ecotox
SERVICES AUSTRALASIA

24 November 2005

Ms Maureen Weeks
Committee Secretary
Senate Rural and Regional Affairs and Transport Committee
Department of the Senate
Parliament House
Canberra ACT 2600

Re: National Animal Welfare Bill 2005- Submission

Dear Maureen

Thankyou for the opportunity to provide a submission to the ***National Animal Welfare Bill 2005***, attached to this letter.

Ecotox Services Australasia Pty Limited (ESA) provides ecotoxicological testing laboratory services for the assessment of chemicals, effluents, contaminated ground waters and sediments to fulfil various State and Federal environmental protection and assessment requirements. We are pleased to see the introduction of a federal bill for the protection of animals, however there are several aspects to the Bill in its current form that will negatively impact both on best-practice environmental testing and protection measures as well as have a detrimental effect on the viability of our business. These may be unintended consequences of the Bill, which I believe currently does not give sufficient weight to environmental protection issues. I wish to detail the nature of these points in our submission.

Ecotox Services Australasia Pty Limited complies with the *Australian Code for the Care and Use of Animals for Scientific Purposes* in all its laboratory testing activities. Research with invertebrates in the state of New South Wales is subject to the *Animal Research Act*, and toxicity tests with larval fish are performed by ESA under the Animal Research Authority issued to ESA by the Director-General of NSW Department of Primary Industries (valid from 27 May 2005 to 27 May 2006) and Certificate of Approval from the Animal Care and Ethics Committee of the Director-General of the NSW Department of Primary Industries (valid from 16 May 2005 to 16 May 2008).

I understand that committee members may find some aspects of our work difficult to follow, and so I would be please to be of assistance in explaining these issues should this be of assistance. Should you have any questions or you require further information, please contact me on (02) 9420-9480 or email on info@ecotox.com.au

Sincerely

Dr Rick Krassoi
Director

ECOTOX Services Australasia Pty Ltd ABN>45 094 714 904
unit 27/2 chaplin drive lane cove nsw 2066 T>61 2 9420 9481 F>61 2 9420 9484 W>www.ecotox.com.au

National Animal Welfare Bill 2005

Submission by *Ecotox Services Australasia Pty Limited*

1. Summary

Ecotox Services Australasia welcomes the introduction of a national bill for the protection of animals. The National Animal Welfare Bill in its current form will however place significant and debilitating restrictions on laboratories and organisations using ecotxicity tests ie. tests that use organisms representing those in the environment to determine the likely effects of environmental discharges, contaminated groundwaters, contaminated soils and sediments, and hazardous chemicals. Unlike toxicity tests for products that may be used on humans (cosmetics etc), ecotoxicity tests are used to extrapolate effects of pollutants and protect whole ecosystems. We feel that environmental protection issues have not been given adequate consideration in this Bill.

Ecotoxicity tests (also known as Direct Toxicity Assessment, DTA) are an important tool for the implementation of the following:

- ANZECC/ARMCANZ *Guidelines for Fresh and Marine Water Quality*
- New chemical registration requirement by NICNAS (National Industrial Chemical Notification and Assessment Scheme)
- The assessment of pesticides and veterinary chemicals by APVMA (Australian Pesticides and Veterinary Medicines Authority)
- Environment Australia *National Ocean Disposal Guidelines for Dredged Material* (administered by the Department of Environment and Heritage)
- and various state based discharge license conditions, which are becoming commonplace since the introduction of the ANZECC/ARMCANZ *Guidelines for Fresh and Marine Water Quality*

The proposed bill in its current form will for the first time place tight restrictions on ecotoxicity testing, and will inhibit the above mentioned uses. The Bill proposes to prohibit 'classic LD50 tests or similar', which is extremely problematic as most routine ecotoxicity tests utilise a similar test design. Further, for the first time, larval fish and invertebrates are included in the definition of animals for *Part 8- Animals used for experimental purposes* (Section 96*)*, which will effectively prohibit the use of the most routinely available and reliable toxicity tests. With the absence of any viable alternative tests, environmental protection will be given a lesser priority necessitating a return to out-moded and deficient methods and of assessment of pollutants.

Further, the impact on our company may be devastating. With the prohibition of all ecotoxicity tests using animals (under the definition in Section 96), Ecotox Services Australasia will lose approximately 90% of its revenue, effectively closing the business. Five highly skilled people will be out of work, with no prospect of joining other ecotoxicology laboratories given similar impacts elsewhere. This would also mean a loss of the only NATA endorsed, independent ecotoxicology laboratory in Australia that can fulfil current testing requirements.

To rectify these problems, we urge the Committee to accept the following recommendations:

1. Clarification of 'classic LD50 tests, or similar tests' in Section 81 to ensure LC50 and similar tests used for routine ecotoxicity tests are not encompassed
2. Clarification as to whether definitions of animals in Schedule 2 apply to Part 8-Animals used for experimental purposes.
3. Removal of invertebrates from the definition of animals in Section 96 and Schedule 2
4. The inclusion of larval fish in the definition of 'not an animal', Schedule 2 (e)

2. Introduction

Introduction to Ecotoxicity Testing

Industrial and municipal effluents are regularly discharged into aquatic ecosystems under regulation of the various state environmental protection agencies. These effluents generally consist of mixtures of chemicals that are potentially toxic to aquatic wildlife and therefore, have the potential to cause adverse environmental impacts. The Australian and New Zealand Environment Conservation Council (ANZECC) and the Agriculture and Resource Management Council of Australia and New Zealand (ARMCANZ) released guidelines in 2000 for the monitoring of water quality. These guidelines state that measuring chemical concentrations is insufficient for monitoring the toxicity of effluents being discharged into the environment as they usually contain complex mixtures of unknown compounds. It is recommended by ANZECC/ARMCANZ that toxicity testing with aquatic organisms (ecotoxicological testing) be conducted to monitor the toxicity of effluents prior to discharge into the environment. In accordance with the ANZECC/ARMCANZ approach, a number of state environmental protection agencies have recently included requirements for ecotoxicological testing for monitoring effluent quality in discharge licences. The aim of ecotoxicological testing is to protect aquatic ecosystems by minimising the release of contaminants into the aquatic environment that are harmful to aquatic life. These tests and guidelines also apply to contaminated sediments, soils and ground waters that may enter a waterway and effect aquatic ecosystems.

Further, new chemicals that are to be used in Australia must have a comprehensive ecotoxicity data set performed to determine their potential environmental harm. Federal agencies such as NICNAS and APVMA are responsible for the review of this data, and for the approval for use of chemicals.

Introduction to Ecotox Services Australasia Pty Limited

Ecotox Services Australasia (ESA) provides independent laboratory toxicity testing services for the assessment of chemicals, effluents and industrial discharges, contaminated ground waters, sediments and soils. These tests are generally undertaken in response to requirements by various Federal and State regulatory authorities and in conformance with specific environmental legislation or the ANZECC / ARMCANZ *Guidelines for Fresh and Marine Water Quality*. We are a unique facility in that we are the only independent, private ecotoxicology laboratory in Australia (the other labs being government or university based), and one of only two ecotoxicology laboratories to be endorsed by the National Association of Testing Authorities (NATA) for undertaking various ecotoxicity tests.

Our test programme includes undertaking toxicity tests with algae (unicellular), macro-algae (sea weeds), terrestrial plants, macro-phytes (eg: duckweed), crustaceans (Branchiopoda and Maloconstaca), bivalve mollusc larvae (oysters, scallops and mussel), echinoid larvae (sea urchin) and fish larvae. Toxicity tests with effluents, in conformance with the ANZECC/ARMCANZ *Guidelines for Fresh and Marine Water Quality,* utilise organisms from each trophic level that may be affected. State regulatory authorities with a responsibility for environmental protection utilise ecotoxicity tests for the licensing of environmental discharges, many of which are similar in format to the LD50 type test. These tests are internationally considered ‘best practice’, and are gradually being introduced across Australia as a more relevant means of assessment of environmental harm than traditional chemical assessment.

It should be noted that ecotoxicological assessment is inherently different in scope and relevance to classic toxicity testing (ie: LD50 testing) where effects of toxicants on several laboratory

animals species are extrapolated to effects on just one species; humans. Rather ecotoxicity testing seeks to understand the effects of toxicants and protect whole ecosystems, but based on only a few species and few tests. We feel that testing for environmental protection has received less emphasis and importance with respect to this Bill.

It should be noted that ecotoxiocological assessment is inherently different in scope and relevance to classic toxicity testing (ie: LD50 testing). Traditionally, toxicity testing involved extrapolating the effects of toxicants on several laboratory animal species only to humans (eg testing cosmetics) in contrast to ecotoxicological assessment which using fewer species and tests seeks to understand the effects of toxicants and protect whole ecosystems.

Current compliance with Animal Research Act in NSW

In undertaking our test program, Ecotox Services Australasia Pty Limited complies with the *Australian Code for the Care and Use of Animals for Scientific Purposes* in all of its laboratory testing activities. In addition, research with invertebrates in the state of New South Wales is subject to the *Animal Research Act*, and toxicity tests with larval fish performed by ESA are done so under the Animal Research Authority issued to ESA by the Director-General of NSW Department of Primary Industries (valid from 27 May 2005 to 27 May 2006) and Certificate of Approval from the Animal Care and Ethics Committee of the Director-General of the NSW Department of Primary Industries (valid from 16 May 2005 to 16 May 2008).

There is a conflict between the NSW Animal Research Act and the proposed Bill. Considerable effort has been made to gain approval in NSW to undertake tests with larval fish. We are fearful that this effort will need to be duplicated, with significant costs to this business. Would we be required to comply with both sets of legislation, which do differ in many aspects and requirements?

Likely Effects of the Bill on Ecotoxicology Laboratories

Several aspects of the proposed Bill, if passed un-amended, will prevent us and other ecotoxicology laboratories from undertaking the majority of the tests required to fulfill State and Federal requirements for the generation of ecotoxicity data for respective environmental protection programs. These are detailed in the following Sections.

The effects of the Bill on ecotoxicity testing may be unintentional, but they will have a significant effect on the viability of Ecotox Services Australasia Pty Limited. We estimate that depending on the final definition of animal (Section 96 definition vs Schedule 2 definition), between 30 and 90% of our revenue will be affected. The result will at a minimum, be the loss of staff, and at worst a collapse of the company. This is largely due to the fact that most direct toxicity tests use methodologies similar to the LD50 test, which in Section 81 (b) of the Bill (page 48) would become unlawful (without the Authorities' written approval).

Who would then undertake ecotoxicity tests for compliance with Australian regulatory requirements?

There may be two unintentional consequences of the introduction of the Bill with respect to compliance testing, where no Australian laboratory is available.

1. Companies wishing to register a new chemical for use in Australia will be forced to seek to have tests performed overseas using test species not of Australian origin as all new chemical registration applications require a full set of mammalian and aquatic toxicity data (NICNAS, 2004). This essentially means that the data generated will be less

relevant to Australian organisms and conditions, as well as a loss of control over the treatment of test animals to foreign jurisdictions.

2. The second likely significant consequence of a loss of ecotoxicity testing facilities will be the removal of ecotoxicity testing requirements from discharge licences, control and clean up orders, and the inability to effectively assess the direct causes of fish kills and other pollution events. This would result in a return to the reliance on chemical assessments, where it is extremely difficult to relate concentrations of toxicants in the environment to actual effects. This would be a major step backwards given the years of solid development of the current internationally acclaimed system by ANZECC / ARMCANZ.

Are alternative tests available for assessment of toxicity?

A number of toxicity tests have been developed which have been touted as possible replacement for traditional ecotoxicity tests that rely on a suite of assays being performed from several trophic levels in the receiving environment. These include the Microtox test (and similar tests) with the marine bacteria *vibrio fisheri*, and a number of sub-cellular assays using DNA, sub-mitochondrial particles and proteins. The use of micro-algae have also been suggested as alternatives for toxicity tests with animals. However none of these assays respond in similar ways to animals for all chemicals that may be present in an effluent, and are generally not as sensitive as the organisms that they seek to replace. My own experience with the Microtox test is that it is rarely as sensitive as the routine toxicity tests offered through this laboratory, and often there are false negatives (ie: they miss the presence of a toxicant).

It is instructive to note that the ANZECC/ARMCANZ *Guidelines for Fresh and Marine Water Quality* recommend the use of several organisms (up to 5 from different trophic levels / phyla) that are representative of those in the receiving environment, and the USEPA do not include Microtox or sub-cellular alternative assays in its test suite for the National Pollution Discharge Elimination System (NPDES) for effluent testing. All five toxicity tests in a suite rarely respond in a similar way, and there is no alternative toxicity test available to predict which of a suite would be more sensitive and predict the magnitude of the toxicity effect. Nevertheless, a significant effort is being mounted in various laboratories to identify alternative toxicity tests, but in the short and mid-term, no suitable alternatives exist.

Written Approval to Conduct Tests and Conflict-of-Interest Issue

Should the Bill pass unamended, laboratories wishing to undertake ecotoxicity tests will be required to seek approval as a 'Research Unit' by the National Animal Welfare Authority. Given that we run several tests per week, usually at short notice (1-2 days), we are concerned that the application and approvals process will be too slow and inadequate to meet ours and our clients commercial needs. This assumes that ecotoxicity tests, using tests similar to LD50s, will in fact gain the Authority's approval. An approval process based on one test or project at a time would prove to be an insurmountable hindrance to our business, and an annual type-approvals process would be needed.

A further complication may be a commercial conflict of interest issue. In the case of ecotoxicity testing, Ecotox Services Australasia's only significant competitors are Government institutions and universities. In effect the government, through the National Animal Welfare Authority, will be issuing approvals to undertake ecotoxicity tests with animals even though it has a commercial interest in one or more parties involved in testing and competing for ecotoxicity testing work.

3. Sections of the Bill which require amendment

LD50 tests, or similar tests, unlawful

Section 81(b) of the Bill states that ' *A person must not, without the Authority's written approval: conduct the test commonly known as the classic LD50 test, or a similar test*'. This poses an enormous problem for the field of ecotoxicology as most of the toxicity tests performed by both commercial and government laboratories are similar in design to the LD50 test. Although ecotoxicity tests rarely use 'lethal doses' which are more a feature of mammalian tests used as surrogates for humans, ecotoxicity tests use lethal concentrations (ie: LC50 tests) in water or sediment to determine if effects may be likely at the ecosystem level. There are several variations on this design where endpoints other than lethality are examined (referred to as EC50 tests). Are these test types also covered by Section 81(b)? We are hopeful that this type of testing has been unintentionally covered by the Bill.

It should also be noted that environmentally safe disposal of contaminated marine and estuarine sediments for Australia's commercial ports is governed largely by a demonstration of a lack of toxicity prior to oceanic disposal (Environment Australia, National Ocean Disposal Guidelines for Dredged Material, 2002). This assessment uses one of two amphipod species (the development of which was sponsored by the Environmental Trust grants), which according to the definition of 'animal' in Schedule 2' would be covered by Section 81(b). An inability to run these assays would prevent the implementation of these national guidelines designed for the protection of Australian coastal regions from sediment bourne pollutants.

Recommendation 1a: Removal of 'or a similar test' from Section 81(b), or exempt the use of lethality tests for ecotoxicological testing, or

Recommendation 1b: Remove invertebrates and juvenile (larval) fish from the definitions in Section 96 and Schedule 2, so that limitation on 'LD50 tests, or similar' do not apply to ecotoxicity tests.

Conflicting definitions between Section 96 and Schedule 2

Section 96 defines animals for *Part 8- Animals for Experimental Purposes* as an invertebrate or vertebrate animal other than a human being.

However in *Schedule 2- Definitions*, an animal is (d) a live invertebrate creature of a species, or a stage of the life cycle of a species, from the class Cephalopoda or Malacostraca prescribed under a regulation for this paragraph.

Apart from being confusing and contradictory, the implication, if Section 96 is correct, is that all routine ecotoxicity tests that use similar test designs as the LD50 (and most do), will be unlawful without the Authorities' written approval. This would include tests with single celled animals such as paramecium, microscopic animals such as rotifers, simple crustaceans such as cladocerans, the invaluable bivalve and sea urchin larval development tests through to larval fish tests. Inclusion of tests with these species would be extremely counterproductive in addition to being completely out of step with respect to international moves to prevent mis-treatment of animals, and hinder the implementation of State and Federal environmental protection measures.

Confusing definitions given in Schedule 2

Schedule 2- Definitions, states that an animal is (d) a live invertebrate creature of a species, or a stage of the life cycle of a species, from the class Cephalopoda or Malacostraca prescribed under a regulation for this paragraph.

However it further states "To remove any doubt, it is declared that the following are not animals: a pre-natal, larval or pre-hatched creature, other than a creature mentioned in paragraph (b). Paragraph (b) mentions immature mammalian or reptilian foetus, and avian, mammalian or reptilian pre hatched young.

We read this to say that, with respect to animals used in ecotoxicology, that larval and pre-natal fish and invertebrates (molluscs, echinoids, crustaceans) are not considered animals, as the larval forms of these groups are not mentioned in paragraph (b). However this appears to contradict paragraph (d), which states that on the invertebrates only the Cephalopoda or Malacostraca are considered animals. This needs further clarification in the Bill.

The inclusion of Malocostraca and larval fish as animals

Fulfilment of the ecotoxicity testing requirements of ANZECC/ARMCANZ *Guidelines for Fresh and Marine Water Quality,* various discharge licenses, and product registration requirement by NICNAS and APVMA*, Environment Australia National Ocean Disposal Guidelines for Dredged Material* (administered by the Department of Environment and Heritage), and various state based discharge license conditions, requires the use of Malocostraca (15-day post-larval prawns, juvenile and adult amphipods, juvenile freshwater shrimp) and larval fish. These groups should therefore be removed from the definition of animals, so that ecotoxicity tests are not encompassed by Section 81 (b).

Recommendation 2a: Removal of invertebrates from Schedule 2, paragraph (d) or at least exclude larval and post larval forms, so these may be used for ecotoxicity testing.

Recommendation 2b: Include 'larvae' of fish in paragraph (e) to allow ecotoxicity testing with larval fish

Requirement for Supply Unit licenses for hatcheries etc.

The requirement of the Bill to source animals to be used only from an organisation holding a valid 'Supply Unit license' will have a detrimental effect on our ecotoxicity test program. Although we are able to culture many of the organisms that we use in-house, we are reliant on supply of fish larvae, prawn post larvae, polychaete worms and other tests animals from hatcheries. Unless these hatcheries are required to hold Supply Unit Licenses for their day-to-day activities, the infrequent small volume of animals that hatcheries supply to ecotoxicology laboratories will almost certainly make them disinterested in gaining a Supply Unit License. This would effectively result in an inability to source animals from hatcheries (which breed fish and prawns for human consumption, or worms for bait) to undertake ecotoxicity tests. Removal of invertebrates and fish from the definition of 'animal' in Section 96 and Schedule 2 would negate this issue.