



**A FAMILY COMPANY**

---

To: Siepie Larkin  
MDP 122  
Therapeutic Goods Administration  
PO Box 100  
Woden ACT 2606  
Australia

Submission of comments for proposed changes to disinfectant requirements April 2008 from SC Johnson & Son Pty. Ltd.

SC Johnson & Son manufactures and sells disinfectants in the Australian and New Zealand markets primarily for domestic use. We have been manufacturing and selling these products for over 20 years under the trade names "Duck" (in Australia) and "Jeyes" (in New Zealand).

SC Johnson is the second biggest manufacturer of household and hospital grade disinfectant products in Australian retail outlets, and welcomes the opportunity to contribute to the regulatory reform proposed.

Currently SC Johnson & Son holds the following entries on the Australian Register of Therapeutic Goods:

Listed Disinfectants

62410 S.C. JOHNSON & SON DISINFECANTS, WITHOUT CLAIMS NON-STERILE 'SODIUM HYPOCHLORITE/SODIUM HYDROXIDE' (3 products)

62416 S.C. JOHNSON DISINFECTANTS, WITHOUT CLAIMS NON-STERILE 'QUATERNARY AMMONIUM COMPOUNDS' (12 products)

124316 SC Johnson & Son Pty Ltd - Duck Bleach Action Toilet Bowl Cleaner - Disinfectant, hospital grade SC Johnson & Son Pty Ltd (1 product)

134066 SC Johnson & Son Pty Ltd - Duck Protection Plus Manual Liquid - Disinfectant, hospital grade SC Johnson & Son Pty Ltd (4 products)

Registered Disinfectants

145645 SC Johnson & Son Pty Ltd - Oust 3 in 1 - Hospital Grade Disinfectant, With Claims, Non-Sterile (2 products)

### **Specific comments on the proposal**

1. SC Johnson does not support Option 1 as proposed.

Option 1 proposes that only products that claim "Hospital Grade" be subject to regulation and assessment by the TGA, and that all other products be regulated by NICNAS. This includes Household and Commercial Grade products with or without specific claims. The concern is that the need for pre-evaluation and assessment for specific claims on Household and Commercial grade disinfectants would disappear. Under Option 1 a manufacturer could make a specific claim against potentially lethal viruses such as Hepatitis and HIV on a Household Grade Disinfectant without having to meet the current robust requirements for assessment. We believe this proposal would endanger public health by opening up the market to products that have less than acceptable efficacy and safety profiles. Such instances would undermine public confidence in the disinfectant industry in general, and the regulatory body in particular. It would also increase the burden on the regulator by having to police such instances.

2. Concern on cost implications

SC Johnson & Son does not currently market any Household or Commercial Grade disinfectants, however we are concerned about the cost implications of moving responsibility of these products to NICNAS. SC Johnson understands that NICNAS is a 100% industry funded body and the increased responsibility will eventually be required to be funded by industry.

SC Johnson believes Option 4 is an appropriate starting point for framing the regulations for disinfectants. Under Option 4 all disinfectant products would be regulated by NICNAS, except if they make either a "specific claim" or claim to be "Hospital Grade". In either of these cases the products would require assessment by TGA and listing on the ARTG.

### **Further comments and points for discussion**

We believe that there is further clarification required on the following issues:

- Will there still be scope for Hospital Grade Disinfectant products without specific claims to exist for the domestic consumer market as per current arrangements? Currently these products must meet the requirements of TGO 54, but do not have to submit data and have a reduced application fee compared to products making specific claims. SC Johnson would prefer this category of products to remain as is.
- The definition of "hospital grade" disinfectant will not be consistent with the product reality, in that manufacturers such as SC Johnson & Son will continue to supply

products with hospital grade efficacy to members of the public for general domestic use. We request further clarification on the scope of the definition.

- The role of the TGACC will need to be reviewed and whether or not the proposed products to be regulated by NICNAS will still be considered therapeutic goods, and therefore subject to the requirements of the Therapeutic Goods Advertising Code.
- What labeling requirements for active ingredient declaration, common name usage, and use of key terms such as "antibacterial", "disinfectant" and "kills germs" will be applicable to the products regulated by NICNAS? Hospital grade disinfectants will still be required to meet the labeling requirements of TGO 54, will the Commercial and Household Grade products be required to meet these requirements also? If so how and who will regulate and enforce this?

SC Johnson would appreciate the opportunity to contribute further to the proposed regulatory reform and look forward to further involvement in the process.

Please do not hesitate to contact me for further clarification or information.

Yours sincerely,



Richard Jarvis  
Operations Director  
SC Johnson & Son Pty. Ltd.  
160 Epping Road  
Lane Cove NSW 2066  
(02) 9428 9111