the number of microorganisms on the surface or utensil has been reduced to a level that – <ul style="list-style-type: none"> (i) does not compromise the safety of the food with which it may come into contact; and (ii) does not permit the transmission of infectious disease.

2.3.6 Standards and related documents addressing efficacy of sanitisers

2.3.6.1 Microbiological limits and processing requirements [Standard 1.6.1 & Schedule 27]

Standard 1.6.1 Microbiological limits in food does not directly address the use of sanitisers on food production surfaces; however, Schedule 27 does list limits of foodborne micro-organisms that pose a risk to human health in nominated foods, or classes of foods. The Schedule includes mandatory sampling plans, and criteria for determining when a lot or consignment of food poses a risk to human health and should not be offered for sale or used in the preparation of food for sale. The Standard and Schedule therefore provide guidance to manufacturers of sanitisers regarding the expected levels of hygiene to be achieved on food contact surfaces in food manufacturing and retail applications.

2.3.6.2 FSANZ Compendium of Microbiological Criteria for Food¹⁰

The *Compendium of Microbiological Criteria for Food* is a compilation of process hygiene criteria that have been established for specific food commodities and microbiological Guide criteria used for ready-to-eat foods. It supersedes the Guides for the microbiological examination of ready-to-eat foods and the User Guide to Standard 1.6.1 - Microbiological Limits for Food with additional Guides criteria.

2.3.6.3 Primary Production Standards [Standards 4.2.1 – 4.2.6]

Standards in Part 4 of the Code contains primary production standards which set out food safety and suitability requirements for specific primary products from pre-harvesting up to sale as raw product and may or may not include manufacturing operations depending upon the regulatory jurisdiction. The Standards in this section include:

- 4.2.1 Primary production and processing standards for seafood.
- 4.2.2 Primary production and processing standards for poultry meat.
- 4.2.3 Primary production and processing standards for meat.
- 4.2.4 Primary production and processing standards for dairy products.
- 4.2.5 Primary production and processing standards for eggs and egg product.
- 4.2.6 Primary production and processing standards for seed sprouts.

As a general component these Standards require producers and manufacturers to address food safety and control the growth microbiological hazards through the development of documented food safety programs but do not contain lists of suitable cleaning or sanitising agents.

2.4 Chemicals approved for food contact by other ANZ regulatory agencies

2.4.1 Dairy Cleansers and Sanitisers – Australia

Cleansers and sanitisers used for on-farm dairies in Australia are currently required to be registered as agricultural chemicals by the Australian Pesticides and Veterinary Medicines Authority (APVMA) before being supplied or used in Australia. Prior to registration, the APVMA must be satisfied that it has the required information relating to the proposed product and that it can be satisfied on a range of criteria including safety, trade and efficacy.

The information to be provided with applications is set out in the [legislative instrument](#) for application requirements. Technical data may be required to address safety criteria, efficacy criteria and trade criteria. Registration addresses both the active cleaning/sanitising agent and the product formulation. The APVMA assessment procedure includes an evaluation of the toxicity of the chemical as well as assessment of residue safety. The APVMA has provided [Guidelines for Efficacy Evaluation of On-farm Dairy Cleansers and Sanitisers](#) to assist chemical companies considering or proposing the registration of new or novel on-farm dairy cleansers and sanitisers by identifying ways by which efficacy may be demonstrated.

¹⁰ <http://www.foodstandards.gov.au/publications/Pages/Compendium-of-Microbiological-Criteria-for-Food.aspx>

Dairy cleansers for use beyond the farm gate, for example in milk collection tankers or in dairy processing facilities, are regulated separately and fall under the jurisdiction of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS).

The Australian Commonwealth Government has foreshadowed reforms for dairy cleansers and sanitisers and options for lighter touch regulation are currently under consideration.

2.4.2 Dairy Cleansers and Sanitisers – New Zealand

In New Zealand, Dairy Maintenance Compounds (detergents, sanitisers and other compounds used in farm dairies to clean, sanitise or maintain the milking plant) are required to be approved or recognised by the New Zealand Ministry for Primary Industries (MPI).

MPI maintains a [register](#) with summary information for all approved and recognised dairy maintenance compounds. The register also shows any conditions that have been applied to a product to ensure they are used appropriately.

Approved dairy maintenance compound refers to products approved for use in farm dairies to clean, sanitise or maintain the milking plant (including the bulk milk tank).

Recognised dairy maintenance compound refers to products recognised as suitable for the identified purpose as applies to dairy processing (factory) applications.

Procedure for Approval or Recognition of Dairy Maintenance Compounds

Maintenance compounds used to clean, sanitise or otherwise maintain equipment and facilities are typically part of an integrated, documented programme. Individual products are considered based on their use as per the label instruction within the context of an overall programme.

Information required to get an approval or recognition of dairy maintenance compounds is provided by MPI - [Procedure for approval or recognition of dairy maintenance](#).

2.4.3 Household and Commercial Disinfectants – Australia

2.4.3.1 NICNAS¹¹

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) operates a chemicals notification and assessment scheme.

Under NICNAS, chemicals in these products must be listed on the Australian Inventory of Chemical Substances (AICS) or the introducer must hold a NICNAS assessment certificate or permit which allows introduction. NICNAS will not undertake any assessment or testing of effectiveness against micro-organisms under these proposals, however it will consider occupational health and safety and environmental risk, (currently not part of a TGA evaluation).

The listing of an active ingredient in or a formulation for a cleanser or sanitiser on the AICS may indicate the presence of useful and relevant publicly available data on the potential safety

¹¹ From 1 July 2020, NICNAS will be replaced by the Australian Industrial Chemicals Introduction Scheme (AICIS). The new Australian industrial chemicals law the *Industrial Chemicals Act 2019* creates a new regulatory scheme for the importation and manufacture of industrial chemicals in Australia (to replace NICNAS) from 1 July 2020. A summary of the changes is available on the NICNAS website.

and efficacy on food preparation surfaces. However, such listing is unlikely to address the organoleptic suitability for no rinse applications or provide evidence supporting specific food contact applications, demonstration of which will remain the responsibility of the manufacturer or formulator.

2.4.3.2 Therapeutic Goods Administration (TGA)

The TGA regulates hard surface disinfectants including hospital, household and commercial grade disinfectants and sanitisers. The relevant requirements depend on the intended purpose of the product, as discerned from the claims made in the instructions for use, labelling and promotional material. More information is available on the [TGA website](#).

Exempt and Listed disinfectants must comply with the [Therapeutic Goods Order 104 – \(Standard for Disinfectants and Sanitary Products\) \(TGO 104\), March 2019](#). TGO 104 replaces the previous *TGO 54 – Standard for Disinfectants and Sterilants* which sunset on 1 April 2019.

Exempt disinfectants include hospital grade or household/commercial grade disinfectant liquids, sprays, wipes, sponges and aerosols that do not make specific claims¹².

These products are not required to be included in the Australian Register of Therapeutic Goods before they are supplied to market but they must still meet all regulatory requirements as set out in the relevant legislation and [Guidance](#).

Listed disinfectants include hospital grade or household/ commercial grade disinfectant liquids, sprays, wipes, sponges and aerosols that make specific claims¹³ to kill microorganisms.

These products are required to be included in the Australian Register of Therapeutic Goods (ARTG) before they are supplied to the market and must meet all regulatory requirements as set out in the relevant legislation and [Guidance](#).

Pre-market review of listed disinfectants will only be conducted on products that contain a new chemical entity and/or make new specific claims. The TGA may evaluate test reports to validate the specific claims and the safety of any new active ingredient.

3. Identifying Safe and Suitable Cleaners and Sanitisers

Australian legislation and regulations relating to the use of cleaners and sanitisers in areas where they may come into incidental contact with food, such as in food manufacturing equipment and cleaning-in-place systems (CIP), food preparation areas and food service and catering operations, are outcomes-based. This places a responsibility on manufacturers, food preparers and handlers to ensure that the cleaning and sanitising materials they use will be appropriate and will not make the food unsafe or unsuitable for consumption. This in turn places an obligation on suppliers of cleaners/sanitisers to food businesses to provide reassurance that their chemicals and the recommended conditions of use are safe and suitable.

¹² Virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity are known as 'specific claims'. More information can be found in the TGA's Disinfectant Claim Guide.

¹³ Ibid.

Although the legislation does not explicitly mention the use of individual cleaners/sanitiser, their use is an accepted part of hygienic food handling practices. This provides a basis for concluding that the use of these materials, and the presence of their residues in food, including minimally processed foods, is not, in principle, foreign to the nature of the food. The issue for suppliers is therefore how to demonstrate that their individual product is safe and suitable. For a new chemical, not previously used in food production, it would be necessary for the supplier to undertake a detailed risk analysis of the product to demonstrate its safety and suitability. This is a specialist task beyond the scope of this general Guide, however, in summary the assessment would need to consider both the toxicological profile of the chemical and the levels of exposure that were likely to arise from residues, determined from trials.

Fortunately, most chemicals used as cleaners and sanitiser are well established and safety data and information about accepted uses is reasonably accessible. Sources such as the Australia New Zealand Food Standards Code, DAWR export meat regulations and US and EU regulations contain positive lists of cleaning/sanitising chemicals and/or the residues resulting from their use in food manufacturing and preparation (both direct and indirect contact) which may be referenced to demonstrate safety and suitability under Australian regulations for indirect food contact. To aid suppliers in identifying and providing the necessary reassurances about individual chemicals to customers, auditors and regulators, a number of these sources are discussed below.

3.1 The Australia New Zealand Food Standards Code - Standard 1.3.3

Standard 1.3.3 – Processing aids defines the term ‘Processing aid’ as

References to substances that are used as a processing aid

- (1) In this Code, a reference to a substance that is used as a processing aid in relation to a food is a reference to a substance that is used during the course of processing:
- (a) to perform a technological purpose in the course of processing; and
 - (b) does not perform a technological purpose in the food for sale; and
 - (c) is identified in subsection (3).

Standard 1.3.3 recognises a number of materials listed in Schedules 15 (S15-5), 16 (S16-2), 18 (S18-2), used in cleaning as suitable for use in food processing in accordance with GMP. These materials include all foods, the generally permitted food additives (including solvents such as ethanol) and a list of miscellaneous chemicals such as sodium hydroxide.

In addition, Schedule 18 (S18-6) contains a list of permitted processing aids for water while S18-7 contains a list of permitted bleaching agents, washing and peeling agents, together with maximum residue levels.

3.2 Dairy Cleansers and Sanitisers

Registration of a dairy cleanser or sanitiser in Australia by APVMA or approval or recognition in New Zealand by MPI provide good evidence that a chemical active may be safe and suitable for similar applications in dairy processing facilities (including in milk collection tankers). There may also be evidence that the chemicals are safe for use in other food contact applications, however, it may still be necessary for the formulator or manufacturer to verify efficacy when cleaning other food residues or under other conditions of use.

3.3 Hospital, Household and Commercial disinfectants

Under the current TGA requirements, all disinfectants (hospital, household or commercial grade) must meet efficacy standards prescribed in TGO 104. However, only Listed hospital grade disinfectants which make specific claims undergo pre-market safety assessment. Safety of other Exempt hospital grade disinfectants, and household and commercial disinfectants must be established by the producer. Nonetheless, approval through the TGA is likely to be a pointer to the availability of evidence for the safety and suitability of a disinfectant used in a food contact application. However, it should be remembered that there is the potential for undesirable taints and adverse process impacts from disinfectants that have not been formulated for food contact use even if approved for other non-food applications.

3.4 Department of Agriculture and Water Resources (DAWR)

Up until 30 June 2011 the Export Meat Program of DAWR issued Instruments of Approval (IoA) and Letters of Acceptance (LoA) for the use of chemicals (hazardous substances) at export registered establishments. DAWR has ceased to provide IoAs and LoAs for the use of hazardous substances at export registered establishments as market access requirements ceased to apply and that there was no legal basis for continuation. DAWR has published information about hazardous substances replacing AQIS Meat Order 2011/05 which includes a list in Appendix 1 of general information regarding the use of acceptable and nonacceptable hazardous substances:

http://www.agriculture.gov.au/Style%20Library/Images/DAFF/_data/assets/pdffile/0010/2367595/information-for-chemicals.pdf .

In the absence of IoAs and LoAs, Accord developed the Vendor Declaration – Fit for Purpose (Appendix 1) to assist members to provide information required by customers to satisfy suitability of cleaners and sanitisers used in the food services industry. The Accord template is based on then DAWR model but remains current considering the information contained in its most recent publication about the hazardous substances.

In addition, DAWR maintains a [list of broad spectrum disinfectants and sanitisers for use in approved arrangements](#). The documents provide detailed information and examples of disinfectants and sanitisers, approved and recommended by DAWR for use on surfaces and equipment. This list is specifically targeted at export meat processing, and only contains chemicals in applications which are expressly permitted in the import requirements for Australia's major meat export markets (e.g. the USA). As such, the list provides a useful resource to identify cleaners and sanitisers that are also likely to also be considered suitable for a range of food contact applications by domestic food standards enforcement agencies within Australia.

HOWEVER, it is important, to recognise that the DAWR list should be viewed as an inclusive list and NOT an exclusive list for Australian domestic food manufacturing as it:

- relates specifically to meat processing and does not address any other food applications,
- is limited to chemicals/procedures known to be permitted in major meat export markets, and
- is not a comprehensive list of all cleaners/sanitisers or cleaning protocols that are suitable for food contact use within Australia.

The omission of a cleaning/sanitising protocol/residue (for example a —no rinse application) merely means that it may not be recognised or permitted in major meat export markets. It does not imply that the protocol/residue is not suitable for use within Australia either for meat or for other food applications. Many cleaners/sanitiser not on the DAWR list are accepted by domestic producers and regulatory enforcement agencies as safe and suitable for incidental food contact use within Australia. Examples of cleaning and sanitising and suitability of chemicals used in food businesses can be found in documents published by various state food authorities. Examples from the NSW Food Authority can be found at Appendix 2.

3.5 United States of America regulation

The US Food and Drug Administration (FDA) approves a number of cleaners/sanitiser permitted to be used in conjunction with food as incidental food additives:

- Chemicals that have achieved the status of Generally Recognised as Safe (GRAS) within the scientific community are generally permitted to be used in food production in Accordance with GMP. Sodium hydroxide is an example of a compound that has GRAS status in the USA.
- Individually permitted sanitiser are listed in the US Code of Federal Regulations (CFR) Title 21--Food and Drugs - Chapter I—Food and Drug Administration - [Part 178 Indirect food additives: Adjuvants, production aids, and sanitizers](#). Specific approvals relating to sanitiser may be found within part 178, e.g.:
 - 178.1005 Hydrogen peroxide solution.
 - 178.1010 Sanitizing solutions.

These regulations list both the chemicals that may be used, singly or in combination, and the maximum residue level, if any, that apply to their use in the USA.

In addition, components of cleansers, which may come into direct contact with food may be listed in 21 CFR 178 as indirect food additives, adjuvants or production aids. These regulations provide a useful resource for identifying cleaner/sanitiser protocols and residues that also are likely to be acceptable in Australia. However, it is important to be aware that the FDA process of evaluation addresses the safety of residues in food but does not consider efficacy for sanitiser.

In addition to FDA regulations, the US Environmental Protection Agency (EPA) regulates the use of antimicrobial pesticides. EPA regulation of pesticides includes sanitiser used on agricultural products. The presence of an EPA registration number on the labelling indicates that a product may safely be used as indicated by label instructions. Tolerances for antimicrobial pesticides are published in [40 CFR 180](#).

Pesticide tolerances for direct use of a sanitiser may provide adequate evidence that residue arising from its indirect use will be safe and acceptable under similar conditions in Australia.

3.6 European Union regulation

3.6.1 Cleaners and Sanitiser

At the present time the European Union does not have a fully unified system of regulation for cleaners and sanitiser in contact with food.

The Directorate General for Enterprise of the European Commission is responsible for legislation of chemicals including detergents. [Regulation \(EC\) No. 648/2004](#) came into force in 2005 and harmonized the various existing directives throughout EU Member States. It applies to manufacturers of detergents although it is not specific to food manufacturing and preparation applications.

The Regulation defines a detergent as *'any substance or mixture containing soaps and/or other surfactants intended for washing and cleaning processes. Detergents may be in any form (liquid, powder, paste, bar, cake, moulded piece, shape, etc.) and marketed for or used in household, or institutional or industrial purposes.'*

The regulation also covers:

- Biodegradability of surfactants
- Restrictions on phosphates, and
- How to label detergent products.

As a result of the review on the use of phosphates that was planned under the original document, the Detergents Regulation was amended by Regulation [\(EU\) No 259/2012](#) as regards the use of phosphates and other phosphorus compounds in consumer laundry detergents and consumer automatic dishwasher detergents.

3.6.2 Biocides

A biocidal product is one which controls harmful or unwanted organisms through chemical or biological means. Common examples of such products are disinfectants, wood preservatives and insect repellents. Biocides are used by workers in a wide variety of industries to control organisms such as viruses, bacteria, fungi, insects and animals.

[EU Regulation No 528/2012](#) requires that Biocidal products should neither be made available on the market nor used unless authorised in accordance with this Regulation. Treated articles should not be placed on the market unless all active substances contained in the biocidal products with which they were treated or which they incorporate are approved in accordance with this Regulation. Only biocidal products which contain an active substance listed on Annex I of the Directive will be authorised for use. Existing and new active substances have to be evaluated to ascertain whether or not they can be included in the Annex I.

The [European Commission Regulation 2032/2003](#) initiated a 10-year process for review of biocidal products in the European market. The most current amendment is [EU 2019/227](#).

[Directive 98/8/EC](#) prescribes data requirements for evaluation of the efficacy of active substances in and formulations of biocides.

There is still a limited amount of data at the Community level, although the Scientific Committee for Veterinary Measures relating to Public Health of the EU produced a number of useful texts including the [Opinion on the Cleaning and Disinfection of Knives used in the Meat and Poultry Industry](#) (2001). This opinion includes discussion on the use of alcohol, chlorine and chlorine compounds, hydrogen peroxide and quaternary ammonium compounds and provides a number of potentially useful references on the use and effectiveness of cleaners and sanitisers.

3.7 Canada

The main federal agencies are the Canadian Centre for Occupational Health and Safety (CCOHS), Environment Canada and Health Canada, the latter two regulating chemical substances or ingredients in chemical cleaning products under the Canadian Environment Protection Act (Cepa). Health Canada distinguishes between cleaners, disinfectants, food contact sanitizers, and sterilants. As the intended use and toxicological risks are different, disinfectants used on non-food contact surfaces (e.g., environmental surfaces, medical devices) are regulated differently than those used on food contact surfaces. Food contact sanitizers are regulated by the Bureau of Chemical Safety, Food Directorate, and Health Canada; aspects of toxicity and safety are evaluated (e.g., residue levels). In collaboration with the Canadian Food Inspection Agency (CFIA), a No Objection Letter is issued for the product if, for example, the residue levels are evaluated as acceptable. Although not all food contact sanitizers have disinfectant claims, those that do must have a Drug Identification Number (DIN) in order for the product to be authorized for sale in Canada. A unique DIN for the product is issued by Health Canada, once the product has been evaluated and meets the requirements outlined in the [Health Canada document Guidance Document: Disinfectant Drugs](#).

Evidence of registration of a product or the active components within a formulation in Canada may provide support for its use in similar conditions or for similar soils in Australia.

4. Examples for Commonly Used Chemicals

Chemical	Reference	Details
Sodium hydroxide	ANZ Food Standards Code Standard 1.3.3 – Processing Aids Schedule 18-2	Listed as a generally permitted processing aid. Maximum limits based on use in accordance with GMP
	ANZ Food Standards Code Schedule 3 – Identity and Purity	JECFA
	DAWR	Extensively listed
	US FDA	GRAS
Sodium hypochlorite	ANZ Food Standards Code Standard 1.3.3 – Processing Aids Schedule 18 (S18-7)	Listed as a generally permitted processing aid. MPL 1.0 mg/kg (available chlorine)
	ANZ Food Standards Code Schedule 3 – Identity and Purity	JECFA
	DAWR	Extensively listed
	US FDA 21CFR178.1010 Sanitising Solutions	Aqueous sodium hypochlorite recognised as permitted sanitiser
Quaternary ammonium compounds	DAWR	Various quaternary ammonium products recognised
	US FDA 21CFR178.1010	

Chemical	Reference	Details
	Sanitising Solutions EU	Various Quaternary Ammonium compounds widely used and accepted in food business across EU

5. Glossary

Term	Definition
Agvet	Agricultural and Veterinary (chemical)
APVMA	Australian Pesticides and Veterinary Medicines Authority
DAWR	Department of Agriculture and Water Resources
EPA	US Environmental Protection Agency
EU	The European Union
FDA	United States Food & Drug Administration. Responsible for approval of incidental food additives
FSANZ	Food Standards Australia New Zealand – a statutory authority responsible for developing the food standards that make up the Food Standards Code
GMP	Good Manufacturing Practice
GRAS	Generally recognized as safe
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
TGA	Therapeutic Goods Administration

6. Resources

Resource Name
Australia New Zealand Food Standards Code – A Guide to the food safety standards (third Edition November 2016) - Appendix 6: Cleaning and sanitizing surfaces and utensils.
GFSI: Chemicals in Food Hygiene - Volume 2 Cleaning agents, sanitizers and disinfectants in food businesses: detection of traces and human risk assessment processes.
Department of Agriculture and Water Resources – Information about chemicals and/or chemical compounds (hazardous substances) to be used at export registered establishments: http://www.agriculture.gov.au/Style%20Library/Images/DAFF/_data/assets/pdf/0010/2367595/information-for-chemicals.pdf
Department of Agriculture and Water Resources – Guidelines Approved Arrangements – Meat January 2019: http://www.agriculture.gov.au/SiteCollectionDocuments/export/approved-arrangements-guidelines-meat.pdf
South Australia Health Cleaning and sanitising in food businesses: https://www.sahealth.sa.gov.au/wps/wcm/connect/public+content/sa+health+internet/protecting+public+health/food+standards/skills+and+knowledge+for+food+handlers/cleaning+and+sanitising+in+food+businesses
Victoria City of Melbourne How to Run a Health Business: https://www.melbourne.vic.gov.au/SiteCollectionDocuments/sanitising.pdf
Department of Health Victoria FoodSmart Cleaning and sanitising: http://foodsmart.vic.gov.au/FoodSmartWeb/files/Support%20program%20%20-%20Cleaning%20and%20sanitising.pdf
Government of Western Australia Department of Health Cleaning and sanitising food premises and food equipment: https://ww2.health.wa.gov.au/Articles/A_E/Cleaning-and-sanitising-food-premises-and-food-equipment
Queensland Health Cleaning and sanitising: https://www.health.qld.gov.au/_data/assets/word_doc/0027/440919/cleaning-and-sanitising.doc
NSW Food Authority Cleaning and Santising in Retail Food Businesses: http://www.foodauthority.nsw.gov.au/Documents/industry/cleaning_sanitising_food_businesses.pdf

Appendix 1 – Vendor Declaration – Fit for Purpose

Vendor Declaration for a chemical substance for use in Export Registered Meat and Food Production Establishments

To Whom This Concerns

I declare that [insert name of product] is suitable for use as a [identify product use e.g. hard surface cleaner; direct contact with food] in the food industry. I have provided the following documentation to support this claim:

- a) a signed declaration that the product is fit for purpose by a qualified chemist;
- b) a copy of the label including instructions for use;
- c) the Safety Data Sheet (SDS) as required; and
- d) Accord's Quality Commitment Certificate.

This declaration is based on the same criteria as is now required by Bio Security Australia (formerly AQIS) in their requirements for the uses of chemical substances in export registered meat and meat product establishments as published by the Department of Agriculture and Water Resources *Information about Hazardous Substances, Version 2 - February 2017*.

[Insert company name] is a proud member of Accord Australasia the peak national industry association representing the manufacturers and marketers of formulated hygiene, personal care and specialty products, their raw material suppliers, and service providers. Our company's participation in Accord's Quality Commitment assures our customers and the community delivery in four key quality areas of OHS, environmental values, compliance and continuous improvement and business ethics in commercial practice.

We adhere to Accord's Guide on Cleaners and Sanitisers that may have Incidental Contact with Food which is available from the Accord website at: <https://accord.asn.au/sustainability/codes-guidelines/guideline-cleaners-sanitisers-may-incident-contact-food/>

Yours sincerely

[Name]

[Title]

[Insert date]

Declaration of 'Fit for Purpose'

Company name:
Product Name:
Name of compound:
Category of use:

- (1) [Insert intended area of use for product e.g. The chemical compound is to be used as a general sanitising compound with detergent properties for use in all areas] in accordance with direction of use.
- (2) If used in accordance with the directions of use on its label, [insert Product Name]:
- a) does not have a deleterious effect on food or food products;
 - b) does not deleteriously affect the health or wellbeing of people involved in, or associated with its use; and
 - c) is environmentally responsible.
- (3) The formulation of the chemical compound complies with:
- a) any relevant standard set out in the Australia New Zealand Food Standards Code of the Food Standard Australia New Zealand (FSANZ);
 - b) the requirements for the use of chemicals in export registered meat and meat product establishments as published by the Department of Agriculture and Water Resources *Information about Hazardous Substances, Version 2 - February 2017*; and
 - c) any other relevant standard, for example 40CFR40, (a), (b) and (c).
- (4) [Insert company name] declares that [insert name] is suitable for use in export registered meat and food production establishments for the purposes stated in this Statement. [Insert company name] has supplied a copy of the label (including directions of use) and SDS with this declaration and acknowledges that this declaration is rendered invalid by:
- a) Any change in the formation of the above-mentioned chemical substance.
 - b) Any change in instructions for use in the above-mentioned chemical substance.
 - c) Any incorrect and/or unintended use of the above-mentioned chemical substance.
 - d) Exceeding five (5) years from date of issue.

Name _____

Qualification _____

Signature _____

Date of issue _____

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