Regulation Impact Statement

on

TGA and NICNAS proposed regulation of disinfectants

11 November 2009

A. Introduction

The purpose of this Regulation Impact Statement (RIS) is to further explore stakeholder views regarding possible changes to the regulation of hospital, household and commercial grade disinfectants.

Currently disinfectants are regulated by the Therapeutic Goods Administration (TGA):

- hospital, household and commercial grade disinfectants (with 'specific claims) undergo a pre-market evaluation for quality, safety and effectiveness prior to entry on the Australian Register of Therapeutic Goods (ARTG) as 'registered devices';

- hospital grade disinfectants (without 'specific claims') are not subject to formal pre-market evaluation, although information that reasonably demonstrates the safety and quality of these goods is required, prior to entry on the ARTG as 'listed devices'; and

- 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.

All products are expected to comply with Therapeutic Goods Order (TGO) 54 which describes requirements in relation to composition, packaging labelling and performance.

The regulation of disinfectants (and similar products) has been the subject of review for a very long period of time;

- a 1998 review by the National Coordinating Committee on Therapeutic Goods (NCCTG) followed by TGA consultation in 2005 on proposed changes to the regulatory requirements for hospital, household and commercial disinfectants. The proposals included ongoing regulation of hospital grade disinfectants and household/commercial grade disinfectants (with specific claims) by the TGA and liaison between TGA and the National Industrial Chemicals Notification and Assessment Scheme (NICNAS) for the regulation of exempt disinfectants;

- consideration of disinfectants by the Australian Government's Taskforce on Reducing Regulatory Burdens on Business. The Taskforce recommended that the Australian Government should progress industry reforms for regulating disinfectant products and report progress to the Council of Australian Governments (COAG);

- a review in 2007/2008 by Dr Simon-Brooke-Taylor to consider the responses from the 2005 stakeholder consultation, examine the regulation of disinfectants in other countries and present best practice options for streamlining the regulation of disinfectants in Australia; and

- further consultation in 2008 and 2009 by the TGA and NICNAS regarding options presented by Dr Simon Brooke Taylor. This included public meetings in Sydney and Melbourne in April 2008 and circulation of a questionnaire to determine the impact of any regulatory changes in November 2008.

There have been a number of consistent messages emerging from the ongoing review and consultations. Generally speaking:

- there seems to be widespread support for the maintenance of premarket evaluation, including demonstration of efficacy for disinfectants making specific claims and/or intended to be used in hospitals and other clinical establishments. The area of debate has been whether disinfectants making specific claims and/or labelled 'hospital grade' that are being sold to the general public should be regulated by the TGA as registrable or listable products; and

- there has been a desire for certain lower risk products such as household and commercial grade disinfectants (without specific claims), sanitisers, sanitary fluids and antibacterial surface wipes to shift from being within TGA's mandate (as exempt products) to being regulated by NICNAS, based on the ingredient chemicals.

As noted above, the debate has tended to be around the demarcation lines and which disinfectants should be regulated as registrable devices (pre-market assessment by TGA), listable devices (entered on ARTG but not pre-market assessed) or regulated by NICNAS.

The Brooke-Taylor Report and subsequent TGA and NICNAS consultation outlined four regulatory options all with different points of demarcation for the transfer of certain regulatory responsibility to NICNAS:

- TGA regulation of hospital grade disinfectants irrespective of specific claims made and other disinfectants regulated by NICNAS (option 1);

- TGA regulation of disinfectants making specific claims, irrespective of hospital grade label, and other disinfectants regulated by NICNAS (option 2);

- demarcation based on use/clinical setting (i.e. disinfectants for use in medical or health services regulated by TGA and all others by NICNAS) (option 3); and

- regulation of hospital grade disinfectants, with or without specific claims, and other disinfectants making specific claims by TGA and all others by NICNAS (option 4).

After consultation on these issues, option 4 emerged as the preferred option of a majority of stakeholders (noting that Option 2 was the preferred option of one major industry representative body).

In order to confirm whether option 4 remains the preferred option, the TGA and NICNAS wish to undertake a further round of consultation.

The main reasons for this are:

- the Brooke-Taylor Report largely tested conceptual options. The TGA and NICNAS are now in a position to provide stakeholders with more detail about what the preferred option would entail in a practical regulatory sense; and

- during consultations to date, the TGA and NICNAS have received very limited information from stakeholders about the likely impacts of the preferred option. By providing additional information about the model proposed and by broadening the consultation base, it is hoped that stakeholders will be better able to assess, and communicate to the TGA and NICNAS, the impacts and issues of these options.

The purpose of this RIS is to specifically focus on the detail of this option, to assess it against the status quo and to confirm:

- whether regulatory change is warranted in the circumstances (taking into account the problems identified and the objectives sought to be achieved); and
- the impact of the proposed option on industry, consumers and government.

As there have already been a number of rounds of consultation on these issues, some of the material will be familiar to stakeholders or will cover 'old ground' that some may consider it unnecessary to revisit. However, for the purpose of completeness and to ensure that all relevant issues are considered prior to confirmation of a preferred option, the RIS has been drafted so as to logically detail the problems sought to be addressed, the objectives of Government action and to draw out all impacts.

B. Current regulation

As noted in the Introduction, currently disinfectants are regulated by the TGA as therapeutic goods. Disinfectants are regulated in one of three ways:

- hospital, household and commercial grade disinfectants (with 'specific claims) undergo a pre-market evaluation for quality, safety and effectiveness prior to entry on the ARTG. Such products must comply with TGO 54 which describes requirements in relation to composition, packaging labelling and performance;

- hospital grade disinfectants (without 'specific claims') are regulated as listed therapeutic devices. This means that they are not subject to formal pre-market evaluation by the TGA, however information that reasonably demonstrates the safety and quality of these goods is required and they must still be entered on the ARTG and comply with TGO 54; and

- 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 but are expected to comply with TGO 54.

Sterilants and instrument grade disinfectants have been regulated since October 2002 under the regulatory system for medical devices. These products are outside of the scope of this review.

C. The Problem

Government seeks to address the following problems identified with the current regulation of disinfectants:

- an absence of adequate regulation, commensurate with potential risk, for household and commercial grade disinfectants (without specific claims), sanitisers, sanitary fluids and antibacterial surface wipes (referred to in this RIS as 'other products').

    - Currently, listable or registrable disinfectants that contain a new chemical entity undergo a toxicological evaluation by the TGA. In the case of other chemical products (not regulated by the TGA), NICNAS applies a legislated risk framework and, where necessary, undertakes toxicological evaluation of new chemical entities. However, there is a regulatory anomaly for household and commercial grade disinfectants (without specific claims) and other products. These products fall within the TGA regulatory framework but are exempt from entry on the ARTG.

    - There is no provision under the *Therapeutic Goods Act 1989* for the TGA to undertake a pre-market risk assessment or toxicological evaluation for new chemical entities contained in these products. Equally, NICNAS has no jurisdiction to undertake such assessments because the products do not fall within the regulatory remit of NICNAS.

    - This poses potential public health and safety risks and is inconsistent with public expectations that such products are adequately regulated. The likelihood or extent of the potential public health and safety risks is not currently known, particularly as the identity of the chemicals within disinfectant products that are exempt under the TGA regulatory system is not known.

- household and commercial disinfectants (without specific claims) and other products do not comfortably fit within the TGA regulatory system (even as exempt products) because the products have less connection to a therapeutic purpose, such as the prevention of disease. This is by contrast to hospital grade disinfectants or disinfectants with specific claims, where there is a clear expectation that the products serve to minimise or prevent the spread of disease.

The Taskforce on Reducing Regulatory Burdens on Business also referred to differing regulation of disinfectants in New Zealand and the impact this has for competition within the Australian and New Zealand markets. The comments of the Taskforce were made in the context of consideration of a trans-Tasman therapeutic products regulator. As this has not progressed, the issues identified by the Taskforce have not materialised and are not therefore a specific problem sought to be addressed. However, as detailed below, any option should minimise unnecessary trade barriers or restrictions on competition not only between Australia and New Zealand but also with other international trading partners.

D. Objectives of government action

The objectives of Government action are to:

- ensure the level of regulation for household and commercial disinfectants (without specific claims) and other products is commensurate with their proposed use;

- determine an appropriate regulatory framework for these products that:

  - maintains or enhances the current health, safety and environmental standard of the products, without imposing unnecessary regulatory burden on lower risk products;

  - is consistent with the objectives of the *Industrial Chemicals (Notification and Assessment) Act 1989* and *Therapeutic Goods Act 1989*; and

  - is in accordance with national approaches to ecologically sustainable chemicals management;

- as far as possible, align Australia's regulation of such disinfectants and other products with the international regulatory standards of major trading partners, therefore minimising any trade barriers or adverse impacts on competition;

- ensure that there is no automatic listing ("grandfathering") of unassessed chemicals onto the Australian Inventory of Chemical Substances (AICS) or the ARTG. This does not preclude generating alternative arrangements for products currently in commerce that contain unassessed chemicals;

- ensure that all costs associated with any change in regulation are cost-recovered from industry, noting that cost-recovery is Australian Government policy for chemicals and therapeutic goods;

- ensure clarity and certainty regarding the regulation of all disinfectants and other products, regardless of whether they are regulated by TGA or NICNAS; and

- enable proper monitoring and enforcement of compliance with any regulatory requirements (noting that the level of regulation should be commensurate with the risk of the product or its constituent chemicals).

E. Impacted Parties

The groups likely to be affected by any changes to the regulation of disinfectants are:

- industry

  - The disinfectants industry is global, characterised by companies marketing products across international boundaries.

  - Based on estimates provided by *Retail World,* as part of its 42nd Annual Report of trends in the grocery industry, disinfectants had a grocery value of

$50.6 million in Australia in 2008. This represented an increase of 9.6% on 2007. While this estimate is the best estimate available to Government, it should be noted that the *Retail World* report contained no definition of disinfectants so this may not directly equate with the types of products considered by TGA and NICNAS to be disinfectants.

- As disinfectants (without specific claims), sanitisers, sanitary fluids and antibacterial surface wipes are currently exempt from TGA regulation, Government does not hold any data on the number of companies operating in this sector. Attempts were made to address this data gap. This included sending surveys to industry bodies, phone contact with individual companies and peak bodies, review of data held by ABS and customs, internet searches and review of industry survey data. However, no reliable information was identified regarding the type or number of companies currently importing or manufacturing disinfectant products of the type under consideration.

- Different industry bodies will potentially be impacted in different ways. For example, under the NICNAS system, introducers of new chemicals (not currently in disinfectant products) will be required to be registered. The chemicals that they manufacture or import (i.e. introduce) will be required to be included on AICS or subject to an assessment certificate or permit, unless exempt. Formulators (e.g. downstream users of chemicals) will not be subject to new chemical notification and assessment or NICNAS registration requirements. However, formulators will still need to comply with efficacy standards for their disinfectant products.

- consumers – Household and commercial disinfectants (without specific claims) and other products are widely available and commonly used. It is therefore expected that the majority of Australian consumers have the potential to be affected by any proposed changes to regulation; and

- the Australian Government – The two organisations most likely to be affected by any changes will be NICNAS and TGA.

F. Options and Impact analysis

Options

Option 1: Maintain the status quo. This would mean that:

- hospital, household and commercial grade disinfectants (with specific claims) and hospital grade disinfectants (without specific claims) would continue to be regulated by TGA as, respectively, registrable or listable devices; and

- household and commercial grade disinfectants (without specific claims) as well as sanitisers, sanitary fluids and antibacterial surface wipes would continue to be exempt from entry on the ARTG but would be required to comply with TGO 54.

Option 2: Maintain current TGA regulation of registrable and listable disinfectants but transfer responsibility for the regulation of household and commercial grade disinfectants (without specific claims) as well as sanitisers, sanitary

fluids and antibacterial surface wipes to NICNAS (for regulation of their constituent chemicals). This option is based on the option referred to in previous consultation documents as Option 4.

- Under NICNAS, all new chemicals (i.e. chemicals not currently in commerce in disinfectant products) must be subject to a NICNAS assessment certificate or permit which allows introduction. Chemicals subject to an assessment certificate would then be listed on the AICS after no more than five years. Some exemptions may apply for low risk chemicals introduced in low volumes. The efficacy requirements for these products would also be maintained through a Code, standard or other document which would reflect the content of TGO 54.

- For chemicals already in commerce in disinfectants but not currently on the AICS, there will be no automatic listing of unassessed chemicals on the AICS. Instead, a mechanism will be developed whereby these chemicals will be recognised by NICNAS as existing chemicals in disinfectant products only. This will enable continued introduction without further assessment. However, under current revisions to the NICNAS Existing Chemicals Program, these chemicals, as with all existing chemicals on the AICS, would be screened and prioritised for assessment based on the risk profile of the chemicals.

- In conjunction with these changes it is also proposed that the definition of 'hospital grade disinfectant' be revised to more clearly indicate that it relates to hospitals and other clinical applications and to remove references to commercial premises such as beauty therapy, hairdressing and podiatry practices

As noted in the Introduction, three other options were considered in the Brooke-Taylor Report. These options are not considered viable for the following reasons:

- options 1 and 3 were not supported by the majority of stakeholders;
- option 1 (TGA regulation of hospital grade disinfectants only, with all others regulated by NICNAS) would result in products that make specific therapeutic claims being regulated by NICNAS (ie outside of the therapeutic framework). It is appropriate that all products used in a clinical setting and products making specific disease related claims are regulated in a therapeutic framework by the TGA;
- option 2 (TGA regulation of all products with specific therapeutic claims, irrespective of hospital grade status) would result in significant confusion for hospital/clinical facilities relying on the marketing claim of "hospital grade" as this requires the introduction of two different hospital grade marketing systems – one under the TGA (for products claiming to be hospital grade whilst making therapeutic claims) and one under NICNAS (for products claiming to be hospital grade whilst not making therapeutic claims); and
- option 3 (demarcation based on use/clinical setting, i.e. disinfectants for use in medical or health services regulated by TGA and all others by NICNAS) is not practical to implement as again, in common with option 2, two systems of hospital grade marketing claims would need to be implemented, with consequent confusion for the market.

As these options have been subject to extensive consultation and are not considered viable, no further analysis has been undertaken of these options in this RIS.

Impact analysis

Impacts of Option 1: Retain the status quo

Industry:
For companies that manufacture or supply products that are currently exempt disinfectants (or other products) there will be very little impact as the result of retaining the status quo. These companies will continue to be free from any regulatory fees or charges (in respect of the exempt products) but would continue to be expected to comply with TGO 54. As the TGA does not actively monitor compliance for exempt products, it is possible that some companies are non-complaint while others are compliant. This may continue any uneven playing field. While regulation of disinfectants varies between countries, it is not expected that the status quo creates unnecessary barriers to trade or restrictions on competition because exempt products are currently subject to such minimal regulation by the TGA (eg compliance with TGO 54 only).

Consumers:
Retaining the status quo is unlikely to have a significant impact on consumers. It could however be argued that the absence of any capacity by TGA or NICNAS to undertake toxicological assessment of new chemicals in exempt disinfectants and other products may pose risks to health and safety and potentially undermine consumer confidence. It is considered a less likely scenario that consumers do not expect the products, or the chemicals in such products, to be regulated by a national therapeutics or chemicals regulator.

Government:
This option does not address the Australian Government's directive, which has been supported by industry, to progress industry reforms for regulating disinfectant products.

There are risks to Government if the status quo is maintained. Both the TGA and NICNAS consider that there may be risks associated with the introduction of new chemicals into these products where such chemicals have not been subject to a risk assessment. The absence of risk assessment for new chemicals in these products is inconsistent with: the regulation of other disinfectants; and the regulation of chemicals in other household products. By maintaining the status quo Government would continue to only be able to take reactive action in the event of adverse health effects flowing from use of exempt disinfectants (or other products). Both the TGA and NICNAS would continue to have no opportunity to take a proactive, pre-market approach to addressing any risks.

Should public health and safety risks eventuate as a result of retention of the status quo, Government would also experience indirect impacts (such as health care costs which would ultimately be paid for by taxpayers) and criticism for inadequate regulation.

Impacts of Option 2: **Maintain current TGA regulation of registrable and listable disinfectants but (a) transfer responsibility for the regulation of exempt disinfectants and other products to NICNAS; and (b) make changes to definition of hospital grade disinfectant.**

Industry:

(a) Transfer of TGA exempt household and commercial disinfectants to NICNAS regulation

Appropriate regulation of these products has the potential to increase consumer confidence and this may have flow on benefits to industry.

For introducers of chemicals currently in commerce in disinfectant products and not on AICS (or subject to an assessment certificate or permit or eligible for exemption), the immediate impact will be the need to notify NICNAS of such chemicals. Once notified to NICNAS, the chemicals will continue to be able to be introduced. If the chemical is subsequently screened and prioritised by NICNAS as requiring assessment, various controls on the manufacture, handling, use and disposal of the chemical may be recommended, with costs dependent on the nature of the controls necessary to minimise public health, safety and environmental risks. However, it is not expected that these costs would be additional to what is currently in place as these chemicals are already subject to controls under state poisons and environmental protection legislation.

For introducers of chemicals contained in household and commercial grade disinfectants (without specific claims) and other products, the change in regulation is likely to lead to an increase in compliance costs. The extent of this increase will depend on a range of factors including:

- in relation to assessment fees, whether the disinfectant contains: chemicals currently in commerce in disinfectants; chemicals already on AICS; or, in the future, new chemicals. If, in the future, the product contains a new chemical or chemicals, the costs associated with pre-market assessment by NICNAS will be influenced by:

    - the volume of the chemical proposed to be introduced per year;
    - the hazard profile of the chemical; and
    - whether a toxicological assessment of the chemical has already been undertaken by TGA or a recognised overseas authority (eg Canada).

  Depending on these factors, the NICNAS fees and charges for pre-market assessment of a new chemical would vary from $16,199 at the upper end to $2742 at the lower end.

- in relation to registration costs regardless of whether the chemical introduced is new or existing, whether the introducer is already registered with NICNAS or is a new introducer of chemicals. If the introducer is already registered, then there will be no new regulatory costs (unless the level of registration changes). If the company is a new introducer, it will be required to be registered. Currently

NICNAS registration fees are tiered based on the total value of all relevant industrial chemicals imported and/or manufactured each year by each company. The current fees are:

Registration Level Description 2009-10	**Prices**
Tier 1 level : (total value: $1 - $499,999)	$381
Tier 2 level: (total value: $500,000 - 4,999,999)	$1,522
Tier 3 level: (total value: $5,000,000 or more)	$8,881

It should be noted that only the introducer of the chemical (be they the importer or Australian manufacturer of the chemical) must be registered and pay the appropriate fee. Any downstream users of the chemical (including formulators) are not required to be registered with NICNAS nor pay any fees, although they would still need to comply with product efficacy standards.

- whether the manufacturer of the product currently complies with TGO54. If the company manufacturing the end product (the household and commercial grade disinfectant or other product) is already complying with TGO54 (as they should be) then there will be no increase in compliance costs. If, however, they are not compliant and they choose to become so, there will be compliance costs associated with complying with the new equivalent of TGO 54.

The total number of chemicals in household and commercial disinfectants (and other products) that are not currently on AICS and the total number of introducers that are not currently registered with NICNAS are not known. The total costs to industry can not therefore be estimated. Attempts have been made to access this information but it is not publicly held and industry bodies have not, to date, provided the information.

The only data available to Government is that obtained from the ARTG which indicates that in October 2009 there were 138 listed disinfectants, 13 registered disinfectants and a total of 64 manufacturers. In the absence of further industry information, it is not possible to draw conclusions regarding the number of exempt disinfectants, the number of exempt products containing chemicals that are not on AICS or the number of manufacturers or introducers of exempt products containing chemicals that are not on AICS.

In terms of potential impacts on trade and competition, it is difficult to make a proper assessment in the absence of information about how many new chemicals are likely to be introduced, by how many introducers and whether these introducers operate domestically only or globally. As each country regulates these chemicals differently, it is also a challenge to measure the potential trade and competition impacts. It is, however, expected that this option would have greater potential impacts than Option 1.

(b) Changes to definition of hospital grade disinfectant

By changing the definition of hospital grade disinfectant so that it relates specifically to hospitals and other clinical applications and not to commercial premises such as beauty therapists, the strictest performance requirements will continue to apply to disinfectants manufactured for use in the high risk settings. The standards applying to

disinfectants manufactured for use in beauty therapy, hairdressing and podiatry would be the same as for all other commercial and household disinfectants not making specific claims. Amending the definition of hospital grade disinfectant:

- provides greater regulatory certainty for industry;
- ensures there are no arbitrary differences in regulation based on the type of commercial premise using the disinfectant; and
- ensures that where the risk of product failure arising from a lack of efficacy is substantially lower (eg disinfectants used in household or commercial setting that do not claim benefits in relation to disease) the regulatory burden is also lower.

It should be noted that there is nothing precluding beauty therapy salons etc, or for that matter ordinary consumers, from purchasing a hospital grade disinfectant or a disinfectant with a specific claim.

Consumers:
Regulation by NICNAS better ensures continued protection of public health, occupational health and safety and the environment. The main benefit to consumers is that there will be pre-market assessment of new chemicals in household and commercial disinfectants (without specific claims). This provides greater assurance of the safety of these disinfectants. As there will be likely increases in costs to industry, it is possible that these costs will be passed onto consumers. However, given the large size of the market and the fact that only introducers and not downstream formulators will be potentially subject to increased cost, it is not expected that the impact on consumers will be significant.

Government:
This option is the preferred option of TGA and NICNAS.

This option addresses the Government directive to progress regulatory reforms for disinfectants that are currently regulated by the TGA to ensure the level of regulation is commensurate with their proposed use.

This option reduces risks to Government because it enables NICNAS to act proactively by undertaking pre-market assessment of new chemicals (i.e. future disinfectant ingredients currently not in commerce). The level of pre-market evaluation required will depend on matters such as the volume of the chemical to be introduced and the hazard profile of the chemical. This risk-based approach reduces the risk of unnecessary over regulation.

This pre-market, proactive approach also reduces the risk of product failure in the case of household and commercial disinfectants not making claims (and other products). There will be costs to Government as the result of NICNAS undertaking additional chemical assessments but these costs will be recovered from industry through the NICNAS fees and charges regime.

G. Consultation

In addition to the consultation undertaken by NCCTG, the Banks Taskforce and by Dr Simon Brooke-Taylor, both NICNAS and the TGA have consulted widely on the

original four Options proposed in the Brooke-Taylor Report. This consultation has included:

- discussing the issues at meetings held with the NICNAS Industry Government Consultative Committee on 18 March 2008 and with the NICNAS Community Engagement Forum on 28 August 2007 and 27 November 2007;

- public meetings to discuss Dr Simon Brooke-Taylor's report and options in Sydney on 1 April 2008 (23 attendees) and in Melbourne on 7 April 2008 (24 attendees). Two meetings were held in each city, one at 10:00 am and one at 7:00 pm. At both venues only industry stakeholders attended. Some 250 people were sent an email advising meetings were planned and asking for an expression of interest form to be completed and returned. The meetings were also advertised on 29 March 2008 in the Melbourne Age, the Melbourne Herald Sun, the Sydney Daily Telegraph, the Sydney Morning Herald and on the TGA and NICNAS web-sites;

- stakeholder information session at the Canberra Hospital for the Infection Control Association on 22 April 2008 (21 attendees); and

- sending questionnaires to 51 stakeholders to collect regulatory impact data. Stakeholders to whom the survey was sent included ACCORD Australasia, the Medical Technology Association of Australia, Australian Self Medication Industry and the Australian Grocery Council peak bodies. Of these only 8 were returned by the due date, NICNAS followed up with calls to 14 organisations and received in total 10 completed questionnaires. The survey was also notified in the NICNAS Chemical Gazette and placed on the Government's Business Consultation Website.

As noted previously, consultation was largely on conceptual models for regulation. On the whole:

- health clinics and hospitals that purchase disinfectants for hospitals and health service use, strongly supported ongoing regulation of the safety and efficacy of hospital grade disinfectants and disinfectants making specific claims (such regulation is proposed to continue under either Option 1 or Option 2);

- industry stakeholders generally supported NICNAS, rather than the TGA, regulating disinfectants that do not make specific claims and are not hospital grade (as proposed by Option 2);

- there were mixed views from industry regarding the current TGA regulation, including the demarcation between registrable and listable products (this is not proposed to change under Option 1 or Option 2);

- various stakeholders noted:
    - the need to ensure safety and efficacy standard were maintained;
    - the need for further information about the costs of reforming regulation (one of the purposes of this RIS is to gain such information from industry);

- some public health stakeholders noted that environmental risk assessment by NICNAS would be an advantage (as proposed under Option 2 of this RIS); and

- a very wide range of views were advanced regarding TGO54 and necessary changes (this will be subject to a separate consultation process).

H. Conclusion and Recommended option

Option 1 does not appear to address the existing problems that are described in Part D of this RIS, is not supported by the majority of stakeholders and is not consistent with the objectives of Government action.

Option 2 would appear to be the preferred option. However, both NICNAS and TGA are aware that limited information is available about the likely impact because Government does not hold, and has not been able to access, information about:

- the number of products currently in commerce that contain chemicals that are not currently on AICS (or have not been assessed by TGA); and

- the likely number of introducers that are not already registered with NICNAS.

As noted above, in conjunction with this RIS, a further survey is being circulated to industry. It is hoped that this will generate further data on which realistic estimates of costs can be derived. This will assist in informing the final decision of Government regarding the preferred option.

I. Implementation and review

Should Option 2 be the final preferred option, this would be implemented through:

- the creation of a NICNAS mechanism to enable disinfectant ingredients currently in commerce to be recognised as existing chemicals for the purposes of continued introduction in disinfectant products – this may require amendments to the *Industrial Chemicals (Notification and Assessment Act) 1989;*

- preparing an Excluded Goods Order to exclude the exempt products from the TGA regulatory framework so that they can be regulated by NICNAS; and

- the creation of a new mechanism to enable the substance of TGO54 to continue to apply to disinfectants (and other products) no longer regulated by the TGA;

These amendments and instruments would be the subject of further consultation with stakeholders.

NICNAS would monitor the effectiveness of the changes on an ongoing basis and would provide routine reports on the operation of, and compliance with, the new requirements to the following groups:

- the Industry Government Consultative Committee;

- the Community Engagement Forum; and
- the NICNAS Industry Engagement Group;
- the National Coordinating Committee on Therapeutic Goods; and
- States and Territories Memorandum of Understanding Group.

Each of these committees (collectively comprising all of the key stakeholders) will be able to provide advice on implementation issues.

It is expected that in accordance with NICNAS standard practice, a review of the regulation of disinfectants would be undertaken following a reasonable implementation period.