Report on the SETAC Symposium on Chemicals Risk Assessment Approach and Needs for the Asia-Pacific Region

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Executive Summary

The "Symposium on Chemical Risk Assessment Approaches and Needs for Asia-Pacific" took place on 16 September 2016 in Singapore. The objectives of the symposium were to understand chemical risk assessment approaches in the developing Asia-Pacific legislations and to identify scientific research needs in the region. Regulatory experts from six countries in the region shared the current status and key challenges of their countries' chemical management framework. SETAC global experts discussed the best practices of chemical risk assessment and management, as well as their applications. After the presentations, a discussion period was facilitated. Through tripartite discussion, the symposium provided insights from both the regulators and the regulated points of view.

After identifying the challenges faced by regulators as well as academics and business leaders, the following solutions were proposed: 1) harmonization of risk-based assessment approaches that allow for country-specific considerations, and 2) collaboration on exposure and effects data gathering and sharing mechanisms among countries in the Asia-Pacific region. Further, to satisfy the added challenge of language barriers, a clear request from business representatives was to ensure that country-specific guidance and information is available in English.

Based on the discussion, the following areas for potential future collaboration, amongst experts who conduct regulatory risk assessment across sectors and regions, were identified:

- Development of data quality standards for both exposure and effect assessments
- Advancement and harmonization of toxicity test methods with a focus on endemic species
- Development of country and regional exposure assessment models and tools
- Use of weight-of-evidence approaches in risk-based ecological assessment
- Application of advanced Quantitative Structure-Activity Relationship (QSAR) modeling
- Discussion on approaches to define common environmental protection goals where possible
- Refinement of methods used for scientific derivation of environmental quality benchmarks (e.g., water quality criteria, sediment quality guidelines, safety standards of chemical contaminants, etc.)

SETAC can play an important role towards achieving progress in chemical management in the Asia-Pacific region, as identified above, by hosting regional symposia, workshops, and training sessions where global experts in regulatory risk assessment share their experiences and best practices. SETAC can contribute by planning and managing these events and providing an outlet to publish the conclusions and recommendations of the forums.

Introduction

The SETAC International Programs Committee together with SETAC Asia-Pacific held the "Symposium on Chemical Risk Assessment Approaches and Needs for Asia-Pacific" on 16 September during the 2016 SETAC Asia-Pacific Conference at the National University of Singapore campus. The symposium joined governmental experts in chemical management functions from six countries – Australia, China, Japan, Korea, Thailand, and Vietnam – and experts in SETAC from the Asia-Pacific and global communities, with 101 participants from 19 countries across the tripartite sectors.

The development of effective risk assessment frameworks for the management of chemicals is crucial for safeguarding the environment in a way that is consistent with encouraging technological innovation, economic development, and regional employment growth in Asia-Pacific. Chemicals risk assessment is an important element for evaluating the safety of chemicals in commerce and identifying appropriate management measures for those compounds that may present a risk to the environment. This one-day symposium sought to share the status of risk assessment approaches being pursued in Asian countries and identify the chemicals risk assessment, management, and capacity development needs in Asia, for which SETAC is uniquely positioned to make a contribution.

Table 1. Program for the "Symposium on Chemical Risk Assessment Approaches and Needs for Asia-Pacific"

Topic	**Speakers**
Session I	
Chemical Risk Assessment Framework Overview - Korea	Jee Yoon Lee, Vice Chair, Korea Chemicals Management Association (KCMA)
Chemical Risk Assessment Framework Overview - Japan	Yoshinori Momose, Assistant Director, Office of Chemical Examination, Ministry of Environment
Chemical Risk Assessment Framework Overview - Australia	Chris Humphrey, Program Leader, Aquatic Ecosystems Protection, Environmental Research Institute of Supervising Scientist, Department of the Environment and Energy
Chemical Risk Assessment Framework Overview - China	Liu Zhengtao, Director, Chinese Research Academy of Environmental Science
Chemical Risk Assessment Framework Overview - Vietnam	Nguyen Anh-Tuan, Head, Pollution Control Department - Vietnam Environment Administration
Chemical Risk Assessment Framework Overview - Thailand	Somsri Suwanjaras, Head, Hazardous Substances Control Bureau, Department of Industrial Works, Ministry of Industry
Session II	
Best Practices for Environmental Risk Assessment Framework	Patrick Guiney, President, SETAC World Council
Best Practices and Challenges for Risk Management	Charlie Menzie, Global Executive Director, SETAC
Case Study on Risk Assessment Approach and Framework and Risk Management • #1 – Consumer Product Ingredients • #2 – Metal and Inorganic Compounds	#1: Scott Belanger, Research Fellow, The Procter & Gamble Company #2: Jenny Stauber, Chief Research Scientist, CSIRO Land and Water
Session III	
Opportunities for SETAC Regional Engagement • Training • Capacity Building • Scientific Support	Kuan-Chun Lee, Vice President, SETAC Asia-Pacific Bruce Vigon, Scientific Affairs Manager, SETAC

Regional Priorities and Needs for Environmental Risk Assessment and Management	Kenny Leung, Professor, The University of Hong Kong

Sessions I and II

The presentations from sessions I and II are provided on the SETAC website at https://www.setac.org/resource/resmgr/store/Asia-Pacific-Chemical-Risk_A.zip. Presentations in session I and II presented the current state of risk assessment within the region and globally, respectively, as follows:

- Session I: Overview of chemical risk assessment approaches being pursued in Asia
  The governmental experts presented the country-specific chemicals assessment framework and reviewed critical elements associated with conducting an ecological assessment of chemicals.
- Session II: Best practices for chemicals risk assessment and management
  Global SETAC experts presented the best approaches and practices for chemicals risk assessment and management, with case studies highlighting application of best practices in assessing organic and inorganic compounds in consumer product and mining industries.

Session III

Session III included a discussion of priority regional needs and exploration of priorities and opportunities for future SETAC planning, and outreach and capacity building with local authorities to support sound chemical management in Asia. The discussion was informed by the presentations and questions & answers during the first two sessions. The symposium participants were also asked to complete a survey during the afternoon. Based on the discussion and results of the survey, regional priorities as well as opportunities for SETAC were identified and are summarized below.

Regional Priorities

Regional priorities identified in this symposium stemmed from current challenges faced by the regulators and those faced by scientists in the academic and business sectors.

Challenges for country regulators

Session I Presentations from 6 countries (Korea, Japan, Australia, China, Vietnam, and Thailand) offered an opportunity to categorize the common challenges faced by Asia-Pacific economies in terms of developing sustainable chemicals management systems. Several of the presenters included case studies illustrating the adverse outcomes of inappropriate use and storage of chemicals, underscoring the need for systematic and consistent measures.

One common challenge faced by the regulatory community is the scale of the task at hand. A huge variety of chemicals are being produced and imported, for which relatively few ecotoxicity data are available. Several examples of solutions were provided, including the use of Quantitative Structure-activity Relationships (QSARs) that allow for extrapolating ecotoxicity data from well-characterized chemicals to others less well-characterized. The selection of validated QSARs and related tools for routine risk-based assessment is, however, not yet implemented in many countries. The value of tiered approaches for evaluating chemicals was also recognized, although not all countries have selected appropriate screening tools for higher tiers in their systems.

All of the countries recognized the societal benefits of chemical industries, and to this end, the presentations accepted the need to reduce the burden of complying with chemical regulations as much as possible. A key challenge is finding the appropriate balance between achieving legislative protection goals and a reasonable effort on the part of industry. This is especially true in the Asia-Pacific region, where trade occurs among many

different economies; avoiding obstacles to the importation of chemicals and minerals is therefore a goal among all of the countries. Agreeing to common protection goals, ecotoxicity data and relevant endpoints, exposure scenarios, and risk management options would ease the burden on industry and ensure consistent levels of environmental protection. However, country-specific information is still required to determine environmental exposure to adequately assess risk. The availability of this information is unevenly distributed among the different countries, and efforts are required to fill these gaps. A promising solution to these challenges to regulators is: 1) harmonization of risk-based assessment approaches, while considering country-specific challenges, and 2) collaboration on exposure and effects data gathering and sharing mechanisms.

Challenges for industry and academia

From the industry perspective, the chief obstacle is the significant task of having to satisfy different chemicals management systems for a given chemical substance for each country within which a company imports or produces the substance. Facing different systems for each country presents challenges at every step of the compliance process, beginning with understanding country-specific guidance.

Satisfying minimum ecotoxicity data requirements was also debated. Several countries stipulate that ecotoxicity data from endemic species are required to satisfy certain regulations. When considering that refined approaches like Species Sensitivity Distributions (SSDs) may be needed to satisfy product safety requirements and that some countries require data from 8 to 15 species from at least four taxonomic groups to populate an SSD, the potential costs of replicating this data generation for each region or country becomes a major obstacle. This is of particular concern given the uncertain benefits in terms of ecological protection that come from this approach as opposed to using ecotoxicity data from other sources.

Similar challenges are experienced when attempting to satisfy exposure assessment requirements. Several emerging chemicals legislations place the responsibility of performing chemical safety risk assessments on the producer or importer. Often, the most reliable environmental monitoring data that can be used in this process are held by governments; however, access to these data is not always straightforward, and mechanisms for industry to use their own post-market surveillance data are not always recognized in the legislation. The same solutions proposed to satisfy challenges to the regulators also satisfy challenges identified by the business and academic sectors, and those are: 1) the harmonization of risk-based assessment approaches, while considering country-specific issues, and 2) collaboration on exposure and effects data gathering and sharing mechanisms. Further, to satisfy the added challenge of language barriers, a clear request from industry representatives was to ensure that country-specific guidance and information is available in English.

Opportunities for Progress in Risk Assessment in the Asia-Pacific Region via SETAC

A survey completed by the symposium participants identified many opportunities for achieving progress in chemical management in the Asia-Pacific region via SETAC, and most of these reflected the benefits associated with the harmonization of approaches. Several elements are required to ensure high levels of environmental protection from chemical exposure, and collaboration among different countries and stakeholder sectors would facilitate the delivery of these elements. Hosting regional symposia or workshops, where global experts in regulatory risk assessment share their experiences and best practices, could benefit the emerging chemicals management systems in the Asia-Pacific region. SETAC can obviously play an important role in these processes, from identifying global experts, managing the forums, and providing an outlet to publishing the conclusions and recommendations of the forums.

The presentation and panel discussions highlighted the following key priorities where SETAC's tripartite community can contribute to advancement of science-based risk assessment for chemical management in the region. These areas are focused on helping to address the challenges identified above in achieving the legislative protection goal enabled by development and application of advanced scientific risk assessment approaches and

tools. This is not an exhaustive list, but it serves as a starting point for SETAC to establish outreach programs (e.g., targeted trainings, scientific workshops, and symposiums) in the Asia-Pacific region.

A. **Development of data quality standards for both exposure and effect assessments**
First and foremost, high quality environmental exposure data and ecotoxicity data are needed on the range of chemical substances subject to regulation. Agreeing on the quality control and assurance of data collection and screening would reduce effort and ensure regional consistency.

B. **Advancement and harmonization of toxicity tests methods with a focus on endemic species**
The toxicological responses by the ecologically relevant species is critical in determining the toxicological data and requirements for effect assessment of chemicals in different countries and regions. Recent researches on endemic species have shown gaps on responses in different environments based on the standard methods. This calls the need for further evaluation to ensure scientific relevance and representation of the existing data and information. A set of principles and criteria may need to be developed to guide the cross-application of the toxicological data and requirements.

C. **Development of country and regional exposure assessment models and tools**
The fast-growing economy in the Asia-Pacific region is driving more industrial and technological innovations, manufacturing, and consumption. The environmental infrastructure is also developing and that is changing the water and wastewater treatment availability and exposure scenarios of chemicals to the natural environment. It is an important opportunity for SETAC and legislative safety communities in the region to update the current understanding of the state of the environment and develop comprehensive fate modeling and tools to enable effective and efficient chemical exposure assessment at country or regional scales. A SETAC scientific workshop could be a forum for sharing available assessment approaches and tools.

D. **Use of the Weight-of-Evidence (WOE) approach in risk-based ecological assessment**
The WOE approach provides a comprehensive, integrated judgment of all relevant information and supporting conclusions regarding a toxicological effect, including Mode of Actions. It supports risk characterization based on dose-response, regulatory protection goals, biological sensitivity, chemical properties, and uncertainty of exposure estimates in a cohesive and specific way. Further training and discussion will be needed to promote and drive application at the local, regional, and tripartite levels.

E. **Application of Advanced Quantitative Structure-Activity Relationship (QSAR) models**
QSAR has been demonstrated and is increasingly used as a cost-effective tool for evaluating the ecological and health effect of chemicals. It helps delineate the adequacy of existing data and further data needs for decision-making and priority-setting by the regulatory authority. To expand the applications of QSAR in achieving regulatory protection goals, it is important for the SETAC tripartite community and regulatory authorities to further understand the knowledge gaps and local considerations to address the limitations identified in the symposium.

F. **Discussion on approaches to define common environmental protection goals where possible**
Identifying common environmental protection goals would help harmonize chemical management in the region.

G. **Refinement of approaches used to determine environmental quality benchmarks**
Discussion on consistent approaches for the derivation of environmental benchmarks (e.g., water quality criteria, sediment quality guidelines, safety standards of chemical contaminants, etc.) would clearly provide broad efficiencies.

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Symposium Steering Committee