Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

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Dear Siepie

ACCORD is pleased to provide the following submission in relation to the Consultation Document *A new regulatory framework for disinfectants* (Consultant's Report) prepared for NICNAS and the TGA by Dr Simon Brooke-Taylor and released for public consultation in February 2008.

ACCORD Australasia is the peak national industry association representing the manufacturers and marketers of formulated consumer, cosmetic, hygiene and specialty products, their raw material suppliers, and service providers. ACCORD's members market fast-moving consumer and commercial goods primarily in Australia and New Zealand.

Our industry's products play a vital role in:

- keeping our households, workplaces, schools and institutions clean, hygienic and comfortable;
- personal hygiene, grooming and beauty treatments to help us look and feel our best;
- specialised uses that assist production and manufacturing to keep the wheels of commerce and industry turning; and
- maintaining the hygienic and sanitary conditions essential for our food and hospitality industries and our hospitals, medical institutions and public places.

These benefits are essential to safe, healthy living and maintaining the quality lifestyle we all too often take for granted.

With an estimated $10 billion in annual retail product sales, the formulated consumer, cosmetic, hygiene and specialty products industry is a significant part of a prosperous Australian economy. We are a dynamic and growing industry, employing Australians and - through our industrial and institutional sector - supplying products essential for Australian businesses, manufacturing firms, government enterprises, public institutions, farmers and consumers.

Our industry has more than 50 manufacturing operations throughout Australia and member companies include large global consumer product manufacturers as well as small dynamic Australian-owned businesses. A current list of ACCORD member companies is provided at *Attachment 1.*

ACCORD, on behalf of its member companies, has a specific and direct interest in revised regulatory arrangements for disinfectants and welcomes the opportunity to provide this

submission for consideration by the TGA and NICNAS. We note that consideration of reform to this class of products has been underway for a considerable period of time without much progress to date**.** It is hoped that the current review process will lead to positive outcomes resulting in a streamlined regulatory approach to these low regulatory concern products.

ACCORD's approach to regulatory efficiency

ACCORD supports the Australian Government's approach to regulatory best practice and recommends that the Council of Australian Governments (COAG) Principles and Guidelines for National Standard Setting and Regulatory Action by Ministerial Councils and Standard Setting Bodies (COAG Principles) should be rigorously applied in the finalisation of the reform process.

ACCORD supports the following as good regulatory practice principles.

Regulatory solutions should:

- be the **minimum required** to achieve the stated objectives;
- adopt a risk management approach to forming and administering regulation;
- minimize the impact on competition;
- be compatible with international standards and practices;
- cause no restriction to international trade;
- be developed in consultation with the groups most affected and be subject to regular review;
- be flexible, not prescriptive and be compatible with the business operating environment;
- standardize the exercise of bureaucratic discretion; and
- have a clear delineation of regulatory responsibilities and effective and transparent accountability mechanisms.

General comments – a principled approach

Reform to this class of products provides an opportunity to develop a regulatory framework which is the **minimum required** to achieve the stated objectives. The Productivity Commission (PC) in its recent draft report on the regulation of chemicals and plastics has made a number of recommendations regarding the future of NICNAS and the transfer of the Cosmetic Standard to the Australian Competition and Consumer Commission (ACCC).

Implementation of these recommendations will have a significant impact on the control measures for consumer products currently subject to the ICNA Act's national standard setting process. These have a flow on effect regarding consideration of the Consultant's recommendations as it is likely that assumptions made regarding NICNAS's possible role in a revised regulatory framework for disinfectants will no longer apply. Consequently, a new framework is required taking into consideration the possible outcome of the PC's study into the chemicals and plastics sector and the Government's response to its recommendations.

ACCORD believes that while the regulatory intervention must be commensurate with the risk, the first issue is to identify the problem which is to be solved and then consider within a risk management framework, the minimum effective level of regulation to address the demonstrated market failure.

In considering our approach to a new regulatory framework for disinfectants the vast majority of ACCORD members agree on the following principles:

- reform is warranted;
- the reform process should put in place a regulatory framework which is the minimum effective level required to address the problem - in general, these products present a low regulatory concern, should not be therapeutic goods and should not be regulated by the TGA;
- *hospital grade disinfectant* is well understood within the retail sector as an indicator of efficacy and quality and should continue to be used as such;
- consumers should have continued access to "hospital grade" non therapeutic products;
- only those products which are for clinical use and are marketed as therapeutic goods should be regulated by the TGA;
- regulatory treatment of disinfectant products which are not for therapeutic use should be as for other general consumer and commercial products, i.e.
    - new chemical entities with NICNAS,
    - product standards (if required) with industry (industry codes) or the ACCC product information standards,
    - consumer information, product safety and product liability with the ACCC,
    - OHS applies to those products for use in the workplace; and
- products within the TGA's jurisdiction should only be *listable* and GMP should not apply to this class of products.

Specific comments

Consultant's 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;*

ACCORD comment

While ACCORD agrees that the current definitions in TGO 54 require revision to emphasise more clearly a distinction between a therapeutic and non therapeutic disinfectant, we do not believe that the Consultant's proposed definition will provide clarity and certainty. Further in adopting the proposed Consultant's Recommendation 1 it would mean that the descriptor *hospital grade* would no longer be able to be used for household and commercial disinfectants as consumer cleaning products, other than with prior approval by the TGA. This is not acceptable to industry.

The current definitions for therapeutic devices, goods and use as they appear in the Therapeutic Goods Act 1989 (as amended 2008) are as follows:

> ***therapeutic device*** *means therapeutic goods consisting of an instrument, apparatus, appliance, material or other article (whether for use alone or in combination), together with any accessories or software required for its proper functioning, which does not achieve its principal intended action by pharmacological, chemical, immunological or metabolic means though it may be assisted in its function by such means, but the expression does not include therapeutic goods declared by the Secretary, by order published in the Gazette, not to be therapeutic devices.*
>
> ***therapeutic goods*** *means goods:*
>
> *(a) that are represented in any way to be, or that are, whether because of the way in which the goods are presented or for any other reason, likely to be taken to be:*
>
> *(i) for therapeutic use; or*
>
> *(ii) for use as an ingredient or component in the manufacture of therapeutic goods; or*
>
> *(iii) for use as a container or part of a container for goods of the kind referred to in subparagraph (i) or (ii); or*
>
> *(b) included in a class of goods the sole or principal use of which is, or ordinarily is, a therapeutic use or a use of a kind referred to in subparagraph (a)(ii) or (iii);*
>
> *and includes medical devices and goods declared to be therapeutic goods under an order in force under section 7, but does not include:*
>
> *(c) goods declared not to be therapeutic goods under an order in force under section 7; or*
>
> *(d) goods in respect of which such an order is in force, being an order that declares the goods not to be therapeutic goods when used, advertised, or presented for supply in the way specified in the order where the goods are used, advertised, or presented for supply in that way; or*
>
> *(e) goods (other than goods declared to be therapeutic goods under an order in force under section 7) for which there is a prescribed standard in the Australia New Zealand Food Standards Code as defined in subsection 3(1) of the Australia New Zealand Food Authority Act 1991; or*
>
> *(f) goods which, in Australia or New Zealand, have a tradition of use as foods for humans in the form in which they are presented.*
>
> ***therapeutic use*** *means use in or in connection with:*
>
> *(a) preventing, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals; or*

(b) influencing, inhibiting or modifying a physiological process in persons or animals; or

(c) testing the susceptibility of persons or animals to a disease or ailment; or

(d) influencing, controlling or preventing conception in persons; or

(e) testing for pregnancy in persons; or

(f) the replacement or modification of parts of the anatomy in persons or animals.

ACCORD does not believe that the current definition of therapeutic device makes it clear that a disinfectant for use in a hospital or within a clinical setting for the purposes of general disinfection of building and fitting surfaces really fits the definition of a therapeutic device.

Further the explanation provided on the TGA website in relation to revised regulatory arrangements for medical devices does not add clarity regarding the regulation of disinfectants used for a more general purpose.

DR4"

Australian medical device requirements under the Therapeutic Goods Act 1989 (version 4)

The document DR4 is a guidance document that now applies only to the regulation of therapeutic devices that are regulated under the Therapeutic Goods Act 1989 and the Therapeutic Goods Regulations 1990.

A new regulatory framework for medical devices was introduced on 4 October 2002, and the transition period for moving product from the 'old' regulatory framework, for which DR4 was the relevant guidance document, ended on 4 October 2007.

DR4 is not relevant to medical devices regulated under the new regulatory system. Any medical devices marketed in Australia must meet the requirements which are set out in Chapter 4 of the Therapeutic Goods Act 1989, and in the Therapeutic Goods (Medical Devices) Regulations 2002. See: New Australian medical device regulatory system implemented 4 October 2002 <http://www.tga.gov.au/docs/html/meddevreg.htm>, and other guidance documents available on the TGA website.

The information contained in DR4 is now relevant only for:

- *Diagnostic goods for in vitro use*
- *Devices incorporating human materials*
- *Hospital, household and commercial grade disinfectants*
- *Menstrual tampons*

All information contained in DR 4 for other medical devices is of historical interest only.

NOTE: Sponsors should note that, for a period of time beyond 4 October 2007, a limited number of listings and registrations will remain on the ARTG.

In mid August 2007 the Therapeutic Goods Amendment Act 2007 (Amendment Act) was passed. This amendment provides for any registered or listed device in the ARTG that was the subject of an effective application for either inclusion in the ARTG or TGA Conformity Assessment Certificate submitted by the 4 October 2007 deadline, to be treated as a transitioning device and continue to be supplied under the terms and conditions of Chapter 3 of the Therapeutic Goods Act 1989 (the Act) until such time as the application is finally determined.

The DR 4 is therefore still applicable to those listings and registrations where applications for inclusion on the ARTG under the new regulatory system are still to be determined.

From the above definitions it is obvious that clarification is required.

ACCORD accepts that disinfectant products used within a hospital and/or other clinical settings for the investigation or treatment of a disease, ailment or injury; or procedures that are carried out involving the penetration of the human skin could be regarded as therapeutic and hence would fall into the definition of a therapeutic good given that they are used in connection with the prevention, diagnosing, curing or alleviating a disease, ailment, defect or injury in persons or animals.

However, the products covered by the scope of this review also include general purpose disinfectants that are used generally within a consumer or commercial setting and do not come into contact and are not meant to be used with therapeutic and/or medical devices.

The term *hospital grade* is already in commercial use for these consumer and commercial disinfection products, has an extremely high level of market penetration and is well understood by the consumer as an indictor of an efficacious and quality product. We see no reason to change current commercial practice and labelling.

We believe that a tightening of the definition of products used for general purpose disinfection within a therapeutic context is warranted but that this should not extend its reach to include products which are clearly not intended to have a therapeutic use. Hospital grade in itself is not a therapeutic use, but rather a performance claim.

The current definition of disinfectant as used by the TGA in TGO 54 is considered too broad and should be revised to reflect that it is a therapeutic good.

> ***"disinfectant"*** *means a substance*
> *(i) that is recommended by its manufacturers for application to an inanimate object to kill a range of micro-organisms; and*
> *(ii) that is not represented by the manufacturer to be suitable for internal use (TGO 54 1998)*

When the Cosmetic Guidelines were developed, the issue of defining antibacterial products which were for consumer or therapeutic use was dealt with by applying the following definition:

> *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.

The same demarcation could be used to distinguish between disinfectants for a therapeutic use and those disinfectants for general consumer and/or commercial purposes.

ACCORD believes that the first step is to define what class of products comes under the TGA's regulatory control as therapeutic goods.

We believe that it should be consistent with the demarcation used to distinguish between a therapeutic antibacterial product and consumer antibacterial product as described above and already used by the Commonwealth in its regulatory tools.

ACCORD recommends that consideration be given to adopting the following as the definition of disinfectant for the purposes of the Therapeutic Goods Act:

disinfectant *means a product that is recommended by the manufacturer 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 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.

In this way, disinfectants intended for therapeutic use and/or clinical setting would be clearly labelling and readily identified with an ARTG number as a further indication of their suitability for that purpose.

ACCORD is not proposing that there should not be specified efficacy requirements and performance standards for general consumer and/or commercial disinfectant products claiming hospital grade. These requirements are well documented in the existing TGO54 and could be transferred as relevant to industry codes and/or ACCC product information standards.

Consultant's 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).

ACCORD comment
ACCCORD agrees that the presence of 'specific claims' on a product is the point of demarcation irrespective of "hospital grade" status i.e. disinfectants with specific claims would be regulated by the TGA as listed products.

Regulatory control for products outside of the TGA would be as described above with NICNAS assessing new ingredients, false, misleading and deceptive conduct and product liability would be managed through the ACCC and efficacy standards could be set by either an Industry Code or ACCC Product Information Standard.

Consultant's 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.

ACCORD comment
ACCORD does not support Recommendation 3.

Consultant's Recommendation 4
NICNAS legislation 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.

ACCORD Comment
ACCORD fully supports this recommendation and has put this forward as a reform proposal in a number of submissions to key government inquires for at least the last five years. While we believe that this is practical we note the difficulty NICNAS has had with making arrangements to transfer commonly used cosmetic ingredients in commercial use listed on

the ARTG to AICS for use in cosmetic purposes only as was agreed as part of the cosmetic reform process.

Consultant's 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.

ACCORD Comment
ACCORD fully supports this statement except to re-enforce that NICNAS is a chemicals entity notification and assessment scheme and not a product registration scheme. We note that progress is being made with regard to consideration of reform issues within the context of the PC study into chemicals and plastics regulation.

Conclusion and recommendations

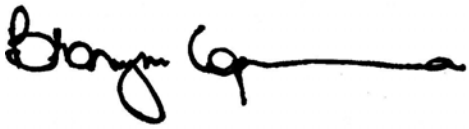
ACCORD recommends that:

- the TGA and NICNAS take a simple approach to creating a new regulatory framework for this class of disinfectant products;
- the demarcation of which products fall under the TGA's jurisdiction be aligned with that already in use in the Cosmetic Standard;
- hospital grade, household grade and commercial grade disinfectants that are not intended for clinical use be regulated by NICNAS and the ACCC;
- products regulated by the TGA only require to be listed on the ARTG and that no GMP is required;
- consumers continue to have access to *hospital grade* disinfectants that are consumer cleaning products;
- greater use be made of industry codes to set efficacy and performance standards; and
- the TGA and NICNAS develop a simple process to transfer chemicals from the ARTG to AICS as a matter of priority.

ACCORD welcomes the opportunity to provide this submission on the Consultant's Report for a new regulatory framework for disinfectants as a basis for further consultation and dialogue.

ACCORD looks forward to working collaboratively with the TGA and NICNAS in further developing the proposals contained in this submission.

Yours sincerely



Bronwyn Capanna
Executive Director

30 May 2008

ACCORD
Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry

Members

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Scental Pacific Pty Ltd
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Three Six Five Pty Ltd
Tigi Australia Pty Ltd
Trimex Pty Ltd
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Unilever Australasia
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Callington Haven Pty Ltd
Campbell Brothers Limited
Castle Chemicals Pty Ltd
Chemetall (Australasia) Pty Ltd
Chemform
Ciba (Australia) Pty Limited
Clariant (Australia) Pty Ltd
Cleveland Chemical Co Pty Ltd
Deb Australia Pty Ltd
Dominant (Australia) Pty Ltd
Ecolab Pty Limited
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