PUBLIC HEALTH

DIVISION

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# SUBMISSION: TO NICNAS & TGA

## Comment on: Proposed changes to regulatory requirements for hospital, household and commercial grade disinfectants


Dr David Simon

Director, Scientific Services Branch
PUBLIC HEALTH
DEPARTMENT OF HEALTH
SOUTH AUSTRALIA


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**Summary Statement**

The Public Health Division of the SA Department of Health supports 'in principle' the transfer of regulatory responsibility for commercial grade and household disinfectants (with and without specific claims) and sanitisers, sanitary fluids and antibacterial wipes from the TGA to NICNAS, while the TGA retains responsibility for all 'hospital grade' disinfectants. However, although the consultant claims that the intent is for current health and safety standards to be maintained, the Department is concerned that in the future NICNAS may not have the regulatory capacity to maintain product safety standards that are currently enforceable by the TGA. Therefore support of the preferred recommendation 3 and option 1 for a new framework is conditional on NICNAS being able to maintain the current standards for labelling, packaging and performance of the designated products as required by the Therapeutic Goods Order 54 (TGO54) under the therapeutic goods legislation. The Department does not support removal of references to commercial premises such as beauty therapy, hairdressing and podiatry practices from 'hospital grade'.

**Comments**

1. SA Department of Health is not in a position to provide comment on the potential business compliance costs, impacts on business and individuals including restrictions on competition.

2. Recommendation 1 - not supported.

   *To review the definition of 'hospital grade' so that it relates to hospitals and other clinical applications but removes references to commercial premises such as beauty therapy, hairdressing and podiatry practices.*

   From a public health perspective, the standard for a disinfectant used in any setting where skin penetration occurs needs to be the same as for a 'hospital grade disinfectant'. The risk from transmissible diseases is not modulated to such an extent that non-clinical settings can be excluded, indeed the opposite may be true due to a lower level of competency in the operators of such facilities. For instance, the level of risk is no different whether a HIV or hepatitis infected person has skin penetrated in a 'hospital', a podiatry clinic or any non-clinical setting.

3. Recommendation 2 - Option 1 supported

   *Division of disinfectants based on the public health risks represented by the manufacturer's intended use.*
   *Option 1*
   *High risk – all hospital grade disinfectants irrespective of label claims*
   *Low risk – all other disinfectants and sanitisers*

   Recommendation 3 - conditional support

   *All 'hospital grade' disinfectants (with and without specific claims) to be classified as therapeutic devices required to be listed on the Australian*

*Register of Therapeutic Goods (ARTG) and regulated by the Therapeutic Goods Order 54 (TGO54) under therapeutic goods legislation. All household and commercial grade disinfectants, sanitisers, sanitary fluids and antibacterial wipes to be regulated by NICNAS with product ingredients to be listed on the Australian Inventory of Chemical Substances (AICS).*

Perceived impacts of these recommendations:

- listing of ingredients (AICS) rather than products (ARTG),
- commercial grade and household disinfectants making specific claims will no longer undergo pre-market product evaluation for quality, safety and efficacy,
- additional environmental risk assessment by NICNAS for new chemicals on the AICS would be an added benefit,
- household and commercial grade disinfectants and sanitisers etc. will no longer be required to comply with labelling, packaging and performance requirements as per Therapeutic Goods Order 54 (TGO54).

To be effective NICNAS must be able to replicate the current standards for labelling, packaging and performance currently applied by TGO54. In particular TGO54 requires that clear and adequate instructions for correct preparation, dilutions, storage and use including method, dangers and safety instructions and expiry date. These requirements have public health benefits resulting from protection of the user and broader protection of the public from best disinfecting practices. This information is also important as it is used by enforcement officers in food premises when they are evaluating whether sanitation of food contact surfaces is being performed correctly.

- The capability of NICNAS to emulate TGO54 is of concern. NICNAS has suggested the intent would be to replace the TGA mechanism for regulating labelling, packaging and performance requirements (TGO54) with a similar tool to ensure that safety standards are maintained. If the intent is for NICNAS to use "Standards" to replace "TGA orders" the recommendation is supported.

  However, a recent Productivity Commission draft research report released for public consultation recommends that NICNAS' regulatory powers such as responsibility for the Cosmetic Standards should be transferred to other agencies (e.g. Australian Competition and Consumer Commission – ACCC). If Productivity Commission recommendations remove NICNAS' regulatory powers and prevent the agency from establishing national Standards for disinfectants under legislation, the <u>recommendation is not supported.</u>

- Although commercial grade and household disinfectants making specific claims will no longer undergo pre-market product evaluation for quality, safety and efficacy, these products are classified as medium to low public health risk therefore the

potential risk of adverse health effects should not be markedly affected by this proposal.

- SA Department of Health would support regulatory standards that include reference to TGO54 rather than the current industry standard - *ACCORD Code of Practice for Household & Commercial Cleaning Products Claiming Antibacterial Action* the former being more rigorously prepared.

- Listing ingredients on AICS rather than products on ARTG may broaden the number of chemicals available for use in household, commercial grade disinfectants or sanitisers without public health risk assessment i.e. chemicals already currently listed on AICS will become available for use without further assessment.

4. Recommendation 4 – supported

   *Mutual recognition of existing risk assessments for chemicals used in disinfectants to reduce unnecessarily duplicated assessment efforts and regulatory burden on manufacturers.*

   SA Department of Health supports mutual recognition of international or national assessments (APVMA, TGA) conditional on using methodologies only from approved countries that meet current Australian standards and practices (e.g. EU, USA, Canada).

   The consultant suggests that NICNAS has the legislative capacity to enter new chemicals on AICS and annotate as 'for disinfectant use only' so that if a broader use was needed more extensive public health assessment would be required. However, SA Department of Health is concerned that recent Productivity Commission recommendations to remove NICNAS ability to annotate the AICS may impact on this proposal.

5. Recommendation 5 - supported

   *Review the regulation of products currently registered with APVMA for use on farms (e.g. dairy sanitisers) and other products used in food processing that don't currently require registration that may contain chemicals that are proposed to be regulated by NICNAS.*

   SA Department of Health supports this recommendation to ensure that conflicting regulation does not occur. However, it is possible that sanitisers currently exempt from listing on the ARTG contain chemicals would now need to be assessed for AICS listing which may increase regulatory burden on industry.