

***ACCORD Guideline on  
Cleaners and Sanitisers that may have  
Incidental Contact with Food***

May 2010



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## ***Foreword to the ACCORD guideline***

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 outcome-based food legislation 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 may be manufactured or prepared.

The purpose of this guideline 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.

The guideline also addresses the relationship between the AQIS list of cleaners and sanitisers approved for use at registered export production plants and domestic food regulations. The AQIS list is a useful list of some of the chemicals that are likely to also be suitable for similar applications within Australia but it is not an exclusive list of all suitable cleaners/sanitisers or cleaning protocols.

This guideline was originally produced by ASPCA in September 2004, with the cooperation of Food Standards Australia New Zealand (FSANZ) and the NSW Food Authority. The updated ACCORD guideline was substantially reviewed to address regulatory changes in Australia and overseas since the original release.

A handwritten signature in black ink, appearing to read "Bronwyn Capanna".

Bronwyn Capanna  
**Executive Director**

30 May 2010

***Important Notice:***

*This Guideline 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 of relevant legislation may be required and specialist regulatory or legal advice may need to be sought to address specific circumstances.*

## **1. Introduction and Scope**

Australian food legislation establishes outcome based measures for the production of foods which set minimum requirements for the processing and handling of food, as well as set standards for the final (finished) product. As a result, there is no system of positive regulation of cleaners and sanitisers that may be used in food manufacturing or preparation 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 guideline has been prepared to assist the manufacturers and distributors of cleaning and sanitising products to source data to demonstrate that their products are suitable for food use and be able to provide assurances to the 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, but 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.

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

Special mention is made of the AQIS list of cleaners and sanitisers approved in Australia’s major meat export markets. This document provides a useful list of chemicals that are likely to also be considered suitable for a range of domestic food contact applications within Australia. It is important to point out, however, that the AQIS list is not a comprehensive list of all cleaners/sanitisers or cleaning protocols that are suitable for food contact use within Australia. Many cleaners/sanitisers accepted by domestic producers and regulatory enforcement agencies as safe and suitable for incidental food contact use within Australia are not on the AQIS list.

This guideline 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). Information on current registration requirements is available at <http://www.apvma.gov.au>

## **2. Australian Food Legislation**

In Australia, the Food Standards Australia New Zealand (FSANZ) develops food standards relating to the manufacture and sale of food which are then implemented and enforced by the individual States and Territories (and New Zealand) in which the activity takes place. The responsibilities of the Commonwealth Government with respect to food are largely restricted to import/export controls, through the Australian Quarantine Inspection Service (AQIS) and the management of coordinated food standards development through Australia FSANZ. Under this system, each jurisdiction has its own individual food law (Figure 1) although throughout the 1980s and 90s significant steps were taken to harmonise these based on a uniform model food act. As a result, the provisions relevant to materials such as cleaners and sanitisers having incidental contact with food are effectively harmonised across all jurisdictions.

In addition to the food acts, each jurisdiction implements food standards relating to labelling, composition and preparation and handling of food,. 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 adopted. These standards, which are developed by FSANZ through a consultative process, are published in the Food Standards Code.

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.

**Figure 1: Australian and New Zealand Food Acts** (as at October 2009)

Food Act 1981 (New Zealand)  
Food Act 2008 (Western Australia)  
Food Act 2001 (Australian Capital Territory)  
Food Act 2006 (Queensland)  
Food Act 2003 (New South Wales)  
Food Act 2003 (Tasmania)  
Food Act 2005 (Northern Territory)  
Food Act 1984 (Victoria)  
Food Act 2001 (South Australia)  
Imported Food Control Act 1992 (Commonwealth)

Links to Australian and New Zealand Food legislation can be found at: [www.foodstandards.gov.au/links/foodlaw.cfm](http://www.foodstandards.gov.au/links/foodlaw.cfm)

## 2.1 The Scope of Food Legislation

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 2).

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.

**Figure 2: "Sell" in relation to the supply of food includes:\***

- (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.

\* *Model Food Bill 2000 – Model Food Provision – Annexe A*

## 2.2 Safe and Suitable Food

The food acts all contain provisions that define unsafe and unsuitable food (Figure 3). 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.

**Figure 3 - Definitions of unsafe and unsuitable\***

### **8 Meaning of "unsafe" food**

- (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:
  - (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.
- (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.
- (3) In subsection (1), processes include processes involving storage and preparation.

### **9 Meaning of "unsuitable" food**

- (1) For the purposes of this Act, food is unsuitable if it is food that:
  - (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.
- (2) However, food is not unsuitable for the purposes of this Act merely because:
  - (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.
- (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.

\* NSW Food Act 2003

Due to the 'outcome-based' nature of the state 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 matter 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 would not generally be considered to be foreign to the matter of the food.

## 2.3 The Food Standard Code

The State and Territory food acts require that where a relevant food standard exists then food must comply with it. The Food Standards Code<sup>1</sup> 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.

Standard 1.3.3 Processing Aids

Standard 1.3.4 Identity and Purity

Standard 1.4.2 Maximum Residue Limits

Standard 1.4.3 Articles and Materials in Contact with Food

Standard 1.6.1 Microbiological Limits for Food

Standard 3.2.2 Food Safety Practices and General Requirements

### 2.3.1 Standard 1.3.3. Processing Aids

Processing aids are substances intentionally added to food to fulfil a technological purpose relating to treatment or processing, but not performing a technological function in the final food. Standard 1.3.3 includes a number of cleaners, eg sodium hydroxide, as a generally permitted processing aid. While not directly applicable to cleaners and sanitisers for incidental food contact use, the Standard contains a list (Clause 12) of permitted bleaching agents, washing and peeling agents that may be used directly on food, together with permitted maximum residue limits in food (Figure 4). Many of these chemicals also have applications as cleaners and sanitisers in food manufacturing and preparation.

**Figure 4: Standard 1.3.3 processing aids\* – Clause 12 permitted bleaching agents, washing and peeling agents**

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
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

(\*to amendment 70)

<sup>1</sup> Complete Food Standards Code on-line at [www.foodstandards.gov.au/thecode/](http://www.foodstandards.gov.au/thecode/)

### 2.3.2 Standard 1.3.4 Identity and Purity (identifying chemicals that are suitable for incidental food contact use)

This Standard lists the reference sources of monographs to be used to identify suitable/food grade additives and processing aids<sup>2</sup>. 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;
- (b) 1 mg/kg\* of arsenic;
- (c) 40 mg/kg\* in total of heavy metals other than lead.

\* 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 residues of that chemical is acceptable for food preparation.

### 2.3.3 Standard 1.4.2 Maximum Residue Limits (chemicals that may also be registered for Agricultural or Veterinary use)

Standard 1.4.2 establishes maximum residue limits for agricultural and veterinary chemicals. A recent amendment to the Standard (14 May 2004) includes the provision that if an agricultural or veterinary chemical is not listed in the Standard, there must be no detectable residue of that chemical and no detectable residue of any metabolites of that chemical in food (whether or not that the particular food is listed). Whilst not applicable to the majority of cleaners/sanitiser, this Standard 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.

### 2.3.4 Standard 1.4.3 Articles and Materials in Contact with Food

This Standard provides permission for unspecified articles and materials to be in contact with food. Although primarily aimed at equipment surfaces, packaging materials and package inserts, the Standard also applies to residues of cleaners/sanitiser that may be on surfaces on which food is manufactured, prepared or served. The Standard requires that if cleaner/sanitiser residues remain on a food surface and thereby come into contact with food that, when the food is eaten, they will not be likely cause bodily harm, distress or discomfort (Figure 5).

This Standard 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 or injury to the consumer.

#### Figure 5 - Standard 1.4.3 Articles and Materials in Contact with Food

2 Permission for articles and materials

Articles and materials may be placed in contact with food, provided such articles or materials, if taken into the mouth, are not

- (a) capable of being swallowed or of obstructing any alimentary or respiratory passage; and
- (b) otherwise likely to cause bodily harm, distress or discomfort.

*Editorial note: This Code does not specify details of materials to be added to or used to produce food packaging materials or articles in contact with food. It is the responsibility of food manufacturers and retailers to ensure that their products are safe and that they comply with all relevant legislation.*

<sup>2</sup>JECFA Specification on-line at [www.fao.org/ag/agn/jecfa-additives/search.html?lang=en](http://www.fao.org/ag/agn/jecfa-additives/search.html?lang=en)

### 2.3.5 Standard 3.2.2 Food Safety Practices and General Requirements

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 6).

#### Figure 6 - 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:

- (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, to a standard of cleanliness where there is no accumulation of:

- (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 –

- (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 –

- (a) is clean; and
- (b) has had applied to it heat or chemicals, heat and chemicals, or other processes, so that the number of micro-organisms on the surface or utensil has been reduced to a level that:
  - (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.

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.

### 2.3.6 Standards and related documents addressing efficacy of sanitiser

Standard 1.6.1 Microbiological Limits For Food does not directly address the use of sanitiser on food production surfaces, however, the Standard does list maximum permissible levels of foodborne micro-organisms that pose a risk to human health in nominated foods, or classes of foods. The Standard 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 therefore provides guidance to manufacturers of sanitiser regarding the expected levels of hygiene to be achieved on food contact surfaces in food manufacturing and retail.

Standards in Part 4 of the Food Standards 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 regulatory jurisdiction. The Standards in this section include:

- 4.2.1 Seafood primary production and processing
- 4.2.2 Poultry Meat primary production and processing
- 4.2.3 Meat primary production and processing
- 4.2.4 Dairy primary production and processing
- 4.2.4A Specialty cheeses primary production and processing

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.

The FSANZ User guide to Standard 1.6.1 – Microbiological Limits for Food with additional guideline criteria contains information supplementary to Standard 1.6.1. Although not a part of the Guide itself, it is intended to help retailers, caterers, manufacturers and food officers interpret and apply the Standard. In addition, to the microbiological limits prescribed in Standard 1.6.1, this guideline also contains criteria for microbial contamination of certain foods where the justification for a standard was not established on public health grounds but it was considered that the identified limits complemented other risk-management strategies. The guideline may provide useful information to manufacturers of cleaners and sanitizers intended for incidental food contact use regarding the accepted standards of efficacy for a range of foods.

## ***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). 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 same chemicals used beyond the farm gate, for example in milk collection tankers or in dairy processing facilities, are not required to be registered but are regulated under food legislation as discussed above. Where a product is registered with the APVMA as a dairy cleanser or sanitiser, it is likely that the same or similar formulations will be acceptable for other food contact applications provided that the recommended conditions of use and cleaning/sanitising residues do not differ substantially from those recognised in the APVMA registration.

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 Food Safety Authority (NZFSA). Where a product is approved or recognised as a dairy maintenance compound by the NZFSA, it is likely that the same or similar formulations will be acceptable for

other food contact applications provided that the recommended conditions of use and cleaning/sanitising residues do not differ substantially from those recognised by NZFSA.

NZFFSA maintains a list of approved or recognised Dairy Maintenance Compounds (<http://www.nzfsa.govt.nz/dairy/registers-lists/approved-maintenance-compounds/dairy-maintenance-compounds-intro.htm>).

### 2.4.3 Household and Commercial Disinfectants – Australia

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) operates a chemical notification and assessment scheme. The Therapeutic Goods Administration (TGA) operates a product registration scheme. Disinfectants are considered to be therapeutic goods. Under the TGA scheme, all therapeutic goods, unless exempt, must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied. Supply occurs under one of three categories: 'registered', 'listed', or 'exempt' goods. The degree of regulation depends on the therapeutic goods category.

- hospital, household and commercial grade disinfectants (with 'specific claims') are categorised as registered therapeutic devices. These must comply with Therapeutic Goods Order (TGO) 54 (available at [www.tga.gov.au/docs/html/tgo/tgo54.htm](http://www.tga.gov.au/docs/html/tgo/tgo54.htm)),
- hospital grade disinfectants (without 'specific claims') are regulated as listed therapeutic devices. These must also comply with TGO 54,
- household and commercial grade disinfectants (without 'specific claims'), as well as sanitisers, sanitary fluids and antibacterial surface wipes, are exempt from entry on the ARTG. However, they must comply with TGO 54.

Registered disinfectants undergo a pre-market evaluation for quality safety and effectiveness against micro-organisms prior to ARTG entry. Listed devices are not subject to a formal pre-market evaluation.

Regulatory reform was been proposed whereby regulation of hard surface disinfectants and sanitisers for use in low risk applications, such as household and commercial use will be transferred from the TGA to NICNAS. 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 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.

## 3. *Identifying Safe and Suitable Cleaners and Sanitisers (defining GMP)*

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 outcome 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.

Although the legislation does not explicitly mention the use of individual cleaners/sanitisers, their use is an accepted part of hygienic food handling. 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 guideline, 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, the majority of chemicals used as cleaners and sanitiser are well established and safety data and information about accepted uses is reasonably accessible. Sources such as the Food Standards Code, AQIS 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 Food Standards Code Standard 1.3.3**

Standard 1.3.3 recognises a number of materials used in cleaning as suitable for use in food processing in general 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 Clause 11 of the Standard contains a list of permitted processing aids used in packaged water and water used as an ingredient while Clause 12 contains a list of permitted bleaching agents, washing and peeling agents, together with maximum residue levels. Standard 1.3.3 refers to substances intentionally added to food during processing, however, it is reasonable to infer from the Standard that any substance recognised as safe and suitable for direct addition is also safe and suitable where incidental contact with food may occur through cleaning or sanitisation, provided the maximum residue levels, if specified, were not exceeded.

### **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 NZFSA 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 procedures for approval of disinfectants by TGA, all disinfectants (Hospital, household or commercial) must meet efficacy standards prescribed in the Therapeutic Goods Orders TGO 54. However, only (registered) hospital grade disinfectants which make specific claims undergo pre-market safety assessment. Safety of other (listed) hospital grade disinfectants, and household and commercial disinfectants must be established by the producer. Nonetheless, approval through 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.

Once the proposed new regulatory arrangements are implemented listing of active ingredients in domestic and commercial grade disinfectants, sanitisers and the like by NICNAS will involve safety assessment and may indicate the potential for safe food use but will not provide any indication of efficacy for food applications, which will remain the responsibility of the formulator or manufacturer.

### 3.4 Australian Quarantine and Inspection Service (AQIS)

AQIS maintains a list of chemicals approved for use at establishments registered to prepare goods prescribed for the purpose of the Export Control Act 1982<sup>3</sup>. 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 AQIS 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/sanitisers not on the AQIS list are accepted by domestic producers and regulatory enforcement agencies as safe and suitable for incidental food contact use within Australia.

### 3.5 United States regulation

The US Food and Drug Administration (FDA) approves a number of cleaners/sanitisers 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 sanitisers 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<sup>4</sup>. Specific approvals relating to sanitisers may be found within part 178, e.g.:

178.1005 Hydrogen peroxide solution.

178.1010 Sanitizing solutions (Attachment 1).

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 sanitisers.

In addition to FDA regulations, the US Environmental Protection Agency (EPA) regulates the use of “antimicrobial pesticides”<sup>5</sup>. EPA regulation of pesticides includes sanitisers 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

<sup>3</sup> AQIS list of approved chemicals on-line at [http://www.daff.gov.au/\\_\\_data/assets/pdf\\_file/0007/129661/new-chem-list.pdf](http://www.daff.gov.au/__data/assets/pdf_file/0007/129661/new-chem-list.pdf)

<sup>4</sup> US Code of Federal Regulations 21 Food & Drug part 178 on-line at [http://www.access.gpo.gov/nara/cfr/waisidx\\_04/21cfr178\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr178_04.html)

<sup>5</sup> US EPA regulation of anti-microbial pesticides <http://www.epa.gov/oppad001/index.htm>

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.

The EPA has commenced a process of re-registration which involves determining the "eligibility" of the active ingredients for all pesticides originally registered before November 1, 1984. These pesticides must be supported with a complete scientific analysis and show that they can be used without causing unreasonable adverse effects to be re-registered. This may potentially impact upon the status of existing food grade sanitisers.

### **3.6 European Union regulation**

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

The Directorate General for Enterprise of the European Commission is responsible for legislation of chemicals including detergents. The EU has recently adopted a regulation on detergents (Regulation (EC) No 648/2004 of the European Parliament and of the Council of 31 March 2004 on detergents) although this not specific to food manufacturing and preparation applications.

Biocide regulation is centralised in the European Union through Directive 98/8/EC concerning the placing of biocidal products on the market. Directive 98/8/EC requires the authorisation of a wide range of biocide products currently not requiring authorisation (including disinfectants, preservatives and a number of other specialist products) as well as non-agricultural pesticides. (i.e., wood preservatives, public hygiene insecticides, rodenticides, surface biocides and antifouling paints). 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.

In addition, European Commission Regulation 2032/2003 initiated a 10 year process for review of biocidal products in the European market. Directive 98/8/EC prescribes data requirements for evaluation of the efficacy of actives 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:

- Opinion on the Cleaning and Disinfection of Knives used in the Meat and Poultry Industry (Attachment 2). 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.

In addition individual regulations and practices in individual EU member states can provide useful resource material on selection of food- grade chemicals and cleaning/sanitising protocols for use in Australia.

### **3.7 Canada**

Health Canada registers hard surface disinfectants, disinfectant-sanitizers, and food contact sanitisers, imported into or sold in Canada to be registered. Substances other than those intentionally added to foods (e.g. food additives, agricultural chemicals, and food packaging materials) which are used in food processing plants and which potentially may become adventitious residues in foods are regulated as incidental additives. These include sanitisers, disinfectants, cleaning agents for food equipment and food handling areas, detergents (dish and laundry). 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

<i>Chemical</i>	<i>Reference</i>	<i>Details</i>
Sodium Hydroxide	Food Standards Code Standard 1.3.3 Processing Aids	Listed as a generally permitted processing aid. Maximum limits based on use in accordance with GMP
	Food Standards Code Standard 1.3.4 Identity and Purity	JECFA specification <sup>6</sup>
	AQIS guideline	Extensively listed
	US FDA	Generally Recognised as Safe (GRAS)
Sodium Hypochlorite	Food Standards Code Standard 1.3.3 Processing Aids	Listed in Table to Clause 12 as a permitted bleaching agent, washing/peeling agent for “All foods”. Maximum residue limit 1mg/Kg as available chlorine
	Food Standards Code Standard 1.3.4 Identity and Purity	No JECFAC Specification. Ensure general contamination limits for “Food Grade”
	AQIS guideline	Extensively listed
	US FDA 21 CFR Ch. I (4 1 04 Edition) 178.1010 Sanitizing solutions.	Aqueous sodium hypochlorite recognised as permitted sanitiser.
Quaternary Ammonium Compounds	AQIS guideline	Various Quaternary Ammonium products recognised
	US FDA 21 CFR Ch. I (4 1 04 Edition) 178.1010 Sanitizing solutions.	Various Quaternary Ammonium compounds and maximum residue levels recognised
	EU	Various Quaternary Ammonium compounds widely used and accepted in food business across EU

<sup>6</sup> JECFA Specification for sodium hydroxide [http://apps3.fao.org/jecfa/additive\\_specs/docs/0/additive-0400.htm](http://apps3.fao.org/jecfa/additive_specs/docs/0/additive-0400.htm)

## 5. *Glossary*

<b>AQIS</b>	Australian Quarantine Inspection Service <a href="http://www.aqis.gov.au">www.aqis.gov.au</a>
<b>EPA</b>	US Environmental Protection Agency. Approves microbial pesticides, including sanitizers for use in agriculture. <a href="http://www.epa.gov">www.epa.gov</a>
<b>EU</b>	The European Union <a href="http://www.europa.eu.int">www.europa.eu.int</a>
<b>FDA</b>	United States Food & Drug Administration. Responsible for approval of incidental food additives <a href="http://www.fda.gov">www.fda.gov</a>
<b>FSANZ</b>	Food Standards Australia New Zealand – A statutory authority responsible for developing the food standards that make up the Food Standards Code <a href="http://www.foodstandards.gov.au">www.foodstandards.gov.au</a>
<b>GMP</b>	Good Manufacturing Practice

**Appendix 1**  
**United States Code of Federal Regulations**

Title 21--Food and Drugs

Chapter 1 – Food and Drug Administration, Department of Health and Human Services

Part 178 – Indirect Food Additives: Adjuvants, Production Aids and Sanitisers

Source: [www.access.gpo.gov/nara/cfr/waisidx\\_04/21cfr178\\_04.html](http://www.access.gpo.gov/nara/cfr/waisidx_04/21cfr178_04.html)

**Appendix 2**  
**European Commission**  
**Health & Consumer Protection Directorate-General**

Opinion of the Scientific Committee on Veterinary Measures relating to Public Health

The Cleaning and Disinfection of Knives in the Meat and Poultry Industry

(adopted on 20-21 June 2001)

Source: [http://ec.europa.eu/food/fs/sc/scv/out43\\_en.pdf](http://ec.europa.eu/food/fs/sc/scv/out43_en.pdf)