

This article was downloaded by: [124.171.113.129]

On: 11 March 2012, At: 23:39

Publisher: Routledge

Informa Ltd Registered in England and Wales Registered Number: 1072954 Registered office: Mortimer House, 37-41 Mortimer Street, London W1T 3JH, UK



International Journal of Environmental Studies

Publication details, including instructions for authors and subscription information:

<http://www.tandfonline.com/loi/genv20>

Letter to the Editor, International Journal of Environmental Studies

A. Bleaney Dr OBE MB ChB FACRRM ^a

^a 4 Bayview Ave, Binalong Bay, Tasmania, 7216, Australia

Available online: 05 Mar 2012

To cite this article: A. Bleaney Dr OBE MB ChB FACRRM (2012): Letter to the Editor, International Journal of Environmental Studies, International Journal of Environmental Studies, DOI:10.1080/00207233.2012.668087

To link to this article: <http://dx.doi.org/10.1080/00207233.2012.668087>



PLEASE SCROLL DOWN FOR ARTICLE

Full terms and conditions of use: <http://www.tandfonline.com/page/terms-and-conditions>

This article may be used for research, teaching, and private study purposes. Any substantial or systematic reproduction, redistribution, reselling, loan, sub-licensing, systematic supply, or distribution in any form to anyone is expressly forbidden.

The publisher does not give any warranty express or implied or make any representation that the contents will be complete or accurate or up to date. The accuracy of any instructions, formulae, and drug doses should be independently verified with primary sources. The publisher shall not be liable for any loss, actions, claims, proceedings, demand, or costs or damages whatsoever or howsoever caused arising directly or indirectly in connection with or arising out of the use of this material.

LETTER TO THE EDITOR

Sir,

For decades, ecotoxicologists have stated that NOEL/LOEL (NOEL = no observed effect level; LOEL = lowest observed effect level) methodology is an unsound scientific concept and should no longer be used [1].

In order to achieve human and environmental protection, guidelines need to be set using reliable, consistent and robust methodology to prevent exposing ecosystems to toxic insults (intermittent and/or continuous) from both individual toxicants and complex mixtures.

Risk assessments for industrial activities, including those in water catchments, currently rely on the production of raw field data along with desktop risk modelling. It is a challenge to interpret the accuracy with which the data represent the actual impacts on the receiving environment due to the differing mixtures of chemicals in varying concentrations present in the real world setting, and the difficulty of determining how to measure their effects on ecosystems.

Guidelines for the protection of water quality and the environment have shifted significantly over the last few decades from simplistic chemical concentration ceilings (ANZECC 1992 [2]) to site specific toxicity testing (ANZECC 2000a & b [3]) in an attempt to overcome these problems. It is critical to have reliable and robust statistical methodology for supporting guideline derivations.

The application of NOEL/LOEL methodology to derive guidelines is flawed because it has the potential to underestimate adverse biological effects of toxicants (and mixtures of toxicants). This is in direct contrast to the intention of the ANZECC 2000 guidelines [3] which aspire to protect environmental health.

The central dogma of toxicology, left over from the seventeenth century, is that the 'dose makes the poison' with a relationship between an acute toxic reaction (the response) and the amount of 'poison' received (the dose). Important adverse biological effects occurring both acutely and decades, if not generations, later have now been repeatedly demonstrated, with non-monotonic dose-response curves.

Yet it is often assumed, that there is always a dose below which no response occurred [4]. There is a distinct difference between 'no response could be measured' (lack of evidence) and 'no response occurred' (no effect). Many chemicals and toxicants, such as endocrine disruptors, adversely affect cell function at extremely low levels (parts per trillion) and at higher doses, but less so at some other intermediate levels (including bi-phasic, non-linear, 'U' shaped response curves) [5,6]. Factors that affect the results of -toxicity tests include temperature, light, food and stressful environmental conditions, including pollution and radiation [7,8]. Other factors relating to the animal itself include age and developmental status, sex, health, and hormonal status.

Many studies [9] have shown that NOEL and LOEL are inconsistent between studies as they are often just exposures selected by those doing the testing rather than reflecting the actual toxicity along a non-linear dose-response curve. The effects measured are usually toxicity and death rates. Adverse hormonal, immune, epigenetic or other more subtle cell malfunctions are not measured. Laboratory derived NOELs/LOELs in which conditions are tightly controlled are unlikely to reflect environmental conditions.

Alternative well described and used scientific statistical methodology exists. Curve-fitting has long been a recognised accurate method to show scientific data for a wide variety of data sets and a Bayesian approach is gaining similar recognition [10,11].

The uses therefore of NOEL and LOEL to describe 'safe' levels of exposure are non-valid and erroneous due to the false assumptions on which they are based. 'Life is not like that'; and science must measure life as it is. This includes allowing for the effects of chemical mixtures [12].

Landis and Chapman [13] have called for regulatory agencies to eliminate hypothesis testing results and revise the methodologies used to model exposure effects and risk. Fox [14] asked that changes be made through education rather than regulation. Landis and Chapman coherently argue [15] that education of ecotoxicologists has not prevented use of these flawed statistical methods in published articles; often allowing false results and conclusions to masquerade as 'best science' to inform policy decisions.

It would seem obvious that the use of these types of statistical analysis (NOEL and LOEL) should not be allowed to continue in peer reviewed published articles that are used by regulators to determine policy which is to the detriment of animal, human and environmental health. It is to be hoped that editors are alert to the risks, as there appears to be a lack of sensitivity in the academic and decision-making circles where such adverse impacts may be underestimated, with very serious consequences for public health.

Yours truly,
Dr. A. Bleaney OBE MB ChB FACRRM
4 Bayview Ave
Binalong Bay
Tasmania 7216
Australia
E-mail: sthelensmedc@vision.net.au
© 2012 Taylor & Francis

TPEHN www.sourcewatch.org/index.php?title=Pollution_Information_Tasmania
Break O'Day Catchment Risk Group
Member of National Toxic Network <http://www.ntn.org.au>
14 February 2012

References

- [1] Chapman, P.M., Cardwell, R.S. and Chapman, P.F., 1996, A warning: NOECs are inappropriate for regulatory use. *Environmental Toxicology and Chemistry*, **15**, 77-79.
- [2] Australian and New Zealand Environment and Conservation Council (ANZECC), 1992, Australian Water Quality Guidelines for Fresh and Marine Waters. ANZECC, Canberra, Australia.
- [3] Australian and New Zealand Environment and Conservation Council (ANZECC), 2000a, Australian and New Zealand Water Quality Guidelines; 2000b, Australian Guidelines for water quality monitoring and reporting. ANZECC, Canberra, Australia.

- [4] Sheehan, D.M., Willingham, E., Gaylor, D., Bergeron, J.M. and Crews, D., 1999, No threshold dose for estradiol-induced sex reversal of turtle embryos: how little is too much? *Environmental Health Perspectives*, **107**, 155–159.
- [5] Welshons, W.V., Thayer, K.A., Judy, B.M., Taylor, J.A., Curran, E.M. and vom Saal, F.S., 2003, Large effects from small exposures. I. Mechanisms for endocrine disrupting chemicals with estrogenic activity. *Environmental Health Perspectives*, **111**, 994–1006.
- [6] Andrade, A.J.M., Grande, S.W., Talsness, C.E., Grote, K. and Chahoud, I., 2006, A dose–response study following *in utero* and lactational exposure to di-(2-ethylhexyl)-phthalate (DEHP): Non-monotonic dose–response and low dose effects on rat brain aromatase activity. *Toxicology*, **227**, 185–192.
- [7] Mancuso, M., Pasquali, E., Leonardi, S., Rebessi, S., Tanori, M., Giardullo, P., Borra, F., Pazzaglia, S., Naus, C.C., Di Majo, V. and Saran, A., 2011, Role of connexin43 and ATP in long-range bystander radiation damage and oncogenesis *in vivo*. *Oncogene*, **30**, 4601–4608.
- [8] Guinan, E.C., Barbon, C.M., Kalish, L.A., Parmar, K., Kutok, J., Mancuso, C.J., Stoler-Barak, L., Suter, E. E., Russell, J.D., Palmer, C.D., Gallington, L.C., Voskertchian, A., Vergilio, J.A., Cole, G., Zhu, K., D’Andrea, A., Soiffer, R., Weiss, J.P. and Levy, O., 2011, Bactericidal/permeability-increasing protein (rBPI21) and fluoroquinolone mitigate radiation-induced bone marrow aplasia and death. *Science Translational Medicine*, **3**(110), 110–118.
- [9] Warne, M. St J. and van Dam, R., 2008, Opinion piece. NOEC and LOEC data should no longer be generated or used. *Australian Journal of Ecotoxicology*, **14**, 1–5.
- [10] Fox, D.R., 2010, Statistics and ecotoxicology: shotgun marriage or enduring partnership? *Integrated Environmental Assessment and Management*, **6**, 499–506.
- [11] Fox, D.R., 2010, A Bayesian approach for determining the no effect concentration and hazardous concentration in ecotoxicology. *Ecotoxicology and Environmental Safety*, **73**, 123–131.
- [12] Kortenkamp, A., Backhaus, T. and Faust, M., 2009, *State of the Art Report on Mixture Toxicity*. (The School of Pharmacy, University of London (ULSOP)).
- [13] Landis, W.G. and Chapman, P.M., 2011, Well past time to stop using NOELs and LOELs. *Integrated Environmental Assessment and Management*, **7**(4), vi–viii.
- [14] Fox, D.R., 2012, Response to Landis and Chapman (2011). *Integrated Environmental Assessment and Management*, **8**(1), 4.
- [15] Landis, W.G. and Chapman, P.M., 2012, Author’s reply. *Integrated Environmental Assessment and Management*, **8**(1), 5.