

Regulatory options identified by the consultant

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)	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	<p>‘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</p> <p>Unjustified regulatory burden for commercial/household disinfectant product intended for low risk commercial/ household use that make specific disease related claims?</p>
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			
<p>Disinfectants specifically intended to be used in premises providing medical or health services</p> <p>[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.]</p>	TGA	<p>Effective regulation for all disinfectants manufactured for use in health & other clinical facilities.</p> <p>Consistent with the approaches taken in the general identification of medical devices and at the food-drug interface,</p>	<p>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.</p> <p>Would require development of criteria for determining disinfectants intended to be used in a clinical setting.</p> <p>May lead to confusion about the meaning of “hospital grade”</p>
Low risk disinfectant			
Disinfectant, sanitisers, sanitary fluids, sanitary wipes/cloths, except disinfectants intended to be used in premises providing medical or health services	NICNAS	<p>Effective regulation for all disinfectants used in low risk applications in commercial or household locations irrespective of whether labelled hospital grade or not.</p>	<p>Likely to be difficult to identify “hospital grade” disinfectants that are only intended for the household market.</p>

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	