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**Department of Health and Ageing**  
**Therapeutic Goods Administration**



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# **REGULATORY REFORM OF DISINFECTANTS IN AUSTRALIA**

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## **Why hold public meetings?**

- **To discuss findings from the consultant's final report to stakeholders**
- **Seek stakeholder comment on the impacts of the proposed changes on the community, industry and government**
- **Specifically to seek stakeholder views on the consultant's preferred option**



## Background

- 1998/99 - issues arising from TGA legislation
- 1999 - NCCTG review of regulatory controls for disinfectants
- July 2005 - TGA consultation with stakeholders on new regulatory system for disinfectants



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## Driver

January 2006 - Report of Taskforce on Reducing  
Regulatory Burden on Business (Banks  
Report)

### Recommendation 4.61

*“The Australian Government should progress industry reforms for regulating disinfectant products and report progress to COAG”*



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## **Therapeutic Goods Administration (TGA)**

- Currently all disinfectants are therapeutic goods
- Product registration scheme
- Australian Register of Therapeutic Goods (ARTG)
  - 'registered' or 'listed', or
  - 'included' - medical devices only, or
  - 'exempt' goods - not on ARTG.
- Products intended for use on medical devices (sterilants and instrument grade disinfectants) not part review
- Disinfectants for use on skin regulated as medicines



## Disinfectants

- *Definition*
  - Intended for use on an inanimate object to kill a range of micro-organisms
- *Types of disinfectants*
  - hospital grade disinfectants
  - household/commercial grade disinfectants
  - antibacterial clothes preparations
  - sanitary fluid and powders
  - sanitisers



## Therapeutic Goods Administration (TGA)

- Therapeutic Goods Order 54
  - Includes packaging, labelling and efficacy requirements
  - Guidelines
  
- Assessment – may include product efficacy but not environmental impact
  
- Good Manufacturing Practice requirements do not apply



## Current regulatory requirements

<b>Disinfectant Product</b>	<b>Regulatory Process</b>
Hospital Grade and Commercial /Household Grade <i>with</i> specific claims	Registrable Therapeutic Goods Order 54 applies
Hospital Grade <i>without</i> specific claims	Listable Therapeutic Goods Order 54 applies
Commercial /Household Grade <i>without</i> specific claims	Exempt from registration or listing Therapeutic Goods Order 54 applies
Antibacterial cleaning wipes Sanitisers Sanitary fluids/powders	Exempt or excluded, depending on claims



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# **National Industrial Chemicals Notification and Assessment Scheme (NICNAS)**

- Chemical entity based notification and assessment Scheme
- Australian Inventory of Chemical Substances
- Assessment – includes environmental impacts of ingredients: no assessment of product efficacy
- Exemptions from assessment balanced by post-market reporting and record keeping
- Annual registration of chemical introducers



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## The Review

- TGA and NICNAS are working together to develop a best-practice regulatory model for disinfectants
- Engaged Dr Brooke-Taylor to:
  - Review current Australian regulatory framework
  - Review comparable overseas models
  - Consult with stakeholders
  - Document findings and make recommendations for change



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## Consultant's approach

- **Objective:** Minimum effective regulation to ensure maintenance/enhancement of public health and safety
- Based on public health risks of product failure
- Level of risk determined by manufacturer's intended use for disinfectant (the prescribed use situation)
- Risks relate to:
  - Public health risks from failure to control micro-organisms
  - Lack of efficacy in food production
  - Direct toxicity to humans or the environment



## Level of risk associated with product failure

<b>Place of use</b>	<b>Consequence of failure</b>	<b>Public health risk</b>
Hospitals/ clinics: to prevent infection transfer between patients/staff	Disease outbreaks, epidemics, deaths	High - catastrophic
Hospitals/medical centres public areas	Visitors/admin staff exposed to disease causing organisms	High
Veterinary practice/animal care areas	Disease outbreaks, human/animal deaths	High - catastrophic



## Level of risk associated with product failure (cont)

Place of use	Consequence of failure	Public health risk
Commercial premises – food preparation areas	Food borne disease outbreak if accompanied by HACCP failure	Medium
Commercial premises	Unclean premises/toilets	Low
Home kitchen	Low level food borne disease	Medium - low
Home toilets/ general areas	Unclean premises/toilets	Low
Hairdressing, beauty therapy	Low level disease transfer - not life threatening	Medium - low



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## Consultant's recommendations

- Five recommendations based on risk analysis
- Recommendations 1 to 3 define the proposed scheme
- Four regulatory options are presented to demarcate between therapeutics and non-therapeutics
- Recommendations 4 & 5 are more general – will not impact on regulatory proposal



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## **Recommendation 1**

- Review the current definition of “hospital grade disinfectant ” to clearly indicate that products are intended for use in a hospital or clinical setting



## **Recommendation 2**

Regulatory division of disinfectants to be based on public health risk of product failure when used as intended by the manufacturer

- High risk from product failure regulated as therapeutic devices by the TGA
- Low to medium risk from product failure regulated by NICNAS as industrial chemicals



## Recommendation 2 (cont)

- Options differ in **point of demarcation** that determines regulatory framework: TGA or NICNAS

Option 1 - revised definition of hospital grade disinfectant

Option 2 – specific claims on product (only)

Option 3 – use situation (only)

Option 4 – revised definition of hospital grade and specific claims on product



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## **Recommendation 2 - Option 1**

Point of demarcation – revised definition for “hospital grade”

- TGA to regulate all hospital grade disinfectants (high risk products) irrespective of label claims
- NICNAS to regulate all other disinfectants, sanitisers, sanitary fluids/powders and wipes



# Option 1

## Advantages

- Uses recognised term ‘hospital grade’ as point of demarcation
- All ‘hospital grade’ disinfectants regulated by TGA
- Assurance of efficacy through assessment

## Disadvantages

- High regulatory burden for ‘hospital grade’ disinfectants marketed for household use (manufacturer choice)
- No assessment of efficacy claims made for commercial/household products



## **Recommendation 2 - Option 2**

- Point of demarcation – specific claims on product, irrespective of ‘hospital grade’ status
- TGA regulates all disinfectants making specific claims (hospital, commercial and household grade)
- NICNAS regulates all disinfectants without claims (including hospital grade), sanitisers, sanitary fluids, sanitary wipes/cloths



## **Option 2**

### **Advantages**

- All efficacy claims subject to TGA assessment irrespective of use situation

### **Disadvantages**

- ‘Hospital grade’ label meaningless
- Possible confusion about appropriate disinfectant for use in clinical facilities: assume hospital grade will have efficacy verified
- Unjustified regulatory burden for low risk commercial and household products



## **Recommendation 2 - Option 3**

- Point of demarcation – use situation (eg clinical setting, home)
- TGA regulates disinfectants specifically intended to be used in premises providing medical or health services
- NICNAS regulates all other disinfectants, sanitisers, sanitary fluids, sanitary wipes/cloths



## Option 3

### Advantages

- Effective regulation for disinfectants intended for use in a clinical setting

### Disadvantages

- Confusing and difficult to administer
- Need to develop criteria for determining disinfectants intended for use in clinical setting
- ‘hospital grade’ label meaningless



## **Recommendation 2 - Option 4**

- Point of demarcation – “hospital grade” and/or presence of ‘specific claims’ on label
- TGA regulates hospital grade disinfectants and other disinfectants making specific claims
- NICNAS regulates all other disinfectants, sanitisers, sanitary fluids, sanitary wipes/cloths



## Option 4

### Advantages

- All ‘hospital grade’ and disinfectants with specific claims subject to TGA regulation

### Disadvantages

- Potential confusion about status of ‘hospital grade’ products vs disinfectants with specific claims
- High regulatory burden for household/commercial disinfectants with specific claims intended for low risk applications



## **Recommendation 3**

- The consultant's preferred option is Option 1
- All disinfectant products labelled “Hospital Grade” (with or without claims) regulated by TGA
- All commercial and household disinfectants (with or without claims), antibacterial cleaning wipes, sanitisers, cleaners & deodorisers regulated by NICNAS



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# **Will NICNAS ensure the current standards are maintained?**

- Despite the differences in the NICNAS and TGA schemes, it is intended that current health and safety standards are maintained through regulatory and administrative processes
- False and misleading conduct will be regulated under Trade Practices Act and Fair Trading legislation
- Efficacy standards could be the responsibility of the manufacturer – eg Industry Code of Practice
- Safeguards will be determined after stakeholder consultations



## Next steps

- Closing date for public submissions - 28 April 2008
- Government response - mid June 2008
- Implementation strategy including further consultation – late 2008
- Commencement of reforms – late 2009



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## Submissions should be sent to:

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## Further information

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