National Toxics Network Inc.

working towards pollution reduction, protection of environmental health and environmental justice for all

TRICLOSAN: Priority Existing Chemical Draft Assessment Report

Submission to the Department of Health and Aging NICNAS

Application for Variation of Report Form 4a (attached)

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Summary

The assessment is inadequate and inconclusive in some areas due to lack of data or conflicting data and the subsequent conclusions and recommendations drawn.

Despite the evidence that triclosan is finding its way into the Australian environment through discharges from sewage treatment plants and the use of treated effluent and biosolids, which presents a significant environmental risk, and triclosan's detection in human breast milk, urine, maternal blood and cord blood, the assessment still supports the continued use of triclosan in a broad range of products with only relatively minor recommendations for further investigation and regulation.

The complete omission of determining the amounts of triclosan in imported articles and products (which could be very significant) as well as determining the level of leaching from such articles, undermines the validity of the assessment and its recommendations, because it's not based on an accurate assessment of how much triclosan is being imported into Australia and the risks of exposure from these sources and different use and disposal patterns.

Given the continued risks posed to the environment and public health by the widespread use of triclosan in cosmetics, personal care products and household articles, NTN believes regulators should act with precaution and only permit triclosan for use in contexts where its benefits clearly outweigh the risks such as in hospitals and clinics.

The beneficial uses of triclosan should not be compromised by the overuse of triclosan in a wide range of items where it is not required and it is known to cause pollution and may contribute to microbial resistance.

NTN's position is that triclosan should only be permitted in domestic products and articles (locally manufactured and imported) if independent and conclusive evidence indicates that it does not cause unnecessary harm to human health or the environment and there is evidence of benefits from consumer products containing triclosan over similar ones not containing them.

1. Imported articles and products

"This assessment did not take into account the health or environmental effects of Triclosan imported as part of finished plastic and textile articles, as no information was provided on the amounts of Triclosan in imported articles." (page xiv).

Millions of Australians, including babies and children, are exposed to triclosan from imported articles and products. Considering that the embedded triclosan apparently provides its antibacterial effect by being released at the surface of an article, this type of article is deliberately releasing triclosan, which comes under the control of NICNAS.

If a consumer addressed a concern to the ACCC surely the ACCC would work with NICNAS as the chemical control authority to manage the issue.

NTN fails to understand why NICNAS did not find a way to determine quantities of triclosan in imported articles as well as arranging to analyse typical items for the actual embedded triclosan concentration and to determine the surface concentration achievable that could be released in order to get a more accurate picture of triclosan use and exposure in Australia.

2. Dioxin impurities in Triclosan

Impurities in Triclosan from Indian and Chinese producers (p10) show levels of 2,3,7,8-TetraChloro-Dibenzo-p-Dioxin to range from 17.2 to 1720 pg/g and 2,3,7,8-TetraChloro-DibenzoFuran to range from 0.43 to 207.3 pg/g respectively. The USP limit for both is 1 pg/g.

Considering the potentially high levels of dioxin impurities found from some of these sources, and the fact that a large proportion of triclosan embedded in imported products is likely to originate from these sources, NTN believes a stronger Recommendation (6b) is required for industry than a 'voluntary measure for importers to check'.

NTN recommends that it be mandatory for the values provided in the Certificates of Analysis for raw materials from all sources to be audited and independently analysed until they are shown to be complying with the USP.

Given Australia's obligations under the *Stockholm Convention on Persistent Organic Pollutants* and requirements under the *National Dioxins Program,* NTN believes all agencies with responsibility for products containing triclosan should have a responsibility to ensure those products comply with the USP specifications.

Subsequently, NTN recommends stronger wording in Recommendation (6a). Rather than just 'note' that the USP has set limits for dioxins in therapeutics, the TGA should act to ensure products that they regulate meet those requirements. This obligation should also be extended to all agencies that have responsibility for products potentially containing these dangerous impurities, including NICNAS, APVMA and ACCC.

3. Classification of Triclosan

Triclosan raw material as the powder, is being classified as a Class 6.1 TOXIC Dangerous Goods due to Acute Inhalation Toxicity.

NICNAS has used data obtained from a 21-day repeat dose inhalation toxicity study in rats (Ciba Geigy Limited, 1974) to determine that Triclosan as a raw material is Acutely Toxic by inhalation. "Considering that >50% deaths occurred after a single exposure (2 h) at 1.3 mg/L, the LC50 for Triclosan is determined to be <1.3 mg/L (or <1300 mg/m3)." (page 278).

Based on advice given to NTN from Mr Jeff Simpson, Hazardous Materials Consultant, this will raise the issue for industry that raw material Triclosan shipped by sea will arrive in Australia as Class 9 ENVIRONMENTALLY HAZARDOUS SUBSTANCE, SOLID, N.O.S. (TRICLOSAN) UN 3082 and provide them a dilemma as to which UN No. they order it with.

Then industry will have to provide a local MSDS and relabel it as Class 6 TOXIC, SOLID, ORGANIC, N.O.S. (TRICLOSAN), UN 2811 to transport Triclosan in Australia.

Note: The ADG Code Competent Authorities will need to look at this classification and decide whether they agree that raw material TRICLOSAN is correctly classified as Class 6.1.

It would have been useful in the time that NICNAS has taken prepare the PEC, for it to have arranged that the actual Acute Inhalation LC50 test on rats be carried out. This would then have provided test data using today's testing protocols, and have provided a firm basis to ask for a change worldwide.

4. Triclosan an environmental pollutant

Triclosan is highly toxic to fish and aquatic invertebrates (EC/LC50 < 1 mg/L) and very highly toxic to algae (EC50 < 0.1 mg/L) indicating that potential for damage to the environment. Triclosan would meet the adverse environmental effects criterion of POP chemicals, but the assessment states it was unlikely to meet the persistence criteria for a Stockholm Convention Persistent Organic Pollutant (POP).

Triclosan's high environmental toxicity was the reason it was declared a PEC. It has been shown that triclosan *is* relatively persistent under anaerobic (low oxygen) conditions. Triclosan has become one of the most frequently detected compounds in waterways in the USA[1] and Sweden, and Australia.

The assessment says: "*Triclosan is predominantly released to the sewerage system in various cosmetics and personal care products" (page xvii).*

The assessment says: "*Studies indicate that Triclosan is present in biosolids at levels which, when applied to soil may result in adverse effects on plants" (page xviii).*

NTN fails to see how recommendations (8a, 8b, 8c) will effectively address environmental safety. If the source of the pollutant is known and, it's known that it causes environmental damage and it persists in the environment, then the best way to protect the environment would be to limit the pollutant at the source. There seems little point recommending studies that won't result in any reduction of the pollutant and risks to the environment.

More exposure sources

As well as cosmetics and personal care products, triclosan is also released to the environment (aquatic and terrestrial) from the use of household articles that have not been assessed by NICNAS such as sponges, cutting boards and fabrics for example.

The use of triclosan in paints is more extensive than suggested and presents a greater risk of exposure than stated. Triclosan is also found in acrylic paints specifically recommended for use inside homes to protect against 'harmful bacteria'[2]. These paints require washing out of painting equipment in water, which would find its way into the environment.

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[1] Kolpin, D. W., E. T. Furlong, M. T. Meyer, E. M. Thurman *et al*. (2002) Pharmaceuticals, Hormones, and other organic wastewater contaminants in U. S. streams, 1999-2000: A national reconnaissance. Environ. Sci. Tech-nol. 36:1202-1211.

[2] For examples see Taubmans Easy Coat with Microban and White Knight paints http://www.taubmans.com.au/Professional/Easycoat.asp and http://www.whiteknightpaints.com.au

The ACCC must also investigate whether the claims made by these paints are indeed correct and whether they contain dioxin impurities or could create dioxins when exposed to sunlight.

Methyl triclosan

"Several studies highlight the production of methyl-triclosan during wastewater treatment, probably due to microbial methylation" (page 139)

Methyl triclosan, a breakdown product of triclosan, is actually more lipophilic than the parent compound and, therefore, more bio accumulative[3]. It has also been measured in fish[4].

While the assessment makes recommendations in relation to to STPs, biosolids and soils for triclosan, NTN believes these recommendations do not go far enough. It is vital that the toxic breakdown products are also tested for in the environment, including STPs, wastewater, biosolids and soil as they potentially represent a greater risk.

Chloroform

Research in 2005[5] has shown that triclosan used in household dishwashing soaps reacts with chlorinated water to produce significant quantities of chloroform, which can exceed US EPA regulatory levels.

US EPA classifies chloroform as a probable human carcinogen. The presence of trihalomethanes such as chloroform in drinking water has already been linked with human bladder cancers and miscarriages. In light of other studies showing that the levels of trihalomethanes in people's blood increase when they shower, the research raises questions about exposures to chloroform when antimicrobial soaps are used.

The study also suggests that the reaction of triclosan with chlorine could be producing highly chlorinated dioxins in the presence of sunlight. Under normal household washing up conditions, triclosan reacts with free chlorine to generate more than 50 parts per billion (ppb) of chloroform in the dishwater. When combined with the other trihalomethanes already in the water, the additional chloroform could easily exceed the concentration of total trihalomethanes (80 ppb), the US EPA's maximum allowable amount.

Since chloroform and other trihalomethanes are highly volatile, there is a likelihood that washing dishes with triclosan-containing liquid could cause additional significant exposure to these volatiles through inhalation and potentially through skin absorbtion. The research also shows that triclosan's reaction with free chlorine produces a number of chlorinated triclosan intermediates or breakdown products, including 2,4 dichlorophenol, which is now detected in the blood of adults and children. In the presence of sunlight, these chlorinated intermediates can also produce dioxins.

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[3] Lindstrom, A., I. J.Buerge, T. Poiger, P. Berqvist *et al*. (2002) Occurrence and environmental behavior of the bactericide triclosan and its methyl derivative in surface waters and in wastewater. Environmental Science and Technology 36(11): 2322-2329.

[4] Balmer, M.E., Poigner, T.,Droz K.R., Berqvist, M.D.,and Busler, H.(2004) Occurenence of methyl triclosan in fish from various lakes in Switzerland. *Environ Science and Technology, Vol 38, 390-395*

[5] Krista L. Rule, Virginia R. Ebbett, and Peter J. Vikesland (2005) Formation of Chloroform and Chlorinated Organics by Free- Chlorine-Mediated Oxidation of Triclosan *Environ. Sci. Technol.,* 39 (9), 3176 -3185,

Other studies have demonstrated that sunlight converts triclosan in river water to produce dioxins[6], the highly chlorinated more toxic dioxins could be generated from triclosan's breakdown products.

While it is unlikely that such dioxins would be generated during dishwashing even near a window on a sunny day because the glass would screen out most of the ultraviolet light necessary to produce the dioxin, the research suggests that dioxins could be forming near swimming pools in some situations and perhaps on people using triclosan in hand soaps and moisturizers.

5. Triclosan and health risks

"The available data in humans and animals provides no evidence that Triclosan has the potential to cause harm to breastfed babies." (page xvi)

While this finding is welcome, NTN believes there is no place for any levels of a lipophilic bio-accumulative chemical in breast milk, especially if it can be avoided. We remain concerned about the levels of triclosan and its metabolites in breast milk and as it is closely correlated with personal care and cosmetic use, a consumer education program is warranted to warn people of potential risks.

Evidence of contact dermatitis, skin irritation and photoallergic contact dermatitis as well as eye irritation calls for a recommendation to require label warnings and consumer education for products likely to come onto dermal and eye contact.

NTN supports recommendation 4, to schedule triclosan in the SUSDP and further monitoring of cleaning products, however we would also like to see an assessment of imported articles containing triclosan such as plastics, fabrics and paints, and in particular babies and children's products.

Human plasma and milk

Triclosan has been shown to be present in human plasma and milk at concentrations that are well correlated to the use of personal care products containing triclosan. Whereas an Australian study suggests that the exposure to triclosan among different groups of the Australian population is relatively homogenous.

These Australian blood datasets were compared with previous measurements of triclosan concentrations in human plasma from Sweden, where the use of triclosan is expected to be low due to consumer advisories. **The triclosan concentrations were a factor of 2 higher in Australian serum than in Swedish plasma.**

In a 2006 Swedish study[7], plasma and milk were sampled from 36 mothers and analyzed for triclosan. Nine of the mothers used toothpaste, deodorant or soap containing triclosan. Triclosan and/or its metabolites were omnipresent in the analyzed

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[6] D. E. Latch, J. L. Packer, B. L. Stender, J. VanOverbeke, W. A. Arnold*, K. McNeill*, Aqueous photochemistry of triclosan: Formation of 2,4-dichlorophenol, 2,8-dichlorodibenzo-p-dioxin and oligomerization products, *Environ. Toxicol. Chem.* (2005), *24*, 517-525.

[7] Allmyr M, Adolfsson-Erici M, McLachlan MS, Sandborgh-Englund G. Triclosan in plasma and milk from Swedish nursing mothers and their exposure via personal care products. *Sci Total Environ.* 2006 Dec 15;372(1):87-93. Epub 2006 Sep 26.(Institute of OdontInstitutet, PO Box 4064, SE-141 04 Huddinge, Sweden. mats.allmyr@itm.su.se)

plasma and milk.

The concentrations were higher in both plasma and milk from the mothers who used personal care products containing triclosan than in the mothers who did not. This showed that personal care products containing triclosan were the dominant, but not the only, source of systemic exposure to triclosan. The concentrations were significantly higher in plasma than in milk, indicating that infant exposure to triclosan via breast milk is much less than the dose in the mother.

Endocrine Disruptor

Triclosan's endocrine disrupting potential needs further investigation. The chemical structure of triclosan closely resembles certain estrogens and one study suggests that triclosan is weakly androgenic, causing changes in fin length and sex ratios in fish.[8]

Triclosan can affect the thyroid gland, significantly altering frog metamorphosis at exposure levels equivalent to those currently found in the environment and human tissues. [9] The researchers concluded that triclosan may represent a potential health risk to human hormone action as well.

ENDS

[8] Foran, C. M., E.R. Bennett, W.H. Benson (2000). "Developmental evaluation of a potential non-steroidal estrogen: triclosan." Marine Environmental Research 50: 153-156.
[9] Veldhoen, N., R. C. Skirrow, et al. (2006). "The bactericidal agent triclosan modulates thyroid hormone-associated gene expression and disrupts postembryonic anuran development." *Aquat Toxicol* 80(3): 217-27.