Chemicals Management Plan Science Committee second term report

Fall 2017 to Spring 2021

On this page

1.Background

Ensuring a strong science foundation for decision-making is 1 of the priorities of the Chemicals Management Plan (CMP). As 1 of several steps in support of this, Health Canada (HC) and Environment and Climate Change Canada (ECCC) (hereafter referred to as the Departments) created a CMP Science Committee (hereafter referred to as the Committee) in 2013 to contribute expertise pertaining to scientific considerations moving forward under the CMP.

The creation of the Committee followed the end of the mandate of the Challenge Advisory Panel (2006-2013), which was established in the first phase of the CMP to examine the use of weight-of-evidence and precaution in risk assessments.

The Committee's first term took place from Fall 2013 to Fall 2016. Its second term was initiated in September 2017 and ended in March 2021.

2. Purpose

The purpose of the end-of-term report is to summarize the Committee meetings and their outcomes for interested stakeholders and the public.

3. Scope

This end-of-term report summarizes the 6 meetings that took place during the Committee's second term. The meetings took place in Ottawa, Canada, in January 2018, July 2018, November 2018, June 2019, February 2020 and February 2021 (via video teleconference).

This end-of-term report represents the status and opinions of the Committee members (both core and *ad hoc*) at the time they were presented and discussed at the various meetings, as well as any progress/advances in science that may have been made since the meetings were held.

The report also summarizes the review of the Committee's work and its findings.

4. Message from the co-chairs

As co-chairs of the second term of the Committee, we begin by expressing our sincere thanks to the core and *ad hoc* members of the CMP Science Committee for their contributions throughout the second term from January 2018 to 2021. Their robust scientific background combined with an open and flexible attitude ensured that we could tackle a wide variety of topics. The Committee members showed substantial personal commitment to the process, enabling informed, innovative, and highly stimulating reflections and debates during the meetings, and the tabling of thoughtful and comprehensive Committee reports.

We recognize that this high level of commitment, which ensured that fulsome consideration was given to the subject matter, resulted in Committee reports that

provided well-considered, relevant, and scientifically up-to-date input to the Government of Canada.

Most reports focused on considerations and opportunities for the CMP post-2020. The reports benefited from the knowledge of the core and *ad hoc* Committee members as well as that of government departments. It was rewarding for the Committee to see how HC and ECCC shared and considered the Committee's input.

The co-chairs recognize and thank the Directors of the Existing Substances Risk Assessment Bureau (HC) and the Ecological Assessment Division (ECCC) for their leadership, facilitation and overall support of this work to facilitate robust discussions that led to scientifically sound and independent results. We also thank the Directors General of the Safe Environments Directorate (HC) and Science and Risk Assessment Directorate (ECCC).

Lastly, we wish to thank the CMP Secretariat (HC) for its tireless logistical support in ensuring that Committee processes run smoothly, recognizing that all members of the Departments have contributed to the Committee's work with great dedication. This support included a much needed and much appreciated supply of fresh coffee and tea at the most critical times.

The Committee is truly an integrated team effort. As such, we are grateful to members and government representatives alike for all of their hard work, dedication, and commitment.

Miriam Diamond, Geoff Granville, and Mike Rasenberg

5. Mandate of the Science Committee

The mandate of the Committee is defined in the Committee terms of reference as:

"The Committee will contribute expertise to the Departments pertaining to scientific considerations moving forward under the CMP. These Departments have the responsibility and sole authority to make decisions informed by input provided by the committee."

For information on the roles and responsibilities of the Committee, the Executive Secretary and the Secretariat, view the CMP Science Committee Terms of Reference.

6. Science Committee membership

During its second term, the Committee comprised 9 core members who collectively provided comprehensive expertise in key scientific areas, such as environmental chemistry, exposure assessment, toxicology and chemicals management. The areas of expertise for members were updated since the first term to reflect the need for greater expertise in areas such as cancer risk assessment methodology, risk assessment of chemical mixtures, aggregate and cumulative risk assessment, multimedia fate assessment, and expertise in population health from an epidemiological or clinical perspective. Core members were appointed for a 3-year term, which was then extended by 6 months.

While the members were selected for their expertise, the Departments also invite *ad hoc* members to participate at meetings. These members were leading international experts on the topic under discussion. Once the topic for a Committee meeting was determined, experts in the field were invited as *ad hoc* members to contribute their expertise to the deliberations and writing of the final report.

The following section lists the names of the second term Committee members, along with their biographies. To maintain openness and transparency, all members of the Committee disclose affiliations and interests, including any direct or indirect financial interests and other affiliations and interests that relate to the Committee's mandate. These might include investments in companies, current employment, research support, grants, contributions, board memberships, professional/scientific societies, and so forth. Summaries of the affiliations and interests for the core members are available.

Dr. Jon Arnot

Biography

Dr. Arnot is the president of ARC Arnot Research & Consulting and an adjunct professor in the Department of Physical and Environmental Science and in the Department of Pharmacology and Toxicology at the University of Toronto. He has 17 years of research experience in the development, application, and evaluation of databases, methods, and models to assess the exposure, hazard, and risk of organic chemicals to humans and the environment. His research has focused on the application of high-throughput screening methods for prioritizing chemicals

for risk assessment. He is the principal investigator or co-investigator of various international projects including collaborations in the United States (U.S.), Europe, and Canada. Dr. Arnot served on the National Academies of Sciences, Engineering, and Medicine Committee on Incorporating 21st Century Science into Risk-Based Evaluations. He was the recipient of the James M. McKim III Innovative Student Research Award (2008) from the International Quantitative Structure-Activity Relationship (QSAR) Foundation to Reduce Animal Testing and the Society of Environmental Toxicology and Chemistry Best Student Paper Award (2009). Dr. Arnot holds a PhD in Environmental and Life Sciences from Trent University, an MSc from Simon Fraser University, and a BSc from the University of Alberta.

Dr. Niladri Basu

Biography

Dr. Basu is a professor in the Faculty of Agricultural and Environmental Sciences at McGill University where he holds a Canada Research Chair in Environmental Health Sciences. He is jointly appointed in the Department of Natural Resource Sciences and the School of Human Nutrition and is also a member of the Department of Epidemiology, Biostatistics, and Occupational Health and the McGill School of Environment. Prior to joining McGill in 2013, Dr. Basu was an assistant professor at the University of Michigan School of Public Health, where he now holds an adjunct professorship. He is an associate editor of *Environmental Toxicology and Chemistry*, is active within the Society of Environmental Toxicology and Chemistry, and is involved with the United Nations Global Mercury Partnership. Dr. Basu holds a PhD in Wildlife Biology from McGill University, an MSc from the University of British Columbia, and a BSc from Queen's University.

Dr. Richard Becker

Biography

Dr. Becker is a senior director at the American Chemistry Council (ACC). He joined the ACC in 1999. Dr. Becker leads the ACC's Science and Research Division and directs the Long-Range Research Initiative, which focuses on catalyzing innovations for toxicity testing, exposure science, and safety assessments in the 21st century. Before joining the ACC, he served as a senior scientist with the State of California from 1987 to 1999. He is a diplomat of the American Board of Toxicology. Dr. Becker has been an active member of the Society of Toxicology for 25 years. He is also a member of the Society for Risk Analysis, the International

Society for Regulatory Toxicology and Pharmacology, and the American Chemical Society. Dr. Becker served on the Board on Environmental Studies and Toxicology of the National Research Council from 2014 through 2018. In recognition of his contributions to the field of risk assessment and the regulation of chemicals, Dr. Becker received the Arnold Lehman Award from the Society of Toxicology in 2015. Dr. Becker holds a PhD in Pharmacology and Toxicology from the University of California and a BA in Chemistry from Swarthmore College.

Dr. Weihsueh Chiu

Biography

Dr. Weihsueh A. Chiu is a professor in the Department of Veterinary Integrative Biosciences in the College of Veterinary Medicine and Biomedical Sciences at Texas A&M University. Before joining the university in 2015, he worked at the U.S. Environmental Protection Agency (EPA) for over 14 years. Throughout his career, he has been involved in a diverse span of risk-related topics, such as defence against chemical-biological warfare agents, radioactive contamination in biosolids, human health risks from environmental chemical exposures, and the interface between science and policy. His recent research has focused on human health risk assessment, particularly with respect to toxicokinetics, mechanisms of toxicity, physiologically based pharmacokinetic modelling, dose-response assessment, characterizing uncertainty and variability, systematic review, and meta-analysis. Dr. Chiu has served on a variety of expert advisory committees for U.S. federal, state, and Canadian government agencies, the U.S. National Academies of Sciences, Engineering, and Medicine, the World Health Organization, and the Organisation for Economic Cooperation and Development (OECD). Dr. Chiu received an AB in Physics from Harvard University, a MA and a PhD in Physics from Princeton University, and a Certificate in Science, Technology, and Environmental Policy from the Woodrow Wilson School of Public and International Affairs.

Dr. Elaine Cohen Hubal

Biography

Elaine Cohen Hubal is a senior science advisor in the U.S. EPA's Center for Public Health and Environmental Assessment. She has over 25 years of experience in the field of environmental health with broad scientific background in environmental science, human exposure, and chemical safety evaluation. Her primary research interests are in understanding complex systems at the nexus of the natural

environment, built environment, and human health with an emphasis on impacts to vulnerable groups. She has served in a series of science leadership positions in U.S. EPA's Office of Research and Development (ORD) and in her current capacity, Dr. Cohen Hubal leads the ORD research efforts to advance models for estimating human exposure to per- and polyfluoroalkyl substances (PFAS). As the EPA principal investigator on an Interagency Agreement with CDC/ATSDR, she investigates PFAS exposures in impacted communities. She is also focused on translating EPA exposure information and tools for use by multiple sectors to generate new insights and on working with stakeholders in government, industry and academia to access and apply EPA information and tools to inform decisions on chemicals and products. Currently, Dr. Cohen Hubal is editor-in-chief for the *Journal of Exposure Science and Environmental Epidemiology*, and is a member of the California Department of Toxic Substances Control's Green Ribbon Science Panel. She was a member of the Government of Canada's CMP Science Committee during its first term (2013-2017). Dr. Cohen Hubal received her PhD and MS in Chemical Engineering from North Carolina State University and a S.B. in Chemical Engineering from Massachusetts Institute of Technology.

Dr. Miriam Diamond (co-chair, September 2017 to March 2021)

Biography

Dr. Diamond is a professor in the Department of Earth Sciences and also the School of the Environment at the University of Toronto. She is cross-appointed to the Department of Chemical Engineering and Applied Chemistry, the Dalla Lana Faculty of Public Health, the Department of Geography and Planning, and the Department of Physical and Environmental Sciences at Scarborough College. Dr. Diamond was the Co-chair of the Ontario Ministry of the Environment's Toxics Reduction Scientific Expert Panel and the Ontario Ministry of the Environment's Multi-Stakeholder Panel on the "Living List" of the *Toxics Reduction Act.* She is an Associate Editor of the journal *Environmental Science and Technology*, and is on the editorial advisory board of the *Journal of Exposure Science and Environmental Epidemiology*. Dr. Diamond is a member of the Board of Directors of the Canadian Environmental Law Association and a member of the Science Advisory Board of Environmental Defence. She is a Fellow of the Society of Environmental Toxicology and Chemistry, a Fellow of the Canadian Geographical Society, and was named Canadian Environmental Scientist of the Year in 2007 by that society. She was a member of the Government of Canada's CMP Science Committee during the first term (2013-2017). Dr. Diamond has a PhD in Chemical Engineering and Applied Chemistry from the University of Toronto, MScEng in Mining Engineering from

Queen's University, MSc in Zoology from the University of Alberta and a BSc in biology from University of Toronto.

Dr. Michelle Embry

Biography

Dr. Embry is the associate director of Environmental Sciences at the Health and Environmental Sciences Institute (HESI). Prior to joining HESI in 2006, she was an ecological risk assessor at the U.S. EPA's Office of Pesticide Programs. She has expertise in both human health and ecotoxicology, with an emphasis on integrated approaches and alternative methods. Her current project portfolio includes the Bioaccumulation and the Animal Alternatives in Environmental Risk Assessment technical committees, 2 of HESI's projects aimed at improving ecological risk assessment. Dr. Embry's work also includes the Risk Assessment in the 21st Century (RISK21) project, which developed a scientific, transparent, and efficient approach for human health risk assessment, including a web-based tool that has led to outreach and training activities on risk assessment approaches worldwide, as well as a program on physiologically based pharmacokinetic modeling applications in chemical risk assessment. In addition, she co-leads the Botanical Safety Consortium, an initiative aimed at developing tools to evaluate safety of botanical dietary supplements. She was an elected member of the Society of Environmental Toxicology and Chemistry (SETAC) North America Board of Directors (2014–2017), past-chair of the SETAC Global Partners Advisory Committee (2014–2017), and is a member of the SETAC Bioaccumulation and Animal Alternatives Advisory Group Steering Teams. Dr. Embry holds a PhD in Toxicology, as well as a BSc in Biology and Environmental Science & Policy from Duke University.

Mr. Geoff Granville (co-chair, September 2017 to June 2019)

Biography

Following his retirement in 2006 from the position of toxicology and product stewardship manager at Shell Canada, Mr. Granville has worked as a private consultant with expertise in environmental and population health. At Shell Canada, his responsibilities centred on occupational and environmental health issues relating to chemical substances, including toxicity testing, health risk assessments, and regulatory compliance. He is an adjunct professor at the University of Alberta and previously at the University of Toronto. In 1991, he took on the role of

associate director within HC's Environmental Health Directorate in Ottawa as part of a 2-year executive exchange program. Mr. Granville has participated on many committees; examples include membership of the Science Management Committee of the federal Toxic Substances Research Initiative, and participation as co-chair of the Alberta Human and Animal Health Team of the Clean Air Strategic Alliance. Mr. Granville was a member of the Government of Canada's Challenge Advisory Panel for phase 1 of the CMP (from 2007 until 2011), and was co-chair of the CMP Science Committee from 2013-2019. Mr. Granville has a BSc in biochemistry and toxicology from the University of Surrey, United Kingdom.

Mr. Mike Rasenberg (co-chair, June 2019 to March 2021)

Biography

Mr. Rasenberg is the acting director of Information Systems at the European Chemicals Agency (ECHA). Chemicals management has been the central theme of his work since 1999. Mr. Rasenberg has broad experience in this area, ranging from hazard, exposure, and risk assessment of individual chemicals to leading activities to prioritize and address chemicals of concern or develop generic approaches and methods to assess chemicals. During this work, he has used and been exposed to alternative ways of hazard identification (alternative approaches). He has a leading role at ECHA in relation to the promotion and use of alternative test methods. Some examples include the development of the Read-Across Assessment Framework and the work on the OECD QSAR Toolbox. He represents the European Commission at the bureau of the OECD Working Party for Hazard Assessment. Mr. Rasenberg studied analytical chemistry and environmental chemistry at the Zuyd University of Applied Sciences in Limburg, The Netherlands.

7. Meetings

7a. Topic: Informed substitution

January 10 and11, 2018 (Ottawa, ON)

7a(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu

- Richard Becker
- Weihsueh Chiu
- Elaine Cohen Hubal
- Miriam Diamond
- Michelle Embry
- Geoff Granville
- Mike Rasenberg

***Ad hoc* members**

- Joel Tickner, Associate Professor, University of Massachusetts Lowell
- David Widawsky, Director, U.S. EPA, Washington, DC
- Meredith Williams, Deputy Director, California EPA

Government of Canada officials

- Tara Barton-Maclaren, Research Manager, Existing Substances Risk Assessment Bureau (ESRAB), Safe Environments Directorate (SED), Healthy Environments and Consumer Safety Branch (HECSB), HC
- Andrew Beck, Director, Risk Management Bureau (RMB), SED, HECSB, HC
- Maya Berci, Director, New Substances Assessment and Control Bureau (NSACB), SED, HECSB, HC
- Mark Bonnell, Senior Science Advisor, Ecological Assessment Division (EAD), Science and Risk Assessment Division (SRAD), Science and Technology Branch (STB), ECCC
- Andy Nong, Computational Toxicologist, Environmental Health Science and Research Bureau (EHSRB), HECSB, HC
- Christine Norman, Director, ESRAB, SED, HECSB, HC
- David Morin, Director General, SED, HECSB, HC
- Jake Sanderson, Manager, Program Development and Engagement Division, SRAD, STB, ECCC
- Sarah Vanden Hoven, Science Advisor, ESRAB, SED, HECSB, HC

Secretariat

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Helen El-Koura, Senior Science Advisor, ESRAB, SED, HECSB, HC

Guest presenters

- Nicholas Ball, Dow Europe (Horgen, Switzerland)
- John Davis, Dow USA (Midland, Michigan)
- Christine Lukas, Dow Europe (United Kingdom)

- David Shortt, Dow Canada (Sarnia, Ontario)

7a(ii). Background information provided by the Government of Canada

Informed substitution (IS) is the considered transition from chemicals of concern to safer chemicals or non-chemical alternatives. The Departments are exploring ways to advance the responsible replacement of chemicals of concern, and from a program design perspective are looking to consider how applying an informed substitution lens could support chemicals management. IS may be encouraged and facilitated by a number of different policy means, including mandatory restrictions of certain substances in certain applications, development of tools for risk management and for the assessment of potential alternatives, and provision of support for research, development, and innovation.

The Departments sought input from the Committee on considering opportunities to support IS as part of core CMP activities (such as information gathering, priority-setting, risk assessment, risk management, research and monitoring), exploring comparative chemical hazard evaluation tools, and building on CMP work and information to date.

Information on core CMP activities, data that have been collected throughout these activities and existing comparative chemical hazard evaluation tools were provided to the Committee.

7a(iii). Information provided by the guest presenter

The Government of Canada invited Nicholas Ball (Product Sustainability Consultant, Dow Chemical), John Davis (Senior Environmental Scientist, Dow Chemical), Christine Lukas (Product Stewardship and Fire Safety Manager, Dow Building Solutions), and David Shortt (Dow Canada) to present: *Informed Substitution: A Practitioner's Perspective*. An example of the informed substitution process undertaken by Dow Chemical was presented and discussed.

7a (iv). *Ad hoc* members' perspectives on the charge questions

The 3 *ad hoc* members, Joel Tickner (University of Massachusetts Lowell), David Widawsky (U.S. EPA), and Meredith Williams (California, EPA), gave short presentations on the topic of discussion.

Joel Tickner presented on advancing and mainstreaming green and sustainable chemistry and its relevance and timeliness to IS. He described the Green Chemistry and Commerce Council, its vision and mission, and discussed the selection of targets for new collaborative and innovative projects. He concluded his presentation with lessons learned, which include the following:

- incumbent technologies are often difficult to substitute, and there is hesitation when alternatives may not function similarly or there are costs involved in the switch
- market pressure from key retailers and brands were noted to provide an important signal for innovation
- supply-chain dialogue and collaboration are critical to accelerating commercialization of green chemistry solutions

Meredith Williams delivered a presentation on *California's Safer Consumer Products (SCP) Regulations*. The presentation provided an overview of the SCP framework, which encompasses the candidate chemical list, priority products, alternatives analysis, and lastly regulatory response. The 2-stage alternatives analysis process and guidelines were reviewed. Examples of factors to be considered, including adverse environmental impacts, adverse public health impacts, physical chemical hazards, physicochemical properties, associated exposure pathways, and life cycle stages, were highlighted. The challenges to manufacturers were also discussed and include trade-offs to be considered, company's values and criteria, available information, data gaps, performance criteria, and any downside to the alternative.

David Widawsky delivered a presentation on informed chemical substitution from experiences at the U.S. EPA. The specific roles of chemicals in industry (for example, solvent, lubricant) and supply-chain requirements were contrasted with prevailing public policies to address chemical safety on a chemical-by-chemical basis rather than by function or use. The complexities of employing and/or indexing suites of chemicals' hazard endpoints, as well as both human health toxicity and environmental fate and effects, were presented and reviewed. The U.S. EPA's Safer Chemical Ingredients List (SCIL) serves as a data-driven tool to identify safer chemicals based on such suites of chemical hazard endpoints, along with well-defined hazard endpoints. Where there are gaps in systematic hazard data for groups of chemicals of interest, new approach methodologies (NAMs), such as quantitative structure-use relationship (QSUR) models, can be used to help predict both function and hazard for chemicals (or groups of chemicals) based on known hazard and functional use data for groups of chemicals with similar structures. The presentation concluded with a list of caveats for consideration.

7a (v). Committee input

The Committee looked at 3 charge questions related to: considering opportunities to support IS under the CMP, exploring comparative chemical hazard evaluation tools, and building on CMP work and information to date to support industry and other stakeholders in evaluating and selecting safer chemicals.

The Committee briefly examined the main difference between IS and alternatives assessment (AA). However, it did not distinguish explicitly between the 2 terms in its deliberations, and thus most comments and responses may be general to both. In their deliberations, the Committee noted that adopting an explicit IS approach in Canada will present new and unique challenges, as has been the case with adoption of IS frameworks by other jurisdictions. The Committee believed that the comments and suggestions in this report would, if addressed, accelerate formal activities to support the adoption in Canada. The Committee also noted that developing an approach to support IS in Canada can be guided by considerable efforts undertaken within other jurisdictions.

As outlined in the its report, the Committee identified a range of opportunities that the Departments could explore to advance IS in Canada under the current chemicals management framework. The Committee noted that the subject of AA and IS cannot be easily summarized into a “one-size-fits-all” approach. A case-by-case approach may be necessary, particularly in order to avoid decisions that are subsequently found to belong in the “regrettable substitution” group.

When deliberating on comparative chemical hazard evaluation tools, some Committee members highlighted the need to also consider comparative exposure-oriented activities in parallel with the more traditional hazard-related options for AA/IS initiatives. The Committee noted there are many methods and approaches available to conduct comparative hazard and exposure screening; it also cautioned against reinventing the wheel. Broad consensus was reached that a panel approach of key endpoints tailored to a functional use and exposure profile are preferred over an approach that aggregates information into a single overall score. While this charge question was focused on comparative hazard evaluation tools, some Committee members noted that overall risk (that is, the inclusion of exposure considerations) is also a consideration for a broader perspective to identify safer alternatives and support IS.

The Committee agreed that making data collected, generated and analyzed throughout the CMP available to industry and other jurisdictions would support IS.

It was recognized that these data could be used to contribute to existing tools, inform the development of new tools, and evaluate existing models to support IS.

The Committee agreed that the subject of IS is complicated and may initially require a case-by-case approach. The Committee strongly encouraged the Departments to continue with their international engagement on chemicals management and to work with other jurisdictions to identify opportunities for data sharing, to create consistent databases, and to work towards formalizing a generic IS paradigm.

For more information, view the January 2018 combined discussion paper and meeting report

7a(v). Use of committee input

As a method of knowledge transfer, a summary of the Committee deliberations was presented to the following external and internal bodies:

- CMP senior management meetings
- OECD *ad hoc* group on substitution workshop (May 2018)
- CMP Stakeholder Advisory Council (November 2018)
- Retailers workshop (November 2018)
- Industry Coordinating Group bilateral meeting (May 2019)

Dr. Joel Tickner of the Lowell Center for Sustainable Production at the University of Massachusetts Lowell developed a study report under contract with ECCC entitled "Options for Advancing Informed Substitution and Alternatives Assessment within Canada's Chemicals Management Program." The options presented in the study report are consistent with those outlined in the European Chemicals Agency's 2017 Substitution Strategy, outcomes from the November 2017 CMP Stakeholder Advisory Council and the January 2018 CMP Science Committee, and recommendations from the June 2017 Standing Committee on Environment and Sustainable Development report (CEPA review). HC and ECCC launched an online public consultation of this study report on Canada.ca from January 16 to March 18, 2019. The public consultation generated 16 sets of comments from Canadians, which were summarized in the "What we heard: Informed substitution within Canada's chemicals program".

The majority of respondents were supportive of the vision outlined in the aforementioned study report, and most were in agreement that chemical

assessments should be based on sound science and include a life-cycle approach. Most respondents felt that alternatives assessments and chemical substitutions should be led by industry with support by government policies and initiatives.

Comments received during the public consultation, in addition to the Committee's input, will be used to inform activities related to informed substitution as part of the CMP's modernization.

7b. Topic: Advancing consideration of endocrine disrupting chemicals

July 18 and 19, 2018 (Ottawa, ON)

7b(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu
- Richard Becker
- Weihsueh Chiu
- Miriam Diamond
- Michelle Embry
- Geoff Granville
- Mike Rasenberg
- Elaine Cohen Hubal (by teleconference)

***Ad hoc* members**

- Rebecca Clewell, Associate Director with ToxStrategies, North Carolina
- Kevin Crofton, Consultant, R3Fellows, North Carolina
- Markus Hecker, Professor, University of Saskatchewan,

Government of Canada officials

- Tara Barton-Maclaren, Senior Manager, ESRAB, SED, HECSB, HC
- Maya Berci, Director, NSACB, SED, HECSB, HC
- Mark Bonnell, Senior Science Advisor, EAD, SRAD, STB, ECCC
- Marisol Eggleton, Manager, EAD, SRAD, STB, ECCC
- Matthew Gagné, Senior Evaluator, ESRAB, SED, HECSB, HC
- Jacqueline Gonçalves, Director General, SRAD, STB, ECCC

- Jean Grundy, Senior Biologist Evaluator, NSACB, SED, HECSB, HC
- Magdalena Jagla, Senior Science Advisor, EAD, SRAD, STB, ECCC
- Thomas Kruidenier, Acting Director, EAD, SRAD, STB, ECCC
- Robert Letcher, Research Scientist, EAD, SRAD, STB, ECCC
- David Morin, Director General, SED, HECSB, HC
- Christine Norman, Director, ESRAB, SED, HECSB, HC
- Joanne Parrott, Research Scientist, Aquatic Contaminants Research Division, Water Science and Technology, STB, ECCC
- Sarah Vanden Hoven, Science Advisor, ESRAB, SED, HECSB, HC
- Mike Wade, Manager, EHSRB, Environment and Radiation Health Sciences Directorate (ERHSD), HECSB, HC

Secretariat:

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Witnisse Mereus, Acting Senior Policy Analyst, ESRAB, SED, HECSB, HC

External observers

[For the introduction of the topic and charge questions, and the Government of Canada presentation (agenda items #5-6)]

- Shannon Coombs (President, Canadian Consumer Specialty Products Association)
- Amardeep Khosla (Executive Director, CEPA-ICG)
- Aleksandra Pogoda (Director, Canadian Steel Producers Association)
- Dave Saucier (Regional Director, Responsible Distribution Canada)
- Meg Sears (Chair, Prevent Cancer Now)

7b(ii). Background information provided by the Government of Canada

The Departments were seeking input from the Committee on scientific considerations related to how the Government of Canada could evolve the current approach for the identification and assessment of endocrine-disrupting chemicals (EDCs).

An EDC is an exogenous chemical that interacts or interferes with the function of the endocrine system. This may include the control of growth and maturation; reproduction and development, behaviour and reaction to stimuli; the production,

use, and storage of energy; and balance and maintenance of water and electrolytes in the body. Exposure to an EDC may therefore change the production, transport, metabolism, and receptor activation of downstream action of a hormone, resulting in disrupted messages received by a target tissue. Exposure to EDCs during critically susceptible periods of development, such as development/differentiation of the brain, the reproductive tract, or the reproductive organs, can result in adverse effects, including long-term and possibly multigenerational changes in function.

The goal of this meeting was to focus on the scientific considerations needed to guide the advancement of a potential program of work on EDCs in Canada that builds on international best practices and benefits from new and emerging methodologies and data. Towards this objective, the Committee was asked to answer charge questions presented within the respective sections in this paper. Given that the Departments carry out various activities related to chemicals management, including information gathering, priority-setting, risk assessment and management, and research, monitoring and surveillance, the Committee was generally requested to consider their input from a "fit-for-purpose" lens, identifying uncertainties as relevant to the decision context.

The assessment of EDCs presents potential challenges and uncertainties pertaining to sensitive developmental windows, multigenerational effects, non-monotonic dose-response relationships, and low-dose effects. In many cases, a shift away from point estimates to probabilistic analyses could allow for richer characterization of individual risk, population incidence, and statistical confidence. Currently, existing test methods and guidelines, such as U.S. EPA tests, OECD tests, and the OECD Conceptual Framework for Endocrine Disruptors, are suitable methods for evaluating EDCs in certain endocrine-related pathways, such as the estrogen, androgen, thyroid, and steroidogenic (EATS) pathway. However, in the future, medium-throughput assays—likely in combination with computational models—may be able to provide more confidence in identifying potential EDCs and predicting adverse effects, thus allowing for EDC identification in the absence of *in vivo* tests and/or to focus *in vivo* testing for adverse human health or ecological effects.

Individual test guidelines can have limitations, and often, the identification of an EDC or potential EDC may require a complement of these available tests—or supplementation by appropriate NAMs-—to identify a potential endocrine mode of action and related apical adverse effects. A weight-of-evidence evaluation across multiple studies and multiple levels is often required for evaluating the results of

these test methods and integrating various streams of information to determine targeted necessary next steps (OECD Conceptual Framework and Guidance Document 150).

It was noted that non-EATS mediated modes of action for endocrine-disrupting action is a growing area of research; assay development continues.

7b(iii). *Ad hoc* member perspectives on the charge question

The 3 *ad hoc* members, Rebecca Clewell (ToxStrategies North Carolina), Kevin Crofton (R3Fellows, North Carolina), and Markus Hecker (University of Saskatchewan, Saskatoon), gave short presentations on their perspective on EDCs and the charge questions.

Rebecca Clewell presented case studies towards developing a tiered approach to the evaluation of endocrine disrupting compounds. Central to this presentation was the use of *in vitro* toxicity data to support chemical risk assessments. The tiered approach ultimately leads to what was described as “fit-for purpose” risk assessments. Adverse outcome pathway (AOP)-based assay development was recognized as comprising Tier 1. Tier 2 testing *in vitro* was also discussed using high-throughput screening (HTS) assays. The presentation concluded that the complexity of the *in vitro* system used depends on the purpose and, specifically, that high-throughput assays support prioritization by combining exposure modelling and bioactivity data, while more organotypic assays may support point-of-departure (PoD) value determination. AOP-driven assay development supports robust biological readout. Well-designed *in vitro* assays can provide reasonable predictions of human response.

Kevin Crofton presented considerations for matching hazard data uncertainties to regulatory needs. Central to this presentation was the discussion of benefits and challenges in adopting different methodologies to inform risk assessments of endocrine disrupting compounds. He also suggested that the development of case studies using diverse data sets with ranges of uncertainty could highlight current usefulness and residual uncertainty of data and that these uncertainties could drive data needs for research, risk assessment and risk management moving forward. It was highlighted that the real proof of reliability is in the replication of effects and in judging the uncertainty in data.

Markus Hecker presented on endocrine disruption from a chemical and ecological risk assessment perspective. The presentation began with a review of the impacts

of endocrine-disrupting chemicals on wildlife and human health. Next-generation risk assessment approaches for environmental contaminants and the development of alternative testing strategies to animal testing for chemical prioritization and ecological risk assessment were also discussed. Dr. Hecker highlighted the fact that mixed messages in regulation/decision making among jurisdictions can be problematic and may lead to confusion. When communicating risk, scientists may disagree on certain approaches or interpretation of data; however, they speak the same language and can communicate efficiently among each other. What is needed is for scientists to improve the communication of results and risks with the public and decision makers who may not have a scientific background.

Two core members also provided short presentations.

Core member Richard Becker presented a review of relevant frameworks for organizing and integrating knowledge of bioactivity, toxicity, and exposure.

Weihsueh Chiu's presentation was entitled: Endocrine Disruptors: Lessons Learned from the U.S. National Academies' Report *Application of Systematic Review Methods in an Overall Strategy for Evaluating Low-Dose Toxicity from Endocrine Active Chemicals.*

7b(iv). Committee input

Some members of the Committee considered that the identification, assessment, and management of EDCs can be adequately conducted according to current and evolving science-based processes. Other members considered that EDCs could be unique and therefore concluded that additional policy-based responses may be appropriate. The Committee did not further address these differing perspectives.

The Committee responded to all 3 charge questions. Highlights are as follows:

- The Committee offered a workflow consisting of a tiered testing and evaluation framework, starting with non-test methods, such as *in silico* and predictive models, then moving on to high-throughput *in vitro* testing and medium-throughput assays, which include greater complexity, and ending with *in vivo* testing if warranted. This workflow aligns with the risk

characterizations for non-EDC pathways, but the discussions focused on EDC-specific pathways.
- The greatest certainty lies with characterizing EATS pathways through high- and medium-throughput assays. However, non-EATS pathway assays, such as for developmental neurotoxicity and obesity, require additional development.
- Issues that arose but were not, or only partially, resolved included: (1) adequately capturing population variability, including vulnerable populations and life stages, (2) performing cross-species extrapolation, and (3) assessing cumulative risk from exposures to chemical mixtures and non-chemical stressors.
- In addition, the Committee noted the need to better consider the full range of chemicals, metabolites, and degradation products of parent compounds.
- The Committee discussed using the AOP framework to organize future work (as a paradigm to translate between molecular initiating events and key events), which can inform assessment endpoints from high-throughput or medium-throughput assays and to help to provide context related to apical endpoints as well as to inform data needs and methods development.
- In discussing the threshold of toxicological concern (TTC) approach for human risk assessment, the Committee suggested developing an EDC-TTC for both human and ecological health.
- Improvements to exposure assessment should be considered, such as greater reliance on biomonitoring and environmental effects monitoring.
- The Committee also made the following 6 major recommendations: conducting a “strengths, weaknesses, opportunities, and threats” (SWOT) analysis; conducting case studies to glean “lessons learned”; convening expert panels to advance EDC-related risk assessment activities; fostering improved data sharing; and stepping towards “big and bold” thinking to address the challenges with respect to EDCs from a multidisciplinary perspective.

For more information, view the July 2018 committee report.

7b(v). Use of committee input

Elements of the Committee proposed NAM-based conceptual strategy were used to inform the development of post-2020 science proposals to support program modernization. These projects have progressed and continue to be actively worked on by the Departments. For example, the clustering of Domestic Substance List (DSL) substances based on endocrine activity, the development of *in silico* models

and approaches to address gaps identified with existing predictive methods, and continued investigation of specialized *in vitro* assays to determine suitability for a dose-response assessment of potential endocrine disrupting substances were presented at an internal technical workshop on advancing Canada's approach to EDCs under the CMP. As methods advance and data emerges, the approaches being developed and incorporated into the NAM-based strategy will continue to evolve and be used for other known endocrine modalities beyond estrogenicity which was the initial focus given the breadth of available information. To support the identification of future priorities and screening and risk assessment activities, an automated data analytics, reporting and integration platform is under development to enhance the screening approach for EDCs and other toxicity endpoints of interest.

Concepts outlined in Figure 1 of the Science Committee's report have been integrated into version 2.0 of the Ecological Risk Classification (ERC2) approach by ECCC. ECCC's new substances program is also evaluating ERC2's EDC profiling concept to determine its applicability in new chemical assessment.

The Committee proposed the need for case studies to evaluate the ability of lower-tiered (*in silico* and *in vitro*) approaches to appropriately identify EDCs using computational approaches. Examples of case studies include a bisphenol case study integrating *in silico* predictions and *in vitro* data generated using human cells evaluating gene expression changes and ERC2 for ecological prioritization. Data generation and studies are being conducted collaboratively under the international multidisciplinary team grant research project "Endocrine Disrupting Chemicals: Towards Responsible Replacements."

In addition, the Committee identified the medium throughput zebrafish assay as a promising area for further research. It has been suggested that the CMP should promote the development of the zebrafish assay by convening a group of experts that are studying zebrafish in Canada.

7c. Topic: Public health approach to chemicals management in Canada

November 28 and 29, 2018 (Ottawa, ON)

7c(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu
- Elaine Cohen Hubal
- Miriam Diamond
- Michelle Embry
- Geoff Granville
- Mike Rasenberg

Regrets

- Richard Becker
- Weihsueh Chiu

***Ad hoc* members**

- John McLaughlin, Chief Science Officer and Senior Scientist, Public Health Ontario, University of Toronto, Ontario
- Leonardo Trasande, Vice Chair for Research and Director, New York University Langone Health, New York

Government of Canada officials

- Yemi Agboola, Division Manager, Population Studies Division (PSD), EHSRB, ERHSD, HECSB, HC
- Tara Barton-Maclaren, Senior Manager, ESRAB, SED, HECSB, HC
- Nicole Davidson, Director, EAD, SRAD, STB, ECCC (Day 1)
- Louise Hayes, Manager, Chemicals and Environmental Health Management Bureau (CEHMB), SED, HECSB, HC (Day 2)
- Graham Howell, Senior Advisor/Policy Development Manager, Director General's Office, Policy, Planning and Integration Directorate, HECSB, HC
- Kathy Hughes, Manager, ESRAB, SED, HECSB, HC
- Muna Idris, Program Coordination Manager, CEHMB, SED, HECSB, HC (Day 1)
- Daren Kelland, Manager, RMB, SED, HECSB, HC
- Ellen Lye, Toxicologist, EHSRB, ERHSD, HECSB, HC
- Arezoo Matin, Policy Analyst, ESRAB, SED, HECSB, HC (Day 1)
- David Morin, Director General, SED, HECSB, HC
- Christine Norman, Director, ESRAB, SED, HECSB, HC
- Patricia Pelletier, Director, EHSRB, ERHSD, HECSB, HC
- Tim Singer, Director General, ERHSD, HECSB, HC (Day 1)

Secretariat

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Christine MacKinnon-Roy, A/Science Advisor, ESRAB, SED, HECSB, HC

Guest presenter

- Kacee Deener, Office of Research and Development, U.S. EPA, Washington, DC

7c(ii). Background information provided by the Government of Canada

The Departments are exploring the potential development of a roadmap on how to address chemical risks with a public health (or population health) approach in Canada. Such an approach could support the government's post-2020 program for chemicals management.

This meeting focused on what foundational elements would be required to develop a roadmap to advance a public health approach to chemicals management in Canada. It is understood that such an approach would take significant resources and time to move forwards, so the goal of the meeting was to identify the first steps to move towards such a goal.

With advances in science, together with outcomes and learnings of the CMP, a public health-based approach to chemicals management is becoming increasingly important. A public health approach would attempt to tie increased risk of specific diseases or outcomes to chemical management actions (such as research, monitoring and surveillance, priority setting, risk assessments, risk management). This approach would build on the traditional risk-based approach and be complementary.

A public health approach to chemicals management would start with building the required knowledge base regarding which human health diseases we know or expect are associated with exposures to chemicals. It would then screen known chemicals (for example, via biomonitoring and epidemiological studies) to determine which ones might be the greatest contributors to those diseases and would either identify priorities for traditional assessments and risk management actions, if needed, to reduce those contributors to those diseases or provide adequate evidence to support prevention strategies without a traditional assessment. In many cases, a shift away from point estimates to probabilistic analyses will enable a richer characterization of individual risk, population incidence, and statistical confidence.

A public health approach to chemicals management in Canada would allow the Government of Canada to focus efforts as required on priority areas post-2020, such as vulnerable populations and cumulative risk, as suggested in the "Follow-up Report to the Standing Committee on the *Canadian Environmental Protection Act*." Regarding vulnerable populations, the Lancet Commission highlights that

> "in countries at every income level, disease caused by pollution is most prevalent among minorities and the marginalised. Children are at high risk of pollution related disease and even extremely low-dose exposures to pollutants during windows of vulnerability in utero and in early infancy can result in disease, disability, and death in childhood and across their lifespan."

Accurately estimating chemical exposure and toxicity information are required in order to determine the impact of chemicals on human health. Exposure science fundamentally informs decisions that relate to smart and sustainable design, prevention, and mitigation of adverse exposures, and ultimately, health protection.

To address this, a public health approach could generate data and epidemiological studies that could characterize the multitude of chemical exposures across populations and time. This would involve developing and implementing better tools (such as new study designs and statistical methods) to generate complex information on multiple exposure-response relationships encompassing disease incidence, progression, and mortality (rather than a single health endpoint).

Although the roadmap should encompass a long-term timeline (in other words, more than 20 years), the activities described should be those that could be carried out in the short- and medium-term (5 to 10 years) and which could provide the evidence to determine whether such an approach would be useful and achievable for a post-2020 chemicals management program.

7c(iii). Information provided by the guest presenter

The Government of Canada invited Kacee Deener from the U.S. EPA's Office of Research and Development to present at this Committee meeting.

Kacee Deener provided an overview of risk assessment challenges and opportunities using a public health approach and presented the public health approach as a mechanism to problem solving. An example using air pollution and cardiovascular disease was provided. The presentation concluded by summarizing

key points including the fact that a public health perspective can complement traditional risk assessment approaches, and that it is important to consider all data streams. Finally, the need for partnerships was emphasized.

7c(iv). *Ad hoc* member perspectives on the charge question

The Government of Canada invited 2 *ad hoc* members to participate at this Committee meeting: John McLaughlin (Public Health Ontario and University of Toronto, Ontario) and Leonardo Trasande (New York University, New York. Two core members, Elaine Cohen Hubal and Niladri Basu, gave short presentations on their perspective on a public health approach to chemicals management and the charge questions.

John McLaughlin reviewed different public health approaches, provided examples and considered their impacts. A conceptual model of exposomics, genomics, and health over the life course was discussed. The ability to link health records across platforms was highlighted as a distinct Canadian advantage. Other advantages include already established cohort studies of large populations. There is a unique capacity to link data systems, including environmental, occupational, socio-demographic and health systems, and it was highlighted that institutions across Canada have invested in infrastructure and capacity that can be applied to support initiatives that protect health and prevent disease. A public health approach can deliver diverse impacts, such as detecting at-risk populations, monitoring exposures, fostering discovery, managing interventions, managing risks, and providing evidence to guide priority setting. Platforms for discovering, monitoring, and characterizing chemical effects can be informed by public health surveillance systems, and in applications to detect and respond to disease risks.

Leonardo Trasande from New York University, School of Medicine, presented on harmonizing approaches for estimating burden of disease due to environmental chemicals. It was emphasized that estimating the burden of disease is extremely important to policy making. Current environmental burden of disease approaches were described as being “disharmonized” and, as a result, there is a need to embrace concepts such as “probability of causation” as well as subclinical effects. Data availability was identified as a gap, particularly as it relates to the availability of biomonitoring data. It was highlighted that biomonitoring programs therefore need to be more coordinated.

Elaine Cohen Hubal provided a brief overview of the U.S. EPA’s Children’s Environmental Health Research Roadmap and concluded with methods (from

exposure and discovery science) to elucidate contributions of modifiable exogenous environmental factors to health outcomes**.**

Niladri Basu presented on the 2017 Lancet Commission on Pollution and Health Report with a public health approach lens.

7c(v). Committee input

Overall, as outlined in the its report, the Committee provided detailed comments on potential opportunities and challenges for the development of a public health approach, on potential data gaps and available tools, and on key elements that should be considered as part of a roadmap in the development of the approach in the short to medium term.

The Committee identified key elements that should be considered when developing a public health approach in the short to medium term. Members discussed the concept of “One Health” which is a concept that incorporates both human and eco-burdens of health. Some examples for types of activities included developing new partnerships to leverage data sources, adopting new technologies and approaches and, integrating environmental monitoring into the approach.

The Committee suggested moving to a more holistic approach based on multiple determinants of health, where 1 or more of those determinants is chemical exposure. They identified the public health approach as an opportunity to work with other groups and jurisdictions to leverage expertise and to assess the economic costs of inaction. The Committee also highlighted that there may be challenges in coordinating work across multiple groups due to potential institutional barriers, finding appropriate long-term cohort studies, and communicating issues to a broader audience.

When asked about data and tools that were required to develop a public health approach, the Committee highlighted the need to first identify data gaps. They also suggested focusing on smaller subgroups (such as vulnerable populations), engaging existing cohorts, and considering different methodologies to answer different population health questions (for example, non-targeted testing versus geospatial analyses), as well as investigating “known knowns” (in the context of case studies), which are linkages between a toxic chemical and adverse health effects. The Committee also discussed the types of case studies that could be followed. For example, a study that is smaller scale yet data rich would be

beneficial to use as a proof of concept in order to move the public health approach forward.

For more information, view the November 2018 committee report.

7c(vi). Use of committee input

The Committee's report has been extensively shared internally in the Departments. As the Departments look forward to chemicals management post-CMP, this approach will be fundamental.

As per the Committee's recommendation, the Departments agreed that the public health approach should be considered more broadly in order to include ecological concerns. Consequently, it was renamed the "Environmental Public Health Approach." In order to broaden the approach, a working group of researchers from ECCC was convened in the summer of 2019 to develop a concept paper outlining ecological considerations. Recently, a new Office of Environmental Health (OEH) was established at HC to advance an environmental public health approach to chemicals. The OEH will develop a roadmap and pursue proof-of-concept case studies conducted through interdisciplinary research and across public health, clinical, and disease surveillance fields. The OEH also chairs a new Environmental Public Health Approach Advisory Group that meets monthly and includes representation from HC and ECCC.

The environmental public health approach has also been highlighted as a topic of interest outside of the CMP. In December 2018, the HC deputy minister had an opportunity to discuss environmental health with the chief science advisor, and it was agreed that more discussions were needed in order to explore the topic. In response to this, HC hosted a meeting in November 2019 with representatives from ECCC, Statistics Canada, Indigenous Services Canada, the Public Health Agency of Canada, and the Canadian Institute of Health Research to discuss overcoming institutional barriers and integrating their respective resources as a first step towards collaborating on a public health approach.

7d. Topic: Integrating Chemical Fate and Scale in Exposure Assessments

June 12 to13, 2019 (Ottawa, ON)

7d(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu
- Richard Becker
- Elaine Cohen Hubal
- Miriam Diamond
- Michelle Embry (Day 2)
- Claire Franklin
- Mike Rasenberg

Regrets

- Weihsueh Chiu
- Geoff Granville

***Ad hoc* members**

- Todd Gouin, Environmental Consultant, TG Environmental Research
- David Tobias, Physical Scientist, U.S. EPA

Government of Canada officials

- Maya Berci, Director, NSACB, SED, HECSB, HC
- Virginie Bergeron, Manager, ESRAB, SED, HECSB, HC
- Mark Bonnell, Senior Science Advisor, EAD, SRAD, STB, ECCC
- Pamela Cebrowski, Acting Manager, ESRAB, SED, HECSB, HC
- Sean P. Collins, Scientific Evaluator, ESRAB, SED, HECSB, HC
- Mathew Gagné, Senior Evaluator, ESRAB, SED, HECSB, HC
- Jacqueline Gonçalves, Director General, SRAD, STB, ECCC (Day 1)
- Nancy Hamzawi, Assistant Deputy Minister, STB, ECCC (Day 1 by teleconference)
- Tom Harner, Research Scientist, Atmospheric Science and Technology, STB, ECCC
- Thomas Kruidenier, Acting Director, EAD, SRAD, STB, ECCC

- Mark Lewis, Senior Evaluator, NSACB, SED, HECSB, HC
- Christine Levicki, Environmental Specialist, CEHMB, SED, HECSB, HC (Day 1)
- Vanessa Lyon, Environmental Specialist, CEHMB, SED, HECSB, HC (Day 2)
- David Morin, Director General, SED, HECSB, HC (Day 1)
- Andy Nong, Computational Toxicologist, EHSRB, ERHSD, HECSB, HC
- Deborah Ratzlaff, Acting Director, ESRAB, SED, HECSB, HC
- John Westgate, Evaluation Officer, Environmental Risk I V Section, Environmental Assessment Directorate, Pest Management Regulatory Agency, HC

Secretariat

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Mary Lysyk, Senior Policy Analyst, ESRAB, SED, HECSB, HC
- Luc Nakashoji, Project Officer, ESRAB, SED, HECSB, HC

External Observers

(For the introduction of the topic and charge questions, and the Government of Canada presentation, items #8 and #9)

- Barbara M. MacKinnon, President and Chief Executive Officer, New Brunswick Lung Association
- David Saucier, Regional Director, Responsible Distribution Canada (RDC)

7d(ii). Background information provided by the Government of Canada

The Government of Canada seeks to better integrate chemical fate and spatial and temporal scale of exposure in an effort to improve the quantitative estimation of multimedia exposure beyond the local scale, considering dynamic (episodic, non-steady state) as well as steady-state emission conditions. Such quantification of exposure would result in refined, more realistic exposure scenarios and predicted environmental concentrations, as well as increased accuracy in the estimation of risk. The integration of chemical fate and the spatial and temporal scale would decrease uncertainty in exposure assessment, increase confidence in CMP risk assessment conclusions, and ultimately aid in the decision-making process in chemical risk management. This integration would also benefit subsequent risk management and pollution prevention efforts because the efficacy of emission reductions can be better understood across spatial and temporal for example (MacKay and Reid, 2008). In order to understand how connections across these

scales of exposure can be made, however, an understanding of emission patterns and chemical fate, including persistence, is needed.

Estimating media concentrations of chemicals in the environment adds an important source of uncertainty to chemical risk assessments. This stems largely from the variable and dynamic nature of environmental conditions, chemical fate, and chemical emissions. Most environmental concentrations used for ecological risk assessments in the CMP are based on local-scale scenarios, while local- and/or regional-scale scenarios are considered for human health risk assessments. More specifically, in many instances, there is currently limited consideration of how emission rate, fate, and transport quantitatively affect exposure to human and non-human receptors beyond the local scale.

Other than assessing long-range transport potential, exposure at the regional and far-field scales is not routinely considered in ecological exposure assessment conducted by the Government of Canada within the context of the CMP. Bonnell et al. (2018) suggest that 1 reason for this is the limited integration of chemical fate and distribution information when estimating environmental concentrations, particularly beyond point-source emission areas. This can result in a spatial and temporal mismatch between the environmental concentrations driving prioritization or risk assessment and actual or anticipated exposures. This challenge has also been identified by the National Academy of Sciences (NAS) report “Using 21st Century Science to Improve Risk-Related Evaluations” (NAS, 2017).

7d(iii). *Ad hoc* member perspectives on the charge question

Dr. Todd Gouin presented some of the improvements and challenges in advancing environmental fate and exposure models over the past 40 years. He discussed the progress made in integrating field data, chemical property data and emission data to develop better models and to improve model-field comparisons. Dr. Gouin then outlined how these tools will be especially useful to estimate the environmental impact of increased economic growth (for example, impacts resulting from increases in pesticide use, the release of industrial chemicals and chemicals used in personal care products). He highlighted that, in the context of a chemical assessment program, model results could also be used to prioritize chemicals, to assess exposure scenarios in risk assessments, to guide monitoring efforts and to prioritize the effective and efficient use of resources in the development and application of higher-tier assessment tools.

7d(iv). Committee input

The Committee examined the strengths, weaknesses, and approaches for integrating fate and exposure models to compliment or enhance current efforts for ecosystem risk assessment and for assessing far-field human exposures. The Committee expressed a consensus view that increasing incorporation of multimedia mass balance models into current assessment would be of benefit for numerous reasons. The Committee did not arrive at a clear path for implementation, but rather suggested options for implementing the expanded use of exposure models. The main points from the 2-day discussion on fate and far-field exposure modelling are below.

1. The Committee derived a list of characteristics of substances that can act as a guideline for determining when a multimedia exposure modelling approach is warranted.
2. After determining that a multimedia approach is warranted, the Committee provided 2 options for guiding which model or models could be used: (1) taking a tiered approach to determine which level of complexity is needed for the situation (fit-for-purpose), or (2) run a battery of models or a single, nested model to provide comprehensive information on chemical fate. Each option has its advantages and disadvantages.
3. The following needs were identified for better integrating fate and far-field exposure modelling into the current risk assessment approach:
    - Develop and support a series of mass balance models taken from existing and emerging exposure science.
    - Support efforts to collate existing data to support the use of models and integrate monitoring (data gathering) and modelling efforts.
    - Support efforts to collect priority data required as model inputs and parameters (for example, collect data to improve emissions estimates, which are the most significant data gaps constraining model application, and create databases and QSARs for degradation half-lives).
    - Support work on extending the domain of mass balance models from “classical” nonpolar organic compounds to include, for example, ionogenic compounds, unknown or variable composition, complex reaction products or biological materials (UVCB) substances, dyes and pigments, organic salts and organometallics, and some polymers.

- Consider supporting in-house modelling expertise as well as fostering collaborations and strategic partnerships among sectors within and beyond Canada to support model development and application.
- Consider strategic partnerships with academia and other authorities; for example, a possible alliance between ECCC and the EU/OECD (specifically in the context of the EUSES/Chesar software developments) could lead to a robust implementation of the science developed under the leadership of Canada.
- Consider supporting development of a higher-tiered model(s) with modules tailored to the diversity of Canadian environments in terms of functions (for example, urban, agriculture), ecozones, temporal variations in emissions, and environmental changes (including the consideration of extreme events).
- Use case studies to guide model development and implementation.
- Integrate model development and chemical monitoring/surveillance to optimize the value of each.
- Develop experience with expressing uncertainty associated with model estimates and model evaluation.

4. The Committee listed numerous advantages to increasing incorporation of mass balance models into current assessment as well as a number of disadvantages, key uncertainties, and solutions for overcoming the challenges associated with using exposure models. The Committee also commented on activities that could be taken in the short, medium, and long term as part of an implementation strategy.

7d(v). Use of committee input

From a human health context, HC is already looking beyond the local scale when considering potential far-field exposure in many situations. It regularly uses mass balance models to derive predicted environmental concentrations (PECs) in CMP screening assessments (for example, ChemCAN). However, the Committee noted that considerable advancements have been made in mass balance modelling. HC needs to determine what environmental media assessment approach will best address needs post-2020 (including models).

ECCC is using the objectives paper and report as guidance for informing the future direction of exposure assessment under a renewed CMP, particularly for restructuring and updating an eco-exposure framework post 2020 (see Figures 1 and 2 in the Committee report). For example, ECCC has incorporated mass balance modelling into ecological risk-based prioritization frameworks to better target chemicals of concern from different spatial and temporal scales of exposure. ECCC understands that capacity building is needed to accommodate some of the Committee's recommendations.

Similar to the findings of the Committee, ECCC also believes that collaboration with fate and exposure experts is crucial to future development of fate and exposure assessment for CMP. Accordingly, ECCC continues to work with external experts to advance fate and exposure assessment on projects that include improved mass balance approaches to determine the fate of contaminants in environmental media and biota at different spatial and temporal scales.

HC is evaluating the existing landscape of mass balance environmental models, to identify the potential need for model updates and/or new model development. Model analysis and the Science Committee report will help inform the future direction of environmental media exposure assessment and internal guidance document development post-2020, which are anticipated to address when to consider local vs regional scale (or beyond) and considerations for choosing appropriate models.

HC anticipates that it will further collaborate with ECCC on an approach to environmental media exposure assessment. Any changes made by ECCC to its ecological exposure assessment approach as a result of the Committee report would also be considered by HC within a human health context.

Development of in-house modelling expertise in HC is ongoing and the Department intends to seek out more opportunities to integrate the use of models and monitoring data (such as in continual model evaluation).

7e. Topic: Occupational health

February 5 and 6, 2020 (Ottawa, ON)

7e(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu
- Richard Becker
- Weihsueh Chiu
- Elaine Cohen Hubal
- Miriam Diamond
- Michelle Embry
- Mike Rasenberg

Regrets

- Geoff Granville

***Ad hoc* members**

- Paul Demers, Director of the Occupational Cancer Research Centre and Professor, Institute for Medical Sciences and the Dalla Lana School of Public Health, University of Toronto
- Colin Murray, Senior Manager, Risk Analysis Unit, WorkSafeBC
- Cheryl Peters, Occupational Hygienist and Epidemiologist, Department of Cancer Epidemiology and Prevention Research at Alberta Health Services and Occupational Exposures Lead, CAREX Canada

Government of Canada officials

- Andrew Beck, Director, RMB, SED, HECSB, HC (Day 1)
- Maya Berci, Director, NSACB, SED, HECSB, HC
- Lynn Berndt-Weis, Office of Emerging Priorities, HECSB, HC (Day 1)
- Mark Bonnell, Senior Science Advisor, EAD, SRAD, STB, ECCC (Day 1)
- Bill Casley, Associate Director, EHSRB, ERHSD, HECSB, HC (mornings only)
- Nicole Davidson, Director, ESRAB, SED, HECSB, HC
- Kirsten Jacobsen, Manager, Workplace Hazardous Materials Bureau (WHMB), Consumer and Hazardous Products Safety Directorate (CHPSD), HECSB, HC
- Boniface Koudjonou, Manager, Exposure and Biomonitoring Division, EHSRB, ERHSD, HECSB, HC (afternoons only)
- Thomas Kruidenier, Director, EAD, SRAD, STB, ECCC
- Ellen Lye, Senior Scientist, EHSRB, ERHSD, HECSB, HC
- Miranda MacPherson, Director, Office of Environmental Health, ERHSD, HECSB, HC (Use of Committee Input presentation only)
- David Morin, Acting Assistant Deputy Minister, HECSB, HC (Day 1; morning)
- Heather Patterson, Manager, ESRAB, SED, HECSB, HC

- Pat Rasmussen, Research Scientist, EHSRB, ERHSD, HECSB, HC
- Tim Singer, Director General, ERHSB, HECSB, HC (Use of Committee Input presentation only)
- Sarah Vanden Hoven, Senior Science Advisor, ESRAB, SED, HECSB, HC
- Angelika Zidek, Senior Manager, ESRAB, SED, HECSB, HC

Secretariat

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Luc Nakashoji, Project Officer, ESRAB, SED, HECSB, HC
- Roxanne Vandenbeek, Science Advisor, ESRAB, SED, HECSB, HC

External observers

(For the introduction of the topic and charge questions, and the Government presentation, items #8 and #9)

- Anne-Marie Besliu, Technical Specialist, Canadian Centre for Occupational Health and Safety
- Jessie Callaghan, Science Advisor, HC
- Jacques Cerf, Consultant, Chemistry Industry Association of Canada
- Shannon Coombs, President, Canadian Consumer Specialty Products Association
- Jennifer Dipper, Manager, Canadian Centre for Occupational Health and Safety
- Kevin Hedges, Occupational Hygienist, Occupational Health Clinics for Ontario Workers
- Rob Hoffman, Director, Government and Stakeholder Relations, Canadian Fuels Association
- Donald Lafleur, Executive Vice President, Canadian Labour Congress
- Barb Mackinnon, President and CEO, New Brunswick Lung Association
- Anne McConnell, Consultant, Canadian Consumer Specialty Products Association
- Tara Peel, National Director for Health, Safety and Environment at the Canadian Labour Congress
- Dave Saucier, Regional Director, Responsible Distribution Canada (RDC)
- W. Scott Thurlow, Legal Counsel & Director, Dow Chemical Canada ULC
- Valerie Wolfe, Executive Director, Occupational Health Clinics for Ontario Workers

7e(ii). Background information provided by the Government of Canada

HC is exploring ways to reduce the risks to Canadians from exposure to chemicals by considering exposures in the workplace and enhancing the protection of workers by leveraging the information, tools, and/or technical expertise of the CMP.

The objective of this meeting was to identify what considerations and sources of information could inform future work related to the protection of workers from exposure to chemicals in Canada.

Although pesticides are within the scope of the CMP, the *Pest Control Products Act* has specific protections in place for pesticides in the workplace. Therefore, the focus of these deliberations was on considerations for identifying potential priorities from exposures to industrial chemicals or consumer products used in the workplace.

Committee deliberations were informed by presentations from international chemicals management agencies (from the U.S., Europe and Australia) describing the consideration of workers in their programs and key lessons learned, presentations from *ad hoc* members on projects underway at Carcinogen Exposure Canada (CAREX), the Occupational Cancer Research Centre (OCRC) and WorkSafeBC, as well as by HC's objectives paper that provided an overview of potential occupational exposure data sources that could help identify potential priorities for further work.

This meeting considered the key lessons learned from international federal chemicals management agencies to inform potential future activities in Canada, with a particular focus on the scientific considerations for identifying potential priorities (that is, risks) from exposure to industrial chemicals or consumer products used in the workplace.

7e(iii). Information provided by guest presenter and *ad hoc* member perspectives on the charge question

Dr. Paul Demers discussed some of the challenges and opportunities in developing an approach to occupational health in Canada. One of the principal challenges is related to jurisdictional issues where the federal and provincial/territorial governments are not aligned. Currently, there is no central organization to coordinate the efforts made by specialized research centres and academic institutions. Improved coordination and funding could enable collaboration on larger Canada-wide projects, development of more robust data sets, and

engagement with other groups (for example, labour ministries) to leverage existing data. He concluded that while gaps exist, there is still great work being done to address occupational exposures to chemicals for smaller groups.

Mr. Colin Murray presented on the work that WorkSafeBC does to address occupational disease prevention. One of the teams, the Risk Analysis Unit, is responsible for developing risk profiles for substances using the following criteria: number of workers exposed, probability of exposure, risk profiles, acute health effects and fatalities, carcinogenicity and exposure registry, and claims data. Using these profiles, the group develops risk management strategies and prevention programs to reduce the exposure levels for existing and emerging risks, resulting in better protection for workers. He emphasized the importance of building industry awareness, providing officer support and developing a targeted inspection program for developing a strategic occupational disease prevention plan. Mr. Murray also provided an example of an assessment tool that helps employers to understand how they can mitigate certain workplace exposure risks.

Dr. Cheryl Peters presented on the work that CARcinogen EXposure (CAREX) Canada does to help lower Canadians' exposures to known and suspected carcinogens in workplaces and communities. She highlighted that CAREX has a large amount of historical exposure data and well-trained occupational hygienists to support the efforts of other groups. One issue raised was the lack of current data on new or emerging chemicals and the lack of CAREX estimates for non-carcinogenic chemicals. She discussed the prioritization considerations at CAREX, a process that includes looking at the presence or likelihood of presence of a chemical in Canada, measuring the toxicity of chemicals, assessing the feasibility of making a difference, and seeking input from stakeholders.

7e(iv). Committee input

The Committee supported HC in seeking ways to reduce risks in workplaces arising from chemical exposures. The Committee considered lessons learned from other jurisdictions that have addressed worker protection or that consider occupational exposure in risk assessments, while being aware of the occupational health and safety system jurisdictional arrangements in Canada.

The following are the main points from the 2-day meeting held to discuss considerations that could inform HC moving forward to reduce workplace risks due to chemical exposures.

1. The Committee supported the recommendation of the UN Special Rapporteur to incorporate workplace considerations under the CMP.
2. HC can play an essential role in coordinating and sharing information at a national level and in providing training to the provinces and territories, with the goal of enabling best practices, but not necessarily harmonization. Jurisdictional conflict should be avoided through, for example, not being overly prescriptive but rather by fostering inter-jurisdictional cooperation.
3. HC can play a key role in convening a multi-party committee to recommend priorities, drawing representatives from labour, federal/provincial/territorial governments, academia, clinicians non-governmental organizations, and possibly industry.
4. It will be important for HC, in working to forge partnerships and coordinate funding efforts, to operationalize an integrated and national system of surveillance, prioritize substances for regulatory action (for example, risk assessment/management, occupational exposure limit setting, hazard classification), and to be involved in information gathering, education, and action.
5. HC can take a more proactive role in centralizing information related to emerging or rapidly changing types of work (such as nail care services, cannabis growing, recycling).
6. Modelling should be investigated as a means to provide estimates of workplace exposure in the absence of monitoring data and to build generalizations. The Committee discussed the merits of modelling that could consider substances using a life-cycle assessment and risk assessment framework.

   The Committee identified the need for better disclosure and availability of information for prioritization and hazard classification. In addition, "workers' right to know" and worker education should be enhanced so as to ensure that workers are sufficiently informed of the hazards associated with various chemicals and substances with which they work or may come in contact in the workplace, including products not intended for occupational use and products for which full disclosure of hazardous substances is lacking.

7. Information for hazard classification and prioritization can be obtained from other international programs such as Europe's REACH, the U.S. *Toxic*

Substances Control Act (TSCA) and the Australian program under the authority of the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). Canadian sources of information include CMP risk assessments, data from the provinces and territories, academia, and other Canadian sources such as occupational health clinics. Information can include measurements where the Committee saw a role for HC to coordinate data curation and availability.

8. Case studies conducted or coordinated by HC could inform how to best move forward to consider workplace exposures under CMP and to prioritize further activities.

For more information, see the February 2020 Committee report.

7e(v). Use of committee input

HC shared the Committee report with federal, provincial and territorial occupational health and safety regulators to inform and advance discussions on how HC could support the protection of workers from exposure to chemicals. The Committee input will also be shared and presented with CMP stakeholders and at other external events to solicit further thoughts and ideas.

7f. Topic: The Evolution of Risk Assessment under the Canadian Environmental Protection Act, 1999

February 17–18, 2021 (virtual online format)

7f(i). Attendees

Committee members

- Jon Arnot
- Niladri Basu
- Richard Becker
- Weihsueh Chiu
- Elaine Cohen Hubal
- Miriam Diamond
- Michelle Embry
- Geoff Granville
- Mike Rasenberg

***Ad hoc* members**

- Cristina de Avila, Head of Unit, Sustainable Chemicals, Directorate-General for Environment, European Commission
- Bob Diderich, Head of Division, Environment, Health and Safety Division, Organisation for Economic Co-operation and Development (OECD)
- Jeffery Morris, Chemical Policy Consultant, Jeff Morris Solutions LLC
- José Tarazona, Senior Scientific Officer, Scientific Committee and Emerging Risk Unit, European Food Safety Authority (EFSA)

Government of Canada officials

- Tara Barton-Maclaren, Senior Manager, ESRAB, SED, HECSB, HC
- Maya Berci, Director, NSACB, SED, HECSB, HC
- Mark Bonnell, Senior Science Advisor, EAD, SRAD, STB, ECCC
- Nicole Davidson, Director, ESRAB, SED, HECSB, HC
- Marc Demers, Acting Director, EAD, SRAD, STB, ECCC
- Brad Fisher, Manager, Risk Assessment Bureau, CHPSD, HECSB, HC
- Don Gutzman, Manager, EAD, SRAD, STB, ECCC
- Alison McLaughlin, Acting Senior Manager, ESRAB, SED, HECSB, HC
- David Morin, Director General, SED, HECSB, HC (Day 1)
- Heather Patterson, Manager, ESRAB, SED, HECSB, HC
- Darren Porter, Acting Manager, EAD, SRAD, STB, ECCC
- Deborah Ratzlaff, NSACB, SED, HECSB, HC
- Michele Regimbald-Krnel, Acting Director, EHSRB, ERHSD, HECSB, HC
- Jonathan Tigner, Manager, EAD, SRAD, STB, ECCC
- Angelika Zidek, Senior Manager, ESRAB, SED, HECSB, HC

Secretariat

- Julie Chouinard, Manager, ESRAB, SED, HECSB, HC
- Anthony Coles, Senior Policy Advisor, ESRAB, SED, HECSB, HC
- Marisol Eggleton, Manager, Assessment Priorities and Planning, EAD, SRAD, STB, ECCC
- Luc Nakashoji, Project Officer, ESRAB, SED, HECSB, HC

Contractors

- Robert Chénier, Retired - Former Director, EAD, SRAD, STB, ECCC
- Christine Norman, Retired - Former Director, ESRAB, SED, HECSB, HC
- Greg Leonard, Associate, The Intersol Group
- Marc Valois, Principal and Senior Consultant, The Intersol Group

7f(ii). Background information provided by the Government of Canada

This meeting of the Committee provided an opportunity to reflect on how risk assessment carried out by the Existing Substances Program under the authority of the *Canadian Environmental Protection Act, 1999* (CEPA 1999) has evolved through the CMP (2006-2020). Importantly, this was also an opportunity to explore potential future directions and provide suggestions to HC and ECCC.

The CMP was introduced in 2006 to strengthen the integration of chemicals management programs across the Government of Canada. CMP risk assessments take into consideration a range of uses and sources, including uses addressed by provisions of various statutes, namely CEPA 1999, the *Pest Control Products Act*, the *Canada Consumer Product Safety Act*, and the *Food and Drugs Act*. In addition, work under the CMP has included extensive research, monitoring and surveillance of chemicals in humans and the environment.

A key element of the CMP has been addressing 4,300 substances that are or may be in commerce in Canada and that were identified as priorities for assessment in 2006, pursuant to obligations in CEPA 1999. In parallel, pre-market assessments of substances proposed to be introduced into Canadian commerce, as notified through the New Substances Notifications provisions of CEPA 1999, have ensured that the potential risks of these new substances are identified and addressed by appropriate risk management measures. As of March 2020, about 6,300 notifications of new substances had been assessed and addressed under the CMP.

It is recognized that there is intersection in risk assessment approaches, tools and methodologies used in New and Existing Substances Programs under CEPA 1999,

and under other federal statutes. It is also recognized that a number of CMP elements have and will continue to have a bearing and relevance to these assessments. For example, research, monitoring and surveillance provide key data important to inform exposure, hazard and risk characterization and can be critical in setting priorities and work planning for assessment and management of substances.

The Committee was asked to reflect on the evolution of the CEPA 1999 Existing Substances Risk Assessment Program (Part I of the background paper) and on considerations for moving forward (Part II of the background paper) and, in so doing, to consider the charge questions identified in Appendix A of the background paper. Specifically, the Departments are looking for strategic science input, with a focus on strengthening Canada's risk assessment program for existing substances. The charge questions were open-ended in order to support a broad dialogue.

In the spirit of continuing to capitalize on the expertise of Committee members, for this meeting, the Secretariat employed the services of an experienced on-line meeting facilitator. This was to enable all members to participate fully and to ensure that the on-line format was used to its fullest potential. This included having the facilitator's team prepare the meeting report.

Christine Norman and Robert Chénier provided a summary of the background paper prepared for the Science Committee meeting and presented an overview of CMP to date. Key accomplishments included:

- Using a fit-for-purpose approach, the program has addressed nearly 4,000 substances
- Assessments considered multiple sources of exposure (for example, environmental media, food, products), or in other words, they adopted a '1 assessment, many uses' approach
- Assessment outcomes have resulted in 180 risk management actions, as well as preventative actions for substances with high hazard characteristics

They specifically addressed the implementation of the identification of risk assessment priorities (IRAP) process; the evolution of a fit-for-purpose approach and a risk assessment toolbox; a progressive focus on NAMs[1] for hazard

characterization, priority-setting and assessment; characterization of fate and exposure; risk characterization; and the importance of domestic and international collaboration and partnerships.

Looking to the future of the CMP, they noted key considerations for moving forward, including exploration of an ecological public health approach, enhanced priority-setting and information gathering, risk assessment modernization, vulnerable populations, including occupation-based considerations in assessments, cumulative risk and enhanced consideration of endocrine disrupting chemicals.

In their discussion of where chemical risk assessment is moving, Tara Barton-Maclaren and Angelika Zidek emphasized the need for new approaches. These include fit-for-purpose approaches, growth of NAMs, application of the AOP framework, and strengthening of the data and computational infrastructure. Data sharing and computational approaches will become increasingly important, as will expansion of the exposure toolbox and consideration of occupational exposure.

In the discussion period, a program research–regulatory 'centre of excellence' was raised by the speakers as an effective model for developing new tools, sharing resources, and better integrating science into policy and decision making.

Mark Bonnell provided an overview of topics including inherent toxicity, mechanisms across species, the concept of 'One Toxicology', what exposure means in an ecological context, and biomonitoring. He indicated that regulatory uptake of NAMs is starting, but has been limited so far in decision-making. On the data front, because Canada relies on international partners for much of its data needs, an integrated testing strategy would be very useful. Management of high volumes of data will be increasingly necessary and that data will need to be effectively shared across the Government of Canada. Hazard science and exposure science will need to be further developed, and regulations will have to be flexible enough to incorporate the accepted science.

For more information, view the Government of Canada discussion paper.

7f(iii). *Ad hoc* members perspectives on the charge questions

[1] A new approach methodology (NAM) is considered to be any technology, methodology, approach, or combination thereof that can be used to provide information on chemical hazard and risk assessment that avoids the use of intact animals.

Emerging trends, needs and challenges in chemical risk assessment from the OECD perspective
Bob Diderich, Head of Division, Environment, Health and Safety Division, OECD

Bob Diderich explained how the OECD, through initiatives involving collaborative efforts across countries, is supporting transformation of chemical risk assessment. Areas of focus include biomarker testing and prediction (for example, progress with in vitro testing, OECD QSAR toolbox), absorption, Distribution, Metabolism and Excretion (ADME) [for example, physiologically based kinetic (PBK) models] and exposure assessment (for example, harmonization of occupational exposure limits). To enhance regulatory uptake of NAMs, confidence must be established through case studies, documentation, mechanistic understanding, and integration into frameworks. Bringing NAMs into the Globally Harmonized System of Classification and Labelling of Chemicals (GHS) can potentially change the game. Another trend in the European Union (EU) is the use of generic risk assessment [for example, for carcinogens, mutagens, reproductive hazards (CMRs) and specific use cases, certain fate properties] to streamline processes or allowing risk assessment to be skipped in certain cases.

European Commission's chemicals strategy for sustainability
Cristina de Avila, Head of Unit, Sustainable Chemicals, Directorate-General for Environment, European Commission

Cristina de Avila explained that the goal of the European Green Deal is to help protect citizens and the environment and encourage innovation so as to improve health and environmental protection and increase global competitiveness. Its chemicals policy is to ensure a toxic-free environment by 2030 through a shift to chemicals that are sustainable and safe. This target will be reached by boosting innovation, strengthening protective legislation, substituting substances of concern, and ensuring that all chemicals on the market are safe and sustainable. Carcinogens, endocrine disruptors, very persistent substances, immunotoxicants and neurotoxicants are specific targets. Consumers, including vulnerable populations, are of particular concern. It will also simplify and consolidate regulation, and strengthen compliance, enforcement and market surveillance.

On the international stage, the European Commission hopes to provide an example globally by promoting global strategic objectives, targets, standards and harmonization, prohibiting exports of banned chemicals, and providing sound management of chemicals in international cooperation.

In the discussion, issues such as essential use, defining safe and sustainable, and benign-by-design were raised. Cristina de Avila said that addressing these concerns was an ongoing process.

Emerging trends, needs and challenges in chemical risk assessment from the European Food Safety Authority (EFSA) perspective
Dr. José Tarazona, Senior Scientific Officer, Scientific Committee and Emerging Risk Unit and former Head, Pesticides Unit, EFSA

José Tarazona said that a '(r)evolution' of the risk assessment paradigm was needed, incorporating NAMs data and integrating exposure assessment to produce more informative risk characterizations. By using the toxicology of the 21st century, the 'One Health' goal is to have healthy people, healthy animals, and a healthy environment. He explained that a shift from animal studies to an integrated paradigm using NAM-based integrated approaches to testing and assessment (IATAs) will provide a better understanding of chemical hazards and mechanistic processes.

For environmental risk assessment, the variability in environmental factors and use patterns will have to be taken into account. Specific protection goals can be defined based on the concept of ecosystem services, using 5 factors: the ecological entity (organism to ecosystem), its attributes, the magnitude of acceptable impact, the temporal scale and the spatial scale. The use of big data will support a move from risks to impacts directly relevant for environmental policy objectives. For pesticides and other agrochemicals, the separation between directly intended impacts, inevitable impacts and avoidable impacts is proposed. The EFSA New Approach Methodologies Project is working to move NAMs forward using collaborative case studies with researchers and risk assessors.

Emerging trends, needs and challenges in chemical risk assessment
Dr. Jeffery Morris, Chemical Policy Consultant, Jeff Morris Solutions LLC and former Director, U.S. EPA's Office of Pollution Prevention and Toxics

Jeffery Morris discussed bringing social and economic factors into the process of identifying susceptibility to adverse effects from chemical exposure as a means to advance risk assessment. The current model for estimating human health impacts is incomplete, in the sense that human variability typically is captured only in biological terms, leading to a narrow concept of susceptibility and a limited view of what constitutes a subpopulation. Poverty, access to health care, lack of social

services, crime, noise, congestion, environmental degradation, and reduced ability to conduct cultural practices, are examples of relevant factors.

Engaging stakeholders in case studies can foster common understanding, facilitate transparency, allow for comparison, sensitivity and analysis, and shorten the period between investigation and application. The “One Health” approach discussed by the Committee in 2018 is an important direction, and including social and economic considerations supports that direction. Social justice considerations will be an important driver of policy action related to chemicals. Consideration of social and economic stressors in identifying susceptible and vulnerable subpopulations can play an important role in increasing the utility of chemical risk assessment to informing policy actions.

7f(iv). Committee input

Please see the “What was heard” meeting notes included as an Annex to the meeting record.

7f(v). Use of committee input

The input received at this wrap-up meeting will help inform future directions for the risk assessment program specifically and more generally for chemicals management moving forward.

8. Review of the Chemicals Management Plan Science Committee

The HC Policy on External Advisory Bodies (2011) recommends that the purpose and functioning of an advisory committee should periodically be reviewed to ensure that the body is operating effectively and efficiently, to confirm that the work is still required, and to identify opportunities for administrative and management improvements. The policy also provides suggestions for the scope of the review, the review approach and the timing of the review. In accordance with this recommendation, a review of the Committee was undertaken in 2020, via an external contract. Given that the review was performed just prior to the final meeting, the intent was that the results of the review would help inform future directions with respect to accessing external advice.

The approach to the review was based on a review framework and interview guides that addressed themes of relevance, contributions/impacts, and operations. Core background documents were reviewed and select interviews were conducted among core members of the Committee, government officials responsible for supporting and guiding the Committee's work, and *ad hoc* members of the Committee. Findings were then analyzed, synthesized, and prepared as a report submitted to the Secretariat.

8a. Review findings

Relevance

Key findings indicate that the Committee continues to be relevant, has been effective in supporting program development, and stands as a viable model for continuing to engage external scientific expertise. Many interviewees supported renewing the Committee with some minor modifications and recognized its strength in providing a validation function in reviewing scientific approaches and methodologies employed by the CMP. Interviewees generally agreed that the topics brought to the Committee were appropriate, relevant, and within the scope of its mandate.

Contributions/impact

Participants were asked for their views on what kind of impact the advice provided by the Committee has had on the CMP. This contribution was defined in terms of impacts on the thinking of Government officials, on the resources allocated to consider topics raised by Committee members, and on the design/implementation of the CMP. Respondents reported that the Committee was impactful in helping to influence and shape Government of Canada thinking and/or allocation of internal resources.

Governance

Interviewees were generally pleased with the way in which the Committee was being administered and governed, with multiple interviewees praising the hard work of the Secretariat in particular. Some key strengths on which to build included the pre-meeting preparations, which help ensure that a quality discussion takes place during the meetings, and the use of *ad hoc* members to complement the expertise provided by the core committee members.

Several interviewees expressed a desire to have more transparency around governance processes, such as the selection criteria for co-chairs, meeting topics, and *ad hoc* members.

Operations

With respect to membership, interviewees generally respected the quality and experience of the Committee members, both core and *ad hoc*. The importance of the *ad hoc* members was unanimously noted, with interviewees acknowledging the critical roles they play in providing depth of expertise, creative ideas to spur innovation, and up-to-date knowledge of global practices in a specific area.

Some interviewees flagged that there is a significant level of effort associated with bringing a topic to the Committee for discussion and pointed to the potential duplication of information (and thus effort) between the information contained in the discussion paper, the pre-meeting webinar, and the overview presentation given at the beginning of each meeting.

Finally, all respondents reported that the Committee report development process requires further streamlining to make it more timely and less onerous for members. It was felt that delays in the preparation of the reports affected the Committee's ability to provide impactful advice on CMP decision making.

Meeting dynamics

The review revealed a diversity of opinions related to challenging group dynamics. While this is expected in a group with such diverse members, a number of suggestions are outlined in the following section to address future issues.

8b. Suggestions for Improvement

Explicitly identify the function that the Committee is meant to serve

It was suggested that the Committee should be given clear direction as to which function it is meant to serve, whether it be validation of ideas being proposed, driving innovation to inform new approaches, ensuring that the CMP stays current with the latest thinking from around the world, or informing the long-term strategy and direction of the CMP. Members felt that their input would be enhanced if there was greater clarity on their function, especially as this function

might vary depending on the topic. It was suggested that this should be discussed at the first orientation meeting and form part of the terms of reference developed.

Adopt a new approach to tracking and reporting on the impact of Committee advice

Despite the Government of Canada providing use of Committee input presentations at each meeting and developing a mid-term and end-of-term report with that information presented, some Committee members had trouble recalling specific examples of the impact the Committee's advice had on the CMP. It was suggested that the reports include more precise, action-oriented advice and that the Secretariat track and report progress on these.

Develop a process to manage challenging meeting dynamics more effectively

To help ensure that challenging meeting dynamics are managed more effectively, it was suggested that a code of conduct be agreed to at the onset of the Committee term and that a protocol for dealing with disagreements be developed.

Better document and increase transparency of internal Government of Canada processes related to the Committee

As stated above, some respondents expressed an interest in having greater transparency with various internal processes of the Committee. In addition to the selection of meeting topics, *ad hoc* members, and other participants, there was also an interest in improving transparency with respect to the selection of co-chairs.

It was suggested that these governance processes could be explained in a more detailed on-boarding process.

Test and adopt new approaches to finalizing meeting records and committee reports in a timelier manner

Several suggestions were put forward as to how meeting report development could be improved. This included having the Secretariat prepare the report, having core members support the writing process, or having an independent rapporteur generate either a draft or the full report.

Develop a broad CMP-wide strategy for engaging external scientific expertise

When addressing options for engaging external science experts in the future, the review suggested that a broad CMP-wide strategy should be developed.

It was noted that CMP officials already access scientific expertise in multiple ways beyond the Committee, including bilateral engagement of external experts, peer reviews, and partnerships with other jurisdictions. As a result of the interview process, respondents offered additional ideas for external engagement, such as convening groups of *ad hoc* experts for individual engagements/workshops, greater engagement with professional societies, and increased and targeted engagement with similar officials and scientists working in other jurisdictions.

The review's suggestions are welcome and will help inform external advisory body options for the future.

9. Renewal of the CMP Science Committee

The core members of the Committee were appointed for an initial term of 3 years. This first term began in February 2014, which was when the inaugural face-to-face Committee meeting took place. The first term ended in the fall of 2016.

The Committee was renewed for a second 3-year term, which began in the fall of 2017. For the second term, the Departments revised the areas of expertise required for membership in order to better address emerging priorities and the needs of the program. The second term, originally planned to end in the summer of 2020, was extended until March 2021.

The Committee has made significant contributions to the delivery of the CMP. Moving forward, HC and ECCC are evaluating and considering options for accessing external science expertise in the future and are exploring a variety of engagement mechanisms.