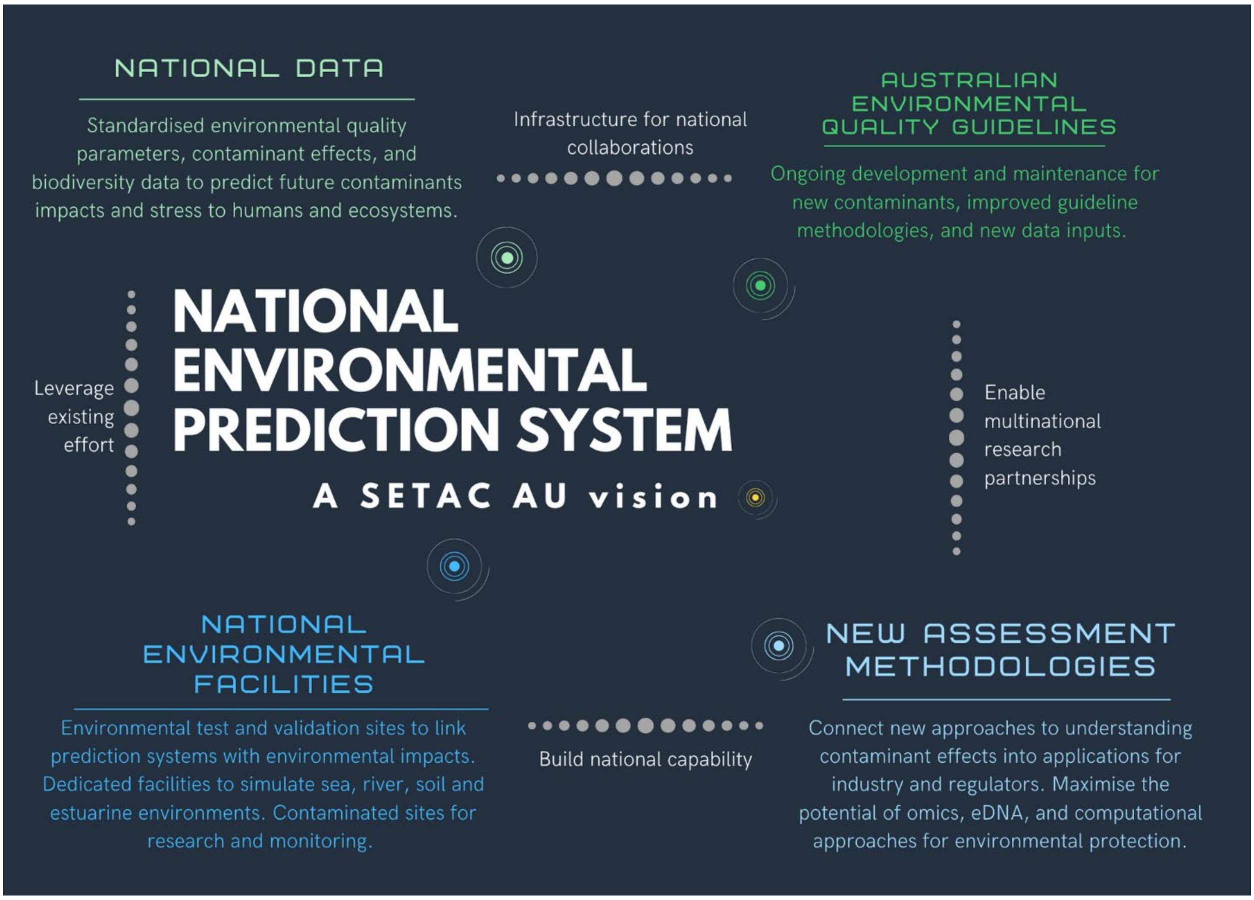
RESPONSE TO THE PROPOSAL FOR A NATIONAL ENVIRONMENTAL PREDICTION SYSTEM (NEPS)

BY THE SOCIETY OF ENVIRONMENTAL TOXICOLOGY AND CHEMISTRY - AUSTRALASIA (SETAC-AU)



Executive Summary

This document is a response from the Society of Environmental Toxicology and Chemistry, Australasia (SETAC-AU) to the NCRIS-funded proposal for a National Environmental Prediction System (NEPS). SETAC-AU is supportive of the NEPS proposal but there was agreement that water, soil, air quality, and biota should all be included in the NEPS to maximize the value of the NCRIS investment.

The NEPS proposal was raised during our recent national conference and a workshop with SETAC-AU members was conducted on 3 September 2021, to ensure the views of the Society on this important matter were adequately discussed. This document reflects the collective view of SETAC-AU and does not reflect the views of our members' affiliate institutions, organisations, and companies.

The workshop identified several considerations for the NEPS project that would add value to the NCRIS investment and aid in maintaining Australia's high environmental quality standards:

1. Curated national datasets and governance linking contaminant-stressor exposure, effects, and biodiversity data. Collating and synthesising large spatial and temporal environmental quality datasets could harness the power of Big Data for predicting risks to human and ecological health, and informing national policies to protect and manage the quality of the Australian environment.
2. A long-term national strategy for the maintenance and updating of Australia's environmental quality guidelines. These guidelines are already essential pieces of national infrastructure but strategic investment is required to ensure they have adequate coverage and maintain currency with the state of the science.
3. National facilities and demonstration or reference sites that can be used to gather knowledge about the exposure and effects of contaminants. This will improve our knowledge of contaminant effects within the complexity of the real and changing environment conditions.
4. A national strategy to progress New Approach Methodologies (NAMs) from the R&D phase into applications for industry and regulators. These tools promise to make risk assessments faster, more accurate and cheaper.

The benefits of these elements in the NEPS cannot be understated. They aim to protect the health of Australians now, and into the future, and protect our environment from degradation. They will result in a reduction of costs for both industry and governments and increase certainty for commercial activities. They will enable strategic international research partnerships. They will also improve the trust of the community and Indigenous people, providing social licence to operate.

The strengths of SETAC-AU

SETAC-AU is an independent professional society with a global network of some 5,000 members. SETAC-AU has a strong professional network across Australia and New Zealand with formal linkages to the Asia-Pacific region. We have a multidisciplinary membership that is focused on understanding contaminant impacts and improving environmental quality through science-based decisions. We provide forums and education to evolve our research into Australia's newest best-practices for managing environmental quality. We focus on building the technical capacity of our members and invest in the nation's future through developing our early career professionals. As a chapter of a global society, we have strong international links that give us the advantage of learning from the world's leading experts and their practices, and we share our knowledge through productive collaborations.

The society has a strong tripartite philosophy and we practice this through involving government, industry and academia in our activities. We are trusted independent advisors for government, regulators and industry and our forums help shape government policy and commercial practice through education and debate of issues. A core value of the society is the inclusion of Aboriginal, Torres Strait and Tiwi Islanders in our science and decision making and we engage at every opportunity. Our members have been key in providing guidance on engaging Indigenous people and SETAC has a global movement to improve our understanding of Indigenous Knowledge and Values.

At the core of SETAC-AU expertise is the prediction of contaminant impacts through modelling. We have strengths in Human Health and Ecological Risk Assessments and our members have driven research that has developed the tools currently used to regulate chemicals and contaminants throughout their lifecycle. Examples include Species Sensitivity Distribution (SSD) modelling and Quantitative Structure Activity Relationship (QSAR) modelling. Our members' expertise is in aquatic ecology, particularly water, sediment, and soil quality sciences. We conduct our work at multiple scales from cellular and individual responses in the laboratory to whole-of-ecosystems responses in the field. Much of our current research is focused on linking these scales and improving our predictions under real-world conditions that change the bioavailability and toxicity of contaminants. Within our rank are the key authors of seminal national guidance documents for the management of chemicals and contaminant impacts, e.g. the Australian and New Zealand Governments' Guidelines for Fresh and Marine Water Quality (ANZG 2018), drinking water, groundwater protection, recycled water, and the Industrial Chemicals Environmental Management Standard (iChEMS).

SETAC-AU and our members are custodians of large datasets that could contribute to the NEPS project. We have collected these data for projects aimed at assessing environmental quality and understanding the potential impacts of contaminants. For example, the SETAC-AU website hosts a comprehensive collection of ecotoxicological datasets that have been used to derive water quality guideline values for aquatic contaminants under the National Water Quality Management Framework (ANZG 2018). We also have extensive contaminant and environmental quality monitoring data that has been collated from State and Territory jurisdictions. These have been collected to assess the risk of contaminants in various conditions, but they are managed on an ad-hoc basis and strategic national coordination would maximise their value.

Challenges for Australia's environmental quality management

There is much attention on the *quantity* of water required to ensure our water security, but the degradation of water quality has a potential to substantially limit that supply. Reflecting this, we understand that the revamped National Water Initiative will include a greater focus on water quality than in the past. The challenge of predicting contaminant sources, their movement and adverse effects, within the complexity of the real environment is immense. Often the fundamental biology of our local species and the ecosystem functions are not well understood, let alone their response to contaminants. In 2019, SETAC-AU published a list of the top 20 priority questions for our fields of science. This list had four broad categories:

1. Improving risk assessments [for contaminants];
2. Advancing tools to measure chemical exposure and effects;
3. Understanding our unique ecosystems and their response to stressors, and
4. Working with Indigenous people and communities (see our Global Horizon Scanning Project webpage and our peer-reviewed paper).

There are more than 350,000 chemicals registered for use today and roughly 2,000 new chemicals are introduced each year, many of which haven't been assessed for safety by any government agency. Hence, the regulation and monitoring of emerging chemicals is a huge challenge. The IChEMS system is Australia's system for prioritizing chemical risk assessment and management. Understanding the source and potential impacts of new chemicals is a substantial task that needs to be backed with modelling to screen the multitude of chemicals entering Australia. Unfortunately, there are still knowledge gaps when accounting for the environmental risk, and the complexities of real-world exposures are rarely included as part of a regulatory review of product safety, such as indirect and secondary effects, e.g. bioaccumulation or contaminant transfer within food chains. It is not possible to thoroughly assess the environmental risk of all new and old chemicals released into the Australian environment, and therefore we are heavily reliant on predictive tools to prioritise our assessments.

Large environmental quality datasets are needed to understand nation-wide trends in contaminant impacts and develop bioregional protection goals for ecosystems. There has been no coordinated effort to generate and collate large environmental quality datasets, apart from those environmental quality parameters that are measurable remotely with spectral analysis, i.e., vegetation cover, turbidity, chlorophyll and salinity. Other environmental quality parameters, such as water pH, hardness, major ions and dissolved organic matter, are needed to understand contaminant impacts in local ecosystems. Databases of these parameters are held by individual state or territory governments, researchers, or private companies; however, these lack standardised data collection and reporting protocols. A standardised data framework for environmental quality parameters is needed to reduce duplication, maximise the potential of existing datasets. Standardised data reporting and data governance will improve data interoperability and will support national research into environmental change and protection. Existing datasets are held by individual, if collated, will reduce duplication and provide.

Given current legislative mandates to assess the safety of thousands of chemicals and the slow pace at which conventional testing proceeds, a number of people envision a paradigm shift towards the use of novel tools and techniques that promise to reduce costs and delays. Models that predict real-world cumulative effects of multiple stressors at low concentrations is a current challenge and active field of research for SETAC-AU. There are strong links between activities on land and water quality and risk assessment that would benefit from a whole of catchment approach that considers other ecological measurements, e.g. vegetation cover. The society is also researching the ability to scale-up effects observed in the laboratory to whole of ecosystems responses. We are actively researching New Approach Methodologies (NAMs), such as in-vitro bioactivity assays (including those conducted in High Throughput Screening, short-term in-vivo tests with pathway-specific molecular/biochemical endpoints, and bioinformatic/computational models). Several of these pathway-based predictive toxicology avenues offer opportunities to address data gaps and uncertainties associated with assessment of the ecological risk of contaminants. While the types of NAMs described above can produce effects data more efficiently and rapidly than conventional whole-animal tests, there remains the task of translating this mechanistic information into the apical endpoints meaningful to risk assessors/managers. To help address this translation challenge Adverse Outcome Pathways (AOPs) have been used, which aim to link molecular scale changes to human-health and ecosystem effects. We aim to evolve our risk assessments into systems that are faster, accurate, safe and minimise animal experiments. Data from NAMs is useful for guiding the need for more comprehensive testing of contaminants. However, the interpretation of NAM results and their use by regulators requires that they be robust and defensible. The validation of NAMs requires considerable R&D investment and solid demonstration studies.

The cumulative impact of climate change on contaminant toxicity is largely unknown. We do know that climate change will result in direct physical and chemical effects, e.g. heat stress, decreasing oxygen levels and ocean acidification, but there may also be indirect effects through changing factors that modify contaminant bioavailability and toxicity, e.g. pH and salinity. Hence, climate change modelling should account for both direct, indirect and cumulative effects associated with contaminants released in Australia. SETAC-AU has the expertise to provide guidance on which chemicals should be monitored as a result of a changing climate, e.g. impacts of contaminants associated with bushfire runoff.

Tools that will improve Environmental Quality

SETAC-AU has identified the tools that would improve the management of contaminant impacts, of which some are easily achievable. We propose that monitoring for a suite of environmental quality measures could track environmental health status through time, which would improve our ability to model spatial and temporal contaminant impacts. This would involve establishing comprehensive national baselines and regularly repeating measurements. A curated national dataset containing exposure (e.g. monitored contaminant data) and effects (e.g. laboratory or field (biodiversity) data) would harness the power of Big Data into predictive risk assessment through collating large-spatial scale environmental quality datasets. This would enhance predictions of pollution risks to humans and ecosystems.

Our members identified the need for comprehensive datasets to improve our understanding of environmental exposure to contaminants and the factors that modify toxicity. For example, developing a quality-controlled national water quality database that includes chemical parameters relevant to environment quality, e.g. pH, organic carbon, major ions (salinity), nutrients and other contaminants. Water quality data that is essential for contaminant bioavailability and toxicity (pH, hardness, organic carbon) should be considered for integration with IMOS and TERN monitoring programs to enable environmental quality assessment in the NEPS. Considering the remoteness of some Australian ecosystems, we should also be investing in a new generation of technologies that allow the measurement of remote contaminated sites, e.g. legacy mines. Examples include real-time, in-situ contaminant sensors with telemetered dataloggers and passive samplers that that absorb specific contaminants when deployed in the field, e.g. Diffusive Gradients in Thin-films (DGTs). The current rapid rise of aerial and aquatic drone applications also has the promise to measure remote contaminant concentrations while monitoring other biotic and abiotic parameters over a large spatial scale. Such data will enable better spatial resolution and regional specificity for environmental protection goals and facilitate strategic research into the cumulative impacts of multiple stressors in Australian ecosystems.

Our national environmental quality guidelines are key pieces of national infrastructure that are used by the State and Territory jurisdictions to assess contaminant impacts, e.g. the ANZG Default Water Quality Guidelines (DGVs) and Assessment of Site Contamination NEPM's Human and Ecological Investigation Levels for contaminated sites (HILs and EILs). However, due to a lack of long-term strategic investment in their maintenance and development, these environmental quality standards are slow to be updated, which has the potential to hinder efforts to protect the environment, and can also cost industry and governments millions of dollars due to overly conservative approaches applied when there are limited data. It took 18 years for the guidance on national water quality management framework to be updated and only a small number of contaminants have had new DGVs approved. SETAC-AU is also the custodian of a database that contains ecotoxicological effects data used to derive these DGVs. However, it is an on-going task to keep it maintained (currently by our volunteer members) and such datasets should be part of a NEPS to enable the re-modelling of environmental risk as new data are acquired.

There is a need for datasets and advanced modelling of contaminant effects, which consider the complexity of varying environment conditions. National "mesocosm" facilities such as the Sea Simulator (SeaSim) located at the Australian Institute of Marine Science (AIMS, Townsville) have enabled large, long-term, experiments that measure the effect of contaminants and key environmental factors. However, the SeaSim research has been focused on coral reefs and the construction of other large-scale mesocosms would improve our knowledge on the effects of contaminants in other contexts, i.e., rivers, soils, sediments, catchments, estuaries and oceans. There are also unstudied contaminants that need purpose-made containment facilities, e.g. natural occurring radioactive materials found in decommissioned oil and gas infrastructure, which are limited globally.

Although our members have researched the impact of contaminants at many sites, there is still an untapped power in using field observations to model contaminant effects under real environmental conditions. A strategic investment in a combination of nationally important unimpacted and contaminated sites (similar to the USA's Superfund sites) would also improve our predictions of exposure and effects to aid in the development of remediation strategies. Ultimately, it would provide Australian-specific demonstration-sites aimed at solving pollution issues using Australia's leading science. Environmental "omics" technologies have also recently matured to a point that their application will grow in the near future, i.e. the measurement of DNA, RNA, proteins and metabolites in the environment. There have been numerous demonstrations of the ability of eDNA/eRNA to detect impacts of contaminants on biodiversity and ecosystem function. They also enable the analysis of ecosystem functions that have been previously unattainable, e.g. microbial biogeochemistry. Furthermore, Australian researchers are now producing long DNA sequences of multiple gene targets from fully-described species, which will allow definitive species identifications from DNA barcoding. However, these growing datasets would benefit from a curated national repository for these of Australian DNA reference barcodes, which markedly increase the power of eDNA biodiversity surveys.

These eDNA biodiversity datasets should be linked to environmental quality data to enable the modelling of impacts.

The use of omics to determine Adverse Outcome Pathways has noteworthy attention from OECD and USEPA and there are international efforts to advance the science. AOPs are a conceptual framework that promotes the systematic organization of adverse effects data to support development of predictive, causal relationships. They aim to link the measurements of the initiation chemical-induced perturbation (e.g. a subcellular or cellular response) to adverse outcomes occurring at a level of biological organization relevant to regulatory decision-making, e.g. human-health or ecosystems. They promise to provide tools for Australia to improve the speed, accuracy and costs of our Human Health and Ecological Risk Assessments and a strategic effort would facilitate moving these technologies into the regulatory space.

The use of Artificial Intelligence (AI) and Machine Learning (ML) will be a valuable tool for regulatory decision-making as it will allow assessments of complex cause-effect relationships, which are beyond our current hypothesis-driven and systematic approaches that explore simpler relationships. There is already an increasing variety of models to predict toxicity that are used for different applications and these in-silico tools make significant contributions to understanding AOPs at different stages of the process. At the initial phase, they provide information on chemical properties (e.g. solubility, partitioning behaviour, chemical reactivity) that can be sourced from databases and/or predictive models. Computational methods such as quantitative structure-activity relationship (QSARs) provide valuable insight into the behaviour of unknown chemicals, and thus facilitate High-Throughput Screening that determine responses at a cellular level. Although, these models can be used to make predictions about the properties of new compounds, modelling through multiple levels along the AOP pathway requires advanced statistical frameworks. Moreover, modelling the effects of contaminant mixtures, and their modifying factors, will need to use the power of AI and ML.

How these tools will be applied

Environmental Quality Guidelines are already an essential piece of national infrastructure, allowing governments to protect the environment, but there are significant improvements that should be made. Integrating a broader range of measurements and models in the NEPS project will generate holistic measures of environmental health on a national, regional and local scale. This will improve the nation's risk modelling capacity for the protection and recovery of the environment. It will enable proactive and more successful contaminant mitigation/management as these tools will provide early-warning indictors for new chemicals that are potentially harmful. The growth of these suggested NEPS datasets would be used to check performance of risk models and to refine them based on new measurements.

We anticipate that the refinement of existing NAMs, the development of novel NAMs and the application of NAMs in case studies that are relevant to Australian conditions and species will pave the way for an evolution towards well-established integrated testing strategies for the assessment of chemical safety. The proposed NAMs will allow rapid and cost-effective risk assessments. Linking the responses at the DNA level to populations and ecosystems will enable accurate scaling-up of risk assessments from the laboratory and allow real-time, in-situ measurements of environmental health at large scales. This will also help prioritise issues and inform plans for monitoring, evaluation, reporting and adaptive management. It will improve our ability to assess cumulative, multi-scale and multistressor impacts, which is a critical knowledge gap. Ultimately, it will solidly embed science-based decision making into the management of contaminants.

The outcomes from the NEPS should be easily communicated to a wide audience and should allow integration of science into policy and priority setting that benefits multiple stakeholders. For example, the outcome should enhance the Federal Government's 'State of The Environment' report and provide more granularity around environmental health measures than we have currently. The addition of the proposed datasets in the NEPS would also help the Federal Government with their international obligations under ratified agreements, such as the Stockholm Convention on Persistent Organic Pollutants, and the pending ratification of the Minamata Convention on Mercury, i.e. the proposed datasets would provide detailed evidence of the effectiveness of restrictions on banned contaminants. A successful NEPS should enable a harmonized approach across jurisdictions for assessing and managing risks.

Benefit to Government, Industry, Culture and Society

SETAC-AU sees great benefit in the idea of a NEPS and supports the NCRIS investment. The benefits of our proposed inclusion of environmental quality datasets for human-health and ecological risk models cannot be understated. The successful application of these tools would help protect the health of Australians and our unique environment. The application of the proposed tools would enable the research needed to clearly link the scientific basis of decisions and provide transparent and defensible methods for industry, which will provide much-needed regulatory certainty for the commercial sector. These improved methods could also provide a basis to harmonize contaminant management across state and territory jurisdictions and reduce red tape. Ultimately, this will result in a reduction of costs for both industry and governments.

Effective contaminant management tools should also be able to provide reports that are understandable to a broad audience. This would provide a social licence for industry and should increase the trust of the community and Indigenous people. Specifically, the application of these tools could provide the evidence for the promotion of clean and green products and increase the community's confidence in recycling of waste, and the clean-up of legacy issues. This project should find opportunities for co-design and collaboration with communities, consider Indigenous Knowledge and Values in the design, and promote co-ownership of the outcomes.

SETAC-AU members participating in the workshop

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