Report from Exposure Workshop

Global Risk Assessment Dialogue
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Rapporteur: Dr. Valerie Zartarian (US Co-Chair)
Chair: Dr. Jose Tarazona
Steering Committee: Dr. Halûk Őzkaynak,
Dr. Hans Yu (CAN Co-Chair), Dr. Helmut Greim (EU Co-Chair)
~40 workshop participants

Exposure Assessment Workgroup Planned Products

- Product 1: Collaborative International Journal Article: "Assessing Human Exposures for Risk Assessment and Risk Management: An International Perspective"

- Product 2: Collaborative Guidance Document: Incorporating Biomonitoring in Exposure Assessment, Risk assessment and Risk Management

- Product 3: Future Collaborative Case Studies for Harmonization of Assessing of Exposures in the Context of Risk Assessment and Risk Management

Issues Discussed in Workshop

1. What are ways to assess human exposures for risk assessment/management from an int'l perspective?

2. How is biomonitoring incorporated in exposure assessment, risk assessment, and risk management?

3. What will be the future of collaborative case studies for harmonization of assessing exposures in the context of risk assessment and risk management?

RECOMMENDATIONS BASED ON EXPOSURE WORKSHOP DISCUSSIONS

1) Clarify objectives/scope of exposure tools paper
2) Expand summary tables of available tools
3) Expand material on (lower) tiered approaches
4) Address biomonitoring recommendations
5) Clarify previous case studies considered
6) Analyze available exposure assessment tools
7) Select [[*and conduct*]] future case studies

- *Additional thoughts from Steering Committee/Co-Chairs*

1) Clarify Objectives/Scope of Exposure Tools Paper

- Provide toolbox (data, models, surveys, diaries, other exposure-related info), and assess which tools are suited for different chemicals, scenarios, questions of interest
- Use example (past) case studies to highlight some of the tools and discuss issues for future collaborations
- Explain justification for models, methods, data, approaches (e.g., screening level, probabilistic, tiered) used for each case study
- Expand material on lower tiers and biomonitoring

2) Expand Summary Tables of Available Tools

- Complete tables across 3 jurisidictions
  - Guidance
  - Databases
  - Survey methods
  - Biomonitoring methods and data (integrate with Product #2)
  - Lower tier models
  - Higher tier models

Initial Examples of Guidance Documents for Exposure Assessments (ECHA)

TABLE 1. ECHA Guidance documents on human exposure assessment
REGULATORY CONTEX: MAINLY REACH REGISTRATION, ALSO OTHER REACH PROCESSES
ECHA (2008) Guidance on information requirements and chemical safety assessment.

TARGET & RECEPTORS	SPECIFICATIONS	ASSESSMENT TYPE	MAIN CHARACTERISTICS	REFERENCE
WORKERS INHALATION & DERMAL	GUIDELINE FOR INDUSTRY, INCLUDES DEFAULT VALUES SUGGESTS LOW-TIER & REFINEMENT TOOLS	WORK PLACE BY SUBSTANCE AND USE OR USE CATEGORY APPLICABLE TO MULTICONSTITUENT MIXTURES	BASED ON INDUSTRIAL PROCESSES	Chapter R.14: Occupational Exposure Estimation
CONSUMERS INHALATION, DERMAL & ORAL	GUIDELINE FOR INDUSTRY INCLUDE DEFAULT VALUES FOR RWC ESTIMATIONS & OVERVIEW OF AVAILABLE TOOLS	EXPOSURE FROM SUBSTANCES AS SUCH, IN MIXTURES AND ARTICLES IN CONSUMER PRODUCTS, BY SUBSTANCE	BASED ON CATEGORIES OF CONSUMER PRODUCTS	Chapter R.15: Consumer exposure estimation
USERS OF ARTICLES (CONSUMERS & WORKERS) INHALATION, DERMAL & ORAL	GUIDELINE FOR INDUSTRY INCLUDE DEFAULT VALUES FOR RWC ESTIMATIONS & REFINEMENT OPTIONS	EXPOSURE FROM SUBSTANCES IN ARTICLES, BY SUBSTANCE ALSO ENVIRONMENTAL RELEASE	BASED ON ARTICLE CATEGORIES, CONSUMER BEHAVIOUR (USE, MISUSSE), AND P-Q PROPERTIES FOR POTENTIAL RELEASE	Chapter R.17: Estimation of exposure from articles
CITIZENS INDIRECT EXPOSURE FROM ENVIRONMENT AIR, FOOD AND WATER	GUIDELINE FOR INDUSTRY INCLUDES SOFTWARE ESTIMATORS & DEFAULT PARAMETERS	BY SUBSTANCE, ESTIMATES ENVIRONMENTAL CONCENTRATIONS COVERS LOCAL & REGIONAL ASSESSMENTS	MAY COMBINE SEVERAL USES BASED ON RELEASES FROM INDUSTRIAL & DISPERSIVE USES AND ENVIRONMENTAL FATE	Chapter R.16: Environmental Exposure Estimation
HUMAN INDIRECT EXPOSURE FROM ENVIRONMENT WASTES RELEASES	GUIDELINE FOR INDUSTRY INCLUDES DEFAULT PARAMETERS AND CONDITIONS	INDUSTRIAL SETTING BY SUBSTANCE AND USE OR USE CATEGORY WORK PLACE AND WASTE TREATMENT PLACES BY CATEGORY	COMBINES WASTE PRODUCTION AND WASTE TREATMENT SCENARIOS ESTIMATING ENVIRONMENTAL RELEASES	Chapter R.18: Estimation of exposure from waste life stage

Initial Examples of Databases for Exposure Assessments (US and CAN)

Pollution Source Emissions | **Meteorological, Housing & Exposure Factors** | **Personal Behavior/ Time Activity**

- Pollution Source Emissions (Air, Water, Land)
  - US EPA Toxic Release Inventory (http://www.epa.gov/tri/)
  - US EPA Total Maximum Daily Load Program (http://www.epa.gov/owow/tmdl/intro.html)
  - US EPA Water (http://www.epa.gov/ow/)
  - US EPA Land (http://www.epa.gov/superfund/)
  - Environment and Health Canada: CEPA Section 71(1)(b) Survey Data
  - Environment Canada: National Pollutant Release Inventory: (http://www.ec.gc.ca/inrp-npri/default.asp?lang=En&n=4A577BB9-1)
  - Chemistry Industry Association of Canada: National Emissions Reduction Masterplan: (http://www.canadianchemistry.ca/EnvironmentBRSustainability/ReducingEmissionsBR/tabid/88/ItemId/34/vw/1/Default.aspx)
- Meteorological
  - US NOAA's National Weather Service Data (http://www.nws.noaa.gov/)
  - US National Climatic Data Center (http://www.ncdc.noaa.gov/oa/ncdc.html)
  - Environment Canada: National Climate Data and information Archive (http://climate.weatheroffice.gc.ca/Welcome_e.html)
  - Environment Canada: Weather Office (http://www.weatheroffice.gc.ca/canada_e.html)
- Housing Factors
  - US Department of Housing and Urban Development Data (http://www.hud.gov/)
  - Statistics Canada (http://www.statcan.gc.ca/start-debut-eng.html)
- Exposure Factors Data
  - US EPA EF and CSEF Handbooks (http://permanent.access.gpo.gov/lps35390/cfpub.epa.gov/ncea/cfm/recordisplay.cfm-deid=55145.htm)
  - Health Canada Handbook for exposure Calculations (http://dsp-psd.pwgsc.gc.ca/Collection/H49-96-1-1995E-1.pdf)
- Time Activity Surveys
  - US EPA Consolidated Human Activity Database (http://www.epa.gov/chadnet1/)
  - US American Time Use Survey (Bureau of Labor Statistics) (http://www.bls.gov/tus/)
  - Statistics Canada: Human Activity and the Environment (http://www.statcan.gc.ca/bsolc/olc-cel/olc-cel?catno=16-201-XWE&lang=eng)
- General:
  - US EPA Exposure Assessment Guidelines (http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=15263)
    - EU ExpoFacts (http://expofacts.jrc.ec.europa.eu)
    - Health Canada: Investigating Human Exposure to Contaminants in the Environment (http://dsp-psd.pwgsc.gc.ca/Collection/H49-96-2-1995E-1.pdf)

Initial Examples of Databases for Exposure Assessments US and CAN (cont'd)

Consumer Product Use Data

Dietary Consumption and Residues

Environmental, Exposure, Biomarker Concentrations

- Dietary Consumption Data
  - USDA Continuing Survey of Food Intakes by Individuals (http://www.ars.usda.gov/Main/site_main.htm?modecode=12-35-50-00)
  - US CDC NHANES (http://www.cdc.gov/nchs/nhanes.htm)
  - US FDA Total Diet Study (http://www.cfsan.fda.gov/~comm/tds-toc.html)
  - Other Market Basket Surveys (FDA, USDA)
  - USDA Pesticide Data Program (http://www.ams.usda.gov/AMSv1.0/ams.fetchTemplateData.do?template=TemplateC&navID=PesticideDataProgram&rightNav1=PesticideDataProgram&topNav=&leftNav=ScienceandLaboratories&page=PesticideDataProgram&r)
  - Canadian Community Health Survey (CCHS) (http://www.statcan.gc.ca/cgi-bin/imdb/p2SV.pl?Function=getSurvey&SDDS=3226&lang=en&db=imdb&adm=8&dis=2)

- Consumer Product Use Data
  - US Consumer Product Safety Commission Data (http://www.cpsc.gov/)
  - US EPA data
  - Health Canada Consumer and Product Safety Division (http://www.hc-sc.gc.ca/cps-spc/index-eng.php)

- Environmental Concentrations
  - US EPA Reports (EPA/600/R-07/013)
  - Human Exposure Database System (http://oaspub.epa.gov/heds/study_list_frame)
  - Water, air and ecological data sources (USGS, Fish and Wildlife Service)
  - CMP Environmental Monitoring and Surveillance (http://www.chemicalsubstanceschimiques.gc.ca/plan/surveil/index-eng.php)
  - Environment Canada: National Air Pollution Surveillance (http://www.etc-cte.ec.gc.ca/napsstations/Default.aspx)

- Biomonitoring (for surveillance and model evaluation)
  - CDC NHANES (http://www.cdc.gov/nchs/nhanes.htm)
  - Canadian Health Measures Survey (CHMS)
  - Maternal-Infant Research on Environmental Chemicals
  - Northern Contaminants Program
  - First Nations Biomonitoring Initiative

  (http://www.chemicalsubstanceschimiques.gc.ca/plan/surveil/bio-initiatives-enquetes-eng.php)

Example Exposure Models Used by USEPA (modified from Williams et al., 2010)

Model	Full Model Name
SCREENING LEVEL	
HAPEM	Hazardous Air Pollutant Exposure Model
SWIMODEL	Swimmer Exposure Assessment Model
PIRAT	Pesticide Inert Risk Assessment Tool
EPA Exposure Factors Handbook Equations	*exposure/dose equations by pathway*
HIGHER TIER	
IAQX	Indoor Air Quality and Inhalation Exposure - Simulation Tool Kit
DEEM™	Dietary Exposure Evaluation Model
WPEM	Wall Paint Exposure Assessment Model
MCCEM	Multi-Chamber Concentration and Exposure Model
APEX	Air Pollutants Exposure Model
SHEDS	Stochastic Human Exposure and Dose Simulation Models
Calendex™	Calendex™
CARES™	Cumulative and Aggregate Risk Evaluation System
LifeLine™	LifeLine™

3) Expand Material on (Lower) Tier Approaches

- Need example(s) of lower tier approach for case studies
- Emphasize decision process for tier selection
- Explain how tiers applied in practice

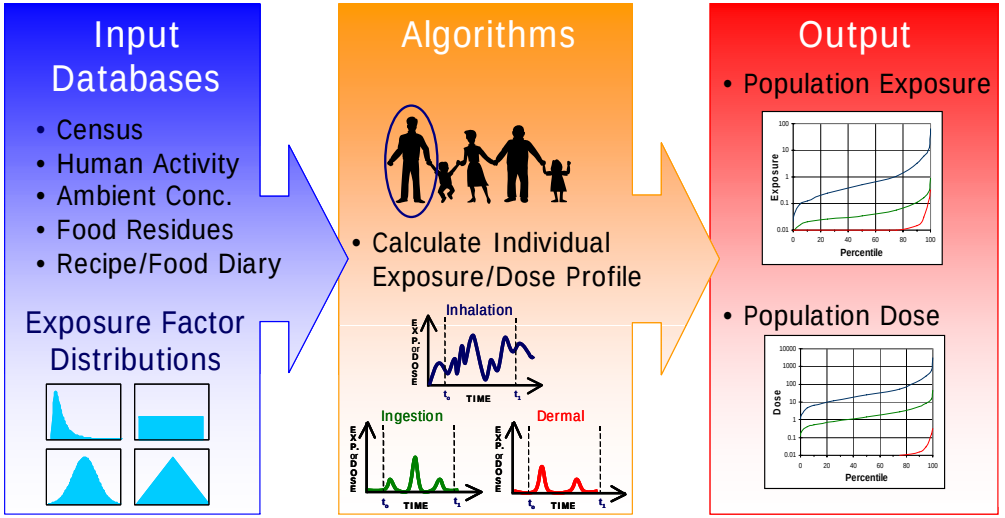
HTM: Exposure Equation and Calculation

ADD *= Average daily dose (mg/kg/day)*

$$\mathbf{ADD} = \frac{\mathbf{(DR * SA * FQ * SE * ET)}}{\mathbf{BW}}$$

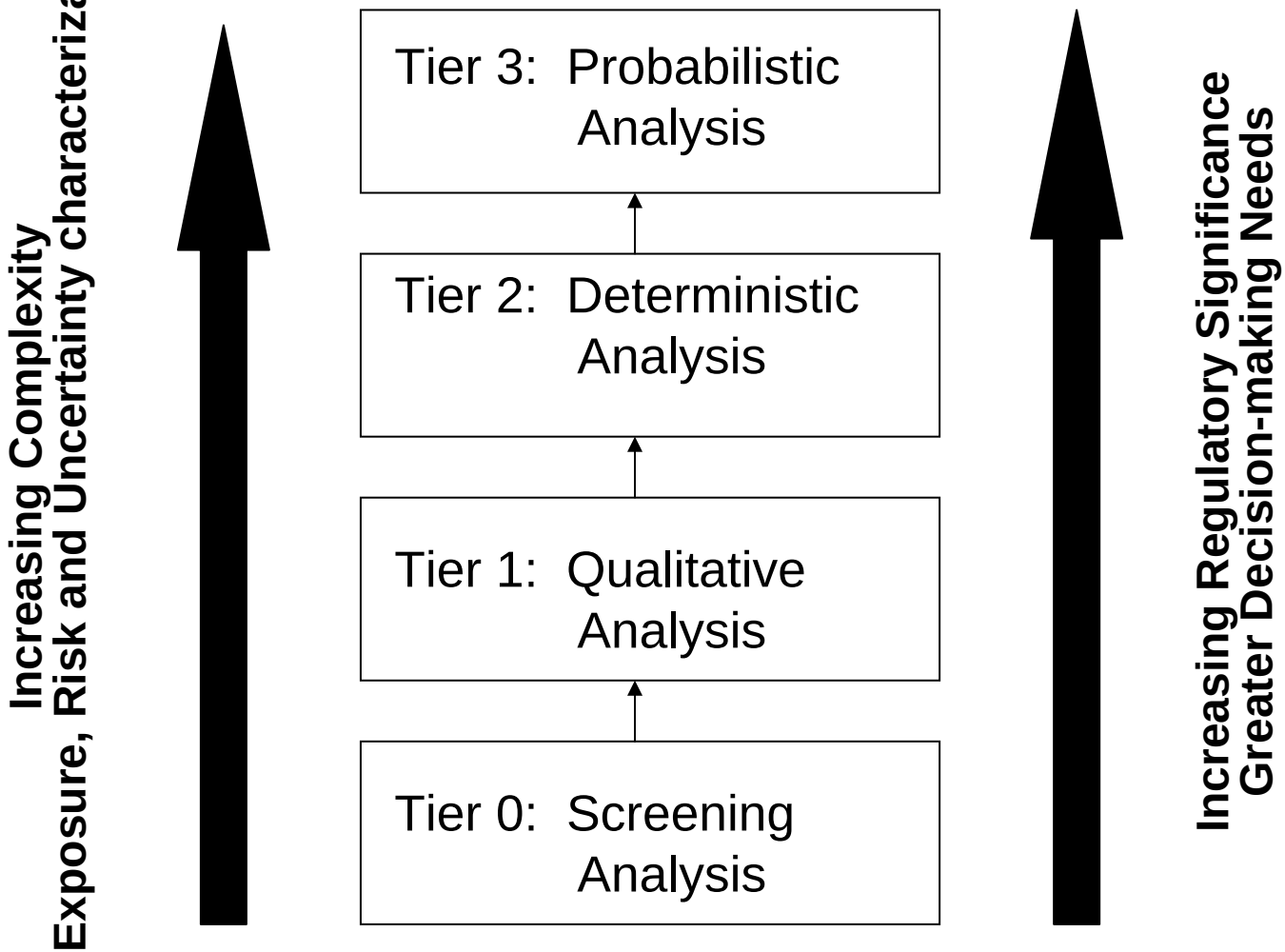
Where:
DR *= Dislodgeable Residue (mg/cm²)*
SA *= Surface area of fingers (20 cm²/event)*
FQ *= Frequency of activity (20/hr)*
SE *= Saliva Extraction factor (50%)*
ET *= Exposure Time (2 hr)*
BW *= Body Weight (15 kg)*

Source: EPA/OPP



Source: EPA/ORD/NERL

Illustration of Tiered Exposure Analysis



4) Address Biomonitoring Recommendations

- Overall framework to integrate biomonitoring into exposure assessment (integrate Product #2 with Product #1)
  - Roles for model evaluation, epi studies
  - How it fits into tiered structure (screening, public health interventions)

- Methodological aspects
  - Appropriate analytical tools and questionnaires
  - Ethical and results communication challenges
  - Appropriate time window, other considerations

- Interpretation of Results
  - Consideration of community level vs general population (e.g., extrapolation)
  - Limitations (e.g., cost and approvals)
  - Examples of advantages where biomonitoring has been done

5) Clarify Previous Case Studies Considered

- Emphasize purpose to highlight key tools and approaches
- Clarify chemical sources, scenarios, populations, questions
- Why lower vs higher tier, research or regulatory
- Integrate biomonitoring document more explicitly

Case Study	Questions being Addressed	Model(s) or Scenarios	Data	Approach	Sens./Uncert.	Evaluation	How Results Used
Benzene							
As in d.w.							
CCA-treated wood							
MeHg fish							

6) Analyze Available Exposure Assessment Tools

- Compare and contrast exposure assessment approaches, models, data through review and case studies
  - Compare input data (e.g., consumption, time-activity) across jurisdictions
  - Discuss commonalities, differences, limitations, and lessons learned
  - Explore differences in case study results (methods? models? data?)
  - Consider how the various tools complement each other
- Match scenarios, data, methods, models, tiered approaches; identification of right tool for given study
- Assess issues and challenges internationally moving forward
  - Recommend steps to address the challenges identified
  - Work towards improving current science and use of exposure assessments to inform risk assessments and regulatory decision-making

7) Select [[*and Conduct*]] Future Case Studies

- Refine and apply selection criteria
- Connect tools in the toolbox with proposed case studies
- Move toward applying, testing, and evaluating international harmonization approaches
  - *Proposal by JRC for a new sub-working group*
    - to test GEXFrame tool as platform for matching tools with case studies
    - develop conceptual framework/decision guidance document on matching tools to scenarios/exposure applications
- Apply exposure models, data sets, tools, and approaches to collaborative case studies
  - Explore integrated ways for jurisdictions to conduct collaborative international exposure assessments
- Provide context and communicate exposure results
  - link to interventions, to demonstrate benefits for improving public health and encourage data collection

Suggestions for Future Collaborations

❖Apply data, exposure models/predictive tools, biomonitoring methods:

- lead (aggregate, air, toys/jewelry, natural remedies; paint; imported cookware; cosmetics)
- BPA
- PFOS/PFOA (biomonitoring)
- aggregate arsenic (food, drinking water, playsets, air)
- cumulative pyrethroid pesticides
- cumulative metals in fish consumption
- consumer products
- microbiological hazards in pathogens in cheese and meat products
- cotinine modeled exposure estimates linked to biomarkers
- thyroid hormone altering chemicals with biomonitoring (dioxins, perc)
- chemicals impacting energy management (obesigens, diabesigens)
- joint oxidative stress
- new/emerging issues TBD

Highlights of Exposure Assessment Considerations Discussed

- Improve and evaluate available exposure tools
  - develop/apply screening tools (data poor, many chemicals)
- Fill data gaps for scenarios, subpopulations, spatial scales
- Address cumulative risks (chemical and non-chemical stressors)
- Integrate biomonitoring in exposure assessment
- Consider exposures of susceptible/vulnerable populations
- Discuss global considerations (imported products & food items)
- Discuss risk management/communication
  - info for voluntary in addition to regulatory efforts (e.g., fish consumption)
  - "smart, sustainable, innovative" approaches , e.g. GIS tools

➢*Additional Thoughts from Steering Committee/ Co-Chairs*

- Seek broader input, within & across jurisdictions, to:
  - summarize and analyze tools available
  - complete and analyze case studies
  - address challenges for integrating/harmonizing going forward
  - complete workgroup products
  - foster future collaborations

- Address logistical challenges
  - more focused subgroup meetings
  - identification of case study and paper section leads
  - improved coordination in order to meet deadlines

- Discuss and select future collaborative case studies

MANY THANKS TO WORKSHOP PARTICIPANTS AND CONFERENCE HOSTS!!!