GUIDE ON PROPOSED CHANGES TO REGULATION OF DISINFECTANTS

A consultant, Dr Simon Brooke-Taylor has reviewed the current Australian regulatory schemes for disinfectants. This guide provides an overview of the recommendations in his report. A glossary is provided in the consultant's report to assist with understanding various technical terms.

The current position

The National Industrial Chemicals Notification and Assessment Scheme (NICNAS) operates a chemical assessment scheme. The Therapeutic Goods Administration (TGA) operates a product registration scheme. Disinfectants are considered to be therapeutic goods. Under the TGA scheme, all therapeutic goods, unless exempt, must be entered on the Australian Register of Therapeutic Goods (ARTG) before they can be supplied. Supply occurs under one of three categories: 'registered', 'listed', or 'included' goods. The degree of regulation depends on the therapeutic goods category.

At present:

- hospital, household and commercial grade disinfectants (with 'specific claims') are categorised as registered therapeutic devices. These must comply with Therapeutic Goods Order (TGO) 54, including any updates, for composition, packaging, labelling and performance (available at http://www.tga.gov.au/docs/html/tgo/tgo54.htm);
- hospital grade disinfectants (without 'specific claims') are regulated as listed therapeutic devices. These must also comply with TGO 54, and any updates;
- household and commercial grade disinfectants (without 'specific claims'), as well as sanitisers, sanitary fluids and antibacterial surface wipes, are exempt from entry on the ARTG. However, they must comply with TGO 54 and any updates.

Registered disinfectants undergo a pre-market evaluation for quality safety and effectiveness against micro-organisms prior to ARTG entry. Listed devices are not subject to a formal pre-market evaluation. Both registered and listed disinfectants can be sampled for laboratory testing as part of TGA post-market surveillance.

Products used for agricultural and/or veterinary applications are assessed and registered by the Australian Pesticides and Veterinary Medicines Authority (APVMA) before they can be supplied. Some disinfectants fall under the APVMA however the consultant has not made specific recommendations for change of the APVMA scheme at this time.

What is being proposed?

The report makes five recommendations based on an analysis of the consequences of product failure. The consultant's preferred approach is to change the regulatory responsibility for hard surface disinfectants and sanitisers for use in low risk applications, such as household and commercial use. Under the preferred approach, regulatory responsibility for these products would be transferred from the TGA to NICNAS. A flow chart showing how this would operate is at the end of this guide.

Under NICNAS, all chemicals in these products must be listed on the Australian Inventory of Chemical Substances (AICS) or the introducer must hold a NICNAS assessment certificate or permit which allows introduction. Some exemptions apply and these are for low risk chemicals introduced in low volumes and are balanced by post-market reporting and record-keeping obligations.

NICNAS will not undertake any assessment or testing of effectiveness against micro-organisms under these proposals, however it will consider occupational health and safety and environmental risk, currently not part of a TGA evaluation.

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. Safeguards will be finalised after proper consultation during the public comment period.

Proposed regulatory pathway for a new disinfectant or sanitiser product