ICCA-LRI and NIHS Workshop · Awaji Island, Japan · 2016 June 15-16 · Awaji Yumebutai International Conference Center

Meeting the Global Challenge of Applying New Scientific Methods to Improve Environmental and Human Health Risk Assessments

The 2016 International Council of Chemical Associations' Long-Range Research Initiative (ICCA LRI) and National Institute of Health Sciences (NIHS) held a workshop on June 15 and 16, 2016 on Awaji Island, Japan to address **Meeting the Global Challenge of Applying New Scientific Methods to Improve Environmental and Human Health Risk Assessments**.

Executive Summary of Findings and Recommendations

The workshop included overall plenary sessions and four concurrent sessions. Session conclusions are presented below, and the workshop is described in detail on the subsequent pages.

- **Session 1 – New Approaches for Weight-of-Evidence Decision Making for Persistent, Bioaccumulative, and Toxic (PBT) Chemicals and Persistent Organic Pollutants (POPs) Compared to Criteria-Based Approaches:** There is a need for global policy changes to redefine PBT and POPs concerns and identify and agree upon protection goals for driving more protective methodologies while not compromising promising technologies with promising benefits and limiting innovation and commercial growth. ICCA LRI can help develop new methods for assessment of chemicals and other substances that may exhibit PBT/POP properties under real life conditions.
- **Session 2 – Emerging Environmental Issues: Case Studies and Solutions Catalyzed by International Cooperation:** Emerging environmental issues can be divided into old types (e.g., toxic heavy metal pollution), new types (e.g., plastic debris), and complex types (e.g., E-waste). ICCA LRI can help create collaborations among countries to transfer technologies, produce innovative methods for control and detection of pollutants, and enhance expertise through training and research activities.
- **Session 3 – Challenges in Read-Across and Building Confidence for Use in Decision Making:** While it is widely recognized that there is both uncertainty and variability in read-across, consensus approaches to quantitatively address these are urgently needed. ICCA-LRI is uniquely positioned to catalyze collaborations for improving read-across approaches and for enhancing training in read across methods, including creating a web-based and multi-lingual repository of training materials, with regional focus as needed.
- **Session 4 – Enhancing Integration of Mechanistic Understanding in Epidemiology to Better Determine Causality:** The integration of the scientific approach of epidemiology, which is observationally based, with mechanistically-based toxicology (termed "epitox") has the potential to improve the scientific basis of determining causality between the nature, magnitude, frequency and duration of chemical exposures and potential occurrence of disease. There are many ways ICCA-LRI can address this in future research, including providing support for combined expertise/collaborative studies and organizing epitox workshops.

Introduction

Recent advancements in new technologies in biology, toxicity and exposure science have considerable potential to improve the efficiency and effectiveness of chemical safety determinations. Through demonstration projects, pilot applications, and detailed case examples the collective knowledge base of potential applications of these advanced approaches has rapidly expanded through the research and regulatory science communities. If sufficient scientific assurance can be established in the health and environmental protectiveness of new technologies and their associated frameworks for interpreting results, regulatory and product stewardship decisions based on these approaches will be able to be made with confidence. The workshop reviewed outcomes from ongoing applications as the foundation for discussing future approaches and to delineate challenges and opportunities faced in determining and communicating confidence in the use of these new technologies for chemical risk assessments and product safety decisions.

The workshop opened with three plenary presentations on how Japan, Europe, and North America address risk-based approaches. Kunihiko Yamazaki (Ministry of Environment, Japan) focused on the EXTEND2010 program, which assessed the endocrine disrupting effects of chemicals. Alan Poole (European Centre for

Ecotoxicology and Toxicology of Chemicals (ECETOC), Belgium) explored how European regulation links to global processes, as well as new challenges in risk assessment in Europe. Kathleen Plotzke (Dow Corning Corporation, USA) examined North American approaches to understanding and integrating exposure in chemical safety assessments. Thereafter, summaries were provided of the recent activities of the three Long-Range Research Initiative (LRI) programs: Tatsuya Mizukoshi presented the Japan Chemical Industry Association (JCIA) LRI overview, Bruno Hubesch presented the European Chemical Industry Council (Cefic) LRI overview, and Richard Becker presented the American Chemistry Council (ACC) LRI overview. Session co-chairs then provided a brief overview of each of the four concurrent sessions, after which participants separated to attend the concurrent session of their choosing.

Session 1

New Approaches for Weight-of-Evidence Decision Making for Persistent, Bioaccumulative, and Toxic (PBT) Chemicals and Persistent Organic Pollutants (POPs) Compared to Criteria-Based Approaches

As chemical regulations and guidelines around the world undergo revision, different organizations and regions have taken diverse approaches to assessing Persistent, Bioaccumulative and Toxic (PBT) chemicals and Persistent Organic Pollutants (POPs). This session reviewed the front line approaches to evaluate PBT chemicals and POPs, discussing both the current approaches being used globally and new and emerging methodologies. Discussions included: development of a quantitative and transparent weight of evidence (WoE) approach for characterization of PBT/POPs compared to criteria-based assessments; REACH's PBT/vPvB criteria; the importance of dietary exposure in evaluating the bioaccumulation of poorly water soluble substances; a Multibox-AQUAWEB model for bioaccumulation assessment; the measurement and influence of metabolism in bioaccumulation assessments; the challenges in assessing the toxicity of poorly water soluble chemicals; a WoE approach for assessing literature on concentrations of environmental chemicals in breast milk and formula; and the challenges of assessing persistence in a regulatory context. The concluding panel discussion covered problems with the current approaches, future research needs, and potential global policy changes.

The major findings and recommendations from this session were:

1. Weaknesses of the current numerical POPs/PBT criteria, including lack of realism in existing standardized testing guidance (current criteria are more of a hydrophobicity metric, log Kow based and biased to aquatic organisms) and lack of understanding/use of realistic exposure potentials for humans and the environment.
2. It is important, and an opportune time, to step back and redefine PBT and POP concerns and the protection goal, and design higher tiered standardized testing to protect against false negatives and false positives in achieving this goal.
3. Decisions based solely on numerical criteria without a weighted evaluation and integration of all scientific evidence could drive technologies with promising benefits out of the market, limiting innovation and commercial growth and could miss chemicals of real concern.
4. The chemical industry is ideally positioned to collaborate and develop partnerships to develop specific proposals for enhancing the realism of PBT/POP assessments globally, and share best practices for acceptance of new methods and approaches.
5. ICCA-LRI can help develop new methods for assessment of substances that may exhibit PBT/POP properties under real life conditions, by working collaboratively across sectors with academics and regulators. ICCA-LRI can catalyze the education of the next generation of experts and also serve as a forum for transfer of information on these new methodologies/best practices especially for emerging countries.

Session 2

Emerging Environmental Issues: Case Studies and Solutions Catalyzed by International Cooperation

Several emerging environmental issues were discussed in this session, including e-waste, nano-particles, mercury, microplastics, veterinary medicinal products, pharmaceuticals and transformation products. Environmental risk assessment/management systems, environmentally friendly wastewater treatment, attempts for eco-towns, and efforts to accommodate new regulations were also discussed. Discussants noted that emerging environmental issues can be divided into three types: old, new, and complex. In some countries, participants indicated that some of the old type of environmental issues, such as toxic heavy metal pollution, is unfortunately currently occurring along with industrialization. Pollution of this type can be mitigated effectively using experiences and technological knowledge from other countries. For new and emerging issues, the importance of investigating practices and technologies to understand and prevent harmful effects on human health and the environment was emphasized. Plastic debris and EPPP (environmental persistent pharmaceutical pollutants) are examples of new issues, and knowledge of sources, levels/ concentrations and significance of effects are areas of active current research. E-waste is an example of a complex issue, i.e., a number of the pollutants are well known but the sources are rather new. The importance of clarifying the core of these issues, and determining and implementing prevention and mitigation actions was emphasized during the discussion.

Based on the presentations and the panel discussion, several possible actions by research and regulatory organizations to encourage further cooperation and scientific studies were suggested:

1. Taking action to mitigate pollutants, including supporting direct regulations to prevent further pollution and developing technologies to recover/remediate existing pollution.
2. Engage in monitoring and epidemiological studies to find existing pollution, use science to understand present and potential future levels of risk based on the type of pollution, the toxicological background of the hazard, and the exposure level to the pollutants, and employ appropriate policy tools to balance between “benefit” and “risk.”
3. Especially now in ASEAN countries, create collaborations to transfer technologies, produce equipment for control and detection of pollutants, and enhance the quality of expertise through training and research activities.

Session 3

Challenges in Read-Across and Building Confidence for Use in Decision Making

Read-across is a method that draws from existing knowledge and data of a specific toxicity endpoint of source chemical(s) to infer the toxicity of the same endpoint to fill a data gap in the dataset for that endpoint for a target chemical. This session focused on understanding the state of science and practice of read-across in different regions across the world, elucidation of the challenges in applying read-across for regulatory uses and recommendations to address and overcome these challenges.

Presentations covered activities and applications of read-across in Europe, Japan, Korea, China, and the United States, as well as activities in the OECD (applicable to all 34 OECD member countries). Other presentation topics included ECHA’s Read-Across Assessment Framework (RAAF), and cutting edge scientific studies applying biological profiling using advanced 21st century in vitro methods to complex mixtures. Following the presentations, a panel discussion was held in which all of the speakers and attendees participated. The discussion session focused on recommendations for overcoming the barriers to enhance the use and acceptance of read-across techniques globally.

Based on the presentations and concluding panel discussion, the major findings and recommendations from this session were the following:

1. Read-across methodologies are currently valuable for optimizing allocation of limited resources and expediting chemical safety assessments.
2. While current procedures have intensified focus on quality data, explicit documentation, and specific justification, there is a lack of globally accepted methods to evaluate uncertainties associated with predictions.
3. The biggest barriers to widespread application of read-across are low confidence in available tools, insufficient documentation of validation, limited number of successful case studies, lack of globally recognized guidelines, limited number of regulators with experience in read-across, and difficulty in communicating to stakeholders.
4. Potential ways to overcome such barriers include: develop and disseminate case studies, develop guidance (beyond ECHA's RAAF), increase training for a variety of audiences, communicate with stakeholders, and recognize that future actions need to address both global and regional needs.
5. Future research should address uncertainty and variability in read-across, and prediction of ADME and toxicokinetics for target substances. There is also a strong need for high-quality databases for source chemicals.
6. In order for the data from new and alternative methods (Tox21, omics, ToxCast, AOPs, etc.) to be used, there is a need for education and outreach to enhance regulators' understanding of these new data streams and biological profiling approaches. These efforts should also plan for upcoming challenges, such as complex products and mixtures.
7. ICCA-LRI is uniquely positioned to contribute to the development and widespread application of read-across methods in several ways, such as developing tools to address biological similarity catalyzing collaborations for training, and promoting development of generic ADME/PBPK methods for chemical categories.

Session 4

Enhancing Integration of Mechanistic Understanding in Epidemiology to Better Determine Causality

The objective of this session was to merge two disciplines – epidemiology and toxicology – which tend to work relatively independently. It is expected that enhancing efforts to combine and integrate the more observation-based discipline of epidemiology with the more mechanistically-based discipline of toxicology-termed "epitox" - has the potential to improve the scientific basis of determining causality between chemical exposure and occurrence of disease. There are regularly allegations of such causalities that the chemical industry often has to reply to, thus this session focused on methods and approaches enhance the integration of these two areas of research.

During the session, comprised of 8 talks and a panel discussion, the cross-discipline activities and approaches in this context were explored through studies from various regions and stakeholders. Presentations covered a variety of topics and methods, including quality of evidence in epidemiology, reverse causality, biomonitoring and plausibility, epitox and metabolism, epitox and carcinogenicity, epidemiology and risk management, epitox and epigenetics, and epitox challenges and opportunities for industry.

The top ten major findings and recommendations from this session were the following:

1. The need to define systematic evaluation for quality and reliability of epidemiological studies.
2. The importance for tools to emerge to predict potential epidemiological associations for ranges of chemicals.
3. The quantitative evaluation for reverse causality must be done at population level.

4. Opportunities for developing and implementing methods to bring together both field-exposure and laboratory in vitro/in vivo studies should be pursued.
5. There is a need for increasing multiple and looped interactions between epidemiology and complex metabolic studies.
6. The importance and necessity for good hypotheses on how people are exposed and understanding of physiology influencing biomarker concentrations.
7. Promising path forwards include further focus on the exposome and life-course epidemiology, development of precision and accuracy epidemiology, and implementation of evidence based off-the-shelf prevention approaches.
8. Epitox collaborations should consider opportunities and challenges for improving scientific understanding of epigenetic mechanisms and transgenerational effects.
9. The need for epidemiologists to quantify error and its direction, harmonize with other lines of evidence, and conduct more validation studies.
10. The opportunity for ICCA LRI to consider supporting combined expertise/collaborative studies and to organize epitox workshops.

Conclusion

The workshop concluded with a panel discussion entitled “Are We Ready to Meet the Global Challenges?” Discussants (the session co-chairs and several of the session speakers) emphasized the importance of global interaction and cooperation, especially since the field is on the verge of a paradigm shift away from traditional toxicity testing, and toward new technologies for data collection, analysis, and interpretation. All agreed that it is essential to continue to bring together scientists, regulators, industry, and the public in order to disseminate new information and knowledge, receive feedback and advice, receive training within and across disciplines, and encourage the use and integration of new methodologies and technologies. Panelists highlighted the success of ICCA-LRI as an international catalyst, and called for ICCA-LRI to continue to bring different groups and sectors together, and to support new methodologies for better risk assessments. For developing countries, training programs brought in to such regions and sending scientists from these regions to different countries for training in new technologies would be helpful. Other panelists agreed, and stressed the importance of supporting the education of the next generation of environmental scientists, toxicologists and epidemiologists. The approaches the three LRI programs employ to select which technologies and research areas to support were also discussed. It was noted that while each LRI program has regional goals and strategic plans, increasingly there are global responsibilities and opportunities that the ICCA LRI should consider undertaking. Panelists pointed out that tools and technologies can be completed at a regional level and still have global applications, if they are adequately supported and promoted through collaborations, education and outreach. Balancing global research needs with budget limits and regional priorities, as well as with country-specific concerns and regional policy terrains, remains an important issue.

Attachment: *Agenda of the June 15-16 2016 ICCA LRI Workshop*

Program at a Glance

	Tuesday, June 14	Wednesday, June 15	Thursday, June 16
7:00			
8:00		7:30 – 8:30 Registration and Coffee	7:30 – 8:30 Registration and Coffee
		8:30 – 8:40 Logistics and Schedule	8:30 – 10:00 Concurrent Sessions
		8:40 – 9:00 Welcome	
9:00	9:00 – 20:00 Registration	9:00 – 10:30 Setting the Stage/Plenary Session	
10:00			10:00 – 10:15 Morning Break
		10:30 – 10:45 Morning Break	10:15 – 12:00 Concurrent Sessions
11:00		10:45 – 11:30 Setting the Stage/Plenary Session (continued)	
		11:30 – 12:10 Overview of Session Aims	
12:00	12:00 – 13:00 Lunch	12:10 – 13:30 Lunch	12:00 – 13:00 Lunch
13:00	13:00 – 17:00 Pre-Workshop Educational Courses		13:00 – 14:00 Report Back From Sessions
14:00		13:30 – 15:30 Concurrent Sessions	14:00 – 14:50 Panel Discussion: Are We Ready to Meet the Global Challenges?
15:00			14:50 – 15:00 Workshop Conclusion
		15:30 – 15:45 Afternoon Break	
16:00		15:45 – 17:00 Concurrent Sessions	
17:00		17:00 – 18:30 Reception and Poster Viewing	
18:00			
19:00	19:00 Welcome Reception	19:00 – 21:00 Group Dinner	
20:00			
21:00			

***All events take place in the Awaji Yumebutai International Conference Center unless otherwise specified.**

Wednesday, June 15		
7:30 – 8:30	Registration and Coffee	Outside Main Hall-2F
Overview of Schedule and Logistics		**Main Hall-2F**
8:30 – 8:40	**Overview** Japan Chemical Industry Association	
Welcome		**Main Hall-2F**
8:40 – 9:00	**Welcome Address** Toshiyuki Katagi, Workshop Co-Chair, Sumitomo Chemical, Japan Hajime Kojima, Workshop Co-Chair, National Institute of Health Sciences, Japan Kathleen Plotzke, ICCA-LRI Planning Group Chair, Dow Corning Corporation, USA Fumiaki Shono, Japan Chemical Industry Association, Japan	
Setting the Stage/Plenary Session		**Main Hall-2F**
9:00 – 9:30	**Development of a Framework About Testing and Assessment of Endocrine Disruption Under Japanese EXTEND2010: Accomplishments and Remaining Issues** Kunihiko Yamazaki, Ministry of the Environment, Japan *The program on the endocrine disrupting effects of chemicals "EXTEND2010" by Ministry of the Environment, Japan has been given priority in testing and assessment. A two-tiered framework was formalized, relevant test protocols were developed, and testing and assessment was implemented. The program's objectives, accomplishments, and remaining issues will be presented.*	
9:30 – 10:00	**How Does Europe Address Risk-Based Approaches?** Alan Poole, European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC), Belgium *The presentation will explore how European regulation links to global processes and discuss the procedures for consultation of interested parties in relation to scientific and technical guidance for risk assessment in Europe. There will be a brief description of the use of the Precautionary Principle in Europe and how the new circular economy package poses challenges in risk assessment.*	
10:00 – 10:30	**Setting the Stage, North America Risk-Based Approaches** Kathleen Plotzke, ICCA-LRI Planning Group Chair, Dow Corning Corporation, USA *On a global scale, regulatory agencies are focusing on implementing risk management measures to control exposure to chemicals considered to be persistent, bioaccumulative, and toxic (PBT), persistent organic pollutants (POPs), or have endocrine activity. Understanding the role of exposure in assessing the actual risk with these chemicals that may have some inherent hazard properties is critical in safety assessments of chemicals. Various approaches being utilized in North America will be discussed.*	
10:30 – 10:45	Morning Break	Outside Main Hall-2F
Setting the Stage/Plenary Session (continued)		**Main Hall-2F**
10:45 – 11:00	**Japan Chemical Industry Association** Tatsuya Mizukoshi, Japan Chemical Industry Association, Japan	
11:00 – 11:15	**European Chemical Industry Council (Cefic)** Bruno Hubesch, European Chemical Industry Council (Cefic), Belgium	
11:15 – 11:30	**American Chemistry Council** Richard Becker, American Chemistry Council, USA	
Overview of Session Aims		**Main Hall-2F**
11:30 – 11:40	**Session 1: New Approaches for Weight-of-Evidence (WoE) Decision Making for PBT Chemicals and POPs Compared to Criteria-Based Approaches** Kathleen Plotzke, ICCA-LRI Planning Group Chair, Dow Corning Corporation, USA Hiroshi Yamamoto, National Institute for Environmental Studies, Japan *As chemical regulations and guidelines around the world undergo revision, different organizations and regions have taken diverse approaches when addressing persistent, bioaccumulative, and toxic (PBT) chemicals and persistent organic pollutants (POPs). This*	

	session will review the front line of approaches to evaluate PBT chemicals and POPs by looking at the current approaches being used globally and new and emerging methodology on the individual lines of evidence. The session will review new evaluation methods of PBT chemicals and POPs, including understanding persistence in the actual environment, understanding the role of exposure and metabolism in bioaccumulation assessments, and evaluating the potential for toxicity or risks to environmental organisms and humans from the presence of these chemicals in the environment.	
11:40 – 11:50	**Session 2: Emerging Environmental Issues: Case Studies and Solutions Catalyzed by International Cooperation** Kazumasa Hirata, Osaka University, Japan Tuyen Van Trinh, Vietnam Academy of Science and Technology, Vietnam *In this session, several emerging environmental issues will be introduced, including microplastics, e-waste, and wastewater. For each issue, speakers will provide an overview, and then discuss how cooperation between international parties, such as LRI and Association of Southeast Asian Nations (ASEAN) countries, could investigate and solve the issue. Finally, there will be a discussion about what kind of research is necessary for future decision-making; suggestions from ACC, Cefic, JCIA, academia, and/or government departments and agencies (MOE, METI, NIES, AIST, NITE, etc.) will be considered.*	
11:50 – 12:00	**Session 3: Challenges in Read-Across and Building Confidence for Use in Decision Making** Richard Becker, American Chemistry Council, USA Ayako Takei, ICaRuS Japan Limited, Japan *Read-across is an important and valuable tool for filling data gaps in categories of chemicals to expedite safety assessment of existing chemicals and new chemicals. In Session 3, presentations describe advances made in using twenty-first century science to improve biological profiling to support read-across, and review challenges that need to be overcome to enable confidence for use and acceptance in regulatory decision-making. The goal of this session is to identify the steps to promote global application of read-across methodologies in regulatory decision-making.*	
12:00 – 12:10	**Session 4: Enhancing Integration of Mechanistic Understanding in Epidemiology to Better Determine Causality** Bruno Hubesch, European Chemical Industry Council (Cefic), Belgium Yoshito Kumagai, University of Tsukuba, Japan *While there is abundant work being done in both epidemiology and toxicology, these disciplines tend to work independently. It is expected that the combination of epidemiology (more observation-based) and toxicology (more mechanistically-based) could help unravel the mystery of causality between chemical exposure and occurrence of disease. This is an allegation the chemical industry often has to answer to, thus this session will address how to enhance the integration of these two areas of research. The cross-discipline activities and approaches in this context will be explored through studies from various regions and stakeholders.*	
12:10 – 13:30	Lunch	Reception Hall B
Concurrent Sessions		
13:30 – 17:00 *Afternoon Break: 15:30 – 15:45*	**Session 1** – Main Hall-2F, pg. 5 **Session 2** – Room 301, pg. 6 **Session 3** – Room 311, pg. 7 **Session 4** – Room 405, pg. 8	
17:00 – 18:30	Poster Session	Reception Hall B
19:00 – 21:00	Group Dinner	The Westin Awaji Island Resort & Conference Center, Grand Ballroom: Stella

Thursday, June 16

7:30 – 8:30	Registration and Coffee	Outside Each Meeting Room

Concurrent Sessions

8:30 – 12:00

Morning Break: 10:00 – 10:15

Session 1 – Main Hall-2F, pg. 5

Session 2 – Room 301, pg. 6

Session 3 – Room 311, pg. 7

Session 4 – Room 405, pg. 8

12:00 – 13:00	Lunch	Reception Hall B

Report Back from Sessions — Main Hall-2F

13:00 – 14:00 **Session Co-Chairs**

Panel Discussion: Are We Ready to Meet the Global Challenges? — Main Hall-2F

14:00 – 14:50 **Panelists**

Richard Becker, American Chemistry Council, USA
Kazumasa Hirata, Osaka University, Japan
Bruno Hubesch, European Chemical Industry Council (Cefic), Belgium
Yoshito Kumagai, University of Tsukuba, Japan
Kathleen Plotzke, ICCA-LRI Planning Group Chair, Dow Corning Corporation, USA
Ayako Takei, ICaRuS Japan Limited, Japan
Tuyen Van Trinh, Vietnam Academy of Science and Technology, Vietnam
Hiroshi Yamamoto, National Institute for Environmental Studies, Japan

Workshop Conclusion — Main Hall-2F

14:50 – 15:00 **Concluding Remarks**

Toshiyuki Katagi, Workshop Co-Chair, Sumitomo Chemical, Japan
Hajime Kojima, Workshop Co-Chair, National Institute of Health Sciences, Japan

Workshop Adjourned

CONCURRENT SESSION 1

New Approaches for Weight-of-Evidence (WoE) Decision Making for Persistent, Bioaccumulative, and Toxic (PBT) Chemicals and Persistent Organic Pollutants (POPs) Compared to Criteria-Based Approaches

Co-Chair: Hiroshi Yamamoto, National Institute for Environmental Studies, Japan

Co-Chair: Kathleen Plotzke, ICCA-LRI Planning Group Chair, Dow Corning Corporation, USA

Wednesday, June 15		Main Hall-2F
13:30 – 14:10	**The Front Line of the PBT Chemicals and POPs: WoE Approach for Siloxanes** Keith Solomon, University of Guelph, Canada	
14:10 – 14:50	**The Front Line of the PBT Chemicals and POPs: Approach by European Chemicals Agency for PBT/vPvB Assessments** Johanna Peltola-Thies, European Chemicals Agency, Finland	
14:50 – 15:30	**Dietary Exposure Bioaccumulation Fish Test: A New Approach to Evaluate the Bioaccumulation Potential of Chemicals** Naoki Hashizume, Chemicals Evaluation and Research Institute, Japan	
15:30 – 15:45	Afternoon Break	Outside Meeting Room
15:45 – 16:15	**New Evaluation Methods of PBT Chemicals and POPs: Development of a Multibox-AQUAWEB Model for Bioaccumulation Assessment** Frank Gobas, Simon Fraser University, Canada	
16:15 – 16:45	**Measurement and Influence of Metabolism on Bioaccumulation** Duane Huggett, EAG, Inc., USA	
Day 1 Conclusion		Main Hall-2F
16:45 – 17:00	**Concluding Remarks by Session Co-Chairs**	

Thursday, June 16		Main Hall-2F
8:30 – 9:00	**Are PBT Chemicals Really Toxic to Aquatic Organisms? Development of a Sediment Toxicity Test Using Benthos** Haruna Watanabe, National Institute for Environmental Studies, Japan	
9:00 – 9:30	**Environmental Chemicals in Breast Milk and Formula and Human Health: Strengths, Limitations and Uses in Human Health Risk Assessment** Erin Hines, U.S. Environmental Protection Agency, USA	
9:30 – 10:00	**Persistence… Degradation… Finding the Right Balance Between Pragmatism and Realism** Marie-Hélène Enrici, Solvay, France	
10:00 – 10:15	Morning Break	Outside Meeting Room
Panel Discussion		Main Hall-2F
10:15 – 11:30	**Facilitators – Session Co-Chairs** **Panelists – All Session 1 Speakers**	
Session 1 Wrap-Up and Conclusion		Main Hall-2F
11:30 – 12:00	**Concluding Remarks by Session Co-Chairs**	
12:00 – 13:00	Lunch	Reception Hall B

CONCURRENT SESSION 2

Emerging Environmental Issues: Case Studies and Solutions Catalyzed by International Cooperation

Co-Chair: Kazumasa Hirata, Osaka University, Japan

Co-Chair: Tuyen Van Trinh, Vietnam Academy of Science and Technology, Vietnam

Wednesday, June 15		Room 301
13:30 – 14:00	**Contamination Issues of Persistent Toxic Substances in E-Waste Recycling Sites** Tatsuya Kunisue, Ehime University, Japan	
14:00 – 14:30	**Characteristics and Composition of Nano-particles Emitted From Diesel Vehicles** Ittipol Paw-armat, Pollution Control Department, Thailand	
14:30 – 15:00	**For Prevention of Environmental Pollution From Veterinary Medicinal Products (VMPs): Regulation and Present Situation** Kaoru Eguchi, Ministry of Agriculture, Forestry and Fisheries, Japan	
15:00 – 15:30	**Investigation of Mercury Contamination in Chalongwang Canal, Prachinburi Province** Pinida Leelapanang Kamphaengthong, Pollution Control Department, Thailand	
15:30 – 15:45	Afternoon Break	Outside Meeting Room
15:45 – 16:15	**Risk Assessment and Communication in K-REACH: A Regulatory Perspective** Jin-sung Ra, Korea Institute of Industrial Technology, Republic of Korea	
16:15 – 16:45	**How to Balance Between Economic and Ecological Factory** Mayuree Didpakdeechol, The Federation of Thai Industries, Thailand	
Day 1 Conclusion		Room 301
16:45 – 17:00	**Concluding Remarks by Session Co-Chairs**	

Thursday, June 16		Room 301
8:30 – 9:00	**Research on Landfill Leachate Treatment and Application for the Nam Son Municipal Solid Waste Treatment Complex in Hanoi City** Tuyen Van Trinh, Vietnam Academy of Science and Technology, Vietnam	
9:00 – 9:30	**Transformation Byproducts and Persistent Pharmaceuticals in the Urban Water Cycle** Norihide Nakada, Kyoto University, Japan	
9:30 – 10:00	**Research and Application of Environmental Friendly Materials for Wastewater Treatment in Vietnam** Tu Thanh Dang, Vietnam Academy of Science and Technology, Vietnam	
10:00 – 10:15	Morning Break	Outside Meeting Room
10:15 – 10:45	**Implementing Marine Litter Solutions: Global Plastics Industry Activities** Emily Tipaldo, American Chemistry Council, USA	
10:45 – 11:15	**Microplastics Pollution: An Emerging Issue for the Global Environment: Current Status, Challenges, and Solutions** Dick Vethaak, Deltares and VU University Amsterdam, The Netherlands	
Panel Discussion, Session 2 Wrap-Up and Conclusion		Room 301
11:15 – 12:00	**Facilitators – Session Co-Chairs** **Panelists – All Session 2 Speakers**	
12:00 – 13:00	Lunch	Reception Hall B

CONCURRENT SESSION 3

Challenges in Read-Across and Building Confidence for Use in Decision Making

Co-Chair: Richard Becker, American Chemistry Council, USA

Co-Chair: Ayako Takei, ICaRuS Japan Limited, Japan

Wednesday, June 15		Room 311
13:30 – 14:00	**Recent Advances in Quantitative Structure Activity Relationship (QSAR) and Read-Across for Chemical Safety Assessment** Takashi Yamada, National Institute of Health Sciences, Japan	
14:00 – 14:30	**OECD Tools and Guidance for Read-Across: QSAR Toolbox and Case Studies Based on Integrated Approaches to Testing and Assessment (IATA)** Yuki Sakuratani, Organisation for Economic Co-operation and Development (OECD), France	
14:30 – 15:00	**REACH-Loaded LRI Cheminformatic System AMBIT Supporting Read-Across** Volker Koch, Clariant (Retired), Germany	
15:00 – 15:30	**Use of Read-Across in China for Regulatory Decision-Making: Opportunities and Challenges** Renjun Gao, The Dow Chemical Company, China	
15:30 – 15:45	Afternoon Break	Outside Meeting Room
15:45 – 16:15	**Read-Across Under K-REACH: Regulatory Contents and Issues** Jongwoon Kim, Korea Institute of Science and Technology – Europe, Germany	
16:15 – 16:45	**Use of Read-Across for the Assessment of Biodegradation and Bioaccumulation Potential of Chemicals Under Japan Chemical Substances Control Law** Yutaka Ikenaga, National Institute of Technology and Evaluation, Japan	
Day 1 Conclusion		Room 311
16:45 – 17:00	**Concluding Remarks by Session Co-Chairs**	

Thursday, June 16		Room 311
8:30 – 9:15	**Case Examples of Read-Across: Uses and Enhancement of the ECHA Read-Across Assessment Framework (RAAF)** Sharon Buring Stuard, The Procter & Gamble Company, USA	
9:15 – 10:00	**Chemical Safety Assessment Using Read-Across: Novel Biological and Chemical Profiling Methodologies** Ivan Rusyn, Texas A&M University, USA	
10:00 – 10:15	Morning Break	Outside Meeting Room
Panel Discussion		Room 311
10:15 – 11:30	**Facilitators – Session Co-Chairs** **Panelists – All Session 3 Speakers**	
Session 3 Wrap-Up and Conclusion		Room 311
11:30 – 12:00	**Concluding Remarks by Session Co-Chairs**	
12:00 – 13:00	Lunch	Reception Hall B

CONCURRENT SESSION 4

Enhancing Integration of Mechanistic Understanding in Epidemiology to Better Determine Causality

Co-Chair: Bruno Hubesch, European Chemical Industry Council (Cefic), Belgium

Co-Chair: Yoshito Kumagai, University of Tsukuba, Japan

Wednesday, June 15		Room 405
13:30 – 14:30	**Human Adverse Health Effects of Endocrine Active Substances: Assessment of the Quality of the Epidemiologic and Mechanistic Evidence** Carlo La Vecchia, Università degli Studi di Milano, Italy	
14:30 – 15:00	**Evaluation of Reverse Causality in Epidemiologic Associations with PBPK Modeling** Miyoung Yoon, ScitoVation, LLC, USA	
15:00 – 15:30	**A Fusion of Field and Laboratory Studies in the Investigation of Arsenic** Yoshito Kumagai, University of Tsukuba, Japan	
15:30 – 15:45	Afternoon Break	Outside Meeting Room
15:45 – 16:15	**Epidemiological and Toxicological Studies on the Carcinogenicity of 1,2-dichloropropane** Gaku Ichihara, Tokyo University of Science, Japan	
16:15 – 16:45	**Biomonitoring Data in Toxicology and Risk Assessment: Concepts and Case Studies** Lesa Aylward, Summit Toxicology, LLP, USA	
Day 1 Conclusion		Room 405
16:45 – 17:00	**Concluding Remarks by Session Co-Chairs**	

Thursday, June 16		Room 405
8:30 – 9:00	**Japan Environment and Children's Study (JECS): A Large-Scale Birth Cohort Study for Better Risk Management** Shoji Nakayama, National Institute for Environmental Studies, Japan	
9:00 – 9:30	**Developmental Origins of Health and Disease (DOHaD) and Toxicology** Keiko Nohara, National Institute for Environmental Studies, Japan	
9:30 – 10:00	**Industry Efforts to Better Integrate Toxicology with Epidemiology** Carol Burns, Burns Epidemiology Consulting, LLC, USA	
10:00 – 10:15	Morning Break	Outside Meeting Room
Panel Discussion		Room 405
10:15 – 11:30	**Facilitators – Session Co-Chairs** **Panelists – All Session 4 Speakers**	
Session 4 Wrap-Up and Conclusion		Room 405
11:30 – 12:00	**Concluding Remarks by Session Co-Chairs**	
12:00 – 13:00	Lunch	Reception Hall B