A new regulatory framework for disinfectants

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Contents

Glossary ii
Acknowledgements iv
Terms of Reference v
Summary vii
Recommendation 1 vii
Recommendation 2 viii
Recommendation 3 ix
Recommendation 4 ix
Recommendation 5 ix
Introduction & Scope 1
Scope 3
Current regulatory arrangements 4
NICNAS 6
TGA 7
APVMA 8
FSANZ 8
Overseas regulations 9
USA 9
Canada 10
EU 10
New Zealand 11
Overview of overseas regulatory frameworks 15
Classifying disinfectants 16
Claims 16
“Hospital Grade” as a claim 16
Efficacy assurance for products carrying hospital grade claims 16
Maintaining and enhancing the protection of public health and safety 17
A risk based approach 17
Defining High Risk 20
Efficacy Standards 22
Public health evaluation of new chemical entities/substances 23
Good Manufacturing Practice(GMP) 24
Proposed modified regulation of disinfectants and sanitisers 24
Recommendation 1 24
Recommendation 2 25
Proposed Regulatory Options 26
Preferred regulatory option 30
Recommendation 3 30
Recommendation 4 30
Recommendation 5 31

Glossary

AICS	The Australian Inventory of Chemical Substances
ARTG	The Australian Register of Therapeutic Goods. A computer database of therapeutic goods maintained by TGA.
APVMA	The Australian Pesticides & Veterinary Medicines Authority
Class IIB Device	A medium-high risk medical device. Includes sterilants and instrument grade disinfectants
Disinfectant	A substance: that is recommended by its manufacturer for application to an inanimate object to kill a range of micro-organisms; and is not represented by the manufacturer to be suitable for internal use.
FSANZ	Food Standards Australia New Zealand
Listable	Refers to therapeutic goods required to be included in the part of the Register for listed goods (Therapeutic Goods Regulations 1990, Schedule 4).
HACCP	Hazard Analysis and Critical Control Points - a systematic preventative approach commonly applied to food safety that addresses physical, chemical and biological hazards as a means of prevention rather than finished product inspection.
Hospital grade disinfectant	a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces: (a) in premises used for: (i) the investigation or treatment of a disease, ailment or injury; or (ii) procedures that are carried out involving the penetration of the human skin; or, (b) in connection with: (i) the business of beauty therapy or hairdressing; or (ii) the practice of podiatry; but does not include : (a) instrument grade disinfectants (since 2002 dealt with as part of medical devices legislation); or (b) sterilant (since 2002 dealt with as part of medical devices legislation); or (c) an antibacterial clothes preparation; or (d) a sanitary fluid; or (e) a sanitary powder; or (f) a sanitiser; *(ref TGO 54)*

Household/commercial grade disinfectant	a disinfectant that is suitable for general purpose disinfection of building or fitting surfaces, but is not: (a) an antibacterial clothes preparation; or (b) a sanitary fluid; or (c) a sanitary powder; or (d) a sanitiser; *(ref TGO 54)*
NICNAS	National Industrial Chemicals Notification and Assessment Scheme
non-specific claim	a claim which includes general antibacterial action or activity against bacteria (excluding mycobacteria) covered by the battery of test organisms included in the specified test, or bacteria of the same genus.
Registrable	Refers to therapeutic goods required to be included in the part of the Register for registered goods (Therapeutic Goods Regulations 1990, Schedule 3).
Sanitiser	Sanitiser means a chemical agent that is represented to be suitable for use in the reduction of pathogenic or food-spoilage micro-organisms to a sanitary level on surfaces with which food for human consumption may come in contact. *(ref TGO 54)*
Specific Claim	a claim which covers virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity. (note: except where claims of activity against fungi (yeasts and moulds) for excluded products are concerned).
TGA	The Therapeutic Goods Administration
TGO 54	Therapeutic Goods Order 54 – Standard for Disinfectants and Sterilants (TGO 54a & TGO 54b – Amendments to the Standard for Disinfectants and Sterilants)

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Terms of Reference

1. **Review the current Australian regulatory framework for disinfectant products** including but not limited to:

a) the regulatory demarcation between hospital grade disinfectants and household/commercial grade disinfectants under the *Therapeutic Goods Act 1989* and the *Therapeutic Goods Regulations 1990*;
b) the regulatory demarcation between disinfectants regulated as therapeutic goods (under the *Therapeutic Goods Act 1989*) and those regulated as industrial food sanitisers under federal and/or state and territory legislation (for example dairy cleansers for on-farm use under the *Agricultural and Veterinary Chemicals Code Act 1994* and food safety regulations pursuant to relevant state/territory legislation);
c) identifying any unintended consequences including duplications, ambiguities and 'grey-areas' in the current regulation of disinfectants,

and having regard to the *'Guiding Principles for reform of disinfectants' (appendix 1)*.

2. **Review the regulation of disinfectants in comparable regulatory schemes overseas**, namely the European Union, Canada, United States of America and New Zealand in order to assist in identifying a best practice model(s).

3. **Consult with appropriate representatives from the stakeholders listed below** about the existing regulatory framework for disinfectants in Australia, including any deficiencies with the framework and any proposed recommendations for regulatory reform:

a) NICNAS;
b) Therapeutics Goods Administration (TGA) – Office of Devices, Blood and Tissues;
c) TGA – Laboratories Branch;
d) Australian Pesticides and Veterinary Medicines Authority;
e) Food Standards Australia New Zealand;
f) Relevant State/Territory food safety authorities and public health authorities;
g) NSW, Victoria and Queensland representatives of the National Coordinating Committee on Therapeutic Goods (NCCTG);
h) Relevant industry associations, namely ACCORD Australasia, Medical Industry Association of Australia, Australian Dental Industry Association, Medicines Australia, Australian Self Medication Industry Association and Ausbiotech.

Where possible, the Liaison Officer will provide details of the appropriate representative with whom the Consultant must consult from a particular stakeholder and in all other cases the Consultant must seek to identify the appropriate representative from a stakeholder with whom to consult.

4. **Prepare and submit a draft report** which includes, but is not limited to, the following matters:

(a) Review of the current Australian regulatory arrangements (as described in paragraph 1 above);

(b) Review of comparable regulatory schemes overseas (as described in paragraph 2 above);
(c) Stakeholder views and comments (pursuant to the stakeholder meetings referred to in paragraph 3 above); and
(d) Make recommendations for an alternative regulatory framework for disinfectants in Australia which:

i. includes a clear demarcation between products that should continue to be regulated as therapeutic goods and those that should be regulated as industrial chemicals;
ii. includes clear and enforceable criteria for distinguishing between hospital grade and household/commercial grade disinfectants;
iii. includes a review of current definitions of "hospital grade disinfectant" and "household/commercial grade disinfectants" as set out in the *Therapeutic Goods Act 1989*;
iv. identifies any additional guidelines and/or industry Codes of Practice required to implement the proposed new arrangements;
v. ensures that the proposed alternative regulatory framework is commensurate with the public protection needs for these products; and
vi. identifies any unintended consequences and possible inconsistencies in the regulatory interface between disinfectants and industrial food sanitisers.

The draft report must include an executive summary which contains the recommendations.

5. **Consult with the Liaison Officer** in relation to the draft report and make any amendments to the report as may be agreed with the Liaison Officer and as soon as the amendments have been finalised, submit the completed version as a final report.

Summary

The Department of Health and Ageing, through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Therapeutic Goods Administration (TGA), is undertaking a review of the current regulatory framework for disinfectant products.

The current report examines the regulatory framework in Australia for :

- hospital grade disinfectants;
- household/commercial grade disinfectants;
- antibacterial cleaning wipes; and
- sanitisers, cleaners and deodorisers,

but does not address products defined as sterilants or instrument grade disinfectants.

Currently, therapeutic devices, including disinfectants, must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied.

At present:

- hospital, household and commercial grade disinfectants (with specific claims in relation to sterilants, fungicides, sporicides, tuberculocides or virucides) are categorised as registrable therapeutic devices, and must comply with Therapeutic Good Order (TGO) 54, 54a and 54b;
- hospital grade disinfectants (without specific claims) are regulated as listable therapeutic devices, and must comply with TGO 54, 54a and 54b; and
- household and commercial disinfectants (without specific claims), antibacterial cleaning wipes, sanitisers, cleaners and deodorisers are exempt from entry on the ARTG but must comply with TGO 54, 54a and 54b

There is widespread support amongst State government and health sector supplier stakeholders for the maintenance of premarket evaluation, including demonstration of efficacy, for hard surface disinfectants intended to be used in hospitals and other clinical establishments.

For other disinfectants and sanitisers, intended to be used in low risk applications (e.g. commercial and household use), stakeholders generally agreed that a more appropriate regulatory approach is listing of the active chemical on the Australian Inventory of Chemical Substances (AICS), maintained by NICNAS.

It is consistent with the COAG guidelines on regulatory reform that the level of regulatory burden be consistent with the risk posed by the substance being regulated. A proposed means of achieving this objective whilst also meeting the opinions expressed by stakeholders is to divide disinfectants into two groups based upon the public health risks presented by the circumstances of use.

Recommendation 1

It is recommended that consideration should be given to reviewing the definition of 'hospital grade" to more clearly indicate that it relates to hospitals and other clinical applications and to remove references to commercial premises (such as beauty therapy,

hairdressing and podiatry practises), for example:

> ***hospital grade disinfectant*** *means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces in premises used for:*
>
> > *(i) the investigation or treatment of a disease, ailment or injury; or*
> >
> > *(ii) procedures that are carried out involving the penetration of the human skin;*
>
> *but does not include :*
>
> *(a) instrument grade disinfectants; or*
>
> *(b) sterilant; or*
>
> *(c) an antibacterial clothes preparation; or*
>
> *(d) a sanitary fluid; or*
>
> *(e) a sanitary powder; or*
>
> *(f) a sanitiser;*

Recommendation 2

It is further recommended that disinfectants be divided based upon the public health risks presented by the manufacturer's intended use for the disinfectant.

- Disinfectants manufactured for use where the public health risk is high, such as in a clinical setting, will be regulated by the TGA. Products will be required to be included in the ARTG, and required to comply with the relevant standards (currently TGOs 54, 54a and 54b), ensuring regulatory oversight of the quality, safety and efficacy of the disinfectants on a product by product basis (note: It is anticipated that TGOs 54, 54a and 54b will be replaced by a new Australian New Zealand Therapeutic Products Authority (ANZTPA) "Managing Director's Order').

  Licensing of manufacturers for Good Manufacturing Practice (GMP) would not be required for these products

- Sanitisers and disinfectants manufactured for use where the public health risk is medium – low, such as for commercial or household use, will be regulated through NICNAS and the individual component chemicals listed in the Australian Inventory of Chemical Substances (AICS) (Appendix 4).

The NICNAS system includes provision for specific conditions to be included in the listing of a chemical. This would enable, for example, a chemical also present in a disinfectant listed in the ARTG to be included in the AICS specifically for use in disinfectants without further public health assessment by NICNAS. Furthermore, by including a reference to the efficacy standards for disinfectants included in TGO54 manufacturers would have a responsibility to ensure that their products met appropriate standards.

Recommendation 3

It is recommended that recommendation 2 be implemented if the following manner:

- All disinfectant products labelled “hospital grade”, whether carrying specific biocidal claims or not, will be classified as therapeutic devices and be required to be listed on the ARTG, and
- All commercial and household disinfectants, except products labelled as “hospital grade”, whether carrying specific biocidal claims or not, antibacterial cleaning wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS

This option provides for appropriate levels of regulation for both disinfectants manufactured for use in potentially high risk applications in health & other clinical facilities as well as for those manufactured for use in low risk applications in commercial and household locations. The option potentially maintains an high level of regulation for a small number of “hospital grade” products primarily intended to be marketed for commercial/household. However, manufacturers, presumably make the claim in expectation of a commercial benefit. The preferred option will continue provide consumers with the same level of efficacy assurance as that applied to other “hospital grade” products.

Recommendation 4

NICNAS legislations potentially allows the use of assessments undertaken by other national or international regulatory authorities in the NICNAS risk assessment. However, further consideration should be given to procedures to avoid unjustified regulatory burden being placed on manufacturers and to avoid duplication of assessment by TGA and APVMA by allowing agencies to have regard to each others evaluations and decisions where appropriate.

Recommendation 5

Attention should be given to reviewing the regulatory arrangements for products registered with APVMA for use on farm (eg dairy sanitisers) and similar or identical products used in commercial establishments (including in food processing) and not requiring registration, that are formulated using chemical substances proposed to be regulated by NICNAS.

Introduction & Scope

The Department of Health and Ageing, through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Therapeutic Goods Administration (TGA), is undertaking a review of the current regulatory framework for disinfectant products not captured under the October 2002 regulatory framework for medical devices. The background to this review is as follows:

- In 1998, a review of the regulatory controls of disinfectants and sterilants by the National Coordinating Committee on Therapeutic Goods (NCCTG) led to a number of recommendations including the following:
    - that the TGA continue to regulate sterilants and instrument grade disinfectants as registrable devices; and
    - that hospital grade disinfectants (with specific claims) and household/commercial grade disinfectants (with specific claims) be regulated as listable devices. Hospital Grade disinfectants (with non-specific claims) would continue to be regulated as listable devices.

In November 1999 NCCTG further recommended that:

- Disinfectants which are exempt from the requirements of Section 3 of the *Therapeutic Goods Act 1989*, ie exempt from inclusion on the Australian Register of Therapeutic Goods (ARTG), should be the subject of appropriate safety assessment of their active ingredients via TGA liaison with the National Industrial Chemicals & Notification Assessment Scheme (NICNAS) to establish appropriate safety assessment for such ingredients; and
- NCCTG supports the principle that all goods included in the ARTG be subject to Good Manufacturing Practice Assessment including listed disinfectants.

- In October 2002 the TGA introduced the new system for the regulation of medical devices. Sterilants and instrument grade disinfectants were now regulated as Class IIb medical devices (medium to high risk) as they meet the definition of an accessory to a medical device.
- Hospital, household and commercial grade disinfectants do not fit the new definition of a medical device. Therefore, the TGA is continuing to regulate these products as listable or registrable devices.
- In July 2005 the TGA undertook extensive stakeholder consultation on a number of proposed amendments to the regulatory requirements for hospital, household and commercial disinfectants, including amendments that would align the regulatory requirements with the NCCTG recommendations above.

In response to the July 2005 consultation:

a. NICNAS provided in-principle support to the proposal, noting that further consultation was required to determine the demarcation between products regulated as therapeutics and those regulated as industrial chemicals.

b. ACCORD indicated that regulating hospital, household and commercial

disinfectants as Australia only requirements under the new joint agency disadvantaged Australian industry.

c. ACCORD suggested that the following products should all be treated as excluded goods and thus the chemicals in these products are subject to NICNAS requirements:

i. Hospital grade disinfectants without specific claims;

ii. Household/commercial grade disinfectants without specific claims (including those with new chemical entities);

iii. Sanitisers;

iv. Sanitary fluid; and

v. Antibacterial clothes preparations.

- The current review is in response to comments on the July 2005 stakeholder consultation (in particular those from NICNAS and ACCORD), and
- Recommendation 4.61 of the Report of the Taskforce on Reducing Regulatory Burden on Business, Rethinking Regulation (January 2006) - "*Recommendation 4.61 - The Australian Government should progress industry reforms for regulating disinfectant products and report progress to COAG*."

Disinfectant products are substances that are applied to an inanimate object or surface to kill a range of micro-organisms. Disinfectants and related products are defined in Therapeutic Goods Order (TGO) 54 (Appendix 2).

disinfectant means a substance:

(a) that is recommended by its manufacturer for application to an inanimate object to kill micro organisms; and

(b) that is not represented by the manufacturer to be suitable for internal use.

hospital grade disinfectant means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces:

(a) in premises used for:

(i) the investigation or treatment of a disease, ailment or injury; or

(ii) procedures that are carried out involving the penetration of the human skin; or,

(b) in connection with:

(i) the business of beauty therapy or hairdressing; or

(ii) the practice of podiatry;

but does not include :

(a) instrument grade disinfectants; or

(b) sterilant; or

(c) an antibacterial clothes preparation; or

(d) a sanitary fluid; or

(e) a sanitary powder; or

(f) a sanitiser;

(TGO 54)

household/commercial grade disinfectant means a disinfectant that is suitable for general purpose disinfection of building or fitting surfaces, but is not:
(a) an antibacterial clothes preparation; or
(b) a sanitary fluid; or
(c) a sanitary powder; or
(d) a sanitiser;
(TGO 54)

instrument grade disinfectant means:
(a)a high level disinfectant; or
(b)a sterilant;
that is used to reprocess medical devices.

sterilant means a chemical agent which is used to sterilise medical devices. A sterilant kills micro-organisms with the result that the sterility assurance level of a microbial survivor is 10^{-6}.

As distinct from a disinfectant, a **sanitiser** is defined in TGO 54 as a chemical agent that is represented to be suitable for use in the reduction of pathogenic or food-spoilage micro-organisms to a sanitary level on surfaces with which food for human consumption may come in contact.

Scope

The current report reviews current regulatory practices and overseas regulatory practices for disinfectants and recommends an alternate regulatory framework for disinfectants in Australia. The review also identifies unintended consequences in other sectors such as the dairy industry and food preparation. This report is intended to facilitate discussion on the development of a new regulatory framework for disinfectants and assist in avoiding unintended impacts on the regulation of disinfectants by other sectors (food and agriculture).

The current report is limited to the regulatory framework in Australia for disinfectant products, being products currently defined as:

- hospital grade disinfectants;
- household/commercial grade disinfectants;
- antibacterial cleaning wipes; and
- sanitisers, cleaners and deodorisers,

It does not address products defined as sterilants or instrument grade disinfectants which are regulated as accessories to medical devices under the regulatory scheme for medical devices implemented in October 2002 under the *Therapeutic Goods Act 1989.* Similar products registered for use for similar purposes in veterinary medicine are also outside the scope of this review.

Current regulatory arrangements

There are four national chemical regulation schemes which cover food, industrial chemicals, pharmaceuticals and agriculture all of which have a role in the regulation of disinfectants (table 1). Provided that the component industrial chemicals are included in AICS, chemical products intended for consumer use and generally available through retail sale to the public do not require product registration unless they fall within the jurisdiction of TGA or APVMA.

Table 1

	Agency	Scope	Relevant Legislation
Therapeutic Products	Therapeutic Goods Administration(TGA)	Assessment & Product Registration	Therapeutic Goods Act 1989
Agricultural and Veterinary Chemicals	Australian Pesticides & Veterinary Medicines Authority (APVMA)	Assessment, Product Registration, Quality Assurance & Compliance	Agricultural and Veterinary Chemicals (Administration) Act 1992 [No. 262 of 1992] Agricultural and Veterinary Chemicals Act 1994 [No. 36 of 1994] Agricultural and Veterinary Chemicals Code Act 1994 [No. 47 of 1994 Agricultural and Veterinary Chemical Products (Collection of Levy) Act 1994 [No. 41 of 1994]
Food chemicals	Food Standards Australia New Zealand(FSANZ)	Assessment and development of standards for chemicals used in food. Performance based criteria for materials used in contact this food or in food preparation premises	State & Territory Food Acts Food Standards Australia New Zealand Act 1991 Australia New Zealand Food Standards Code
Industrial chemicals	National Industrial Chemicals Notification & Assessment Scheme (NICNAS)	Assessment only, not product registration	Industrial Chemicals (Notification & Assessment) Act 1989.

The current regulatory schemes applying to disinfectants, cleaners and sanitisers depend both on the intended use and the claims (table 2)

Table 2 – Current Regulatory schemes applying to disinfectants and related chemicals in Australia

Disinfectant category	**Criteria**	**Agency**	**Details**
hospital grade disinfectants	When claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides	TGA	Evaluation & Registration on ARTG Compliance with TGO 54, 54A & 54b. Manufacturer GMP licence not required.
	if no specific claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides	TGA	Listing on ARTG Compliance with TGO 54, 54A & 54b. Manufacturer GMP licence not required.
household/ commercial grade disinfectants;	When claimed to be sterilants, fungicides, sporicides, tuberculocides or virucides	TGA	Evaluation & Registration on ARTG Compliance with TGO 54, 54A & 54b. Manufacturer GMP licence not required.
	if no specific claim is made that the goods are sterilants, fungicides, sporicides, tuberculocides or virucides.	TGA	Exempt from ARTG entry Compliance TGO 54, 54A & 54B
Sanitisers		TGA	Exempt from ARTG entry Compliance TGO 54, 54A & 54B
Sanitary Fluids		TGA	Exempt from ARTG entry Compliance TGO 54, 54A & 54B
Antibacterial cloths/wipes		TGA	Exempt from ARTG entry Compliance TGO 54, 54A & 54B
Dairy cleansers		APVMA	Evaluation & Registration Compliance with APVMA labelling code
Swimming pool disinfectants and algaecide		APVMA	Evaluation & Registration
Food grade sanitisers and cleaners	Materials used in direct contact with food (e.g. bleaching agents, washing and peeling agents, water treatment agents)	FSANZ	Evaluation and listing of individual chemicals in Standard 1.3.3 – Processing Aids. No individual product registration.
	Materials used in food preparation areas &	FSANZ	Compliance with existing standards and criteria regarding

Disinfectant category	Criteria	Agency	Details
	possibly having incidental contact with food		safety and suitability of the food produced. No evaluation or approval of products
Other relevant chemicals not classified as described above		NICNAS	Notification & safety evaluation of chemicals (individual chemicals and ingredients in products)

NICNAS

NICNAS is a chemical entity based notification and risk assessment scheme and operates in accordance with the *Industrial Chemicals (Notification and Assessment) Act 1989*. NICNAS is the national component of Australia's industrial chemical regulation, the control of use, supply and disposal are all governed by the State and Territory Governments. Under the NICNAS scheme all industrial chemicals require assessment if not on the Australian Inventory of Chemical Substances (AICS) or unless subject to exemptions. NICNAS operates in a complementary role with respect to the other regulatory bodies.

Assessment of a chemical by NICNAS comprises evaluation of:

- Hazard and exposure
- Public health risk,
- Environmental risk, and
- Occupational health and safety risk,

but does not include an evaluation of efficacy

An industrial chemical is defined in the *Industrial Chemicals (Notification and Assessment) Act 1989* as a chemical that has an industrial use, whether or not it also has an excluded use. Excluded use, in relation to a chemical, means:

(a) use as an agricultural chemical or a constituent of an agricultural chemical; or

(b) use as a veterinary chemical or a constituent of a veterinary chemical; or

(c) therapeutic use or use as an ingredient or component in the preparation or manufacture of goods for therapeutic use; or

(d) use as food intended for consumption by humans or animals or a constituent of such food; or

(e) use as a food additive in food.

The Australian Inventory of Chemical Substances (AICS) is a regulatory tool that lists the chemicals that are available for use in Australia. Some chemicals may only be available for specified/conditional use.

The AICS is maintained by NICNAS and contains over 38,000 chemicals and lists chemical identity data; it does not contain information on toxicity, manufacturers or importers. Any chemical not included in AICS or any listed chemical whose importation

and/or manufacture is subject to a condition of use, is regarded as a new industrial chemical unless it is outside the scope of the Act. New industrial chemicals must be notified and assessed before being manufactured or imported into Australia unless they qualify for an exemption. Licensing of manufacturers for GMP compliance is not required for industrial chemicals.

TGA

In contrast to NICNAS, the TGA, operates a product registration scheme. Under the *Therapeutic Goods Act 1989,* therapeutic devices, including disinfectants, unless exempt, must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied.

The ARTG is a computer database of therapeutic goods maintained by TGA. Therapeutic goods are divided broadly into three classes – medicines, medical devices and other therapeutic goods (which includes tampons and hospital, household commercial grade disinfectants). Unless exempt, therapeutic goods must be entered as either 'registered' or 'listed' goods or ‘included’ medical devices before they may be supplied in, or exported from Australia.

At present:

- hospital, household and commercial grade disinfectants (with specific claims in relation to sterilants, fungicides, sporicides, tuberculocides or virucides) are categorised as registrable therapeutic devices, and must comply with Therapeutic Good Order (TGO) 54, 54a and 54b;
- hospital grade disinfectants (without specific claims) are regulated as listable therapeutic devices, and must comply with TGO 54, 54a and 54b; and
- 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 but must comply with TGO 54, 54a and 54b and are required to comply with the labelling requirements, relevant standards and the advertising provisions of the *Therapeutic Goods Act 1989.*

Registered devices undergo a full evaluation for quality, safety and efficacy prior to entry in the ARTG. It is noteworthy here that an environmental assessment is not undertaken for therapeutic goods. Furthermore, listable devices are not subject to a formal pre-market evaluation although information is required that reasonably demonstrates the safety and quality of the goods for the intended use is required to be held by the product sponsor. Other, “lower grade” disinfectant products, such as household/commercial grade disinfectants, for which no claims are made, as well as sanitisers, sanitary fluids and antibacterial clothes preparation are exempt from entry on the ARTG but are still required to comply with the labelling requirements, relevant standards and the advertising provisions of the *Therapeutic Goods Act 1989.*

Currently, under the TGA Act, listable or registrable disinfectants that contain a new chemical entity (as defined in TGO 54) undergo a toxicological evaluation by the TGA as part of the pre-market assessment. In the case of disinfectants excluded from TGA regulation, the toxicological evaluation of new chemical entities is undertaken by NICNAS.

There is a regulatory anomaly for household and commercial grade disinfectants (without specific claims), as well as sanitisers, sanitary fluids and antibacterial surface wipes, that are exempt from entry on the ARTG in that there are no provisions under the TGA Act to undertake a toxicological evaluation for new chemical entities.

The Therapeutic Goods Orders, TGO 54, 54A and 54B - Standard for Disinfectants and Sterilants and Guidelines for the Evaluation of Sterilants and Disinfectants (the Guidelines) specify the standards for performance of disinfectants and sterilants as well as the standards for packaging and labelling. TGO54 applies to disinfectants, sterilants, sanitisers and sanitary preparations, including exempt products other than products represented as suitable for antifungal use only or for the treatment of water only;

APVMA

The APVMA operates product registration for dairy cleansers intended for on farm use and also for swimming pool disinfectants and algaecides (which are deemed to be agricultural chemicals in the APVMA legislation) in accordance with *The Agricultural and Veterinary Chemicals Code Regulations 1995*. Hard surface disinfectants applied to the interiors of animal housing and sheds, for the purpose of disease control, are also required to be registered by the APVMA.

There is the potential for products with similar or even identical formulations to be presented as hospital grade disinfectants, commercial /household grade disinfectants, dairy cleansers, swimming pool disinfectants and veterinary disinfectants. In this event both TGA and APVMA would potentially be involved in the regulation of these products, thereby raising the potential for duplication of regulatory effort.

FSANZ

Food Standards Australia New Zealand develop outcome based food standards that apply both to food products and food preparation and handling. Individual chemicals added directly to food during processing or preparation are subject to assessment and listing in the Australia New Zealand Food Standards Code. Once a chemical listed in an appropriate standard, approval is generic (rather than supplier specific) and subject to compliance with a prescribed specification for the chemical. There is no requirement for notification or registration of individual products or formulations by FSANZ. There is also no requirement for FSANZ to undertake assessment or registration of chemicals used in food preparation establishments that may have incidental contact with food.

State and Territory food laws require that food is safe and suitable. Food safety standards developed by FSANZ, which are enforced under these laws, recognise the use of chemicals on food surfaces and utensils as one of the accepted ways of reducing microbial numbers in order to meet these requirements, provided that the food itself does not become contaminated. There is an expectation amongst State and Territory food law enforcement officials that the safety and suitability of any chemicals used for incidental food contact purposes will have been demonstrable by an appropriate risk assessment, undertaken by a competent Australian or overseas agency.

Overseas regulations

USA

Antimicrobial products, including hard surface disinfectants are registered by the US Environmental Protection Agency (EPA) as antimicrobial pesticides, under the statutory authority of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)[1]. The registration requirements for antimicrobial pesticides include tests to ensure efficacy of public health pesticides when the pests are invisible disease-causing microbes, rather than insects or rodents that may be harbouring disease organisms. These products are divided into two categories based on the type of microbial pest against which they are intended to work:

Non-public health products are used to control growth of algae, odour-causing bacteria, bacteria which cause spoilage, deterioration or fouling of materials and micro-organisms infectious only to animals.

Public health products are intended to control micro-organisms infectious to humans in any inanimate environment.

Classes of antimicrobial pesticides are also recognised, based upon efficacy:

Sterilizers (Sporicides): Used to destroy or eliminate all forms of microbial life including fungi, viruses, and all forms of bacteria and their spores. Spores are considered to be the most difficult form of micro-organism to destroy. Sterilization is critical to infection control and is widely used in hospitals on medical and surgical, instruments and equipment. Types of sterilizers include steam under pressure (autoclaving), dry heat ovens, low temperature gas (ethylene oxide), and liquid chemical sterilants. Gaseous and dry heat sterilizers are used primarily for sterilization of medical instruments. Liquid sterilants are primarily used for delicate instruments which cannot withstand high temperature and gases.

Disinfectants: Used on hard inanimate surfaces and objects to destroy or irreversibly inactivate infectious fungi and bacteria but not necessarily their spores. Disinfectant products are divided into two major types: hospital and general use. Hospital type disinfectants are the most critical to infection control and are used on medical and dental instruments, floors, walls, bed linens, toilet seats, and other surfaces. General disinfectants are the major source of products used in households, swimming pools, and water purifiers.

Sanitisers: Used to reduce, but not necessarily eliminate, micro-organisms from the inanimate environment to levels considered safe as determined by public health codes or regulations. Sanitisers include food contact and non-food contact products. Sanitizing rinses for surfaces such as dishes and cooking utensils, as well as equipment and utensils found in dairies, food-processing plants, and eating and drinking establishments comprise the food contact Sanitisers. These products are important because they are used on sites where consumable food products are placed and stored. Non-food contact surface sanitisers include carpet sanitisers, air sanitisers, laundry additives, and in-tank toilet bowl sanitisers.

Antiseptics and Germicides: Used to prevent infection and decay by inhibiting the growth of micro-organisms because these products are used in or on living humans or animals,

[1] http://www.epa.gov/oppad001/

they are considered drugs and are thus approved and regulated by the Food and Drug Administration (FDA).

Canada

Disinfectant products are regulated through "a single window" by Health Canada under the Food & Drug Act[2 3]. The system recognises two categories of disinfectant antimicrobial product which may be classified as either or both:

- **a drug** - cleaning products that make antimicrobial claims are regulated as drugs under the *Food & Drugs Act***,** and
- **a pest control product** - cleaning products that make sanitizing claims are regulated under the *Pest Control Products Act.*

A disinfectant product may be classed as either or both categories. Both drug and pest control products are regulated products and require a Drug Identification Number (DIN) or a Pest Control Product Registration Number (PCP) prior to marketing.

If a disinfectant product and its labelling comply with all the criteria already established in the regulations for existing products, the product only requires an abbreviated review, not including efficacy assessment. Where a disinfectant product is associated with an active ingredient or an indication that has not been marketed previously in Canada, then its premarket evaluation by HC will be subject to the requirements for a New Drug Submission

Antimicrobial agents for use on environmental surfaces are exempted from the requirements of the legislation for establishment licences and Good Manufacturing Practices. Health Canada has developed a voluntary standard addressing the manufacture of these products.

There is no distinction between household and hospital grade in Canada, other than that implied by the presence of antimicrobial claims on the product.

EU

In the EU, assessment and maintenance of positive lists of active substances is undertaken at a community level through Directive 98/8/EC of 16 February 1998 "*concerning the placing of biocidal products on the market*", which is administered through the Environment Directorate. Registration for marketing of biocidal products is undertaken by a competent authority in a Member State after which mutual recognition applies between Member States [4].

Biocidal products are defined as Active Substances and preparations containing one or more active substances, put up in the form in which they are supplied to the user, intended to destroy,deter, render harmless, prevent the action of, or otherwise exert a controlling effect on any harmful organism by chemical or biological means.

A category of low-risk biocidal product is also defined as a product that pose only a low risk to humans, animals and the environment. A low-risk biocidal product is further defined

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2 http://www.chemicalsubstanceschimiques.gc.ca/categor/what-quoi/index_e.html
3 http://www.hc-sc.gc.ca/dhp-mps/compli-conform/info-prod/drugs-drogues/disinfect-desinfect/index_e.html
4 http://ec.europa.eu/environment/biocides/index.htm

as on which contains as active substance(s) only one or more of those listed in a list of active substances with requirements agreed at community level for inclusion in low-risk biocidal products (Annex IA to the directive) and which does not contain any substance(s) of concern.

A substance of concern is any substance, other than the active substance, which has an inherent capacity to cause an adverse effect on humans, animals or the environment and is present or is produced in a biocidal product in sufficient concentration to create such an effect. Such a substance, unless there are other grounds for concern, would be normally a substance classified as dangerous and present in the biocidal product at a concentration leading the product to be regarded as dangerous according to EU legislation *(Council Directive 67/548/EEC of 27 June 1967 – "On the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances" and Article 3 of Council Directive 88/379/EEC of 7 June 1988 - "On the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations)"*.

An exhaustive list of product types is included in Annexes to the directive. Active ingredients must also be included in an Annex to the directive.

Biocidal products are required to be authorised by a competent authority in a Member State. Low risk biocidal products require a more simplified process of registration with a competent authority in a Member State. Mutual recognition applies between Members States in relation to a biocidal product that has been authorised or registered in another Member State.

Authorisation includes an assessment by the competent authority that the biocidal product:

(i) is sufficiently effective,

(ii) has no unacceptable effects on the target organisms, such as unacceptable resistance or cross-resistance or unnecessary suffering and pain for vertebrates,

(iii) has no unacceptable effects itself or as a result of its residues, on human or animal health, directly or indirectly (e.g. through drinking the biocidal product:

Registration is a simplified process that is required to be completed by the competent Authority within 60 days.

Active ingredients Biocides containing new active ingredients, require evaluation by a Competent Authority. Thereafter, the evaluation is circulated to other member states and, if accepted, the active substance is added to an Annex to the directive. Authorisation is product based and specific data provided for one authorisation cannot be used for another product.

New Zealand

Hazardous substances, including disinfectants, sanitisers and cleaners are regulated in New Zealand by the Environmental Risk Management Authority New Zealand (ERMA NZ)

under the Hazardous Substances and New Organisms Act 1996 (HSNO Act)[5].

ERMA NZ has established Group Standards for a wide range of chemicals, including cleaners – individual approval for products complying with the relevant Group Standard is not required. However, products are required to be certified as compliant by a registered independent (non-government) certifying organisations.

Relevant Group Standards have been developed that apply to products including:

- Industrial and Institutional Cleaning Products
- Domestic Cleaning Products
- Dental products

The group standards are further divided according to the potential hazard presented by the cleaning agent, for example: corrosive, oxidising, flammable. Institutional cleaning products include products that are equivalent to hospital grade disinfectants as defined within the Australian regulatory structure.

The Cleaning Products Group Standards have been created for any material intended for washing and cleaning processes, not including cosmetic products.

Key features of the Group Standards mechanism include:

- Hazardous substances are grouped based on substances being of a similar nature or type, or having similar circumstances of use. A Group Standard may specifically exclude substances of similar nature or type that pose a significantly greater risk.
- Generally, a Group Standard must be a more efficient and effective way of managing the risks of all the substances in the identified group than other methods of approval (for example, a Part V approval).
- Risks posed by the substances within a Group Standard must be able to be managed by one set of conditions.
- Compliance requirements may be attached to a group by way of conditions. If the conditions are complied with, no application for any other HSNO approval is necessary.
- In setting conditions for a Group Standard, consideration is given to the types of controls that might otherwise apply if there were individual approvals for each substance in the group.
- The conditions are legally enforceable and to an extent, more prescriptive and user-friendly. They stand in place of the HSNO controls regulations, unless the regulations are specifically referenced in the conditions.
- While the initial suite of Group Standards were developed by ERMA New Zealand, it is anticipated that future group standards will be developed by industry.
- A Group Standard is established by Gazette Notice following public notification and consultation, and is published in relevant industry publications.

[5] http://www.ermanz.govt.nz/hs/groupstandards/about.html

There are no mandatory efficacy standards for industrial, institutional or domestic cleaning products within the relevant group standards.

For a new hazardous substance that is manufactured or imported into New Zealand, it is the responsibility of the manufacturer or importer to identify an existing group standard for that substance (if one exists). This involves the manufacturer or importer undertaking their own hazard classification using the composition of the substance and other hazard information available with the substance such as that given on a Safety Data Sheet. Any new substance that fits within the scope of a group standard is automatically deemed a HSNO approved substance. There is no requirement for a manufacturer or importer of the substance to contact ERMA New Zealand for an approval, however, they must keep an adequate record of their determination (or of advice received) regarding the group standard applying to their substance and have that record available for inspection. If the substance contains a component that is not on the New Zealand inventory of chemicals, the manufacturer or importer must notify the Authority.

For companies who would prefer not to self-classify or who wish to get some confirmation of their self-classification, ERMA New Zealand offers a product classification service.

If a new hazardous substance is determined as not fitting within the scope of any existing group standard, then the manufacturer or importer must make an application to ERMA New Zealand for an approval to import or manufacture that substance.

Table 3 – Comparison of Australian and overseas regulatory approaches

Country	Product categorisation	Regulatory process	Responsible Agency	GMP standard required? Y/N
USA	Categorised as antimicrobial pesticides. Subcategories: • public health products • non-public health products	Registration as anti-microbial pesticides Anti microbial efficacy testing is required for products intended to control disease causing micro-organisms .	US EPA	N
Canada	• products carrying antimicrobial claims - drugs • other products, sanitisers - pest control products	“Single window” approach. A disinfectant product may be classed as either or both drug & pest control product. Product allocated appropriate registration number(s).	Health Canada	N
EU	• biocidal product • low-risk biocidal product	Assessment and maintenance of positive lists of active substances undertaken at community level. Assessment	Environment Directorate & Member States	N

		and registration of products is by a competent authority in a Member State. Mutual recognition applies to registration. Simplified assessment process for low risk products		
NZ	• cleaning products industrial and institutional cleaning products	ERMA NZ establishes Group Standards for wide range of chemicals, including cleaners – individual approval for products complying with the relevant Group Standard not required. Industry expected to self-assess, with 3rd party verification if necessary commercially.	ERMA NZ & Industry self assessment	N
Australia (current)	• Products with specific claims • Hospital Grade without specific claims • Commercial /Household use without specific claims	All products under jurisdiction of TGA: disinfectants with specific microbial claims are registrable therapeutic devices, • • hospital grade disinfectants without specific claims are listable devices; and • household and commercial disinfectants without specific claims, antibacterial cleaning wipes, sanitisers, cleaners and deodorisers are exempt from registration or lisiting but must comply with Therapeutic Goods Orders.	TGA	N
Australia (proposed)	• *Hospital Grade* • *Commercial /Household use*	• *Hospital Grade disinfectant product, classified as therapeutic devices and required to be listed on ARTG.* • *Commercial and household disinfectants antibacterial cleaning wipes, sanitisers, cleaners and deodorisers – chemical components regulated by NICNAS.* •	*TGA NICNAS*	*N*

Overview of overseas regulatory frameworks

The regulatory systems discussed above each have positive and contrary aspects from

the perspective of regulatory best practice. It is not possible, therefore, to identify any one model as being best "best practice" for application in the Australian context. It is, however, possible to identify appropriate features from each system, including:

USA – The recognition of a two tier system based on public health and the implementation of efficacy testing for public health products may be relevant for Australia. However, due to different jurisdictional responsibilities, regulation through a single agency may be impractical in the Australian federal context.

Canada – The establishment of a "single window" or one-stop-shop for products assessed by different agencies and the two tier model for may be considered good practice applicable to the Australian context. However, in the Canadian model the point of demarcation for regulation is the claims associated with the product, rather than the circumstances of use.

EU – the administrative arrangements in the EU do not appear directly relevant to Australia, however, the differentiation of products based on risk and the implementation of a less onerous regulatory path for low-risk products would be consistent with COAG principles and guidelines.

NZ – The implementation of an essentially self-regulatory model and the devolution of responsibility for compliance to manufacturers may also be consistent with COAG regulatory policy. However, depending on the manner of implementation, self-regulation does not necessarily lower the burden to market for industry, especially if, as a consequence, third party review is considered necessary. The absence of verification, especially of efficacy, for products used in hospitals and other clinical institutions, may also be a cause for concern in the Australian context.

Classifying disinfectants

Claims

“Hospital Grade” as a claim

Under current regulatory arrangements, Therapeutic Goods Order 54 defines hospital grade disinfectants and, by exclusion, household/commercial grade disinfectants on the basis of the product's suitability for use in therapeutic situations. In this context, the designation “hospital grade” on a product label may be considered to be a performance based claim about the product, rather than a differentiation due to product composition. Indeed the same composition may be found in a hospital grade and a household grade product. Furthermore, Hospital grade products are widely available to commercial and home users. The ARTG contains a number of both registered and listed hospital grade disinfectants that appear to be formulated (e.g. containing perfumes) and presented expressly for the household market rather than for clinical applications. It is reasonable, therefore, to conclude that commercial/household customers may choose to buy products claiming to be hospital grade disinfectants for general purpose cleaning, with an expectation of improved performance, when compared to virtually identical products on which no such claims are made. On this basis, “hospital grade” may be considered to be a claim that is not related solely to the place or circumstances of use but to the users’ expectation of performance..

Efficacy assurance for products carrying hospital grade claims

In addition to product definitions, TGO 54 (Appendix 2) also contains efficacy tests for both hospital grade and commercial/household grade disinfectants. The battery of tests required is more stringent for hospital grade disinfectant than for commercial/household grade. From this, it may also be concluded that a higher standard of efficacy is required from disinfectants labelled “hospital grade” than for similar household/commercial grade products, reflecting a higher minimum compositional requirement and a greater expectation of public health protection

The description of a product as a disinfectant, as opposed to a sanitiser, may also be considered to provide assurance that the product has a minimum general level of antibacterial action or activity against vegetative bacteria, as defined in TGO 54, that is intended to affect the decision of the purchaser. Conversely, the designation of a product as a sanitiser implies a potentially lower level of efficacy.

Disinfectants may also carry “specific claims” in relation to virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity. The use of a specific claim in association with a product effectively raises the consumer expectations with regard to the efficacy of the product and also the potential risks associated with product failure.

The term hospital grade may, therefore, be considered to convey both a commercial claim to home and business users but also a degree of public health assurance for clinical users.

Maintaining and enhancing the protection of public health and safety

A risk based approach

In the process of reviewing the regulatory arrangements for disinfectants and related products in Australia, it is consistent with the 1997 Council of Australian Government (COAG) principles and guidelines to address the balance between the regulatory burden proposed and the level of risk posed by regulatory failure. In consultations with stakeholders there was a general support for the introduction of a risk based regulatory system for disinfectants. In the case of disinfectants and sanitisers, the risks relate to:

a. public health risks associated with failure to control micro-organisms associated with infectious diseases in humans, or animals

b. commercial/ production failure due to lack of efficacy in food production

c. direct toxicity to humans (and animals)

d. direct toxicity to the environment

The public health risks associated with product failure for disinfectants and sanitisers will depend both on place of use and the specific circumstances of use, if any (Table 4) and the consequences of failure. The risks have been classified as:

- High to catastrophic – product failure is likely to lead to serious injury, deaths, possible epidemic.
- Medium to low – product failure alone (without concurrent failure of risk management systems such as HACCP) may lead to discomfort but is not likely to result in serious injury, death or epidemic.

Table 4 - Risks associated with failure of disinfectants and related products

Place of use	Specific purpose	Consequence of product failure	Public Health Risk
Hospitals/ clinical contexts	control of specific communicable disease	disease outbreak, possible human deaths/ epidemic	high - catastrophic
Hospitals/medical centres public areas	general communicable disease control	possible exposure of admin staff/ visitors to communicable diseases	high
Beauty therapy or hairdressing	general communicable disease control	Low level disease transfer, not life threatening	medium - low
Veterinary practices - animal care areas	control of specific communicable disease	disease outbreak, possible animal and human deaths/ epidemic	high - catastrophic

Place of use	Specific purpose	Consequence of product failure	Public Health Risk
Commercial premises Food manufacturing, commercial preparation	hygiene, control of food borne pathogens	food product failure (commercial risks), possible food borne disease outbreak only if product failure also coincides with HACCP failure.	medium
Commercial premises On Farm Dairies	general hygiene	Supply of contaminated product to bulk dairy - high commercial risk. Possible food borne disease outbreak also requires a secondary failure of HACCP during subsequent product processing.	medium – low
Commercial premises non-commercial food preparation areas – e.g. staff kitchens	hygiene in food preparation areas	Low level food borne illness amongst staff	medium - low
Commercial premises	general cleaning	dirty premises, toilets etc.	low
Home/ Domestic kitchens	hygiene in food preparation areas	low level food borne illness	medium-low
Home/ Domestic	general cleaning	dirty bathrooms, toilets etc.	low

For chemicals used to control the spread of specific pathogens in patient care areas of a hospital or a veterinary practice the risks associated with product failure may be considered to be potentially very high or even catastrophic, involving disease outbreaks and possible human or animal fatalities. Similarly, the use of general purpose disinfectants in public areas of hospitals, where organisms responsible for communicable diseases may be present, addresses a high risk, particularity for the elderly, very young and immuno-compromised visitors. In contrast, risks associated with failure of a disinfectant, whether labelled hospital grade or otherwise, in beauty therapy or hairdressing premises, in other

commercial activities or in the home is likely to be medium to low, whether the product carries specific claims or not. Effectively, two categories of chemical product may be defined based upon their circumstances of use, as follows:

1. Clinical settings including veterinary clinical settings (high to catastrophic risk)
2. Non clinical settings including homes and various commercial settings (medium to low risk)

In consultations, a number of stakeholders from State governments and medical/dental related industries suggested that the inclusion of specific claims on a household cleaning product may be misleading and may even increase, rather than reduce the risk to the consumer by encouraging the selective growth of pathogens in the home or workplace.

In the case of food manufacturing, there is a potentially high risk to the community from the consumption of food produced in unhygienic conditions. The approach taken by FSANZ to manage this risk has been to establish risk based performance criteria for industry. Industry is required, through legislation to produce safe and suitable food. Food businesses involved in activities considered to be high risk are required to develop HACCP based food safety plans in which the potential for product failure due to breakdown in hygiene is managed throughout the entire production. The only category of food sanitisers subject to specific regulatory oversight are those used on farm (e.g. dairy cleansers) that are required to be registered with the APVMA. This difference appears to relate to the historical regulatory demarcation between food and dairy regulatory agencies in the States and Territories rather than to any inherent difference in public health risk between the use of identical products on farm and in food processing establishments.

The Food Standards Code also contains maximum levels for human pathogens in applicable foods. However, the exact means by which these standards are achieved is left for industry to determine in most cases. In the case of high risk foods, industry is required to develop and implement self regulatory instruments in the form of HACCP plans. Efficacy of cleaning procedures is a matter that is addressed by individual food businesses, having regard to their individual processes. There was general support from food regulators for regulatory changes that would result in the inclusion in the AICS of chemicals that are currently used in exempt or excluded products (ie not listed in the ARTG by TGA) . It was considered that the inclusion of these chemicals in the AICS could provide a point of reference that would assist industry in identifying suitable chemicals for inclusion in cleaners and sanitisers.

A process of assuring the efficacy of products intended for use in medical and related establishments is reasonable on public health grounds. Currently such products are regulated by the TGA The evaluation, whether carried out by TGA or the sponsor, includes a requirement for compliance with efficacy standards. In the case of disinfectants intended to be used in veterinary medicine or for the control of animal borne disease (including zoonoses), efficacy is assessed by the APVMA. Both of these processes potentially impose a significant regulatory burden on industry for the production of data in relation to both active ingredients and products and for individual product by product registration.

In contrast, if disinfectants were regulated under NICNAS regulations, a notification to and assessment by NICNAS would only address direct human toxicity, occupational health and

safety and environmental impact of individual chemicals. Verification of efficacy would become the responsibility of manufacturers, backed up by provisions addressing false and misleading representations in relation to the quality, composition, nature and characteristics of consumer products in fair trading legislation in both State and Territory legislation and the Commonwealth Trade Practices Act[6].

Whilst verification of efficacy through TGA (or APVMA) may be warranted in the case of high risk uses, regulation by NICNAS, with industry self-verification of efficacy, may be adequate for lower risk applications. The ACCORD Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action (Appendix 3) establishes criteria for industry compliance.

Defining High Risk

A number of possible approaches to the identification of high risk applications for disinfectants were proposed in stakeholder consultations:

1. Hospital Grade provides a means of identification of products that, because they meet a standardised minimum level of efficacy are considered suitable for use in clinical/surgical and related establishments. Currently, the classification also encompasses a significant number of products that are marketed to the commercial/ household user, where the risk of failure is not high

   However, whilst it is apparent that the highest risk arising from failure of a product to achieve an adequate level of efficacy occurs when a disinfectant is used for the prevention of the transmission of disease in clinical / surgical settings. When hospital grade disinfectants are intended to be used in a commercial or a household setting, the risk of product failure arising from a lack of efficacy may be substantially lower, for example, if the organisms of concern are either present only at very low levels or unlikely to be present, or the probability of infection from the circumstances of contact is remote (eg infection with influenza virus from a dirty toilet). Imposing a high regulatory burden on these products, such as listing with TGA, may be seen as excessive, when viewed in isolation.

   One strategy to address this issue would be to revise the definition of hospital grade to more clearly reflect the intended places of use as hospitals and other clinical settings and remove references to hair dressing and beauty therapy establishments, for example:

   hospital grade disinfectant *means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces in premises used for:*

   (i) the investigation or treatment of a disease, ailment or injury; or

   (ii) procedures that are carried out involving the penetration of the human skin;

   but does not include :

   (a) instrument grade disinfectants; or

   (b) sterilant; or

[6] NICNAS inspectors can refer breaches of the Trade Practices Act to the ACCC for appropriate action.

(c) an antibacterial clothes preparation; or

(d) a sanitary fluid; or

(e) a sanitary powder; or

(f) a sanitiser;

2. Specific biocidal claims in relation to virucidal, sporicidal, tuberculocidal, fungicidal or other biocidal activity also provide a means of identifying products in which a failure to assure efficacy may carry a high public health risk. However, focussing on this claim alone may ignore "hospital grade" products used for general disinfection (eg in public areas) in medical and related establishments.

Furthermore, it is unlikely that the risks associated with failure for a majority of products with specific claims used in commercial or domestic situations would be high. Requiring such products to be listed with TGA could present an unjustifiable regulatory burden and also potentially add legitimacy to marketing claims that have low public health significance.

3. The development of a new requirement specifically targeting products intended for use in clinical/surgical establishments. This would effectively include any hospital grade product formulated in a way that was relevant to use in a medical establishment but exclude products (e.g. perfumed products and "toilet duck" type cleaners) intended to be sold exclusively to the commercial or domestic markets.

During its review of the regulation of cosmetics, NICNAS drew a similar distinction between antibacterial skin washes used in a clinical context and other antibacterial wipes:

skin washes: the relevant section of the NICNAS Cosmetic Guidelines is reproduced below:

8. Antibacterial skin products
[Interpretive note 4: This provision refers specifically to antibacterial skin products, that is, skin products that are intended to be active against bacteria. It does not apply to skin products that are intended to be active against viruses, fungi or other microbial organisms.]

- *excluding products used for:*

(a) prevention of the transmission of disease
[Interpretive note 5: Products are regarded as being for the prevention of transmission of disease where information is presented on the label or by other means (e.g. advertising, internet site, point of sale material) to indicate that:
• The product is to be used in connection with a specific disease; or
• The product is to be used in connection with piercing of the skin or mucous membrane whether for cosmetic or any other purpose; or
• The product is to be used in connection with any procedure associated with the risk of transmission of disease from contact with blood or other bodily fluids.]

(b) specifically for use in clinical/surgical settings
[Interpretive note 6: Products are regarded as being specifically for use in clinical/surgical settings where information is presented on the label or by other means (e.g. advertising, internet site, point of sale material) to indicate that the product is:
• To be used before physical contact with any person who is accessing

medical or health services, or who is undergoing any medical or health care procedure; or
• To be used in connection with any procedure involving venipuncture or delivery of an injection.

This guidance is consistent with the Infection control guidelines for the prevention of transmission of infectious diseases in the health care setting, Australian Government, Department of Health and Ageing "Medical or health services" include hospitals, general practice, day surgery centres, domiciliary nursing services, residential aged care, community services or office practices such as dentistry or podiatry.]

A similar approach might be employed for disinfectants to differentiate between:

a. disinfectants used in *medical or health services*, for which failure to establish efficacy in the context of use has high risk implications for public health, and for which listing by TGA is warranted, and

b. products intended to be used in the commercial or household environment, where failure to establish efficacy in the context of use has relatively low risk implications for public health and self evaluation of efficacy by manufacturers together with regulation of component chemicals by NICNAS is sufficient.

A disadvantage of this approach is that it effectively establishes a two tier classification for products labelled as "hospital grade", thereby increasing the potential for market confusion.

Efficacy Standards

Therapeutic Goods Order 54 establishes mandatory standards for disinfectant products including test based standards of efficacy for hospital grade and commercial/ household grade disinfectants The efficacy standard for hospital grade is higher than for commercial/ household grade. The Infection Control Guidelines for the Prevention of Transmission of Infectious Diseases in the Health Care Setting (published by the Australian Commonwealth Government, Department of Health and Ageing January 2004) established two levels of infection control for hospitals and other clinical settings:

- Standard precautions are standard operating procedures that apply to the care and treatment of all patients, regardless of their perceived infectious risk.
- Additional precautions are required when standard precautions may not be sufficient to prevent the transmission of infectious agents.

In relation to the choice of disinfectants, the Guidelines state:

7.2.2 Hospital-grade disinfectants

The use of hospital-grade disinfectants is not necessary in health care establishments. The recommended procedure is the manual removal of visible soil and dirt, followed by cleaning with water and detergent (see Section 18.1). However, hospital-grade disinfectants may be used on environmental surfaces such as walls, floors, furniture and equipment that do not come into direct contact with the patient.

7.2.3 Household/commercial-grade disinfectants

Household/commercial-grade disinfectants are also regulated by the TGA. These disinfectants have limited use, as their efficacy has not been tested under conditions likely to be encountered in health care settings.

The guidelines appear to recommend the use of hospital grade products in hospitals and other clinical establishments. Clinical establishments may be expected to choose to use a hospital grade disinfectant with specific activity claims in high risk patient care areas, where additional precautions are necessary, and a general level hospital grade disinfectant in other areas, on an as needs basis for public health reasons. Veterinary practices may do likewise. The maintenance of product based regulation of efficacy for disinfectants used in health care establishments is, generally supported by stakeholders. For hospital grade disinfectants that are listable in the ARTG, compliance with the efficacy test methods in TGO54 was also supported by government and health related industry stakeholders.

The question of efficacy testing for detergents with or without specific claims that are used in commercial premises or the home, whether or not labelled hospital grade, raised questions from stakeholders regarding consumer expectations for these products.

It is widely agreed that consumers select disinfectants carrying specific claims over a generic product anticipating a better outcome in terms of hygiene. However, a number of stakeholders questioned whether it was appropriate, for example, for a household product intended for toilet cleaning to claim to be effective against influenza virus, when the probability of a user contracting the disease from a domestic toilet is effectively zero? It was also suggested that the use of strong disinfectants in the household context may actually increase the risk to the consumer by increasing selection for resistant organisms in, for example, food preparation areas.

To address the use of claims on detergents, ACCORD Australasia has prepared a Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action (Appendix 3). This guideline requires that cleaning products making anti-bacterial claims should be tested against TGO54 or other relevant & comparable tests. However, assurance of compliance is effectively left to individual manufacturers or importers. Whilst this guideline is intended to apply to a range of cleaning products, it establishes an effective precedent for implementing appropriate efficacy standards for disinfectants used outside clinical establishments.

Public health evaluation of new chemical entities/substances

In the process of listing a disinfectant product containing a new chemical entity on the ARTG, a sponsor is required to provide toxicological data to enable TGA to undertake a safety evaluation of the chemical.

The process of assessment of a new chemical substance notified to NICNAS for listing on the AICS involves an assessment of public health, occupational health and safety and environmental risk, that also incorporates evaluation of toxicological data and exposure potential.

Registration of a disinfectant or sanitiser for agricultural or veterinary use, with APVMA also involves toxicological assessment and public health and environmental risk.

There is a significant potential for duplication of public health/ toxicology evaluation for new chemical entities used in disinfectants and sanitisers. Consideration should be given by

relevant agencies to arrangements for sharing public health/ toxicology evaluations in order to avoid duplication of regulatory effort/burden. There is capacity within the NICNAS legislation to have regard to the assessment of chemicals by other national and international regulatory agencies. This potentially allows NICNAS to accept an evaluation of a disinfectant component previously undertaken by TGA (or APVMA) and annotate the AICS listing accordingly (eg. for disinfectant use only). Where a manufacturer requires a broader use approval than that supported by ARTG listing, further more extensive public health and environmental assessment by NICNAS may be appropriate.

Where a chemical is already listed on the AICS and has been through a NICNAS assessment but is new to a product intended to be listed on the ARTG, consideration could be given by TGA to the prior NICNAS evaluation, in order to avoid duplication.

Good Manufacturing Practice(GMP)

Most manufacturers of therapeutic goods regulated by the TGA are required to be licenced for GMP compliance. Under current regulatory arrangements, manufacturers of hard surface disinfectants, whether registrable hospital grade products carrying specific claims, or listable products, are not required to be licensed for GMP compliance. The National Coordinating Committee on Therapeutic Goods, a subcommittee of the Australian Health Ministers Advisory Committee, has indicated that they support the principle that all goods included in the ARTG be subject to GMP assessment. Consideration should be given to the development of an appropriate manufacturing standard for surface disinfectants that are regulated by the TGA.

Proposed modified regulation of disinfectants and sanitisers

Recommendation 1

It is recommended that consideration should be given to reviewing the definition of 'hospital grade" to more clearly indicate that it relates to hospitals and other clinical applications and to remove references to commercial premises (such as beauty therapy, hairdressing and podiatry practises), for example:

> ***hospital grade disinfectant means a disinfectant that is suitable for general purpose disinfection of building and fitting surfaces in premises used for:***
>
> > ***(i) the investigation or treatment of a disease, ailment or injury; or***
> >
> > ***(ii) procedures that are carried out involving the penetration of the human skin;***
>
> ***but does not include :***
>
> ***(a) instrument grade disinfectants; or***
>
> ***(b) sterilant; or***
>
> ***(c) an antibacterial clothes preparation; or***
>
> ***(d) a sanitary fluid; or***

(e) a sanitary powder; or

(f) a sanitiser;

Recommendation 2

It is further recommended that disinfectants be divided based upon the public health risks presented by the manufacturer's intended use for the disinfectant.

- **Disinfectants manufactured for use where the public health risk is high, such as in a clinical setting, will be regulated by the TGA. Products will be required to be included in the ARTG, and required to comply with the relevant standards (currently TGOs 54, 54a and 54b), ensuring regulatory oversight of the quality, safety and efficacy of the disinfectants on a product by product basis (note: It is anticipated that TGOs 54, 54a and 54b will be replaced by a new ANZTPA "Managing Director's Order').**

  Licensing of manufacturers for Good Manufacturing Practice (GMP) would not be required for these products

- **Sanitisers and disinfectants manufactured for use where the public health risk is medium – low, such as for commercial or household use, will be regulated through NICNAS and the individual component chemicals listed in the Australian Inventory of Chemical Substances (AICS) (Appendix 4).**

  The NICNAS system includes provision for specific conditions to be included in the listing of a chemical. This would enable, for example, a chemical also present in a disinfectant listed in the ARTG to be included in the AICS specifically for use in disinfectants without further assessment by NICNAS. Furthermore, by including a reference to the efficacy standards for disinfectants included in TGO54 manufacturers would have a responsibility to ensure that their products met appropriate standards. This could be enforced through both:

  - provisions relating to false and misleading conduct under State and Territory fair trading legislation and the Trade Practices Act. If necessary, NICNAS inspectors have the capacity to refer potential breaches to the ACCC for appropriate enforcement action, and
  - by industry self-regulation, through compliance with the ACCORD Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action (Appendix 3).

Proposed Regulatory Options

Four possible regulatory options to meet this objective have been identified

Option 1 – Compliance with *(revised) "hospital grade" definition is the point of demarcation.*

		Advantages	Disadvantages
High risk disinfectant			
hospital grade disinfectants irrespective of label claims (according to the revised definition for hospital grade on pg 15)	TGA	Effective regulation for all disinfectants manufactured for use in potentially high risk applications in health & other clinical facilities.	High regulatory burden for a small number of "hospital grade" products primarily intended to be marketed for commercial/household use only.
Low risk disinfectant			
All disinfectants, sanitisers, sanitary fluids, sanitary wipes/cloths, excluding hospital grade disinfectants	NICNAS	Effective regulation for disinfectants manufactured for use in low risk applications in commercial and household locations.	No pre-market regulatory verification of efficacy for disinfectants with specific claims manufactured for use in low risk household/commercial applications. Control of such claims would be subject to fair trading legislation and industry self regulation through the ACCORD Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action

Option 2 – presence of '***specific claims' on product is the point of demarcation irrespective of "hospital grade" status .***

		Advantages	Disadvantages
High risk disinfectant			
Disinfectants making specific disease related claims	TGA	Effective regulation (including efficacy testing for all disinfectants with specific claims	'Hospital grade' label would become meaningless. Likely to result in a lot of confusion particularly for hospital/ clinical facilities relying on the fact that 'hospital grade' disinfectants have had their efficacy substantiated. No efficacy testing of any general purpose disinfectants. Clinical facilities will no longer be able to purchase general purpose "hospital grade" disinfectants that have had their efficacy tested/substantiated by the regulator Unjustified regulatory burden for commercial/household disinfectant product intended for low risk commercial/ household use that make specific disease related claims?

		Advantages	Disadvantages
Low risk disinfectant			
Disinfectant, sanitisers, sanitary fluids, sanitary wipes/cloths, except disinfectants carrying specific disease related claims	NICNAS	Effective regulation for general purpose disinfectants manufactured for use in low risk applications in commercial and household locations.	No regulatory verification of efficacy for disinfectants without specific claims used in high risk areas (e.g. clinical facilities)

Option 3 - *use situation, (ie clinical setting) is the point of demarcation.*

		Advantages	Disadvantages
High risk disinfectant			
Disinfectants specifically intended to be used in premises providing medical or health services [Note: "medical or health services" include hospitals, general practice, day surgery centres, domiciliary nursing services, residential aged care, community services or office practices such as dentistry or podiatry.]	TGA	Effective regulation for all disinfectants manufactured for use in health & other clinical facilities. Consistent with the approaches taken in the general identification of medical devices and at the food-drug interface,	Difficult to administer as identification of non hospital grade disinfectants manufactured for use in clinical settings relies on a degree of interpretation of package or evidence of product sold to appropriate facilities, or a revision of the definition of "hospital grade" disinfectant. Would require development of criteria for determining disinfectants intended to be used in a clinical setting. May lead to confusion about the meaning of "hospital grade"
Low risk disinfectant			

		Advantages	Disadvantages
Disinfectant, sanitisers, sanitary fluids, sanitary wipes/cloths, except disinfectants intended to be used in premises providing medical or health services	NICNAS	Effective regulation for all disinfectants used in low risk applications in commercial or household locations irrespective of whether labelled hospital grade or not.	Likely to be difficult to identify “hospital grade” disinfectants that are only intended for the household market.

Option 4 – compliance with *“hospital grade” definition and/or presence of ‘specific claims’ on label provide point of demarcation*

		Advantages	Disadvantages
High risk disinfectant			
Hospital Grade disinfectants and other disinfectants making specific disease related claims	TGA	Effective regulation for all disinfectants manufactured for use in health & other clinical facilities, as well as disinfectants making specific disease related claims	Inappropriate regulatory burden for commercial/household products with specific claims intended for use in low risk applications in commercial/household locations.
Low risk disinfectant			
Disinfectant, sanitisers, sanitary fluids, sanitary wipes/cloths, except Hospital Grade disinfectants and other Disinfectants making specific disease related claims	NICNAS	Effective regulation for disinfectants without specific claims manufactured for use in commercial and household locations	

Preferred regulatory option

The preferred regulatory option is option 1:

- "Hospital Grade" disinfectants, whether carrying specific biocidal claims or not, will be classified as therapeutic devices and be required to be listed on the ARTG
- All commercial and household disinfectants (except products labelled as "hospital grade"), whether carrying specific biocidal claims or not, antibacterial cleaning wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS

This option continues using the well recognised term of 'hospital grade' disinfectants (as revised) as an indicator of a disinfectant that is regulated by the TGA, providing a greater level of assurance of the efficacy of these products for use in potentially high risk applications in health and other clinical facilities. The regulatory oversight of the quality, safety and efficacy of the disinfectant will continue to be on a product by product basis.

It may be argued that this option maintains an inappropriately high level of regulation for a small number of "hospital grade" products primarily intended to be marketed for commercial/household. However, in this context "hospital grade" can be viewed as a voluntary commercial claim. Manufacturers, presumably make the claim in expectation of a commercial benefit, taking into account the costs of regulatory compliance. The preferred option will continue to provide consumers with the same level of efficacy assurance as that applied to other "hospital grade" products.

Recommendation 3

- **All disinfectant products labelled "hospital grade", whether carrying specific biocidal claims or not, will be classified as therapeutic devices and be required to be listed on the ARTG**
- **All commercial and household disinfectants, except products labelled as "hospital grade", whether carrying specific biocidal claims or not, antibacterial cleaning wipes; and sanitisers, cleaners and deodorisers, will be regulated by NICNAS**

Potential Duplication

There is some potential for duplication of safety assessment for chemicals listed with the TGA, registered with the APVMA and listed with NICNAS.

Recommendation 4

NICNAS legislations potentially allows the use of assessments undertaken by other national or international regulatory authorities in the NICNAS risk assessment. However, further consideration should be given to procedures to avoid unjustified regulatory burden

being placed on manufacturers and to avoid duplication of assessment by TGA and APVMA by allowing agencies to have regard to each others evaluations and decisions where appropriate.

Recommendation 5

Attention should be given to reviewing the regulatory arrangements for products registered with APVMA for use on farm (eg dairy sanitisers) and similar or identical products used in commercial establishments (including in food processing) and not requiring registration, that are formulated using chemical substances proposed to be regulated by NICNAS.

Appendix 1

Guiding principles for reform of disinfectants

The Department of Health and Ageing, through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) and the Therapeutic Goods Administration (TGA), is undertaking a review of the current regulatory framework for disinfectant products not captured under the 2002 regulatory framework for medical devices.

The review was commenced in response to an NCCTG recommendation based on stakeholder views received in response to TGA consultation, undertaking in July 2005, in relation to a review of the regulatory requirements of Disinfectants and recommendation 4.61 of the Report of the Taskforce on Reducing Regulatory Burden on Business, Rethinking Regulation (January 2006) that states "*The Australian Government should progress industry reforms for regulating disinfectant products and report progress to COAG*".

The outcomes of this project may include recommendations for reform of the regulation of disinfectant products. Where this is the case, the following principles will apply.

a) The primary consideration will be to maintain and enhance the protection of public health, safety and environmental standards, consistent with the objectives of the *Therapeutic Goods Act 1989* and the *Industrial Chemicals (Notification and Assessment) Act 1989*.

b) Regulatory reform will be undertaken in accordance with 1997 Council of Australian Government (COAG) principles and guidelines.

c) Recognising that cost-recovery is Australian Government policy for therapeutic goods and chemicals all costs associated with reform activities will be cost-recovered from industry.

d) Government and industry acknowledge the need for a national approach to ecologically sustainable chemicals management and regulation.

e) There will be no automatic listing ("grand-fathering") of unassessed chemicals onto the Australian Inventory of Chemical Substances (AICS) or the Australian Register of Therapeutic Goods (ARTG).

f) The TGA and NICNAS will seek the views of their respective consultative committees on the outcomes of the review and recommendations for regulatory reform.

Appendix 2

TGO54

TGO 54 can be located on the TGA web-site at:
http://www.tga.gov.au/docs/html/tgo/tgo54.htm

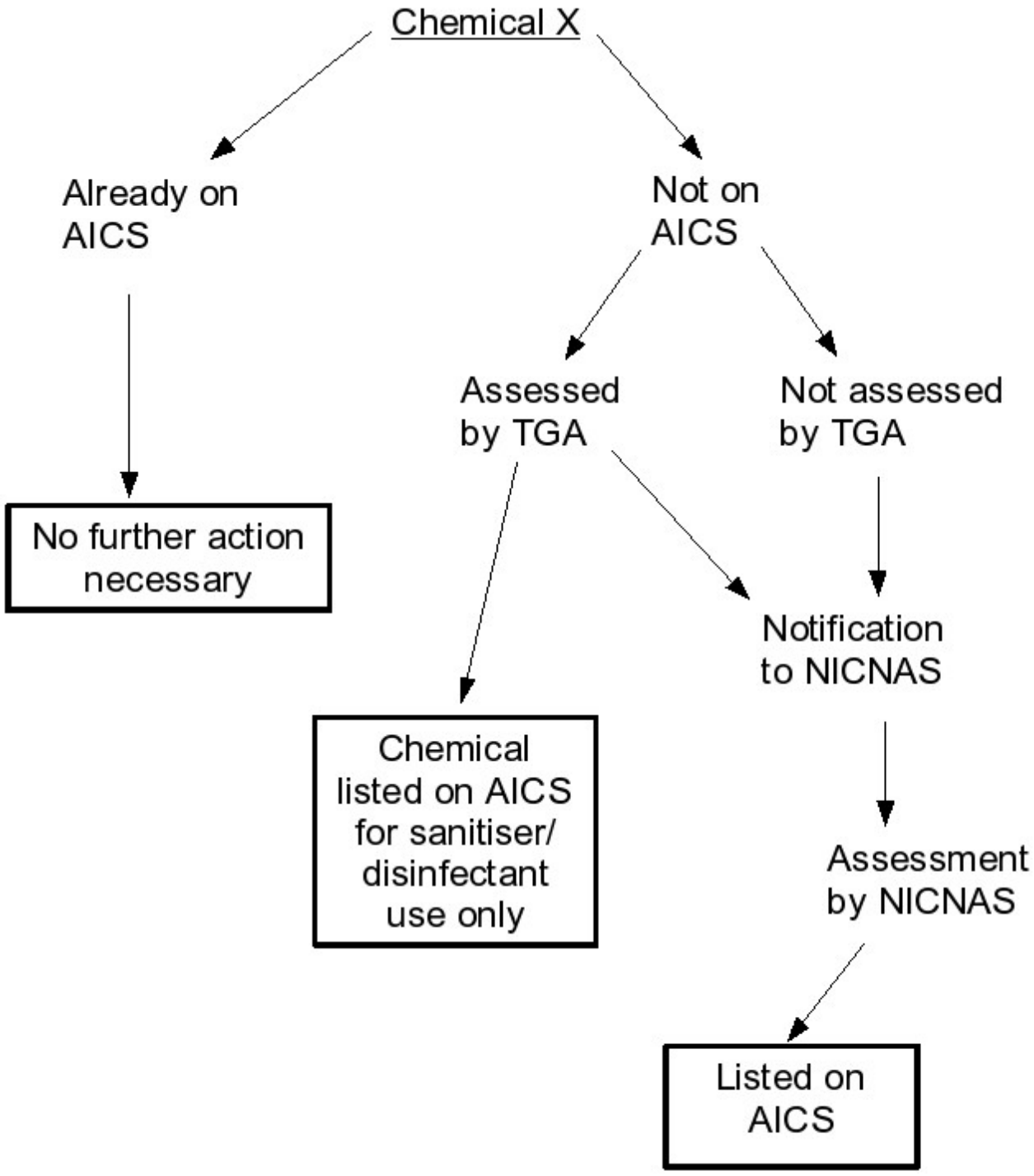
Appendix 3

ACSPA Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action

The ACSPA Code of Practice can be located on the ACCORD web-site at:

http://www.accord.asn.au/freestyler/gui/files//ACSPA_antibacterial_code_of_practice.final_3ffe97f958b32.pdf

Overview of NICNAS notification in relation to proposed new regulatory arrangements for disinfectants



Proposed regulatory pathway for a new disinfectant or sanitiser product