HOW TO INCORPORATE ADVANCEMENTS IN THE SCIENCE TO EVALUATE POPS IN THE EXISTING CONTEXT OF THE STOCKHOLM CONVENTION

Stockholm Convention
Persistent Organic Pollutant Review Committee (POPRC) Meeting
October 19, 2017
Rome, Italy

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SETAC AND THE POPRC: FROM “SCIENCE TO ACTION”? 

- 2017 COP emphasized need to enhance, interaction between scientists and policymakers in processes to promote exchange and growth of knowledge for more informed decision-making for reaching COP goals.

- 2017 COP requested Secretariat to cooperate and coordinate with UN Environment and other relevant organizations, scientific bodies and stakeholders towards strengthening science-policy interface.

- Key goal of current “science to action” roadmap: “Increase effectiveness of information exchange & outreach on scientific aspects of conventions through enhanced collaboration between Secretariat and other entities.”
WHAT SETAC CAN OFFER THE STOCKHOLM CONVENTION?

• Promote the application of interdisciplinary environmental sciences in the management of POPs/PBTs;
• Participate in the interpretation and communication of the best available science in the management of potential risks associated with POPs/PBTs;
• Provide a forum for communication and interaction among environmental professionals on a multisector, interdisciplinary, and multinational basis;
• Offer nonpartisan scientific guidance, not advocacy. Scientific expertise through whatever form and context the UN SC judge to be most efficient and effective (e.g., briefings to staff, letters, one-on-one meetings, and expert testimony);
• Assist with a customized framework of enhanced tools for dealing with POPs and PBTs
KEY MESSAGES TODAY

• (R)Evolution in the science of POPs / PBTs since the UNSC was first envisioned

• Stockholm Convention’s flexible framework provides excellent opportunities to benefit from these (r)evolutions in science

• SETAC can help the convention refine that framework to take advantage of new tools and incorporate a customized, enriched approach
SETAC’S MISSION

Promoting Environmental Quality through Science®

Through:

• The study, analysis and resolution of environmental problems
• The management and regulation of natural resources
• Environmental education
• Research and development
1. Multidisciplinary approaches to solving environmental problems
3. Objectivity: Science-based
MISSION STRATEGIES – SCIENCE ADVANCEMENT

- Publications (Books, journals, technical reports, technical issue papers, press releases, meeting proceedings)
- Annual Meetings for Geographic Units
- Premier Pellston Workshops®
- Focus Topic Meetings
- Technical Symposiums
- Technical Workshops
- Regulatory Agency Science Briefings
MISSION STRATEGIES – OUTREACH & COLLABORATION

Collaboration with other societies, research entities and intergovernmental agencies on:

- Research
- Education
- Mentoring
- Science Policy
SETAC IN NUMBERS

- 6,000 members
- 95 countries
- 5 geographic units
- 38-year history
- 27 interest groups
- 2 esteemed journals
- 2 Newsletters
Environmental Toxicology and Chemistry (ET&C)

ET&C publishes papers describing original experimental or theoretical work that significantly advances understanding in the area of environmental toxicology, environmental chemistry, and hazard/risk assessment.

Integrated Environmental Assessment and Management (IEAM)

IEAM is devoted to bridging the gap between scientific research and the application of science in environmental decision making, management, and policy and regulation.
RECENT SETAC INTERNATIONAL ACTIVITIES

SETAC International Chemical Assessment and Management Symposia

- Barcelona, Spain 2015
- Singapore, 2016
- Salt Lake City, UT 2016
- Santos San Paulo, Brazil, 2017
SETAC COLLABORATIONS

- United Nations Environment (UNE)
  - UNE/SETAC Life Cycle Initiative
  - World health Organization
    - Strategic Approach to International Chemicals Management
    - Chemical Risk Assessment Network
    - Chemical Branch Advisory Panels
- International Organization for Standardization (ISO)
- European Chemicals Agency (ECHA)
- Environment and Climate Change Canada (ECCC)
- United States Environmental Protection Agency (USEPA)
SETAC COLLABORATION WITH UNEP

- UNE/SETAC Life Cycle Initiative (LCI): 15 year partnership in life cycle thinking (LCT) and life cycle assessment (LCA)

- SETAC engaged with WHO/SAICM to support training/capacity building for chemicals management in developing countries

- SETAC members serve on Chemical Branch Advisory Panels, most recently for endocrine disrupting substances

- Emerging Chemical Management: Issues spanning import, transport, handling, and toxicology of chemicals with a focus on developing countries and economies in transition

- Central Mercury Knowledge Platform - UNEP Live
MAKING SCIENCE MATTER FOR U.S. CONGRESS

- An example of SETAC North America’s strategy for public outreach and education

- Presented a 6 hour risk assessment seminar and round table discussion with Congressional staff on:
  - risk assessment and high throughput screening
  - use of QSARs, use of WoE, and PBT screening methods
• Helped them understand the importance between hazard and risk assessment.

• Helped them appreciate how TSCA Reform could be updated to allow for the incorporation of risk-based regulation of chemicals.

• Helped them understand the importance of using a Weight-of-Evidence approach to reach conclusions about how to regulate chemicals.

• Improved scientific approach to regulating PBTs/ POPs.
SETAC PELLSTON WORKSHOP®

- Focus on crucial environmental topics.
- Bring together up to 50 invited experts with a focus on multi-sector balance and unique scientific expertise.
- Continue a renowned tradition of published proceedings.
- A Trade-Marked process.
SETAC AND STOCKHOLM CONVENTION

- 2008 “Pellston” Workshop®
  - 50 scientists from 16 countries
  - Focused on “science-based guidance & framework for evaluation/identification of PBTs and POPs”
  - Paper published in special issue of *Integrated Environmental Assessment and Management* Vol. 5, No. 4, 2009

- 1999 “Pellston” Workshop®
  Focused on evaluation of Persistence and Long-Range Transport of Organic Chemicals in the Environment
ANNEX D (P, B, LRTP & AE SCREENING EVALUATIONS)

• Evidence of persistence, bioaccumulation, potential for long-range transport, and adverse effects

AND

• “Comparison of toxicity or eco-toxicity data with detected or predicted levels of a chemical resulting or anticipated from its long-range environmental transport”
“whether chemical is likely as a result of its long-range environmental transport, to lead to significant adverse human health and/or environmental effects such that global action is warranted” (Annex E language)

Requires:

- Assessment of potential adverse effects (i.e., hazard)
- Assessment of “likelihood” of adverse effects (i.e., probability)
- Assessment of “significance” of those effects

Which in turn requires integration of best science on:

- Hazard
- Exposure
- Dose/response data
KEY MESSAGES REITERATED

• POPs review process could be enhanced with higher tiered evaluations and refinements

• Existing text provides solid framework for review of risks:
  – Annex D and Annex E allow for robust assessment of potential POPs
  – Existing framework provides adequate flexibility to introduce additional new and emerging scientific evidence into process

• Integration of SETAC expertise during POP reviews could help ensure POPRC benefits from latest scientific research advancements applied within existing framework
SETAC’S GOAL

Help make the UN Stockholm Convention (UNSC) on POPs more:

- **Effective**
  Better at Identifying POPs

- **Efficient**
  Evaluate more chemicals in less time at lower cost and/or effort.

- **Credible**
  Receive greater confidence and support from the scientific community.

- **Transparent**
  Open to scrutiny and opportunities for participation and engagement.
EXAMPLES OF LEADING EDGE ENVIRONMENTAL RESEARCH SETAC SCIENTISTS ARE ACHIEVING

- Advances in environmental exposure and sampling (e.g., passive sampling)

- Advances in analytical technology
  nano > pico > femto > ato gram
  (i.e., 0.000 000 000 000 000 000 001 g)

- Advances in computational chemistry (EpiSuite, ChemSpider, Cosmo, etc.)

- Advances in environmental modeling
EXAMPLES OF SETAC RESEARCH (CONTINUED)

- Advances in toxicology mechanisms of action (AOPs)

- Advances in information technology
CHEMICAL ACTIVITY ANALYSIS

Activity = Concentration / Solubility

NOEC

a (unitless)
ADVANCES IN THE USE OF WEIGHT-OF-EVIDENCE ANALYSIS

• Reliability Criteria
  – Study Quality/Replicability/Repeatability
  – Appropriate application of statistics
  – Data Quality and Integrity

• Relevance Criteria
  – Regulatory relevance
  – Exposure response function relevance
  – Biological sensitivity to a chemical
  – Uncertainties of the Exposure Estimate for the Response of the Effects Endpoint
  – Relevance of the Test Chemical Properties
VISION FOR TOXICITY TESTING & EXPOSURE SCIENCE IN THE 21ST CENTURY (NRC)

- Phasing out of animal studies
- In vitro bioassays
- PBPK & TK models for *in-vitro* to *in-vivo* extrapolation
- High through-put testing (e.g., ToxCast)
- *In silico* methods
- Effects of chemical mixtures
- Collection, compilation and evaluation of a exposure data (ExpoCast) from many different sources
SETAC TECHNICAL SUGGESTIONS

• Recommendations for assessments:
  – Rely on QSAR
  – Use of empirically derived & modelled data on analogous chemicals
  – Use of weight-of-evidence approaches

• Measurements of half-live ranges should be made under environmentally relevant experimental conditions & methods

• Use PBPK modelling in appropriate species (i.e., uptake and BCF)

• Improve integration of exposure information
  – Use of published peer-reviewed data for environmental exposure
  – Use of environmental exposure models routinely used by regulators
  – Rigorous assessment of probability that effects will be realized
WHAT CAN SETAC OFFER POPRC?

- Promote application of interdisciplinary environmental sciences in evaluation of potential POPs
- Interpretation & communication of best available science in management of potential risks associated with POP
- Provide a forum for interaction among environmental professionals on multisector, interdisciplinary, and multinational basis
- Customized framework of tools for evaluating and managing POPs
- Offer nonpartisan scientific guidance, not advocacy
HOW?

• POPRC can request that SETAC provide guidance documents on key issues for general use by POPRC
  – E.g., SETAC published papers on POPs and PBT methods

• POPRC can invite SETAC experts to provide advice
  – Scientific briefings to drafters, reviewers, and scientists
  – External third-party technical reviews of POPRC materials:
    • nomination dossiers
    • draft risk profiles
    • draft RMEs
  – Expert testimony at POPRC meetings and technical input into drafting groups
Thank You for Your Time and Attention! Questions are Most Welcomed!