Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

REGULATORY REFORM OF DISINFECTANTS IN AUSTRALIA

Siepie Larkin TGA

Gillian Gardner TGA

Stephen Zaluzny NICNAS

April 2008

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

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"

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

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

Disinfectant Product	Regulatory Process
Hospital Grade and Commercial /Household Grade *with* specific claims	Registrable Therapeutic Goods Order 54 applies
Hospital Grade *without* specific claims	Listable Therapeutic Goods Order 54 applies
Commercial /Household Grade *without* 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

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

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

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

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

Place of use	Consequence of failure	Public health risk
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

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

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

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

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

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

Submissions should be sent to:

- Siepie Larkin at siepie.larkin@health.gov.au.

Ms Siepie Larkin
Therapeutic Goods Administration
PO Box 100
WODEN ACT 2606

OR

- **Stephen Zaluzny at: stephen.zaluzny@nicnas.gov.au**

Mr Stephen Zaluzny
NICNAS
GPO Box 58
Sydney NSW 2001

Further information

NICNAS

Mr Stephen Zaluzny on phone (02) 8577 8883
or e-mail: stephen.zaluzny@nicnas.gov.au

TGA

Ms Siepie Larkin on phone: (02) 6232 8721 or
email: siepie.larkin@health.gov.au.

Australian Government
Department of Health and Ageing
Therapeutic Goods Administration

Australian Government
Department of Health and Ageing
NICNAS

explore

www.nicnas.gov.au

www.tga.gov.au