APPENDIX G

Proceedings of Expert Consultation: Developing a Strategy for Assessing Exposure to and Effects of Toxic Substances in the Great Lakes April 6-7, 2011 Chicago, IL

Highlights of Experts Consultation

On April 6-7, 2011, the United States Environmental Protection Agency (USEPA) hosted a two-day workshop comprised of scientists in the fields of ecotoxicological risk assessment and environmental monitoring to provide input to the development of a *Strategy for Assessing Exposure to and Effects of Toxic Substances in the Great Lakes* (Effects Strategy). Participants reviewed three background documents that were distributed prior to the consultation:

1. Review of the Effects of Chemicals of Emerging Concern (CECs) on the Environment
2. Summary of a Literature Search on Effects-Based Biomonitoring Tools for Ecological Risk Assessment
3. Draft Strategy for Assessing Exposure to and Effects of Toxic Substances in the Great Lakes

Several common themes emerged from discussions over the course of the consultation:

- The Effects Strategy needs to a) define specific management objectives and b) identify criteria for a successful monitoring program.
- The development of conceptual model(s) can help to identify pathways, tools, and species to monitor.
- The selection of species to monitor should consider ecologically relevant, abundant keystone species, and pathways of concern.
- Further research is needed before genomic arrays can be used routinely as part of the Effects Strategy.
- To monitor for changes, there must be an understanding of the baseline reference condition (normal).
- The Effects Strategy should consider confounding factors in addition to CECs.
- The Effects Strategy should leverage existing monitoring efforts by integrating effects monitoring into current programs.
    - Require systematic, standardized monitoring across jurisdictions.
    - Foster collaboration among jurisdictions and sharing of data.
- There are concerns with using the health metaphor as part of a management objective, such as protecting "ecosystem health" or "environmental health." Such terms lack credibility for a monitoring program that is grounded in science.

Next steps are to:

1. Develop a report to the International Joint Commission (IJC) on the Ecological Impacts of Contaminants of Emerging Concern in the Great Lakes

2. Revise the Draft Strategy for Assessing Exposure to and Effects of Toxic Substances in the Great Lakes

Introduction and Objective

Ted Smith of the United States Environmental Protection Agency (USEPA), Great Lakes National Program Office (GLNPO) and co-chair of the International Joint Commission (IJC) Chemicals of Emerging Concern (CEC) Workgroup, thanked participants for attending and acknowledged fellow co-chair Gary Klečka of Dow. The CEC Workgroup has been in place for 4 years and is currently in the 2nd IJC biennial cycle.

Participants around the room introduced themselves. A list of participants is provided at the end of this document.

Ted provided an overview of the purpose and background for the meeting. For the 2007-2009 biennial review cycle, the IJC charged the CEC Workgroup with 1) investigating the presence and effects of CECs in Great Lakes nearshore areas, and 2) undertaking a policy review of chemicals management programs and their efficacy in protecting the Great Lakes from CECs. At the end of the 2007-2009 review cycle, the CEC Workgroup presented its findings and recommendations to the IJC, and the IJC presented the workgroup with a new two-part charge: 1) to assess the performance of wastewater treatment plants (WWTPs) and CEC removal technologies, and 2) to assess human and ecosystem health effects from exposure to CECs.

Focusing on the ecological effects of CECs in the second part of the IJC's charge, an Ecological Effects Subgroup conducted a literature review to determine the impacts of CECs on the aquatic ecosystem, reviewed current surveillance tools and strategies for assessing CEC exposure and impacts to aquatic wildlife, and developed a draft surveillance strategy for assessing exposure to and effects of CECs in the Great Lakes. The purpose of the present experts consultation is to discuss the reports generated from the workgroup's recent research and to develop findings and recommendations for a report to the IJC which is due in June 2011.

The final products expected as a result of the experts consultation are: 1) final literature review on CEC effects, 2) final Great Lakes effects surveillance strategy, and 3) a report to the IJC.

First Plenary Session: Ecosystem Health Effects

Dr. Rebecca Klaper, Associate Professor, Great Lakes WATER Institute, School of Freshwater Sciences at University of Wisconsin-Milwaukee, presented the results of a review of effects of CECs on the Great Lakes ecosystem. The review focused on whole organism effects, mechanisms of action (MOAs), biomarkers, other endpoints of interest in ecological risk assessment, mixtures of chemicals, and the relevance of concentration.

Categories of CECs reviewed included:

- Brominated flame retardants (HBCD TBBPA, PBDE)
- Triclosan and triclocarban

- Pharmaceuticals [Selective serotonin reuptake inhibitors (SSRIs) and Peroxisome Proliferators (PPs)]
- Phytoestrogens
- Perfluorinated surfactants (PFOS, PFOA)
- Synthetic Musks (AHTN, HHCB)
- Chlorinated paraffins (CPs)
- Phthalates
- Bisphenol A (BPA)
- Nanomaterials

Current use pesticides were omitted due to the large size of the category.

The goals of the review were to determine what is known, gaps in knowledge, how known information can be used for monitoring, and what needs to be added (lab/field) for monitoring to be effective.

For acute toxicity studies, concentrations reported in the literature were often much higher than those found in the environment. Mortality was found for a few categories of CECs. There was very little information on the ecological effects of several CECs. Mortality is the main effect investigated in acute toxicity studies, but little information is available, especially on ecological endpoints. Dr. Klaper presented a chart indicating information found in the literature on specific endpoints for each of the CECs reviewed. No information for a CEC could mean that no effect was found or that no information was available for an endpoint.

Organisms represented in the literature included rats and mice, Daphnia, algae, and bacteria. A minority of information was available on ecological effects in frogs and fish, and investigations in birds and terrestrial species were few. Most of these organisms are not representative of effects that may occur in the Great Lakes ecosystem, which represents a gap in available information. It is important to build laboratory information on other species.

In the literature reviewed, mortality was the most frequent endpoint investigated. Reproductive effects were frequently investigated, and progress is being made in characterizing developmental effects. Other endpoints that could affect populations were not commonly investigated.

Concentrations of CECs reported in experiments were not always relevant to observed environmental exposures. High exposures levels were reported in laboratory experiments, whereas concentrations in the environment are much lower. Depending on the compound, concentrations of CECs in the Great Lakes ranged from 10 to 2000 ng/L in water and from 10 to 200 µg/kg in sediment. Dr. Klaper presented a chart indicating effects observed at environmentally relevant doses (represented by red Xs in the chart). The findings underscore the importance of investigating endpoints at appropriate concentrations of exposure.

Exposure levels in the environment are not known for nanomaterials, as they have not been detected. Research is ongoing to identify new detection methods. Unlike many of the CECs investigated, nanomaterials are largely unregulated. Dr. Klaper suggested that it would be a wise use of resources to assess/monitor nanomaterials as unregulated CECs.

Several studies in the literature investigated MOAs for CECs. Reproduction-associated endpoints were the most commonly reported, dominated by estrogen agonists/antagonistic response. Other mechanisms were reported infrequently. The same mechanism cannot be assumed to hold true across species. The distribution of organisms and concentrations reported in the literature made it difficult to draw conclusions. Dr. Klaper presented a chart indicating MOAs reported for the CECs reviewed. Missing information in the chart may mean that no information is available. Hormonal pathways were the most common MOA, but much information is missing for various CEC categories. Oxidative stress was represented more than other MOAs, but neurotoxicity, necrosis, and other MOAs had little information available. Information was also lacking on tissue-specific concentrations.

Mixtures of chemicals are the most likely environmental scenario, but the potential number of combinations and concentrations of CECs make laboratory studies difficult to perform. Findings have shown that the sum (e.g., PBDE mixture) is often greater than the additive contribution of individual CECs, but the effect depends on the chemicals present in the mixture. Mixture effects depend on the action of the chemicals (mixtures of compounds with similar action tend to have additive effects, and mixtures from different classes are synergistic at lower concentrations). There is a need for more mixture studies with different types of chemicals, at realistic exposures, investigating more endpoints than mortality. Additional ecological health indicators to investigate include population size, population dynamics, and genetic diversity.

Low-dose mixture effects can cause a different MOA. For example, a study by Crago and Klaper showed synergistic effects of a CEC mixture on testosterone concentrations. The main findings of the study suggested that combinations that lead to decreased testosterone concentrations were due to steroid metabolism by PXR mediated changes.

Ecological risk assessment tools used in the environment are different than lab studies. No indicators are available for large lake systems. Many ecological indicators could be investigated, including biotic condition, species and populations, chemical and physical characteristics, and ecological processes. These indicators would provide valuable information about how CECs are affecting the environment.

Some semi-field studies have been performed (a microcosm ecosystem put into the field). The effects of PFOA exposure on population richness (with organisms representative of the Great Lakes) indicate that richness decreases with increasing PFOA concentrations (10-50 mg/L) (Sanderson et al. 2003). However, the concentrations investigated were well above environmental levels. Similarly, a decrease in microbial diversity was seen with increases in phthalate concentrations (Kapanen et al. 2007).

Studies of CEC impacts in the field predominantly investigated estrogenic endpoints. Limited population information was available for CECs in the Great Lakes. Studies in the literature were focused on limited pathways with limited outcomes. There is a need for studies investigating the whole physiology of an organism and not only estrogen receptors. One approach is to use a greater number of biological pathways such as genomic markers to develop bioindicators. Ideally, there would be suites of biomarkers to indicate effects, exposure, and MOA.

Biomarkers can be limited in prediction (i.e., vitellogenin mRNA levels can only be used as a predictor of egg production in the short term, <12 days). Biomarkers in lab animals differed from

field organisms. There are limited biomarkers available to assess effects, and there is a need for more lab and field validations. In addition, it is difficult to tie biomarkers to endpoints that are field/population relevant. The effects of breakdown products are another unknown.

Two papers have recently called for the development of a research strategy to evaluate the risks to human health and the environment posed by CECs. Recommendations from these papers that are in common with Klaper's review findings include gathering more data on:

1. Sublethal chronic impacts at realistic exposures
2. Impacts of mixtures
3. Impacts of byproducts or metabolites
4. Mechanisms of action at low chronic exposures
    a. Investigate more mechanisms of action
5. Non-lethal endpoints such as growth, reproduction, metabolism, and behavior
6. Methods to monitor effects in the field
7. Data to tie lab and field studies
8. Data on population, community, and ecosystem levels

Comments and Questions

1. Was there any evaluation of quality in the review? *Response:* Yes, studies with EPA or OECD methods were included as well as other studies with sufficient information describing the method. Government documents were also included.
2. In a few of the charts, if no X was in the box, you could not distinguish between no effect and no information. It is important to distinguish whether there is no effect or whether there is a gap in available information, so negative results are not under represented.
3. Did you mine the mixtures literature or databases for the presence information? *Response:* Dr. Klaper did not use modeling papers. If participants are aware of field studies that are missing from the report, let Dr. Klaper know.
4. What was the objective of the review? *Response:* The objective was to summarize the potential ecosystem effects of CECs at various levels of biological organization.
5. Is the bibliography available? It was not included in the report distributed prior to the meeting. *Response:* The bibliography will be available soon. It is still being edited.
6. There has not been a goal stated for the proposed monitoring program. CECs are being managed in Canada, and many are being banned or have been. Is it worth investigating effects for CECs such as PBDEs, when they have already been banned, or to invest research into nanomaterials, for example, which have not been regulated? *Response:* From an environmental perspective or clean-up strategies, it is still relevant to have an assessment strategy to evaluate the ecological response to chemicals.
7. Some contaminants have been in the environment for a long time (e.g., PAHs), but new information is being developed that is raising the concern. Will the proposed monitoring strategy address chemicals such as PAHs that are a re-emerging concern? *Response:* The strategy is not confined to classes of chemicals as defined in the 2009 CEC Workgroup's report to the IJC. Legacy chemicals can be considered.
8. How did you select SSRIs for pharmaceuticals? *Response:* SSRIs were chosen partly because of Dr. Klaper's familiarity with them, but also because SSRIs are the most prescribed pharmaceuticals. Hormone compounds were not reviewed because they have a wealth of information available. In an effort to narrow the range of chemicals reviewed, CECs with less information available were chosen for the review.

9. Ecosystem health effects are much broader than the cellular and molecular effects described in Dr. Klaper's paper. What is the objective of the next break-out session? *Response:* EPA is trying to develop a strategy for assessing the effects of CECs on the ecosystem at all levels. EPA is trying to determine how to conduct surveillance to determine toxicant stress. It is a challenge to translate organism effects to population level effects.
10. It is a common error to confuse exposure with endpoint, but it is important to be clear with the language and not confuse exposure with endpoint. It will cause problems in translating results to the policy realm.
11. Levels in the environment are relatively low, but to what extent do we take into account biomagnifications, bioaccumulation, and differences in geographical location? *Response:* Dr. Klaper agreed that we need to consider these factors.

First Break-out Session: Discussion of Ecosystem Health Effects

Details of each breakout session's discussions are included in Appendix A. Summaries that were presented in the plenary session are provided below.

Lake Erie Room Break-out Session Findings

The group decided that they would like to see a focus on what is known, using the most robust monitoring data available, and understand or determine the reference condition. In parallel, there is a need to estimate CECs exposures and bin them ranging from acute to chronic. In December 2010, the Water Environment Research Foundation (WERF) published a framework that described a process for this. Once CECs are binned, we can predict CEC effects, and then compare the relationship between monitored and predicted impacts. With this information, we can develop a "smart surveillance" system, which basically outlines an experimental design to verify a hypothesis.

In response to the discussion questions provided for the session, the group agreed that there was much information missing from Dr. Klaper's report.

Lake Superior Room Break-out Session Findings

Much of the discussion focused on management needs, goals, and objectives. The group agreed that more context is needed on the management objective of the proposed monitoring program.

Most participants did not entirely agree with Dr. Klaper's findings, noting that there were many gaps, which was partly due to the limitations of the report. A more thorough approach might have been more valuable.

Some of the gaps in understanding the ecosystem effects of CECs that were discussed included the impact of legacy chemicals, confounding factors and non-chemical stressors. More field studies are needed to evaluate effects. Participants suggested that existing data collection activities could be better integrated. Logical places to begin monitoring might be baseline areas.

Lake Michigan Room Break-out Session Findings

The group discussed the overall problem of designing an Effects Strategy and how that type of monitoring might fit into other stressors to the ecosystem. Ecosystems have different organisms, niches, and functions that change. A signal in the ecosystem may not be observed because the problem is not linear. The group also discussed how indicators tie into the overall monitoring strategy.

There was some discussion of specificity and the concept of pathways. A suggestion was made to begin with broader endpoints and work down into tiers to assess whether the ecosystem is healthy. The group did not have much success identifying indicators to use for monitoring. The science is not mature enough to use genomic arrays in routine monitoring.

Second Plenary Session: Tools and Methods for Effects-based Monitoring

Dr. Irv Schultz, Battelle Pacific Northwest National Laboratory, presented the results of a literature search on tools and methods for ecological risk assessment. The literature review was conducted to support the development of the Effects Strategy through the collection of more comprehensive information that will be used to inform the Effects Strategy's rationale and approaches for the use of systematic, effects-based methods for monitoring the ecological risk of CECs in the Great Lakes aquatic environment.

Dr. Schultz described the literature search approach, methods, and criteria for sorting the literature results. The search included the scientific, published and 'grey' literature from 1995 to 2010, as well as review articles published prior to 1995. The search did not include aquatic plants or algae (macrophytes, algae, diatoms).

Over 5,000 articles or reports resulted from the search. The articles were primarily laboratory studies, rather than in situ field studies. Among the studies reviewed, method validation status ranged from those validated for regulatory use to proposed new research tools. Many studies incorporated a variety of methods. Some validated or compared new methods to well-established standard methods. A trend was observed toward approaches that integrate a variety of endpoints (e.g., tying gene expression to physiological endpoints), and linking behavioral endpoints with other endpoints may be increasing. The biological level of effect ranged from subcellular to tissue/organ-level to individual-level, and studies addressing population-level effects appeared to be relatively limited.

Six overarching themes emerged from the literature results:

1. Traditional survival, growth, development, reproduction endpoints
2. Methods focused on organ-based system responses
3. Biochemical markers/enzyme activity/protein-based measurements
4. "Omic" technologies/gene and protein expression
5. Genotoxicity/mutagenicity
6. Behavioral endpoints

For each overarching theme, Dr. Schultz described a few assays and endpoints reported in the literature, the specificity of the endpoints, the biological level investigated, the commercial availability of assays, and matrices to which the assay or endpoint has been successfully applied.

One example of using traditional sediment toxicity testing is provided in a review paper recently published by Hallare et al. (2011). The authors stressed the importance of selecting species to use for different media and presented the relative number of studies conducted in whole sediment vs. in situ caging and other media. The paper also characterized in vitro testing and endpoints that have been utilized for assessing dioxin-like activity, cytotoxicity, genotoxicity, and proteotoxicity.

Analysis of the literature results suggests that effects-based methods are available that are good indicators of toxic chemical effects. In the lab, these include acute and chronic toxicity tests, endpoints such as the vitellogenin response, and gene expression and gene profiling. In the field, these include organism and population-level responses (e.g., gonado-somatic index (GSI)/liver-somatic index (LSI); condition index; nutritional status, disease resistance; abundance; age structure/recruitment), and in situ biomarkers (e.g., EROD induction, glutathione S-transferase (GST) activity, vitellogenin). The findings also suggest that the integration of methods can be time and cost-effective in assessing multiple levels of biological organization. This was demonstrated in a study of salmonid migration in the Fraser River in which several disciplines were ambitiously integrated, including physiology, behavior, functional genomics, and experimental biology (Cooke et al., 2008).

For purposes of informing the development of a surveillance strategy, the results indicated that promising assays and endpoints are available in the short term for monitoring toxic chemical effects. In vitro assays (e.g., H4IIE cell or reporter gene bioassays) for Ah receptor agonists are useful in multiple media (e.g., sediment, water extracts). In vitro hormone receptor expression and receptor-binding assays are validated methods for assessing reproductive toxicity in fish, and have been applied to endocrine disruptors. The EROD assay is widely used as an early warning system to detect Ah receptor interaction in fish, birds, and invertebrates. Widely used assays of vitellogenin induction in fish (both males and females) detect estrogenic and aromatase-inhibiting substances, primarily in fish. Gonad histology in fish can be measured in reproductive toxicity tests using traditional endpoints or in conjunction with steroid concentrations and vitellogenin, for example. Simple observations can indicate toxic effects, such as tumors and morphology changes associated with sexual dimorphism.

The application of ‘omics methods is rapidly increasing and may become a tool for monitoring toxic chemical effects in the long term. Proteomics studies are becoming more widespread, and metabolomics have demonstrated utility. Transcriptomics methods are the best established ‘omics methods and have been applied to a wider range of ecologically important species. Criticisms of ‘omics methods include the use of lab species rather than ecologically relevant species. The use of ‘omics tools in the field would be enhanced by the incorporation of standardized toxico- ‘omic protocols using specific species (of a specific life stage and gender) to minimize confounding effects of inter-species differences, reproductive status, and other factors.

Phenotypic anchoring (integration of ‘omics with higher level endpoints) is valuable in establishing diagnostic power. The continued growth of bioinformatic knowledge for eco-relevant species is expected to enhance ‘omics value for effects-based monitoring. An increased use of pathway analysis is needed, as it relates to selected transcriptional/physiological processes. In addition, there is a continued need for understanding inter-species differences in pathways and improved inter-species extrapolation.

Dr. Schultz noted that there may be differences in interpretations of MOA. One definition of MOA is a "Complete, detailed sequence of events leading to a toxic outcome." Different MOAs are relevant for discrete molecular targets, pathway perturbations, and individual or organ systems.

Questions

1. Why were aquatic plants omitted from the literature review? *Response:* This was the charge given, presumably to limit the quantity of literature search results.

Second Break-out Session: Discussion of Tools and Methods for Effects-based Monitoring

Details of each breakout session's discussions are included in Appendix A. Summaries that were presented in the plenary session are provided below.

Lake Erie Room Break-out Session Findings

There was some discussion of the need for individual or cellular-based responses. There are far too many tools available to incorporate all into a monitoring program. The group suggested that the focus of a new monitoring program should be on population-level attributes, traits or effects. It is also important to have an explicitly stated management objective that defines what it is the program aims to protect. Then a conceptual model can be developed with a strong rationale for the program. The focus should be more on effects and less on chemicals. The Canadian Environmental Effects Monitoring (EEM) program was referred to as a good example of monitoring broadly for changes, and when a problem is detected, causation investigations are initiated on a site-specific basis.

The group proposed a pragmatic approach for selecting species using field tests as much as possible. The program should select abundant keystone species. With regard to available tools, there may not be a well-established toolbox with regard to accuracy, defined criteria, power, and significance of effect. It would be useful to mine existing data and to coordinate monitoring efforts.

Lake Michigan Room Break-out Session Findings

Beth Murphy of USEPA described different monitoring programs in the US and Canada. Any new monitoring will need to be added into existing programs. There is no systematic biomonitoring being conducted (although some on a small scale). The group agreed that there are many useful tools that could be added into existing programs to assess population-level effects, including those that Ohio EPA is using. The lack of systematic biomonitoring is a clear gap.

Newer tools coming online like 'omics tools are not yet ready for deployment. Rather than mention specific tools, the group suggested addressing five or six key attributes and determining the best tools for assessing them using a biomarker approach (e.g., reproductive success, growth).

A key recommendation was the need to share data among jurisdictions and to continue current collaborations, such as the US Geological Survey (USGS) and US Fish and Wildlife Service (FWS) working together.

It is important to have traditional biologists in the field to assess ecosystem health. It is also important to define a baseline, "normal" condition. In Canada, some benthic monitoring is being conducted by Mark McMaster and others that should be recognized.

Lake Superior Room Break-out Session Findings

The group discussed the need for top-down and bottom-up approaches to monitoring that utilize population-level effects. Some states are using such approaches. Bottom-up endpoints are biomarkers that have been discussed in this meeting, but linkages to higher level effects are needed.

Promising assays/endpoints in the short term for monitoring toxic chemical effects include the obvious: standardized tests, well-validated methods like vitellogenin, histology, EROD induction, and morphological endpoints. New tools ('omics) are not off-the-shelf but can be included in the repertoire for development and assessment for ultimate use. There is a need to make appropriate linkages and pathway-based understanding of changes in measurements.

To deploy tools, the group suggested using a tiered approach that employs a limited set of endpoints at limited sites where impacts are detected. Investigation can then proceed to diagnostic analysis that attempts to associate effects with particular chemicals. This might help with regulatory decision-making.

The group proposed building on existing programs because it is difficult to justify a whole new program. However, the proposed monitoring program may not be congruent with existing monitoring, and changes will need to be made to existing programs.

To begin monitoring, identify places where contaminant effects are likely to be found, such as Areas of Concern (AOCs, for legacy contaminants) but other sites for newer contaminants. Choose pilot sites to conduct proof-of-concept studies. Focus on other species in addition to fish (e.g., birds, terrestrial). In situ exposure, caged fish exposure, and other methods will need to be used.

Discussion

- In designing a program and piggybacking on existing programs, the ecosystem focus of programs and the location of predicted effects can inform questions of which components should be monitored and where we can get the "biggest bang for the buck."
- The WERF framework published in December 2010 is one way of locating sites for pilot studies. The potential for CEC exposure was divided into four categories based on likelihood. The framework analyzed WWTP discharges based on several factors (including non-point sources and land use) and ranked them according to likelihood for investigating. Then, a study was designed for that area.
- How much can the proposed monitoring program cost? There are many parameters and sites that would be good to measure, but not all are realistic. The Effects Strategy should explain the essential features that we need to understand to be able to protect the ecosystem. The Effects Strategy should not consider budget but should prioritize activities in terms of importance, including research and development of new tools.
- The Effects Strategy should ensure that a focus on the nearshore is maintained.

- The Effects Strategy should state how data will be shared and archived (e.g., by including data-sharing requirements in EPA contracts).
- The Effects Strategy should make the policy implications clear to the IJC.

Day 2

Plenary Session: Strategy for Assessing the Effects of Toxic Substances

Joe Tietge, USEPA Mid-Continent Ecology Division, the primary author of the Effects Strategy to date, presented the rationale and approach for a strategy to assess the effects of CECs in the Great Lakes.

Decades of analytical monitoring have detected numerous chemicals in Great Lakes media, and more are expected to be present based on use patterns. Sufficient effects data are lacking to permit risk assessment decisions. However, advances in biology and toxicology are closing the gap in understanding.

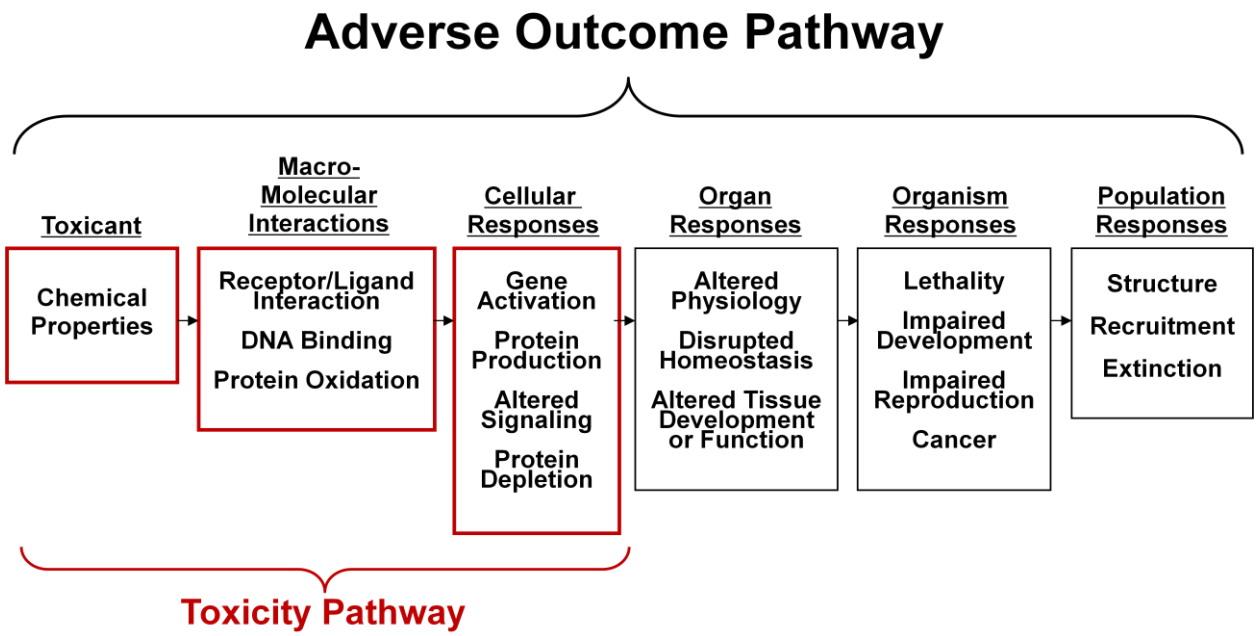
The Effects Strategy seeks to incorporate new biological and toxicological methods into a tiered assessment strategy that will develop and use predictive methods for screening and prioritization. The Effects Strategy will increase effects-based monitoring to evaluate real-world phenomena of the effects of multiple chemicals and multiple stressors at relevant temporal and spatial scales, through the use of rational diagnostic approaches.

The term CEC is used to imply the importance of chemicals that are emerging in the environment. The term is not used consistently and is not a useful term scientifically. Categories of CECs are not comparable. Trace Organic Compounds (TOrC) is a more useful term, defined as "… chemicals that are known or suspected to be released to aquatic environments but are not commonly regulated or monitored, and whose potential risk to human or ecological health are relatively unknown." (WERF, 2010).

In terms of CECs, there are "Known Knowns," which include conventional pollutants such as pesticides, PCBs, PAHs, and metals that we know how to measure and have the data with which to assess risk. There are "Known Unknowns," such as PBDEs, pharmaceuticals and personal care products, and nanomaterials that we suspect or increasingly know are present but lack sufficient effects data with which to assess risk. These CECs are amenable to prospective assessments. Finally, there are "Unknown Unknowns"—chemicals or mixtures that we are not aware of or cannot measure. These chemicals require retrospective (or diagnostic) assessments.

In the risk assessment paradigm, CECs are of uncertain risk, and screening-level information is needed to further prioritize efforts. Traditional chemical testing will not achieve reductions in uncertainty, on the scale needed, to inform decision making. Much work has been done to move toward predictive toxicology, which is the science of making predictions of toxicity outcomes based on previously untested relationships. Predictive toxicology models are used for prioritization, inter-species extrapolation, inter-chemical extrapolation, exposure analysis/reconstruction, and support for diagnostic approaches.

The Adverse Outcome Pathway (AOP) is a conceptual framework that portrays existing knowledge concerning the linkage between a direct molecular initiating event and an adverse outcome, at a level of biological organization relevant to risk assessment (Ankley et al. 2010). The AOP can be used to extrapolate the effect of toxic effects at the molecular level to impacts at the population level. The AOP can be used as a strong scientific rationale for causal analysis, which focuses on pathways relevant to regulatory decisions and leads to prospective and retrospective analyses. Prospective (predictive) analyses evaluate the probability that exposure to a chemical will result in an adverse effect. Retrospective (diagnostic) analyses investigate whether an observed response might be associated with a given chemical.



It is assumed for most CECs that data are lacking with which to derive conventional benchmarks, that they occur at low environmental concentrations and are not generally a lethality risk, and that concerns are for sub-lethal, chronic effects (reproduction, growth, development). Tools currently available for assessing effects are dominated by those used to determine acute/chronic lethality, with few models available for sub-lethal effects.

There are generic and specific endpoints for biological monitoring. Generic endpoints include survival, growth, and reproduction, which integrate multiple toxicity pathways. Specific endpoints include molecular, biochemical, and histological, which are indicative of a specific pathway or AOP.

The AOP approach can be used in endpoint/assay selection. Predictive tools are available that are accepted and validated, such as quantitative structure-activity relationship (QSAR) models and Interspecies Correlation Estimation (ICE), for conducting analyses of effects. Few predictive tools are available for sub-lethal effects. Methods selected must be straightforward and validated. Some special considerations for testing in vitro systems include maintaining media composition and preventing bacterial/fungal/viral contamination. Near-term assays/methods that can be applied include in vitro assays, biochemical measures (e.g., sex steroids, vitellogenin, EROD), and histology. Long-term tools include ‘omics such as transcriptomics, proteomics, and metabolomics.

Canada's EEM program, the BEST program, and TBiOS program in Puget Sound provide examples of existing biomonitoring programs. The BEST program has not sampled since 2004 due to funding restrictions. Only fish, a predatory species, are monitored, generally bass. The BEST program also investigated immune function.

Comparison of major endpoints of the three programs indicates that age, growth, condition, GSI, and LSI are common across all three. Lipid and vitellogenin and histopathology measurements are common across two of the programs. Other endpoints are unique to individual programs, such as fecundity, and spleno-somatic indices (SSI) analyses. EEM's critical effects size process has been established through an exhaustive collaborative process. Periodicity of biomonitoring for the EEM runs on a 3-year cycle due to the length of time required for the government proposal process.

Questions/Comments

1. What is the decision framework for the program? What will the data be used for? What are the management objectives? *Response:* These have not been determined yet. We are trying to determine how to conduct an impact assessment, as charged by the IJC. Canada's EEM program painfully developed an objective: to evaluate the adequacy of national regulation over time.
2. Will mixtures be diagnostically assessed in the program? *Response:* Mixtures will be analyzed through the AOP pathway. Monitoring of other stressors must occur simultaneously with chemical and effects monitoring, as well as reference site monitoring.
3. The Bald Eagle productivity program in Michigan is an example of a monitoring program. The program measures sites annually, and samples are drawn primarily for legacy chemicals. On a 5-year schedule prior to National Pollutant Discharge Elimination System (NPDES) permit review, additional parameters are assessed.
4. In the nearshore framework, knowing the dose is an important consideration, due to other stressors such as runoff, non-point source pollution, etc. *Response:* The value in effects data is observing changes over time (status and trends), to determine cause. The value of the proposed program is overlaying effects with chemical analysis.
5. Using the AOP for prediction suggests that the arrows in the tool should be robust, with models to support them. Can you describe those underlying models? *Response:* The AOP is more of a conceptual communication tool without quantitative models to support it, although there are quantitative structure-activity models that could be overlaid on it.
6. Developing an Effects Strategy requires a clear problem formulation and then development of a conceptual model for the Great Lakes that identifies the CECs and pathways of concern, which will justify the selection of species. The AOP focuses on fish and invertebrates but omits birds and other species.
7. The BEST program chose a metric that gave an indicator of ecosystem health: fish. It is recommended that the Effects Strategy analyze status and trends using apical biomarkers in fish. When abnormal observations are found, more specific studies can be designed. Once a response of concern is observed, the analysis can focus on a site-specific investigation. This spring, a process is being designed for a major monitoring program in Canada (due in June 2011).

8. The endpoints presented for the three monitoring programs do not indicate the health of an ecosystem on a population level. More investigation of the significance of a problem that is found with these endpoints is needed.
9. States and others are monitoring. It would be nice to piggyback on those programs with effects monitoring.
10. We can state a goal of the proposed monitoring program: to develop a reliable tool that can be used to guide management decisions. Then the program can develop baseline information, analyze trends, and incorporate investigative research, with an end goal of providing reliable outcomes for management.
11. It is important to use the risk framework as an organizing tool. There has been no discussion of data quality objectives. We need a management goal, which can be defined as an exploratory fishing expedition, or can be more defined. Methods will be chosen based on the overarching goal. Data generated will be useless without a conceptual model matched to the management objective, with proper analytical methods and appropriate detection limits.
12. Monitoring for monitoring's sake can be useful. For example, Heidelberg and USGS routine monitoring detected phosphorous runoff from farms. Others disagreed with this statement.

Third Break-out Session: Discussion of Proposed Strategy Approach

Details of each breakout session's discussions are included in Appendix A. Summaries that were presented in the plenary session are provided below.

Lake Erie Room Break-out Session Findings

The group agreed that it is not clear what the strategy is trying to measure or what we are trying to determine from the measurements. The group would like to see management goals defined for the proposed monitoring program, as well as better definition of the spatial and temporal scales of the program, number of monitoring sites, frequency of monitoring, etc.

The term "ecosystem health" is troubling, as the proposed monitoring program involves toxicological assessment. It would be better to describe how the Effects Strategy will add biological monitoring to existing monitoring programs.

The group suggested considering the development of a public communication plan. Observations of a significant change through the use of biomarkers might cause undue public alarm.

The group also suggested coordinating with human risk activities.

Much of the group's discussion focused on the need for baseline information. Measuring at the population or community level is noisy, and monitoring needs to occur over a long period. The diagnostic potential of endpoints requires a strategic choice of monitoring sites. Predictive models can help identify sites predominately influenced by a type of CEC effluent. The group suggested starting with limited sampling at chosen sites and then expanding the program.

Lake Michigan Room Break-out Session Findings

The group suggested a few reference documents for developing the strategy:

- EPA Risk Assessment Guideline, which includes risk management and communication elements.
- The 2010 WERF report "Diagnostic Tools to Evaluate Impacts of Trace Organic Compounds."
- The European REACH database contains dossiers that may help identify which CECs to focus on.

The group produced several recommendations:

- Create a database that would allow agencies in the Great Lakes to share monitoring data.
- Require monitoring data from programs be reported promptly to encourage its use and sharing.
- Develop a white paper that summarizes current monitoring programs (include fish, birds, mammals, etc.)
- Investigate all stressors acting on an organism or population, not only CECs/TOrCs.
- Implement a food-web approach that uses fish and benthic community surveys and investigates interactions between communities (i.e., bottom feeders and predators).
    - Plankton can be useful because effects from multi-generation exposure can be monitored in a short time period.

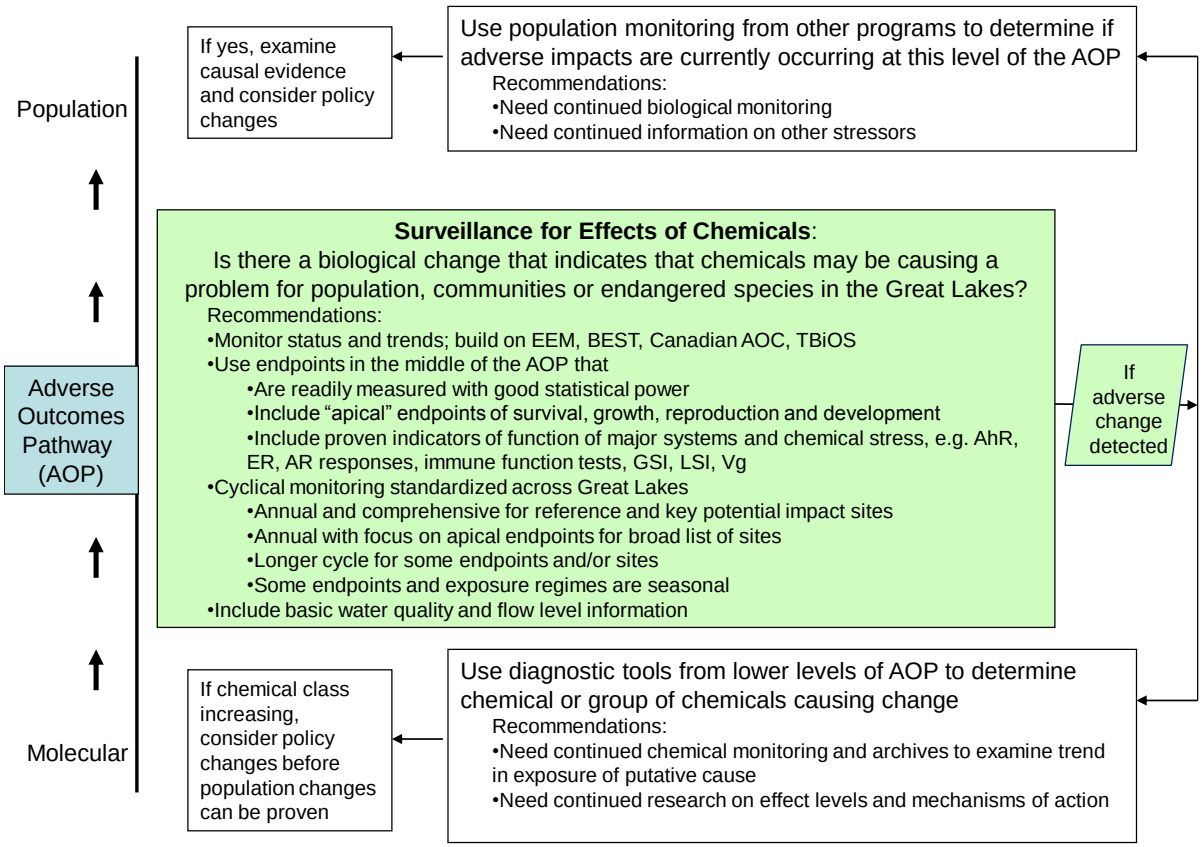
Lake Superior Room Break-out Session Findings

In this session, Burton Suedel of the US Army Corps of Engineers summarized the various insights and recommendations that participants had offered since the inception of the workshop. The summary outlined an approach for developing a biomonitoring program in the Great Lakes. As a first step, the Effects Strategy should develop a problem statement that articulates the goals and objectives of the biomonitoring program. Next, the Effects Strategy should develop one or more conceptual models to identify sources, pathways, and receptors, and to select species of focus for the program. Factors to consider in developing criteria for successful indicators include:

- Top-down and bottom-up approaches
- Predictive response patterns
- Toxicology, biology, and ecology endpoints
- Receptor traits
- Population level
- End use of the data
- Leveraging ongoing biomonitoring programs in the region
- Data quality objectives

A list of potential indicators should be developed and prioritized based on the set of criteria developed. Indicators that best meet the criteria should be chosen. Consideration of how the sampling data will be used will inform the development of the Effects Strategy.

Lisa Williams drew a framework, presented below, that illustrates a proposed approach for the Effects Strategy.



Final Plenary Session: Discussion of Recommendations

Discussion Questions

1. ***What tools, assays, and endpoints are recommended for monitoring eco effects in the short term?***

- One approach suggested was to add a biological component to a chemical program that monitors status and trends, using endpoints such as those utilized in the Canadian AOC program. Community surveys (e.g., fish and birds) could be added at the same time.
  - Young of the year (YOY) index sampling is reliable yearly sampling where you could begin to add biological sampling to assess CECs.
- Monitor at all levels (e.g., community, biomarker) in conjunction with chemical monitoring. This will help interpret observations at the biomarker level.
- Start gathering baseline data to inform the future of the program. Not enough is known at this point.
- Focus on the mid-trophic level and, depending on the change observed, go up to the population/community level or down to the molecular pathway level to conduct additional monitoring.

- Data at higher levels of biological organization will be more sparse. There are many stressors that can cause effects at high levels, and it is harder to determine the effects of CECs.
- Use biomarkers that are specific for pathways of interest.
- Compile an inventory of monitoring programs to identify where collaboration can occur and where data currently being collected can be utilized.
- Set up a database where scientists can contribute, such as WERF is currently doing.
- Ensure binational harmony in assessments so that data are comparable.
- Flexibility will be a key component – don't lock into measurements.
- Consider including a marker for immune status to assess disease resistance. The BEST program used macrophage aggregate, SSI and lysozyme assay to attempt to analyze immune function. It is critical in sustaining populations.
    - EEM is still trying to incorporate markers of immune status.
    - In birds, some assays (PHA skin test and red blood cell antibody test) have been proposed.
    - Mammalian immune function tests are more developed and could be applied.

2. Which tools, assays, and endpoints need to be developed for use in the long term?

- Assessments of the genetic structure of a population.
- Rather than develop more tests, it is more important to determine how endpoints link and how different levels of organization relate to each other—mechanistic modeling that tries to capture pathways (e.g., in AOP model).
    - EEM is trying to understand factors that drive populations from a climate perspective (e.g., differences in temperature and annual rainfall) to build better models. Defining what is normal and variations across seasons, species, etc. is important in order to determine changes that occur.
- The whole issue is driven by stakeholder interest. Are we trying to answer a question that stakeholders are interested in? A recent New York Times article is an example of public alarm regarding CECs. We have data that is assessing the ecological health of the Great Lakes, but will that allay the public's fear?
- Observe chemical impacts on organisms. If effects are observed, then go up and investigate or drill down to find causes of perturbation to find types of chemicals that are causing changes. Combine with chemical analysis to determine levels of chemicals in organisms, and decide on management actions.
    - It is an iterative investigation of causal effects that are observed.
    - We do not have a one-to-one correlation between organism level and population level, but as we learn more, we can modify the process as we go.

Kelly Munkittrick presented a few slides on Canada's EEM program to illustrate examples of the utility of data. Monitoring of pulp and paper mill discharges in Canada showed changes in liver size and gonad size in male fish resulting from changes in mill effluent (data from 65 sites). Kelly presented several charts showing changes in gonad size, weight at age, and liver size for male and female fish (sample size ~180). Some improvements have been observed from a 1991 worst-case scenario compared to 2006. Mining data show a different pattern due to some endocrine stimulation.

Monitoring data can be used to document changes over time. Data allow analyses of changes due to temperature variation across years. The data enable investigations to understand and make predictions for the effect of temperature and number of thunderstorms on size of YOY sculpin, for example.

The EEM program was designed in 1991. Experience has shown that additional parameters would be useful to include in the program. For example, water level flow data would be useful to add at sampling sites. The data have many uses without the need to extrapolate up to the population level.

The EEM program uses 65 different species of fish. There has been some analysis of the use of species and relationships to the time of year. There is much to learn from EEM's experience. Sweden also has a program (which uses 2 species) from which we can learn. Sweden's program requires stakeholder consensus as to what is unacceptable, prior to monitoring.

Monitoring requires measurements over a long period, but it is difficult to maintain funding over a long period. To leverage resources, Kelly is trying to coordinate similar programs to monitor at the same time with consistent methods, and to increase the efficiency of existing monitoring.

The EEM program operates on a mandatory 3-year cycle, which guarantees results every 3 years and generates support for the program. A frequent cycle of reporting is important, as data can become tied up for years, resulting in a loss of interest and funding for a monitoring program.

3. What sampling design should be recommended (location, frequency, matrices, etc.)?

- Locations should include both targeted sites (e.g., WWTP, agriculture-influenced sites) and existing monitoring sites. WERF's research could serve as a starting point in the selection of sites.
    - Include targeted investigations (areas receiving the highest levels of discharge) but also reference sites, on a routine basis.
- The frequency of monitoring might vary. For example, if focusing on an organism, the life history of the organism must be considered.
    - For apical and biological endpoints, need to consider the lifecycle stage of the species monitored. Some endpoints are not relevant if animals are not reproducing.
    - Assess the amount of natural variability—more frequently at the beginning, but annually seems appropriate.
- Matrices for the monitoring program—discussions have focused on fish and birds, but sediments are important, too. Regarding field vs. lab, more controlled experiments can be performed in the laboratory. For example, with some sediment invertebrates, multiple generation tests can be performed (although many mechanisms discussed are not conserved in invertebrates).
    - Consider species with a high reproductive rate.
    - If concerned about food chain bioaccumulation, start at the bottom of the food chain, with benthic organisms.

- Do not focus on fish. While reasonably good "integrators" of diverse exposure pathways, fish are relatively hard to capture, have relatively long lifespans in relation to the perceived temporal characteristics of CECs (faster degradation, lesser adsorption, episodic releases), and may not be distributed spatially or temporally to optimally survey CECs.
- It is important to include both pelagic and benthic food webs.
    1) The Great Lakes have an important pelagic component to ecological energy flows.
    2) Benthic food webs are important due to the focus on nearshore, the site-specific nature of the benthic deposits that may be of concern, and the functional connections between benthic and pelagic food webs.
- There was a suggestion to focus on plankton for two purposes:
    1) Community structure, population abundances, and changes in those measures over time and space provide the biological component of a surveillance program that could be employed over the entire system due to the wide distribution of plankton species throughout the system.
    2) Analysis of the contaminant loads in plankton samples would directly marry the biological with the chemical surveillance and provide data on the food chain implications (including bioconcentration) that could be modeled thereafter.
    3) In addition, a plankton-focused surveillance program would not impact fisheries or established fisheries investigations.
- Consider the presence of species at sites. In situ caged sampling might be necessary in addition to wild populations. Different endpoints, as well as integrated indicators, can be added for caged organisms, too, because it is a more controlled environment.

- USEPA GLNPO is developing a CEC sediment monitoring program, complementary to Environment Canada's monitoring program. NOAA is also monitoring sediments in the Great Lakes.
- It is important to consider water flow and seasonal variability (e.g., a low flow or dry season scenario where concentrations are greatest).
- It is important to consider environmental variables related to energy and nutrient flows (e.g., nitrogen, phosphorous, dissolved oxygen, suspended sediment, aqueous geochemistry, physical chemistry). USGS has automated monitoring in Great Lakes tributaries, but there is no automated collection in nearshore areas of the Great Lakes.
    - GLRI is funding remote sensing in tributaries and expanding tributary monitoring.

4. How can we make the best use of limited resources? How can we leverage binational cooperation (e.g., sharing samples)?

- Survey current programs that are conducting population-level monitoring. The Great Lakes Water Quality Agreement (GLWQA) dictates binational cooperation, and the GLWQA renegotiation is one way of ensuring a continued long-term commitment to binational monitoring.
- Continue to pursue the Coordinated Science Monitoring Initiative (CSMI) and other binational efforts.

- Leverage existing fish surveying operations for chemical surveillance to make samples available for analysis.
- Consider the use of public volunteers for monitoring (with training provided). Public volunteers have been employed in several monitoring programs to collect samples or make observations (e.g., bird behavior).
    - However, this leads to a question of the validity/quality of data collected, particularly in determining status and trends.
    - Stakeholder engagement in a number of ways would be useful—leveraging limited resources, involving the public, and communicating with the public.
- It is difficult to share samples if programs collect for different purposes.
- Develop a framework for the whole program. A risk assessment framework is a good starting point. The framework can be incorporated into a site model and linked to the risk management objective.

Lana Pollock of the IJC gave some final remarks. The IJC has ongoing efforts related to development of the Effects Strategy. One is the International Watershed Initiative, which involves local efforts on a small, watershed scale but is binational. The IJC is considering ways of applying the initiative to the Great Lakes. The second effort is the IJC Data Harmonization project, which is aimed at sharing data across the border and with multiple agencies, and considers ways of making better use of data. USGS has been a major player and driver in this effort. Lana made a plea for doing the science, standing up for the science, translating/communicating the science, and making it accessible. She thanked all participants for their contributions in helping to develop an Effects Strategy for the Great Lakes.

The next step in developing the Effects Strategy will be to prepare a report to the IJC. Then the IJC will make recommendations to the governments, who will be responsible for implementing them.

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APPENDIX A: BREAKOUT SESSION DISCUSSIONS

Full discussions of the three breakout sessions are presented below. Key points are highlighted in bold.

First Break-out Session: Discussion of Ecosystem Health Effects

Lake Erie Room

- Dr. Klaper's report was complicated and incomplete, and there were huge gaps.
  - The CECs were biased toward pharmaceuticals and microbials.
  - The findings were light on immune function, heavy on estrogenicity.

- Need to back up with a broader view that considers sources, relationship to exposure, and mixed models to segregate MOA, which provides the ability to predict.
  - Develop an inventory of where a high signal of a suite of chemicals is expected. Then monitor for effects. Some organisms may have become conditioned to chemicals due to long exposure.
  - Conduct retrospective analysis and compare to prospective monitoring. The WERF is proposing to conduct this type of approach that targets key chemicals using an indicator approach.

- **Need to develop a smart surveillance system**.
  - Look at elevated exposures at key sources (e.g., WWTPs, tributaries) and overlap with ecological sensitivity for developmental endpoints as the most sensitive endpoints. Then use the hypothesis approach to begin to identify key indicators in a controlled setting. Start by observing effects with indicators species, as Ohio EPA has been doing for years (observing intersex characteristics in suckers).

- **An objective for the new monitoring program needs to be defined.**
  - There are too many uncertainties to address all CECs with an overarching strategy. There are many different purposes and missing elements.
  - Perhaps identify indicator classes of chemicals that represent a broader spectrum (e.g., phenol compounds).
  - Monitoring classes of effects might be a good place to start, rather than a chemical by chemical approach.
  - The program should address a specific objective, such as reproductive rates in lake trout.

- Objectives could be set for each chemical or could focus on effects categories, such as when effects deviate from a normal reproductive range. Could focus on categories of responses that are associated with toxicological responses.
- It is difficult to justify a program year after year without clear objectives.
- Once objectives are established, can determine endpoints, select species, etc.

- There is a need for **detecting both mechanisms of effect and causes of effect**.

- There is a need to gather more risk information on some CECs to determine actions that can be taken.
    - There is existing effects information on the Great Lakes that can be accessed (e.g., that does not appear in the literature, particularly data collected in the field, data from FDA or the pharmaceutical industry).
    - USGS has undertaken a large effort to characterize commonly occurring chemicals in specific locations (e.g., pesticides and other classes).
    - On one end is effects monitoring and doing diagnostic work backward, but there is need for some information on the front end so screening level assessments can be done upfront, to determine whether a chemical is a concern.
    - We should delineate between what we need to know and what would be nice to know. Science is necessary but not always sufficient. **There needs to be policy with a lack of sufficient information.** We need to have a qualitative sense of effects and putative causes of effects, and then look at quantity and impacts based on that quantity.

- **We need a good understanding of what the background reference is, what normal is**.

- In the Great Lakes there is no integrated approach to monitoring CECs (a patchwork of state approaches). **Effects monitoring should be systematically applied across the Great Lakes**.

- **Many segmented monitoring programs could be centralized into one database**. WERF set up a database for entering data by geography (lat/long), endpoint, etc. This existing tool could be used.

- A large research gap is mixture effects. Another gap is toxicity of metabolites compared to parent compounds.

- We need robust effects literature to understand which endpoints to monitor – before significant effects are found. There is a deficiency in the literature on effects (i.e., more than mortality).

- We need understanding of the biological and chemical integrity of a lake, which seems daunting, but we can begin with tributaries. If we can understand tributaries, we can understand the lakes.

Recommend a Two-part Approach: 1) Determine what we are confident in to begin a strategy, such as hormone variations among species, and 2) add research needed to bolster monitoring, incorporating new information as it is developed. This iterative approach has been successfully followed in the past.

Lake Michigan Room

The group reviewed the purpose of the consultation:

1. To inform the EPA to direct programs
2. To identify key recommendations and conclusions to include in the report to the IJC.

The purpose of the session was to discuss what the experts gained from Dr. Klaper's report and to come up with some conclusions for the final report to the IJC. Battelle will synthesize all of the information from the consultation and merge into a single report.

The experts need to link together their existing knowledge and create a conceptual model. The conceptual model approach will help to determine what scientists know and what they don't know.

The point of developing a monitoring program is:

- The EPA wants a monitoring program
- To find CECs
- To assess the health of the ecosystem

Canada has designed a monitoring program where biological monitoring is used to complement a chemical monitoring program. The group identified a need to further assess whether there are ongoing programs for the different classes of contaminants.

Conclusion: How to trigger and tier things is an area that needs much work. For example, monitoring and diagnosis need to be approached as different steps. There also needs to be broader endpoints, and it is important to supplement endpoints with some of the pathways. Developing a monitoring program requires a combination of tools.

It was suggested that we need mechanisms of action, further research on mixtures, and biomarkers. However, others pointed out that we already have biomarkers, and they are not all that useful. Why do we want more mechanisms of action that don't transfer and why dedicate more research to finding biomarkers if they haven't proven to be useful in the past? Scientists have been struggling with biomarkers for a long time. There is an additional problem with continuing to focus on one specific pathway and not the whole issue. This is a discussion that has been going on for years as well.

Larry Kapustka advocated for the conceptual model. He suggested framing the model by picking a valued resource to provide a focus – for example, using lake trout to frame the model and then using this lens to look at the organism level and the population level. There is an error in assuming linearity between organisms and systems. There is a need to deconstruct. He suggested studying one level below what you are interested in for understanding mechanisms and one level above for understanding context. It is important to focus on the organism and understand how it interacts with population dynamics.

Conclusion: There is too much focus on the assumption that interactions between different levels such as organisms and population are linear when really they need to be approached as a system. We understand that nonlinear functions drive the ecological system, yet we want linearity between biochemical reactions and the biosphere. For example, studying the impacts on vitellogenin only tells you about one part of an organism. Isolating one particular part will not help to draw broader conclusions. The endocrine pathway may have been overstudied and had too much focus to date.

Research to date is mechanistically driven. It would be beneficial to switch to making things more operational. For example, in Europe scientists are looking at ecological services. Asking the question "what do we specifically need to measure in the population" can guide research.

Questions:

- What ecological effects are people detecting in the Great Lakes?
    - What are the population effects?
    - What are the community effects?
- Is there a recent review of ecological effects in the Great Lakes?

In the Great Lakes there are so many stressors/confounders (for example, zebra mussels). Chemical contaminants are only one stressor. It is important to fold in other stressors for context. If there is too much focus on chemicals, the conceptual model will show false positives. The issues in the Great Lakes are connected, so we need to take into consideration chemicals but use a broader conceptual model to take into consideration other stressors in the environment.

Chemical monitoring alone is not sufficient to address CECs. We need to develop an integrative monitoring program. In other areas, biological endpoints have been used as a means to capture these issues. We should also do a better job of chemical monitoring.

In the past, monitoring for everything that might be a problem in the Great Lakes was the approach. This new program should try to focus on CECs.

A study on ecological indicators in the Great Lakes basin was recently developed that included urbanization and habitat issues, among others. This study would be useful to consider in developing the proposed effects monitoring program.

In assessing the informative value of Dr. Klaper's report, the group decided that it was difficult to draw management conclusions. Understanding the specific effects of a particular chemical is a starting point. There is much research that needs to be done to enable experts to make management decisions.

It is useful to have mechanistic information. For example, knowing dissolved oxygen levels may provide relevant information for narrowing down a focus, as it is important to understand factors that result in a suite of chemical effects. It could be a suite of 60 factors causing an effect. **There is a need to prioritize areas of focus. The conceptual model should include other stressors related to MOAs**.

Having a suite of endpoints can be useful. As there are so many contributing factors, research should focus on more than just reproductive effects. A recent report showed that hypoxia is an endocrine disruptor. Does this mean we should ban hypoxia? This is an example of another confounder, which demonstrates the need to monitor more pathways than just the hormonal one. Currently, we only monitor for chemicals we know how to analyze.

In developing a monitoring program, these questions need to be asked:

1. Are there serious ecological effects?
2. Are there classes of compounds that exist which remain to be measured?
3. Are there chemicals altered that we don't know about?

The Great Lakes system is one of the most disturbed systems. There are so many stressors that it might be valuable to adopt a tiered approach. Larry Kapustka suggested developing a framework for evaluating stressors.

Does Dr. Klaper's information provide insight into the types of indicators that need to be included in the suite?

In a management context, there is not enough information. For example, at what point would you ban a chemical based on this information, and how do you regulate a chemical when there are so many stressors? How do you feel confident to move forward without measuring every species and every chemical? Manifestation of effect will vary across species, but some chemicals will produce a dose response in a particular species, enabling extrapolations to be made.

A lot of detail could result in false negatives as well as false positives.

An important distinction to make is that the ability to detect chemicals does not mean that they need to be regulated. Many stressors are more important in the big picture than chemicals, but our context is to monitor for chemicals and effects. To regulate chemicals, they need to be put into an ecological context.

What other endpoints need to be considered besides estrogenicity, and what other MOAs can be inserted into the monitoring program?

- We have classes, but we can't monitor them all biologically or chemically.
- We need to include some MOA activities to monitor.
- We need to focus on the individual level and work up.

Research is currently being conducted on organism effects, growth, reproductive success, etc. and on causation/exposure. Can this information be scaled up to the entire Great Lakes system from the site-specific effect that was noted?

- We don't know enough about toxicology, so we measure reproductive success as an indicator. Measuring reproductive success is a key element for determining ecosystem effects.
- We can't just use biomarkers. We are still struggling with biomarker identification, and multiple feedback loops are a key issue. Measuring reproductive success would be more beneficial than using a biomarker.
- We might need to look at other assays and other indicators.

Questions to Consider:

- There are multiple issues to get to a single endpoint – so how do you tease out the key variable? For example, PAHs and other compounds can produce similar effects in organisms. How do we isolate a specific endpoint related to a specific CEC?
- How do we monitor – do we look everywhere?
- Could there be a chemical stressor causing an effect?
- What biomarker or activity could be used?
- What activities do we consider to inform further progress?
- When you see a drop in reproduction – how do you know that it is a drop? What are we using as a control for a reference point?
- What indicators do we need for a specific assessment?
- How do you link CECs to effects?
    - You could have a matrix of endpoints and link back to CEC.
    - Need an endpoint that can be translated both upward and downward to cause and effect. Pesticides are designed to do this, but few have this degree of specificity.
- What techniques are there today that could be used as an indicator to make a link?

Understanding pathways would be beneficial in developing indicators. Understanding what pathways are more likely to cause adverse effects on organism traits. **The challenge is identifying pathways. If you understand pathways, you can identify the pertinent indicator or receptor and develop a tool**. Identifying the number of pathways is not linear – it is really a system. Vitellogenin is an example of a pathway. Pathways become very confusing when mixtures come into play. Mixtures are probably important but are difficult to prove.

We like to think an issue is linear when really it is not. **Looking systematically is very important**.

Overall purpose: We are trying to design a program we can implement today. The framework should include growth, survival (if effects process) and reproduction as the key markers. Risk assessment should be included as well for identifying effects.

Further research:

- Consider efforts being performed globally as a basis for prioritizing. In the past, pathways did not have success in identifying indicators.
- Research on ongoing efforts by other agencies should be integrated into the monitoring program.

Lake Superior Room

NOTE: The majority of the break-out session was spent discussing an approach to a monitoring strategy.

Comments on Klaper Paper/Presentation

General

- Many participants had concerns with the use of "emerging chemicals" in Dr. Klaper's paper and presentation vs. "emerging concern," as each term has a different connotation.
- "Emerging chemicals" implies newly developed or introduced chemicals into the environment, whereas "emerging concern" would include both newly manufactured as well as newly detected chemicals where little effects data is available or new effects data is being discovered.
- Some felt there was an issue with the quality of the data used in the paper and many wanted to see the references cited, which were missing from the report.
- The group would like to have more reported on field effects of compounds. Some participants were aware of studies on field effects that were not included in the report.
- It was unclear how the paper fit in with the overall goal of the strategy. The chemical-by-chemical approach of the report may derail the strategy process.

Conclusions

- There was consensus by the group that there were major gaps in data used in the ecosystem health effects paper for the given compounds reviewed (several members could cite papers/research that should have been included but were not, particularly on BPA and CPs).
- The group felt that the compounds/classes of compounds were "cherry picked" and that only those chemicals for which data was readily/easily available was used – the rationale for selection was not very systematic. The group felt the paper would cause people to pick and choose which chemicals to focus on.

Recommendations

- It would be very beneficial for the tables presented in the presentation to be included in the report.
- The term "emerging concern," rather than "emerging chemicals," should be used consistently in the report and presentation.
- Overall, the paper should be more comprehensive (additional data and chemicals). They understood Dr. Klaper was working within limitations and recommended that additional time and budget be given to expand the paper.

Second Break-out Session: Discussion of Tools and Methods for Effects-based Monitoring

<u>Lake Erie Room</u>

- **Too lengthy of a biomarker list. Not all are needed in the proposed monitoring program.** Just because we can measure something doesn't mean we should. The tools should be selected based on the objectives of the program.

- **Need to explicitly agree on how to protect the Great Lakes. Only then can we determine which tools will be useful**. 'Omics tools may enhance monitoring but will be expensive and may answer a different question.
    - Can define health by age, structure, and abundance, for example.
    - Can define parameters or functional traits (e.g., food source, place in food web, bottom feeders) for protecting health (e.g., healthy organisms of individual species).

- **It is not appropriate to talk about health of populations or ecosystem health**.
  - Suggest measuring health of organisms or **developing criteria for a healthy ecosystem (range of healthy conditions**).
  - Surveys in Canada to monitor pulp and paper and other industry effluents employ a suite of biochemical parameters.

- **Recommended approach to monitoring – if a parameter is not met, investigate the reason for perturbation, working backwards**.

- The ecosystem objectives for Lake Superior provide one example of a monitoring objective: to ensure self-sustaining populations of fish species.

- **Need conceptual models that link back to management objectives.** Set an overarching goal (e.g., stable age structure of lake trout) and develop scenarios that the conceptual models will operate under. The conceptual models will provide the rationale for monitoring specific species.
  - Work iteratively using nested conceptual models to address each group of chemicals (not agreement on this).
  - Mixtures present a problem for chemical monitoring. General agreement not to monitor individual chemicals.

- **The strategy should focus on effects rather than chemicals**. Measures such as vitellogenin, intersex, e.g., could trigger which chemicals to focus on.
  - 'Omics methods are expensive to use.
  - Telemetry is one useful tool. For example, in the Great Lakes, could catch walleye, tag them, and follow to observe effects.

- Which species would be relevant to CECs? The **Canadian program chose a pelagic species and one that was abundant in the area (for practical reasons). Species selection should reflect local point sources**.
  - Canada has several criteria for selecting species. Abundant keystone species are important. Sweden and Canada (EEM program) collect species and measure growth, size for livers and condition, differences in growth and reproduction related to reference sites. If effects are observed, further investigation of cause is triggered (site-specific). Some work has been done in the Great Lakes.

- **Start at WWTPs or the location of discharges. Screening for effects can cover a wide geographic region, but then focus down to the site of the problem**. Geographic coverage depends on management objectives. The proposed monitoring program would focus on the nearshore.

- Canada's EEM program has a series of response patterns that indicate eutrophication or endocrine disruption, for example. Also have critical effects sizes (using 25% difference rather than statistical difference) that trigger follow-up studies. There is a broad suite of tools that are used based on the presence of stressors. Sweden has another set of critical effects sizes.

- **Collaboration among programs would be useful**. Most states and provinces have sampling programs.
    - **Could integrate standard tools and methods into programs.** Canada is trying to integrate monitoring at the same time at the same sites with the same methods.
    - Could standardize species across Great Lakes monitoring. EEM has used 65 different species, which makes it difficult to establish a reference range.

- Epigenetic effects of chemicals – is there any evidence that this is important? Would you miss an exposure without looking at epigenetic effects? Epigenetics might be considered if there is no apparent cause to a problem.

- **Look at the Canadian program as an example for ecological and biological endpoints to monitor**.

- **Need a public communication plan.** Beware of creating fear among the public in monitoring for a chemical. This is a risk communication challenge in disseminating results.

- **Focus on an ecological measure (such as age structure) not a population based measure, and not population specific endpoints**.

- **There are not always established tools available that we know will work in the field, with clear acceptance criteria, variation parameters, known accuracy, etc.** There is much research and development needed to practically implement tools with confidence.
    - Some tools are not robust predictors.
    - Molecular tools can be useful if you have clear hypotheses.
    - Gene related thyroid expression is very robust, but its usefulness rests on correlation. Many people are working on correlating organism effect to the population level.
    - **Specific questions can be answered with in situ caging,** although in situ testing still requires correlation to population level. Biochemical responses can be investigated with in situ caging, but fish are affected by caging.
    - **Causation evaluations can use specific methods, developing hypotheses along the way.** The important intermediate step in causation investigations is determining the spatial scale of observed changes.

- **The purpose of surveillance would be the observation of change over time at the population level, addressing population variables that you want to protect.** The length of time will depend on the species monitored. Time and scale must be determined for each question you want to answer.

- For developing a research program, Canada (EEM Program) looked at all available metal mining tools that could be used. Ecological models have an important role to answer questions that cannot be answered over the spatial and temporal scales available.

- Consider biomarkers of exposure, biomarkers of effect, and biomarkers of susceptibility.

<u>Lake Michigan Room</u>

General

- There are several chemical concentration monitoring programs in the US and Canada – air quality (US & Can), CECs and legacy pollutants in fish (US & Can). Environment Canada looks at sediment and water quality for legacy contaminants and is beginning to include CECs. Try to coordinate sampling/monitoring between the US and Canada.
- Monitoring and assessment tools for ecosystem health could be incorporated into current chemical monitoring programs, but timing of chemical and biological sampling needs to be coordinated.
- Some criteria that need to be considered in biological effects monitoring program:
    - Timing and frequency of sampling
    - Types of samples
    - Species to be sampled
    - Where to sample
- It is very important to have traditional biologists/ecologists out in the field to assess ecosystem health.
- Need to know what biomarkers can be linked to particular effects and not other stressors and that the methods used are validated.
- If effects monitoring is added into a current chemical monitoring program, the biological effects sampling may not match up with the chemical sampling.
- There is a need to learn how to interpret the results of new assessment tools (such as 'omics) for future use, as there is a lack of organism and community field studies.
- Need to identify the indicators of a "healthy" community and determine if they can be added into existing chemical monitoring programs.

Conclusions

- Most monitoring programs currently in place are for chemical concentration monitoring, not necessarily ecosystem health outcomes.
- There has been no investment in an inventory of monitoring programs outlining what is being measured, how long a program has been operating, or how it is funded.
- There is a lack of Great Lakes monitoring related to ecosystem health.
- The group agreed the report was a good compilation of types of tools, but there was concern as to the potential use of it, in terms of trying to make the connection between organism health and ecosystem/population health.
- Tools are not in place to systematically assess environmental health.
- Although 'omics is promising, particularly metabolomics, it will still be difficult to determine the cause of the effects (chemical vs. other stressors). 'Omics tools are promising for the future, but they are not yet ready for use now and should be included in research-based programs.

Recommendations

- Data sharing among states and state and federal agencies needs to be improved, possibly facilitated through an IJC recommendation to governments.
- There needs to be incentives through funding agencies for the sharing of data by incorporating collaboration as part of the funding requirement.
- In the monitoring program there should be some measure of the following, the selection of tools for each will be dependent on the species selected:
    - Reproduction

- Development
- Immune system
- Growth
- Behaviour

Lake Superior Room

- EPA is funding monitoring work through the GLRI.

- The conversation needs to be switched to a more structural focus rather than on tools and methods.

Recommendation: It would be valuable to canvas existing, ongoing monitoring efforts. Has there been a compilation of ecosystem modeling efforts in the Great Lakes Basin?

- **Using smart surveillance** will enable us to focus in on areas likely to have problems. It is a tiered approach. For example, if you see a problem, then you can use smart surveillance to determine tools for the diagnostics.

- There needs to be consistent monitoring to show subtle trends/results over time. This could be accomplished by using different monitoring networks.

- Also, there is a need for site-specific directive studies.

- Are we going to do tier 1 ambient condition monitoring? Some examples of tier 1 biomarkers include:
  - EROD
  - Organ histology
  - Immune function
  - Chemical analysis
  - Vitellogenin
  - Steroid hormones
  - Gross morphology – DELTS

- The situation in Lake Superior and Lake Erie is a different scenario. Each location is not transferable, and there may be different approaches to a problem. **The goal is not to create one tool but rather a toolbox.**

- The intent of the monitoring program is to detect effects before they become a problem.

- It is important to conduct monitoring in nursery areas where there are community effects and in nearshore areas affected by point sources.

- How do we assess ecosystem health? We have an inventory of exposure. We now need an inventory of monitoring programs. Most biological monitoring is conducted by states and provinces. For example, there is a caged mussel study every 3 years in the Niagara River. A healthy freshwater fishery is the goal and the focus of Canadian programs.

- Some indicators can be used remotely.

- The Lakewide Management Plans (LaMPs) can drive lake-by-lake monitoring programs.

- **Gap**: fisheries biologists and aquatic toxicologists have nothing to do with each other. The chemical side may be beyond the scope of the biologists' training. This disconnect may also be a result of different mandates. For example, fish researchers solely focus on fish. **Developing the proposed monitoring program is an opportunity for scientists to communicate – cross-pollination between disciplines**.

- Dr. Schultz' report omitted aquatic benthics. Benthic organisms should be considered in the monitoring program, as they may be easier to assess than fish.

Recommendation: There is a need for bottom up and top down monitoring at the same time.

- The program should incorporate the following three activities to move forward sustainably:
    - Monitoring
    - Surveillance
    - Research

- The first step in developing the monitoring program should be to look at community health and then selectively match up other technologies as appropriate. **Piggy backing existing methods may be a good solution for the IJC**. The EPA has a binational monitoring program that is an example of cooperative management within the Great Lakes. They monitor one lake every five years. The focus is not effects-based, and it results in each lake being monitored every 5 years. This year Lake Superior is the focus, and the top issue is nutrients.

Recommendation: We do not need an annual effects-based strategy but one that piggy backs. This may be more feasible from a resource perspective.

- Is there a need for effects-based monitoring?
    - To answer, first look at how the fish are doing. Lake trout, forage fish and perch are not doing well. The next question is whether contaminants can be attributed as the cause when there are multiple stressors at fault.

- If no effect is measured, then the research is often not published. This is a key issue.

- Effects-based monitoring and chemical-based monitoring are two different angles.

- Before initiating monitoring, it needs to be determined what chemicals are at fault. People are wasting their time by measuring pharmaceuticals at ppb levels, as this is probably not relevant.

- There is a need for multi-layer monitoring to tease out what the cause of the effect is.

- The WERF report has a framework that can assist in predicting locations where chemicals are the major stresses. This does not replace the need for baseline monitoring to assess what you are looking for.

- Biological monitoring should focus on classes of compounds.

- There needs to be work done on developing new data that uses lower level toxicology information and on developing more mechanism information.

- 'Omics technique – may be a way to separate toxic stressors from others. Exposure needs to be taken into account as well.

Recommendation: Part of the strategy needs to have a clear statement on how the strategy should be used.

- Effective monitoring could have a big impact on regulations.

- A pragmatic approach to the program could use tiers and target sites in the Great Lakes that are most likely to be affected by these chemicals. The focus should be on sites where chemicals are the main stressor. Why monitor the whole basin if specific sites don't prove to be an issue? AOCs are about sediment and are not necessarily affected by CECs.

- The biomonitoring program should start at the nearshore where chemicals are an issue and use the WERF report as a guide.

- Monitoring should not be limited to fish. It should include birds/mammals and benthic organisms.

Recommendation: Explore where we can leverage different programs. Most importantly, we need a critical assessment to determine where we can leverage. We shouldn't pursue a monitoring program if it cannot be achieved by leveraging other programs.

- The group needs a plan for how to synthesize information into a decision-making framework so that the data is useful and avoids mindless monitoring.

- The program will need a "proof-of-concept" pilot study in a few AOCs based on the WERF report and similar work.

- A good approach may be a multi-level approach, as we don't have any one endpoint. We need a flexible model to deploy tools depending on what we find, and we need to choose locations that are most affected. For example, it may be a waste to monitor in the middle of Lake Superior.

- Selecting the scope of the study is also an important step. There are divisions among ecosystem level, community level, and population level, and we need to decide what level the program will focus on. Ecosystem level may be beyond the scope.

Third Break-out Session: Discussion of Proposed Strategy Approach

Lake Erie Room

- Primarily, we need to determine a management goal. Having a goal will help to decide what the strategy needs to include. For example, what species should be included? There is a difference between trying to find an effect and trying to find an effect relevant to the strategy.
- The other main issue is determining the actual status of the Great Lakes.
- The discussions were missing a focus on stressors. There are a lot of physical stressors that are not being discussed.
- The group needs to consider developing a strategy more holistically.
- One possibility is adding a biomonitoring program to a status and trends program.
- There is a huge amount of data available that can be used to identify trends and patterns.
- The community or population level has too much noise. To minimize the noise, it would be beneficial to select specific sites and smaller watersheds that are dominated by municipal discharges. Once the population and specific sites are analyzed, it will be easier to design a monitoring program.

Recommendation: A small group should develop the strategy.

Recommendation: We need to harmonize programs and bring them together.

- There are quite a few programs already conducting monitoring. For example, the Great Lakes Fishery Commission focuses on population dynamics, and state/federal agencies do this type of work as well. USGS also has monitoring programs.
- Drinking water has been missing from the discussion. This is the main link to human health. Monitoring for the sake of monitoring does not build a strong case. We don't know health effects, and linking the ecological effects to human risk is very important. There is a need for coordination. Risk communication is important, as we don't want to create unwarranted concern. The public is worried about the fish they eat and drinking water. It is important to relate back to what is concerning the public.
- The exposure piece has been downplayed in the workshop.
- Where are we going to find the highest concentrations? Monitoring should focus on these areas - the hot spots. How do you identify the hot spots? There is information available that we are not using. We can model concentration data and overlay it with fish and vertebrate data, and then determine whether there is a potential link.
- It would be helpful to develop an empirical model using toxicological effects and a suite of measurements. It doesn't have to be site-specific once the model has been developed.
- We have tools, and if we confine research to tools, we will miss important information. The challenge is with modeling impacts. Site-specific issues are not known until we actually begin monitoring.
- There is too much variability in population to define a problem according to population. For example, two pulp mills will have a different effect depending on the location.
- There is still much basic information that we do not know. To potentially predict issues, there needs to be good initial data.

- Targeted monitoring needs to be considered to develop a model. What type of model? It could be a combination of models. There does need to be some use of exposure-based models.
- i-Stream is a new tool that is publicly available. It takes the cumulative discharge of "down the drain" chemicals (not agricultural chemicals). The model includes drinking water uptakes. The data comes from multiple sources – USGS, for example.
- A statistically based model does not exist in Canada. It could be implemented as a joint binational effort.

Recommendation: Create a database of existing monitoring programs.

- The WERF program on Trace Organic Compounds (TOrCs) provides useful information. The information can be utilized with latitude/longitude GIS coordinates. It is already in a structured format. TetraTech set up the database. This could help expedite the process of developing a database.
- The group had trouble articulating what exactly the problem was and what the goals of the consultation were.
- The group discussed the term "ecosystem health." Some experts felt that, by referring to health, the science was undermined, and others felt that the word "health" enabled the issue to be related to the public.
- There is a giant tool kit available, but we need to select how specific we are going to be to create a diagnostic definition.
- There is a wide array of parameters to consider. There is a preference to monitor populations as well as communities.
- Having a broader conceptual model becomes useful for organizing information.
- There is not high fidelity to any one biomarker, and multiple factors could trigger them. For example, invasive species, temperature, and climate are all contributors.

<u>Lake Michigan Room</u>

General

- There was confusion about the purpose of the Effects Strategy. What is trying to be managed, ecosystem health? Organism health? Is the purpose to monitor for health effects to determine a chemical cause?
- Several criteria need to be addressed in order to develop a strategy:
    - What endpoints should be monitored (e.g., reproduction)?
    - How should these endpoints be monitored?
    - Where in the Great Lakes should monitoring occur (e.g., AOCs, near WWTPs)? Suggested using Klečka report to identify areas and chemical exposure.
    - What species and populations should be monitored?
    - What are the metrics of a healthy ecosystem? Need a baseline.
    - Monitoring cannot be done in isolation of other stressors. Define stressors in a system and the endpoint that they may have an impact upon.
- Two approaches for a monitoring strategy were suggested:
    - The bottom-up approach: select an area for monitoring where CECs are a known issue (i.e., near a WWTP discharge) and implement organism health assessment tools based on expected chemicals present.

    - The top-down approach: (1) monitor for ecosystem effects (e.g., in birds, fish); (2) identify what endpoints are important in that population (e.g., reproduction, growth); (3) identify the pathways that affect those endpoints; and (4) identify the probable causes of those adverse impacts and manage them (an example of this approach is that of birds and DDT exposure).
- Adaptive management for monitoring strategies is not practicable, as it does not allow for trending analysis or development of baseline data.

Conclusions

- There is much uncertainty in predicting ecosystem effects based on organism effects.
- Whether working from a top-down or bottom-up approach, many data and information gaps exist.
- Overall, participants felt that the monitoring program may not be able to be designed successfully, at this time, due to the lack of data and information available on effects and monitoring tools.

Recommendations

- There needs to be a synthesis or inventory of Great Lakes monitoring data to help guide the development of the monitoring strategy so that we do not: (1) reinvent the wheel or (2) make the same mistakes that other monitoring programs have made.
- Evaluate whether programs currently in place (such as Canada's herring gull egg program or NOAA's mussel watch) can be augmented by adding CECs to the monitoring.
- Stressors other than chemicals are driving health effects on ecosystems. This must be taken into account, and the magnitude that CECs have versus other environmental stressors also needs to be considered (i.e., invasive species, climate change, habitat loss, harmful algal blooms, etc).

Lake Superior Room

- The group agreed that it was not clear what the strategy is trying to measure and what we are trying to determine from these measurements.
    - What do we think it is trying to measure or determine? Assess the risk of CECs to the ecosystem across trophic levels (fish, birds, etc.), focusing on the nearshore. We are trying to protect populations, communities, and endangered species by measuring the effects of CECs at varying levels of effect. In some cases, relationships are known, and there is potential for predicting population level impacts from molecular changes.
    - The discussion of AOP complicates the matter. We will need to use traditional tools (e.g., IVI, growth, reproduction, etc.), and if a problem is observed, then diagnostic investigations can be undertaken using the AOP and other approaches and potentially novel tools. The time and place for monitoring should be determined first, and then the appropriate tools selected. The investigation will determine the dose that was causing or not causing concern. The results will inform management actions to address the problem. Lisa Williams drew a framework that illustrates this approach.
- This is an opportunity to apply tools in the nearshore framework where they can be effective. Non-point sources might present a problem, but the tools might help to investigate. The AOP is useful when you know what you're looking for.

- When are you looking for ecological impacts and when are you analyzing for specific chemicals? The focus has shifted from chemicals (due to uncertainty, mixtures, etc.) to effects on the ecosystem.
- It is insufficient to pick a set of biomarkers in the middle of the AOP alone and use them to evaluate whether organisms are at risk. Growth, survival, age, and basic biomarkers are the traditional tools that could be useful in assessing the health of an ecosystem. Where certain pathways are understood, we can use other endpoints at different levels of organization (e.g., EROD, vitellogenin).
- State agencies know which fish species to monitor for contaminants. Need to tie into existing monitoring programs, such as states, Great Lakes Fishery Commission, etc.
- The State of the Lakes Ecosystem Conference (SOLEC) in the Great Lakes region has 85 indicators to characterize the ecosystem.
- There is some convergence on endpoints with EEM, BEST, and TBiOS. We could recommend reactivating BEST and integrating it with other programs. It would be nice to measure the same endpoints in both US and Canada. This has started with GLRI funding.
- The nearshore framework is the overarching umbrella over CECs and the development of the Effects Strategy.
- The group considered the question of whether a regulatory framework was needed. In Canada, the Fisheries Act is the authority for the EEM program.

Burton Suedel compiled a few slides that distill the comments of the last day and a half:

1. Develop a problem statement – focus on nearshore environments, or start there?

2. Develop conceptual model(s) to identify sources, pathways, and receptors, and criteria for identifying species.

3. Develop a set of criteria to identify indicator tools and methods.

4. Develop a list of indicators that best meet criteria for successful indicators.

5. Determine use of data, sample design, scale, time and space, statistical significance.

6. Leverage and integrate with existing programs for better coordination and use of data.

7. Communicate the program to stakeholders and the public, careful to consider risk communication.

8. Utilize EEM, BEST, TBios, Canadian AOC, state, and other monitoring program expertise to design and develop the proposed monitoring program.

Recommendations

- Focus on problem areas first and see if the selected endpoints work. Then develop a refined list of endpoints for broader deployment.
- Measure apical endpoints at a wide number of sites, some problem sites, and some reference sites. This will establish a baseline condition. Perform intensive monitoring at some sites.

- Consider the WERF guidance document as an approach for site selection and prioritization. Look at EEM, BEST, TBiOS, Canadian AOC, and other programs in the development of the monitoring program.
- Choose strategic sites, primarily impacted by WWTPs and agricultural chemicals. Most important is well-characterized sites for purposes of assessing applicability to the monitoring program. Once sites are selected, statistically design the monitoring program.
- Utilize a tiered approach to assessing effects. Second tiers should investigate other stressors. The ultimate goal is to assess the health of population communities, but we are measuring for chemical impacts or effects at lower levels of biological organization. There are species variations in effect to consider.
- Coordinate with state, federal, and tribal physical/chemical/biological monitoring programs.

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