

## **TRICLOSAN – COMMENTS RECEIVED**

NICNAS received comments from Applicants and other interested parties during the public comment phase of the triclosan report. The comments have been summarised to highlight the issues. Responses to the comments are provided below. The responses to the comments are not part of the variation decisions and are not subject to an appeal to the Administrative Appeals Tribunal.

### **1. SouthAustralian Health (enhealth)**

#### **Comment 1.1:**

The assessment could have chosen local irritation as the critical effect, given that the major route of exposure to triclosan in the general community is by dermal exposure in cosmetic and personal care products.

SA Health is not convinced that triclosan in cosmetic and personal care products are without risk. In the event that the assessment chose a NOAEL for 'local irritation' as the relevant critical effect from the 14-day dermal study in rats [7.5 mg/kg bw day (m) and 3.5 mg/kg bw/day (f)], the calculated MOE would be less than 100 for an adult exposed to approximately 400 µg/kg bw/day triclosan following dermal application of a single product (section 15.4.3). A similar argument can be made for dermal exposure in children.

#### **NICNAS response 1.1:**

The NICNAS risk assessment has addressed the local irritant effect of triclosan as an acute effect. According to the Approved Criteria for Classifying Hazardous Substances (NOHSC, 2004), triclosan at concentrations  $\geq 20\%$  is classified as an irritant to skin in workplaces (Recommendation 1 of the report - 'Irritating to skin (R38)'). The 14-day dermal toxicity study, from which the NOAEL for local irritation is derived used 100% triclosan (at 3.5 and 7.5 mg/kg bw/day dose levels) on rat skin. Protective measures, such as use of overalls and gloves, are included in the Sample MSDS (Appendix I of the report) to protect workers from skin irritation when using 100% triclosan raw material in workplaces.

Consumer products contain triclosan at concentrations ranging from  $<0.01$  to 0.5% (typically 0.3%, Table 15.1 of report). These concentrations are very low and unlikely to cause skin irritation. Therefore it was not considered appropriate to use skin irritation in the repeat dose risk assessment to estimate MOE for the general community including children.

#### **Comment 1.2:**

General omissions or lack of detail - health risks that may arise from incineration of triclosan, disposing of bulk quantities of triclosan-containing personal care products or cleaning products in landfill and potential treatment of landfill leachate containing triclosan; impact of triclosan spills on fresh water and sediment dwelling organisms, potential use of ash containing triclosan/dioxins for soil conditioning and presence of triclosan in greywater in the context of water restrictions and increased greywater usage.

**NICNAS response 1.2:**

It is considered that the disposal of bulk quantities of triclosan in personal care products to landfill will be an infrequent event. Further, given the low percentages of triclosan present in such products (typically 0.3%) it is anticipated that it will not lead to significant leaching of triclosan from the landfill site since triclosan will be adsorbed to soils.

The impact of triclosan spills on freshwater and sediment dwelling organisms would be expected to be significant given the high toxicity of triclosan to aquatic organisms. This will be addressed by strengthening the advice in the Accidental Release on the MSDS to include the following statement: Highly toxic to aquatic organisms, prevent entry into drains and surface waters.

Incineration is limited in Australia. Any incineration will lead to the destruction of most if not all triclosan present and may give rise to small amounts of dioxins. These very low quantities of dioxins are not expected to cause significant health risks. Consequently, the use of ash as a soil conditioning agent is not expected to lead to significant environmental contamination of triclosan or dioxin congeners derived from it (Section 16.1.7 of the report).

The reuse of domestic grey water containing triclosan is not considered to pose a risk to the environment as it is anticipated that triclosan will be present in the grey water in very small amounts (triclosan detected in greywater at ng/L - Section 16.3.1 of the report) and would be expected to degrade when applied to the soil based on recently published literature.

**2. Advocate for the Consumer, Cosmetic, Hygiene and Specialty Products Industry (ACCORD)****Comment 2.1:**

Work with European authorities to harmonise the hazard classification - We understand that the proposed hazard classification “*R23 Toxic by inhalation*” is currently a unique Australian classification. As the Australian hazard classification system is aligned with the European dangerous preparations directive (*Directive 1999/45/EC*) for human health hazards, we urge NICNAS to work with its European regulatory agencies to establish an internationally harmonised classification.

**NICNAS response 2.1:**

NICNAS supports international harmonisation and the final triclosan report will be forwarded to international regulatory agencies for consideration of the hazard classification.

**Comment 2.2:**

Recommendation to the National Drugs and Poisons Scheduling Committee (NDPSC) - Discuss the scope and the wording of the proposed triclosan schedule entry with the Industry prior to submission to the NDPSC.

ACCORD notes in Recommendation 4 of the draft report on page xxi. NICNAS appears to be recommending scheduling of triclosan if it is present in cosmetics as a

preservative unless the concentration of triclosan is less than or equal to 0.3% in cosmetic preparations. ACCORD tentatively supports this recommendation, if the use of triclosan as deodorant is also included in the exclusion. The EU Cosmetics Directive lists both deodorant and preservative as uses of triclosan.

We are also concerned with the way the recommendation is phrased. It is not clear from reading of the recommendation that NICNAS wants scheduling of triclosan with exclusions applied for cosmetics containing 0.3% or less of triclosan. It is also unclear what parent entry is being proposed for triclosan, or the proposal for non-cosmetic categories of industrial chemicals, whether any exclusion from scheduling is being proposed.

We recommend that NICNAS discuss these scheduling matters further with the Industry prior to the finalisation of the recommendations to be put to the NDPSC.

**NICNAS response 2.2:**

A proposal for scheduling of triclosan in cosmetics and personal care products will be submitted to the National Drugs and Poisons Schedule Committee (NDPSC) after finalisation of the NICNAS triclosan assessment. The recommended scheduling of the parent chemical will be based on the hazard profile of the chemical (Section 20.2.1). The submission will consider the current listing of triclosan in the EU Cosmetics Directive to promote harmonisation.

With regard to the non-cosmetic categories, NICNAS will monitor the use of triclosan in cleaning products and consider the need for a cut-off for these products. Based on the information gathered, further recommendations may be made to the NDPSC.

### **3. UNILEVER**

**Comment 3.1:**

From a scientific perspective, this report has been compared with other recent risk assessments resulting in very similar outcomes.

**NICNAS response 3.1:**

Comments noted.

**Comment 3.2:**

Unilever Australasia as a participating stakeholder in the Priority Existing Chemical review respectfully requests NICNAS to consider the views and positions of other international trading economies such as EU to promote harmonised hazard assessment and scheduling implications for Australia to minimise barriers to trade.

**NICNAS response 3.2:**

NICNAS supports international harmonisation and on finalisation of the triclosan assessment report, it will be forwarded to international regulatory agencies for consideration of the NICNAS recommendations.

#### **4. Australian Self-Medication Industry Inc. (ASMI)**

##### **Comment 4.1:**

ASMI is concerned that Recommendation 4 has the potential for unintended implications to registered therapeutic goods where triclosan is present as an active ingredient. In these products triclosan is typically used at levels between 0.5% and 2% in products including acne treatment products, eczema treatment products, antiseptics and toothpastes (with therapeutic claims beyond permitted oral hygiene claims).

The use of the term ‘personal care product’ in the wording would potentially require defining as it has the potential to broaden the scope of the NDPSC’s consideration of triclosan. The wording would need to be very carefully considered to avoid encompassing the use of triclosan as a therapeutic.

Specific implications to registered therapeutic goods to comply should they indeed be impacted.

If therapeutic products are caught up in any triclosan recommendation, this process will not provide a sufficient period for product sponsors to react to implement the change without significant commercial impact to their business. Reacting to either intended or unintended implications of this recommendation does have far reaching consequences to therapeutic goods, which will have significant commercial impact if implementation timeframes are not carefully considered.

In the Overview of the draft, the section *Public exposure and health risks*, is worded in such a way to suggest the data is inconclusive and that the recommendation is extrapolated from very limited data - “Potentially, the greatest source of exposure to consumers (adults, young children and babies), and thus the risk of an adverse health effect, is from the use of cosmetic and personal care products containing triclosan. Although the chronic health risk from such products is generally considered to be low, there are exposure data from volunteer studies that suggest that repeated use of a range of triclosan-containing products could increase the exposure levels, and therefore the potential health risk (see Recommendation 4.)”

As there appears to be no conclusive evidence of a public health imperative requiring immediate achievement of this restriction, the proactive initiative should not be implemented to the disadvantage of industry. Suitable transition periods need to be included in the recommendation to allow reformulation of replacement products to be made available.

##### **NICNAS response 4.1:**

NICNAS’s proposal for scheduling of triclosan and its use in cosmetics and personal care products will be submitted to the National Drugs and Poisons Schedule Committee (NDPSC) on finalisation of the triclosan report. ASMI comments are noted and will be taken into consideration when submitting the proposal to the NDPSC. NICNAS’s proposal to the NDPSC will cover the uses of triclosan that are within the scope of the *Industrial Chemicals (Notification and Assessment) Act, 1989* (the Act). Personal care products will be defined as consistent with the Act Schedule 1 of the *Cosmetics Standard (2007)*.

The NICNAS submission to the NDPSC will be subject to the NDPSC process of stakeholder consultation.

**Comment 4.2:**

ASMI seeks clarification regarding alternative mechanisms within the Industrial Chemicals framework by which restrictions to the use of chemicals within product categories can be affected without unintended impact to other categories and with greater flexibility for implementation timeframes - eg within the Australian Inventory of Chemicals and through Section F of the cosmetic guidelines.

**NICNAS response 4.2:**

NICNAS notes ASMI's comment on alternative mechanisms within the Industrial Chemicals framework for restricting the use of chemicals within product categories such as use of the Australian Inventory of Chemical Substances.

The NICNAS Cosmetic Guideline (2007) is a guidance document and Section F lists chemicals that are currently listed in the SUSDP.