

20TH
Anniversary

CHEMCON THE AMERICAS 2016

INTERNATIONAL CONFERENCE
ON CHEMICAL CONTROL
LEGISLATION & TRADE ASPECTS

Workshop on Canadian Chemicals Management Plan – CMP3

Oct 17th - 21st
Toronto
Canada

Partners:



Organizer:



Royal
HaskoningDHV
Enhancing Society Together



Copyright & Disclaimer

COPYRIGHT

All rights reserved.

No reproduction, copy, transmission or commercial use of any paragraph of this documentation may be made without prior written permission of HaskoningDHV Nederland B.V. or the Authors and in accordance with the law of The Netherlands on intellectual property. Any person who does any unauthorized act in relation to this publication and the related event may be liable to criminal prosecution or civil claims for damages.

GENERAL DISCLAIMER

Information in this electronic handbook is provided 'as is' without warranty of any kind, neither expressed or implied, including, but not limited to, the implied warranties of merchantability or fitness for a particular purpose. No responsibility is assumed by the organiser/editor or the authors for any injury and/or damage to persons or property as a matter of product, negligence or otherwise, or from any use or operation or expectation of any methods, products, instructions or ideas contained in the material herein.

The views expressed and the syntheses and proposal drawn in the material included in this electronic handbook should be considered as the authors' own and do not necessarily represent to opinion of HaskoningDHV Nederland B.V. and/or of the partners or supporters of ChemCon Conferences. In no event will HaskoningDHV Nederland B.V. be liable to any party of any direct, indirect, special, consequential, incidental or punitive damages for any use of this electronic handbook, or any other hyperlinked websites, including, without limitation, any lost profits, business interruption, loss of programmes or other data on your information handling system or otherwise, even if we are advised of the possibility of such damages.

In addition to the above mentioned provision, the law of the Netherlands applies.

ChemCon Conferences
by HaskoningDHV Nederland B.V.
P.O. Box 151, 6500 AD Nijmegen, The Netherlands
Tel: +31 (0)88 348 88 88
Email: office@chemcon.net
Website: chemcon.net
Youtube: youtube.com/ChemConConferences



Handbook Manual

If you move your cursor, for example over the first presentation on the Contents page, you will see that your mouse cursor changes in appearance. If you click on this session you will go to the top of that particular manuscript and/or presentation. Also we have added web links to the links mentioned in the manuscripts and/or presentations.

To go back to the overall program or content click on the link on the bottom of each first page of a manuscript and/or presentation. To go back to the original position press 'ALT + left arrow key (←)' or press 'Previous View' in your PDF toolbar.

On top of the regular printing features of PDF we have included the following enhanced features:

To print a particular manuscript and/or presentation click on 'Printer Friendly' on the first and last page of each document. A new window will pop up on your screen and you will see the manuscript and/or presentation you selected. To print this session, simply click 'print' on the bottom of the first or last page. After you have printed the document, close the window and the main file will appear. If you wish to print a CV, press 'Ctrl + P' and select to print 'current page'.





Organiser's Message

Dear Ladies and Gentlemen,

Toronto is the host city for **ChemCon the Americas 2016**, our 20th anniversary and 5th ChemCon The Americas. Another successful conference in the global series of ChemCon Conferences, which is taking place from 17th to 21st October, 2016 in Canada.



With thanks to the enthusiastic support of the distinguished speakers and partners of **ChemCon the Americas 2016**, we are able to set up a great event in this lovely city. More than 170 experts from 26 countries representing over 100 companies, authorities and associations are attending our conference sessions and exhibition. Together, they will contribute to an inspiring exchange of experiences and discussions about regulatory affairs around the globe.

This workshop will provide an overview of the Canadian Chemicals Management Plan – CMP3.

For this electronic Handbook, the presentations have been slightly adapted in order to provide an easy accessible overview of the content.

We would like to express our gratitude to all speakers in preparing this workshop, as well as the partners, supporters and of course all the delegates at this event.

If you want to learn more about upcoming events in the series of ChemCon Conferences, please have a look at our website: www.chemcon.net. Our next event is **ChemCon Asia 2017** from 19th to 23rd June, 2017.

Thank you for your continued interest in ChemCon Conferences. We look forward to meeting you at one of our future conferences.

Yours faithfully,

Tjeerd Bokhout
Conference Director



Contents

Workshop: Canadian Chemicals Management Plan – CMP3

Canadian Chemicals Management Plan – CMP3

- Progress To-Date
- New and Existing Regimes
- **Dan Bastien**, *Environment and Climate Change Canada*

Industry's perspective and experience with the Chemicals Management Plan

- Challenges and successes
- **Joyce Borkhoff**, *Intertek Scientific & Regulatory Consultancy*

CMP Moving Forward

- Status update and Moving Forward with the CMP
- Information gathering
- Stakeholder Engagement and Opportunities for Involvement under the CMP
- Risk Assessment and Risk Management Work Plans
- **Bio Aikawa**, *Health Canada*

Inventory Update 2016

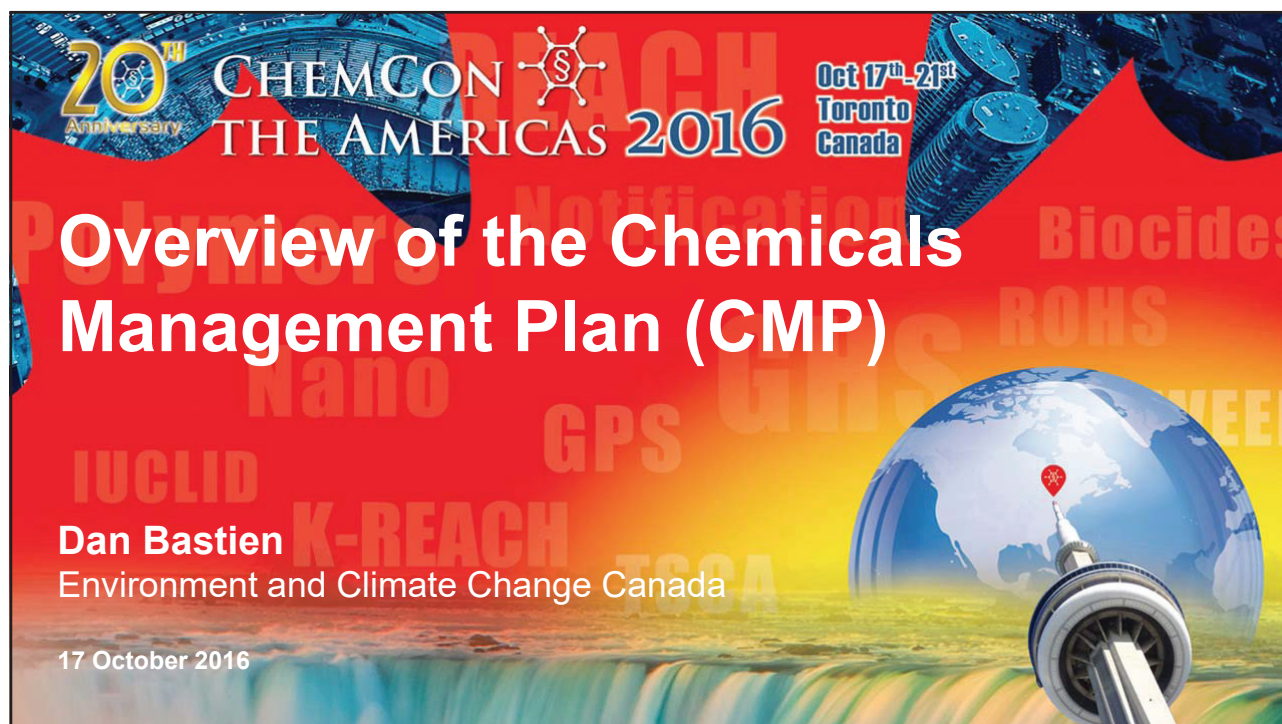
- Domestic Substances List Inventory Update (DSL IU)
- Mechanics of reporting: ECCC Single Window system
- **Bio Aikawa**, *Health Canada*


Speakers

Future Events

Overview of the Chemicals Management Plan (CMP)

Dan Bastien, Environment and Climate Change Canada



20TH Anniversary CHEMCON  THE AMERICAS 2016 Oct 17th-21st Toronto Canada

Overview of the Chemicals Management Plan (CMP)

Dan Bastien
Environment and Climate Change Canada

17 October 2016

The slide features a background with a globe, a stylized chemical structure, and various chemical-related terms like 'Polymers', 'Biocides', 'Nano', 'GPS', 'K-REACH', 'TSCA', 'ROHS', 'WEEE', and 'IUCLID'. A stylized image of the CN Tower is visible on the right side.

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Outline

- Objective of this presentation and discussion
- Overview:
 - Governance under CMP and scope of different Acts/Programs
 - Key Achievements under the CMP
 - Overview of the Science Committee
- Looking Forward:
 - Current Deliverables
 - Risk Management Work Plan
 - Early delivery of the next phase of the CMP

Dan Bastien

2

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Context

- Chemicals management in Canada was dramatically strengthened in 1999 with *The Canadian Environmental Protection Act, 1999*, which created new obligations and provided new tools focused on pollution prevention.
- The Chemicals Management Plan (CMP), initiated in 2006, is jointly delivered by Environment and Climate Change Canada and Health Canada to assess and manage, as necessary, environmental and health risks posed by substances.
- The CMP is a world leading program. Key design features include:
 - Significant strengthening and acceleration of the assessment and necessary management of chemicals in Canadian commerce
 - Integration of Government activities;
 - Strengthening the scientific foundation of the Program, and
 - Robust national and international engagement activities.

Dan Bastien

3

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Chemicals Management Plan (CMP)

- The CMP set clear priorities for assessing and managing chemical substances used in Canada and provided:
 - An integrated, **government-wide approach** to chemicals management;
 - **Targeted action** on chemicals of higher concern;
 - **Transparent, predictable timelines**;
 - Integration of research and monitoring programs between Environment Canada and Health Canada, aligned to priorities
 - A basis to promote **international collaboration**; and
 - Enhanced **engagement with various groups**.

Dan Bastien

4

Overview of the Chemicals Management Plan (CMP)

Governance under CMP

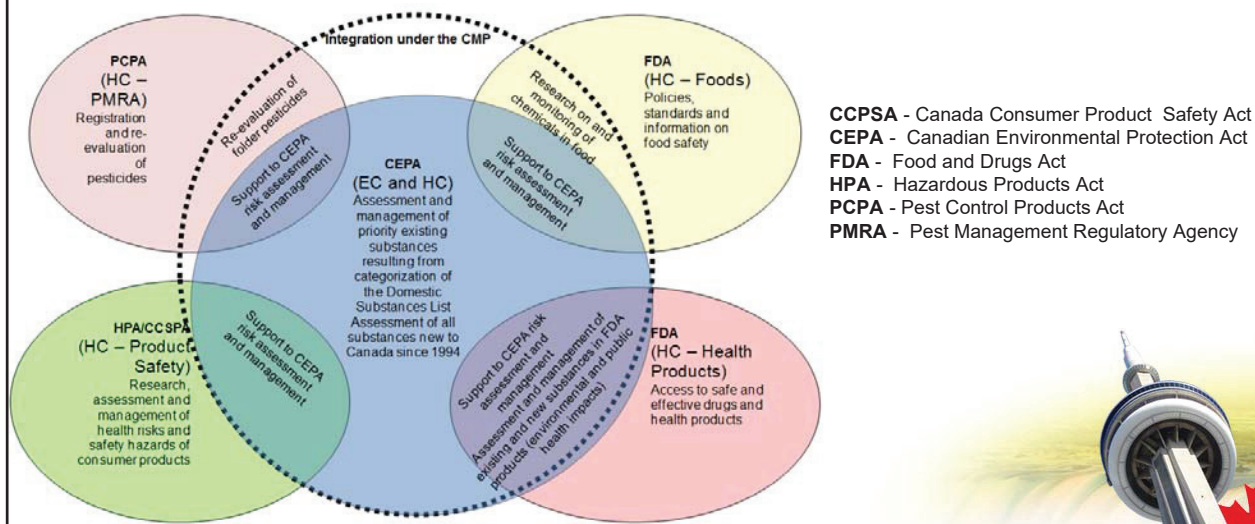
- The *Canadian Environmental Protection Act 1999* (CEPA) is the main tool used to assess and manage harmful substances.
- In addition to CEPA, risks from harmful substances can also be managed by other Acts, where they are best placed to do so including:
 - *Canada Consumer Product Safety Act*
 - *Food & Drugs Act* (e.g. Cosmetic Regulations, Non Regulatory Initiative (NRI), In Commerce List (ICL))
 - *Pest Control Products Act* (e.g. Re-evaluation of registered pesticides, Re-evaluation of older chemicals)
 - *Fisheries Act*
- CEPA is jointly managed by the Minister of the Environment and Climate Change and the Minister of Health

Dan Bastien

5

Overview of the Chemicals Management Plan (CMP)

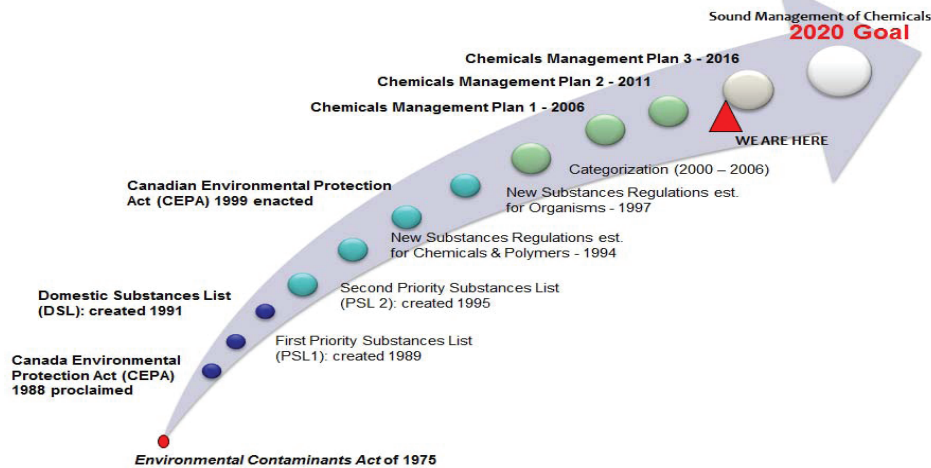
Interrelation Between Chemicals Programs



6

Overview of the Chemicals Management Plan (CMP)

Evolution of Chemicals Management Federally



Dan Bastien

7

Overview of the Chemicals Management Plan (CMP)

Key Achievements: Information Gathering

- Conducted 32 mandatory information gathering initiatives, requiring industry to provide data on over 4600 substances as well as a sizeable number of voluntary initiatives.
- Established linkages with existing sources of information from other departments and governments, and international industry groups through agreements.
- Updated the commercial status of substances through two cycles of inventory update to reflect current commercial status of Domestic Substance List (DSL) substances.
- Began making collected data available to Canadians through published non-confidential summaries for new chemicals.
- Made in-roads to facilitate information sharing throughout the supply-chain.

Dan Bastien

8

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements: Risk Assessments

- Assessed (to dSAR and/or fSAR) approximately **2740** substances in Canada. (including bisphenol A, flame retardants and perfluorinated compounds).
- Assessed the risks of 379 pesticides.
- Introduced the groupings for substances assessed in CMP to increase efficiency.
- Introduced a variety of assessment approaches, including petroleum sector stream approach, polymer approach, rapid screening approach.
- Completed the prioritization of substances on the Revised In Commerce List to identify those requiring further evaluation.

Dan Bastien

9

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements: Risk Assessments

- Assessed an average of 500 new substance notifications under *the New Substances Notification Regulations (Chemicals and Polymers)* and the *New Substances Notification Regulations (Organisms)* for chemicals, bio-chemicals, polymers, biopolymers nanomaterials, Organisms and Micro-organisms and substances used in Food and Drug Act (F&DA) products.
- Introduced the Approach for the Identification of New Assessment Priorities.
 - Identified 28 new priorities for assessment
 - New Substances
 - Requirements imposed for new activities
 - Annual process review

Dan Bastien

10

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements: Risk Management

- Consulted on risk management options for over 200 substances proposed and/or concluded toxic in CMP 1 and CMP 2
 - Published over 70 Risk Management Scope documents on proposed toxics
 - Published over 50 Risk Management Approach documents on final toxics
- 78 risk management actions taken to address CMP 1 substances
 - regulatory instruments under CEPA
 - non-regulatory instruments under CEPA
 - regulatory actions under FDA
 - non-regulatory actions under FDA
 - regulatory instrument under CCPSA

Dan Bastien

11

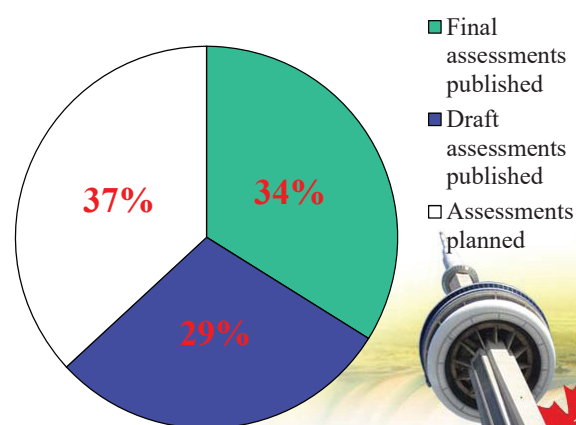
Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements and Results for CMP

- Of the 4,300 substances identified for further attention:
 - 2,740 substances have been assessed.
 - 363 substances (or groups of substances) have been concluded to be toxic.
 - 78 final risk management instruments covering 325 substances or groups of substances have been developed.
 - Additional risk management instruments are being developed.
- On track to meet 2020 goal.

Figure 1: Progress to date on the 4,300 substances identified for further attention



Dan Bastien

12

Overview of the Chemicals Management Plan (CMP)

Risk Assessment Update : Substance Groupings

Substance Grouping (# of substances)	Draft Risk Assessment (RA) and Risk Management (RM) scope publication	Final RA and RM Approach publication
Aromatic azo- and benzidine-based (358)	Completed (October 2014)	Spring 2016
Cobalt-containing (50)	Completed (December 2014)	Fall 2016
Internationally classified (6)	Completed (July 2014)	Spring 2016
MDI/MDAs (7)	Completed (August 2014)	Fall 2016
Selenium-containing (29)	Completed (July 2015)	Winter 2016
Certain organic flame retardants (10)	Summer 2016	2017
Boron-containing (15)	Summer 2016	2017
Substituted diphenylamines (13)	Summer 2016	2017
Phthalates (14)	State of Science Reports published August 2015 <i>new line</i> Draft RA to be published Fall 2016	2017

Dan Bastien

13

Overview of the Chemicals Management Plan (CMP)

RM for substances in CMP 1

Type of instrument	Act/RM Instrument	Proposed / In Development	Implemented	Total
Regulatory	CEPA 1999 - Significant New Activity	1	27	28
Regulatory	CEPA 1999 s93 - Prohibition regulation	1	7	8
Regulatory	CEPA 1999 s93 - Other regulation	3	8	11
Non-regulatory*	CEPA 1999 s56 - Pollution Prevention Plan	1	8	9
Non-regulatory	CEPA 1999 s54 - Guideline	5	4	9
Non-regulatory	CEPA 1999 - Environmental Performance Agreement*	-	6	6
Non-regulatory	CEPA 1999 s55 - Guideline	-	2	2
Regulatory	CEPA 1999 s65 - Virtual Elimination	-	2	2
Non-regulatory	CEPA 1999 s54 - EC Code of Practice	-	1	1
Non-regulatory	CEPA 1999 s55 - HC Code of Practice	1	1	2
Regulatory	CEPA 1999 s93 - Release regulation	-	1	1
Regulatory	CEPA 1999 - s200(1) Environmental Emergencies Regulations	1	-	1
Non-regulatory	FDA - Addition/Amendment to Cosmetic Ingredient Hotlist	-	3	3
Non-regulatory	FDA - Other actions	-	4	4
Regulatory	FDA - Lists of Permitted Food Additives	3	1	4
Regulatory	FDA - Amendment to the Prescription Drug List	1	-	1
Non-regulatory	FDA - Code of Practice	-	1	1
Regulatory	CCPSA - Schedule 2 Prohibition	-	1	1
Regulatory	HPA - Prohibition (prohibition transferred under Schedule 2 to the CCPSA June 2011)	-	1	1
To be determined		2	-	2
Total		19	78	97

Dan Bastien

14

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

RM for substances in CMP 2

Grouping	Proposed risk management as noted in RM Scope includes:
Azo Disperse Dyes	CEPA 1999 – Pollution Prevention Planning Notice or regulation
Pigment Red 4	FDA – Amendment to Cosmetic Ingredient Hotlist FDA – Amending the Natural Health Products Ingredients Database listing
Cobalt and its Compounds	Measures to reduce releases to water <ul style="list-style-type: none"> • FA - Amend Schedule 4 of Metal Mining Effluent Regulations • Gathering additional information <ul style="list-style-type: none"> • Additional risk management if required
Internationally Classified - Ethyl carbamate	FDA – Review existing Canadian Standards (Maximum Levels) guidance for ethyl carbamate in certain alcoholic beverages and consider amending them if warranted.
Methylenediphenyl diisocyanates (MDIs)	CEPA 1999 – Minimize access of general public to DIY two-component spray polyurethane foam products
Selenium and its Compounds under the Selenium-containing Substance Grouping	Measures to reduce releases to water <ul style="list-style-type: none"> • CEPA or FA – Potential regulatory approaches • Consideration of co-benefits of existing controls Measures to reduce human exposures FDA – consideration of lowering maximum doses for multi-vitamins / mineral supplements

Dan Bastien

15

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements: Research, Monitoring and Surveillance

- Completed regular reporting on key substances in the environmental monitoring and surveillance program
- Development of 18 draft environmental quality guidelines to support the interpretation of environmental concentrations
- Reported on three cycles of results from the national human biomonitoring of environmental chemicals program (Canadian Health Measures Survey)
- Completed research to address regulatory knowledge gaps on the effects of exposure of priority substances to humans and the environment, including research on environmental fate and effects, toxicology, and sources or pathways of exposure, and the development of tools, testing and analytical methodologies
- Characterized and conducted pathogenicity/toxicity testing of micro-organisms on the Domestic Substances List

Dan Bastien

16

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Updates – Engagement and Expert Science

- **CMP Stakeholder Advisory Council**
 - Purpose is to provide members the opportunity to offer advice and input to Government on the implementation of the CMP.
 - Meets twice per year, met in May and November 2015.
 - Renewed for a new five-year term, starting in April 2016 following a call for nominations.
- **CMP Science Committee**
 - Contributes expertise pertaining to scientific considerations moving forward in the CMP.
 - Meets twice per year. The next meeting is November 2016.

Dan Bastien

17

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Updates – Engagement and Expert Science

- **CMP Moving Forward Multi-Stakeholder Workshops**
 - Four workshops were held over the past 2 years with an objective to discuss with industry and non-industry stakeholders potential approaches to be used across the program as we move into the third phase of the CMP. Last Workshop held November 24, 2015.

Dan Bastien

18

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Key Achievements : Public Outreach

- **Social media** – Facebook, Twitter and Pinterest, house tour/quiz promotion
- **Media outreach** – e.g., Fifth Story, Science Media Centre
- **Publications** – e.g., “Chemicals at a Glance”, “Chemicals and Your Health”, CMP Fact Sheets, “Hazardcheck”, Seniors guide, plain language summaries for substances of concern
- **Web Sites** – e.g., Chemical Substances, canada.gc.ca/health, partner websites
- **Marketing campaigns** – continued promotion of guides
- **Awareness raising events** – e.g., Learning sessions for front-line care providers, early childhood educators, nurses
- **Trade-shows** – Consumer and industry trade shows, typically in major city centres across Canada (approximately 90/year)

Dan Bastien

19

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Current CMP Deliverables

Risk Assessment

- A number of draft and final screening assessments will be published between 2016-2017
- The publication plan for these assessment reports is presented on the next slide

Dan Bastien

20

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Openness and Transparency

- Publication of the schedule of the release of draft assessments for the first 2 years (provided by quarter for year 1, and by half-year for year 2) on the website
 - In general, final assessments are published one year after the draft
 - Annual updates will ensure a 2-year rolling publication plan is available
- Publication of the CMP Phase 3 Substances List on the website
 - Provides a list of substances in each assessment
 - Indicates the type of assessment approach to be followed in each assessment
 - Indicates the assessment start date (by quarter) for assessments beginning in the first 2 years

Dan Bastien

21

Overview of the Chemicals Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Annex

- Chemicals Substance web site:
 - <http://chemicalsubstanceschimiques.gc.ca/index-eng.php>
- *Canadian Environmental Protection Act*:
 - <http://laws-lois.justice.gc.ca/eng/acts/C-15.31/>
- CMP Science Committee web page and email:
 - <http://www.chemicalsubstanceschimiques.gc.ca/plan/sc-cs/index-eng.php>
 - CMP.Science.PGPC@hc-sc.gc.ca

Dan Bastien

22

Overview of the Chemicals
Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Contact Information

If you have any questions, contact the Substance Management
Information Line:

E-mail: eccc.substances.eccc@canada.ca

Telephone: 1-800-567-1999 (toll free)
(819) 938-3232

Dan Bastien

23

Overview of the Chemicals
Management Plan (CMP)

CHEMCON 
THE AMERICAS 2016

Thank You!



Government
of Canada

Gouvernement
du Canada

Dan Bastien

24



Industry's Perspective and Experience with the Chemicals Management Plan

Joyce Borkhoff

Intertek Scientific & Regulatory Consultancy, Canada

Abstract: *This paper provides an overview and latest update on Canada's Chemicals Management Plan (CMP), including the risk assessment and risk management of the high priority existing substances under the first phase of the CMP (CMP1), e.g. the "Challenge"; the progress made in assessing and managing the medium-priority substances under CMP's second phase (CMP2), e.g. the Substance Groupings Initiative; and the lessons learned by both industry and government thus far and the associated commitment to continuous improvement that we are carrying through to the assessment of the low-priority substances under CMP's third phase (CMP3).*

A.1 Chemicals Management Plan (CMP) – Overview

This year marks the 10th anniversary of the federal government's launching of the Canadian Chemicals Management Plan (CMP), introduced in 2006 as part of the government's comprehensive environmental agenda. The CMP broadly considers a range of "existing" substances including substances on the DSL and regulated under the Canadian Environmental Protection Act (CEPA); pesticides that are regulated under the Pest Control Products Act; and specific environmental interests in ingredients from products regulated under the Food and Drugs Act. Progress to date reflects the importance of industry and government working together to explore and assess opportunities for innovative risk-assessment approaches and risk-management decisions for existing chemicals in the marketplace today.

As a global leader in developing toxic substance management initiatives, Canada's multi-phase CMP has introduced:

- A systematic, science-based process for the "Categorization," and prioritized "Screening Assessment" of the roughly 23,000 legacy substances that formed the initial DSL;
- An "Industry Challenge" that included mandated and voluntary programs for collecting industry's hazard and exposure information for the highest priority substances;
- Regulations that restrict and/or phase out certain substances posing an unacceptable risk to human

health and/or the environment;

- Restrictions on the re-introduction and new uses of high-concern substances that are believed to no longer be in commerce above 100 kg/yr;
- Rapid screening of lower-risk chemical substances;
- Collaborative work between federal and regional governments, academia, industry, and international authorities to support robust information-gathering and risk assessment processes; and
- Collaborative work between government and industry to ensure good stewardship of chemical substances.

B.1 Categorization and Screening of the DSL (CSDSL) – Overview

The CSDSL program was established by Environment and Climate Change Canada (ECCC), formerly Environment Canada, and Health Canada to systematically approach the categorization and prioritized screening assessment of medium- and high-interest substances that were grandfathered onto the DSL, without prior risk assessment, through the nomination process back in the early 1990s. This program has been recognized by government and industry alike as a workable and more-favourable alternative to the burdensome REACH-like programs introduced by other international agencies.

First introduced when the Canadian Environmental Protection Act was renewed in September 1999, the CSDSL program required that the government identify, before September 2006, those grandfathered substances

(i.e., substances not assessed under New Substances Notification assessment program) that either:

- I. Met a prescribed definition of persistent (P) and/or bioaccumulative (B), and were predicted to be inherently toxic (iT); or
- II. Posed greatest concern based on potential high hazard and human exposure (i.e., "Human Health priorities").

Using various computer-modelling programs, existing hazard classifications from international organizations, and assessments of readily accessible test data, Environment and Climate Change Canada and Health Canada "categorized in" for further assessment ~4300 of the ~23,000 DSL grandfathered substances. Substances classified as PiT, BiT, or PBiT, and substances that were classified as Human Health priorities were deemed to be "categorized in" and these substances entered the screening phase of the Chemicals Management Plan launched in 2006. Depending on the outcome of the screening-level risk assessment, a substance can be either: set aside from any further interest; subjected to more rigorous assessment; or potentially added directly to the CEPA List of Toxic Substances (Schedule 1).

Those substances deemed to pose an unacceptable level of risk (i.e., "CEPA Toxic") are likely to trigger any one of a number of risk management actions, including but not limited to:

- A Significant New Activity condition (SNAc), which defines an acceptable use pattern and requires notification and assessment in advance of any new uses that fall outside the stated boundaries;
- Regulation that may prescribe boundaries on the import, manufacture, use, handling or disposal of a substance;
- Annual reporting of the manufacture, import, sale or use of a targeted substance; or
- Virtual elimination/prohibition of a substance to a level below the limit of quantification.

Supporting Canada's commitment to the United Nations Environment Programme's Strategic Approach to International Chemicals Management (UNEP SAICM), Environment and Climate Change Canada and Health Canada have committed to completing the assessment of these 4300 prioritized substances by the Johannesburg Plan's deadline of 2020.

C.1 Risk Assessment and Risk Management of Categorized Substances Under CMP

Of the ~4300 substances that the government deemed "categorized in" and therefore worthy of further attention,

- ~500 substances fell into the highest priority for screening assessment;
- ~2600 substances fell into the mid-level priority for screening assessment; and
- ~1200 substances fell into the lowest-level priority for screening assessment.

The ~1200 lowest-priority substances were the subject of an early rapid-screening program that resulted in 750 of these substances being confidently set aside from any further priority effort, and 350 being moved to the medium priorities. Numbers of substances falling into these priority categories have shifted as the program has progressed.

C.2 CMP Phase 1

The data-gathering activities (i.e., the Challenge and some sector-specific activities) for the high-priority substances are now complete and final risk assessments have been published. Risk-management tools are being developed for those substances that meet the CEPA toxic criteria.

As part of the assessment of highest-priority substances, the Industry Challenge, the targeted ~200 substances that were divided into a number of smaller groups (i.e., "batches") of substances, was developed. These batches were the subject of a series of mandatory surveys, and voluntary questionnaires, requiring manufacturers, importers and users to provide prescribed information to the government. Because the definition of "importer" was broadly defined to include receivers of the substance, (regardless of whether the substances were imported in neat form, as ingredients in mixtures, or in some cases as ingredients in components of manufactured articles), the target audience for this mandatory survey was very broad and proved difficult for those companies that imported mixtures or manufactured goods containing proprietary or unknown compositions. Companies that did not meet the mandatory survey reporting criteria, but who had an interest in these substances from a

global perspective, supported the Industry Challenge by completing the voluntary questionnaires and engaging in direct dialogue with the federal government.

When the Industry Challenge was launched in December of 2006, the government stated that these ~200 highest-priority substances were “predisposed” to the declaration of “CEPA Toxic” and that severe risk management actions would be taken, unless industry was able to show that a substance of interest did not possess the predicted hazard characteristics and/or was being used in a manner that protects against adverse effects to the environment and human health. Given this predisposition to severe restriction, industry has actively participated in the Challenge program to ensure that the government conducts well-informed and scientifically sound assessments and that risk management actions are taken only where needed.

C.3.a CMP Phase 2

During CMP Phase 2, launched October 3, 2011, Environment and Climate Change Canada and Health Canada began to actively address the substances captured as medium priority for action. During this phase, the government introduced additional funding, and a continued commitment to incorporating international data-gathering activities and bilateral relationships, and to addressing all potential sources in risk assessment/risk management activities (e.g. foods, cosmetics, consumer products, releases). The key elements of CMP2 included:

- Targeted approach for data gathering
- The Substance Groupings Initiative
- The Domestic Substance List (DSL) Inventory Update
- The Polymer Approach

C.3.b. The Targeted Approach

The targeted approach introduced in Phase 2 has become a “rule of thumb” for the CMP program and recognizes the commitment of ECCC/HC to focus Section 71 notices on essential data needs for risk assessment and any resulting risk management. As a result of the CMP2 Targeted Approach, Section 71 Notices will now include manufactured items only where there is reasonable potential for exposure, scopes will be refined to users that are of specific interest, use reporting concentration thresholds will be established where appropriate, and there will be a reduction in the need to provide information that has been provided

under “partner” programs. However, in order for the targeted approach to be successful, early stakeholder engagement is crucial. The approach to target essential data needs will be informed by early stakeholder engagement and consultations as future notices are developed. Information provided during early stakeholder engagement will determine the need for a Section 71 Notice and greatly influence its development.

C.3.c. Substance Grouping Initiative

Industry and Government have worked together to establish workable approaches to the medium priority substances through the Substance Groupings Initiative (SGI). The Substance Groupings Initiative was an approach that streamlined data collection and the assessment and risk management process for 9 groups of substances. The substance groupings were identified based on similarities of structure and/or function. This approach allowed ECCC/HC to incorporate the timing of international activities, recognize the stakeholder implications, lead to risk assessment and management efficiencies, and more effectively address potential exposure to children and human health. This initiative began with a Notice of intent for the Aromatic Azo- and Benzidine-based Substance Grouping, published on June 5, 2010. On October 8, 2011 an Announcement that applies to this grouping and eight additional groupings of substances was published in the Canada Gazette, Part I: Vol 145, No. 41 - October 8, 2011. The following groups are captured under the SGI (see also Table 1 on the next page):

- Aromatic Azo- and Benzidine-based substances
- Substituted diphenylamines
- Cobalt-containing substances
- Internationally classified substances
- Methylene diphenyl diisocyanates and diamines (MDI/MDA)
- Boron-containing substances
- Certain organic flame retardants
- Phthalates
- Selenium-containing substances

The SGI took into account the timing of international activities, risk assessment and risk management efficiencies, potential exposure to sensitive populations and stakeholder implications. Again, the key to the success of the SGI comes from the collaborative approach between ECCC/HC and industry. Industry has been involved and committed to an open dialogue

with government and early and active stakeholder engagement was critical to realizing the benefits of this dialogue. ECCCH/HC developed scope and approach documents for each group of substances early in the process. The supporting context information, for the most part, defined the direction and concerns so that stakeholders clearly understood if and how they needed to engage. Multi-stakeholder workshops were provided for many of the groups that initiated science discussions and demonstrated the challenges faced in a groupings approach, e.g. functional groups associated with a range of toxic profiles (phthalates); and overlap of data collection with development of the “state of the science” positions (azo dyes).

Data collection activities in 2013 saw the publication of Section 71 surveys for the remaining substance groupings including selenium-containing substances, certain organic flame retardants, and phthalates. More importantly, the first draft screening assessments were published for a group under this initiative. In November 2013, assessments were published for the azo disperse dyes, the azo solvent dyes, and benzidine-based dyes and related substances. As a group, the azo disperse dyes, along with Solvent Yellow 77, were found to meet one or more of the ‘CEPA toxic’ criteria and an associated Proposed Risk Management Scope was also published. This was our first experience under the CMP with a toxic decision for a group of substances and there was much to be learned, including: the risk

management impact of listing a group rather than individual substances on Schedule 1; and the use of the highest toxicity data endpoint across the group versus the application of a weight-of-evidence approach.

C.3.d. The Domestic Substance List (DSL) Inventory Update

The DSL Inventory Update (DSL IU) was a tool used to gather information on the remaining 2700 medium priority chemicals and polymers. The information gathered benefited risk assessment and risk management activities, informed priority setting and contributed to monitoring trends. The key objectives of the DSL IU were to update the “commercial status” of the remaining priorities under the CMP, assist in planning for CMP3, inform the Rapid Screening Approach and inform the Polymer Approach. Phase 1 of the DSL IU was released in the form of a Section 71 Notice addressing approximately 500 chemicals and 50 micro-organisms. During CMP2, a Notice was issued in the Canada Gazette, Part I: Vol. 146, No. 48 - December 1, 2012 under section 71 of the Canadian Environmental Protection Act, 1999 (CEPA 1999). The DSL IU incorporated the targeted approach and included:

- Tiered information requirements based on a concentration threshold of 0.1%, with substances found in lower concentration requiring less information;

TABLE 1: Status of Groups under SGI

GROUP	Stage				
	1	2	3	4	5
Azo compounds	█	█	█	█	
Substituted diphenylamines	█	█	█		
Cobalt-containing substances	█	█	█		
Internationally classified substances	█	█	█	█	█
Methylenediphenyl diisocyanates & diamines (MDI/MDA)	█	█	█		
Certain organic flame retardants	█	█	█		
Phthalates	█	█	█		
Selenium-containing substances	█	█	█		
Boron-containing substances	█	█	█		

1. Preliminary Assessment and Stakeholder Engagement
2. Information Gathering (including Section 71 surveys)
3. Draft Assessment & Initial Risk Management Discussions
4. Final Assessment & Risk Management Development
5. Risk Management Actions and CEPA Regulation Timelines

- Targeted activities: manufacturers and importers will be required to respond while users will be excluded;
- Targeted categories for manufactured items: notices will contain an itemized list of manufactured items that are likely to be used by consumers that may result in greater potential for exposure.

The increased attention given to manufactured items required reporting for manufactured items 'intended to release the substance during conditions of use such that the substance may be inhaled or come into dermal contact with an individual. This wording would appear to align somewhat with the EU approach to articles and leads one to wonder how manufactured items will be addressed in Canada moving forward.

C.3.e. Polymer Approach

There is still much uncertainty surrounding the risk assessment and risk management of the ~600 polymers captured within the population of the ~4,300 "categorized-in" substances identified as priorities for further action under the CMP. Under CMP2, The Government of Canada developed a proposed polymer approach. The proposed approach was tiered, recognizing the data requirements of the New Substances Program and the timing of upcoming data gathering activities. The document has been revised based on stakeholder input and a final version entitled 'Approach under the Canadian Environmental Protection Act, 1999 to address polymers on the Domestic Substances List that were identified as priorities during categorization' was released in December 2014. Details of the approach as well as a list of candidate polymers falling within the scope can be found in the document.

During Phase 2, preliminary information on polymers was collected through the DSL IU2. Information submitted in response to the DSL IU2 informed the Government of Canada as to whether a candidate substance was in commerce in Canada in a quantity above the reporting threshold of 1000 kg in the 2011 calendar year. For those polymers identified under DSL IU2 as not in commerce above this threshold in the 2011 calendar year, a Rapid Screening Approach was applied. For those polymers identified under DSL IU2 as in commerce at greater than 1000 kg, it was determined that further information gathering was needed.

On July 25, 2015, a Notice was issued in the Canada Gazette, Part I: Vol. 149, No. 30– July 25, 2015 under section 71 of CEPA 1999, applying to the 302 polymers on the DSL. This survey allowed the government to obtain information on the manufacture, import and formulation activities of these polymers for the 2014 calendar year. This data is essential for risk assessment under CMP3 and will ensure decisions made are based on the most relevant and up-to-date, information available. The assessment process will differ based on the polymer's "in commerce" status. Those found not to be in commerce will be assessed for highly hazardous properties and risk managed as necessary, including the use of SNACs as in CMP1.

Table 2: CMP Progress To Date

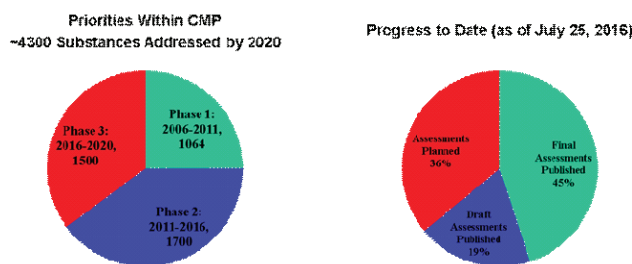
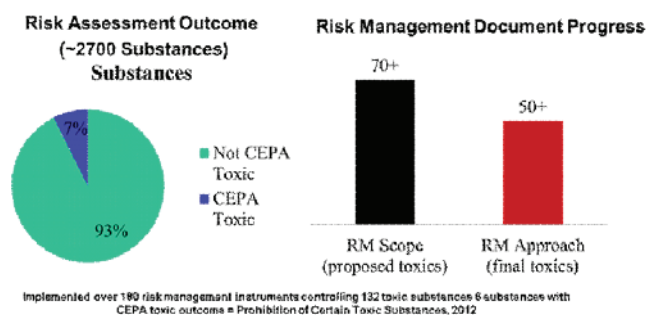


TABLE 3: CMP Outcomes To Date



D.1.a. Summary of Industry Perspective: Successes

The Canadian Chemicals Management Plan has provided the framework to effectively and efficiently assess and manage the potential risk for tens of thousands of substances. Progress to date has demonstrated that a small fraction of these substances require further assessment and an even smaller fraction have associated risks that require management. The outcomes from these risk assessment and risk management activities

are manageable and typically embrace the product stewardship initiatives and Codes of Practice already in place across our industry. The CMP is recognized both within and outside of Canada as a leading program for the risk assessment and risk management of existing chemicals and polymers. The keys to this success are easily summarized.

1. Accelerated pace
 - The CMP has seen more risk assessments than any other jurisdiction
2. Clear, focused priorities
3. Ownership of all affected parties through extensive multi-stakeholder activities
 - Government and industry speak the same language; and
 - Collaborative approach and recognition of every person's role in the plan has contributed to effective data gathering and development and design of risk management instruments
4. Robustness of stakeholder engagements, science based decisions, weight of evidence approach, decision making process
 - External expert input; and
 - Polymer approach, analogues, read-across, grouping and sub-grouping
 - Canada/US Regulatory Cooperation Council
 - Decisions changed based on stakeholder input and deeper risk assessment
 - The decision was reversed for a majority of Challenge substances that were "predisposed" to the declaration of "CEPA Toxic" unless otherwise demonstrated
5. Practical and ongoing risk management development and amendment
 - Robust multi-stakeholder engagement throughout plan to ensure understanding of current use patterns, existing product stewardship activities and Government's risk management objectives supports sound decision-making;
 - Periodic evaluation of progress to measure performance;
 - Periodic data collection (e.g. mandatory surveys, voluntary surveys, monitoring & surveillance) to evaluate progress and the need for additional risk management actions;
 - Ability and commitment to adjust decisions based on new evidence; and
 - Acceptance and encouragement of voluntary actions to meet objectives which result in both efficiency and flexibility

6. Continuous Improvement

- Aligning new and existing substances programs to eliminate redundancy; share approaches, data and operating efficiencies; incorporate what 'works';
- Increasing and amending tools for stakeholder outreach and guidance; and
- Government commitment to incorporate lessons learned and feedback from stakeholders when planning and implementing information gathering activities

7. Integrated approach to chemical assessment and risk management

- Selection of the best placed Act to manage the risks associated with a toxic substance
 - o CEPA
- Pollution Prevention Planning, Environmental Emergency Regulations, Significant New Activity
 - Canada Consumer Product Safety Act (CCPSA)
 - Food and Drugs Act
- Cosmetic Ingredient Hotlist
- Food Packaging

8. Strong Communication Plan

- Transparency regarding substances being reviewed and providing a clear indication as to why they have been included;
- CSDSL decision tables;
- Substance Profiles of the Challenge;
- Subgrouping Approach and background documents of CMP2; and
- Published Draft Screening assessment and Risk Management Scope Document for comment

D.1.b. Summary of Industry Perspective: Challenges

There have been many challenges experienced since the beginning of the CMP initiative and, as a result of the key success factors presented, many have been addressed through the commitment of the government and stakeholders. We do have some challenges ahead to ensure continued progress as the year 2020 quickly approaches.

1. There must be a focus on public outreach to raise awareness among the general Canadian public regarding risk management and raise visibility and understanding of the CMP and its successes
2. Cumulative risk (combined exposure to chemicals with same toxic mode of action) assessment is critical, but complicated

- Progress beyond simple “group” assessment where groups are defined by structure;
 - Chemicals with similar structures often have similar Mode of Action but very different toxicological potency;
 - More complicated than simple addition, thus transparency re: “how” is critical to acceptability
3. How will biomonitoring data be incorporated?
- a. Methodology is new, is not always simpler and is still evolving

E.1 Concluding Remarks

The key messages delivered by government have been, thus far, a commitment to using a “Fit-for-Purpose” approach to ensure that the focus remains on substances of highest concern; allocating resources appropriately; and engaging stakeholders effectively. This message suggests a positive continuation of the accomplishments made with early stakeholder engagements and targeted approaches for data gathering witnessed under CMP2.

The burden on industry to provide volume, exposure and hazard information to inform assessment processes has strongly impacted the resources of individual companies struggling to respond to the continuous string of mandatory CEPA s.71 surveys. Government has declared it will build on CMP2 learnings and will focus future surveys to address only essential data needs, will include only manufactured items with reasonable

potential for exposure and target users of specific interest; thus leading to more efficient and less onerous data gathering activities for industry.

Further, government has indicated that it is moving away from the predisposition to issue mandatory surveys that trigger company-specific compliance activities and, instead will engage with industry through sector approaches and joint industry submissions. Through its experiences with CMP2, the government recognizes that stakeholder participation should increase when the benefits of this approach are evident. This direct line of communication with industry groups should reduce the stress on individual companies, allow associations to provide sufficiently representative hazard and exposure information for their collective membership, and simplify data collection activities.

Industry has played an important role in the success of the CMP. Stakeholders need to continue to ensure that science-based decisions are given due consideration in the assessment and management of priority substances. By working with the government to explore and assess opportunities for innovative risk-assessment approaches, (e.g., substance groupings), and innovative risk-management approaches (e.g., sectoral approaches), industry can join hands with the government to ensure that effective policies for environmentally-sustainable economic growth are designed and implemented.



20th Anniversary CHEMCON 
THE AMERICAS 2016

Oct 17th-21st
Toronto
Canada

Industry's perspective and experience with the Chemicals Management Plan

Joyce Borkhoff
Intertek Scientific & Regulatory Consultancy

17 October 2016

Industry's perspective and experience with the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

Presentation Topics

- Key Elements
- CMP-1 High Priorities: Overview and Status
- CMP-2 Medium Priorities: Overview and Status
- CMP Progress and Outcomes to Date
- Keys to Success
- Challenges Moving Forward

Joyce Borkhoff

2

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016



Joyce Borkhoff

3

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

• **Key Elements**

- Categorization and prioritized assessment of grandfathered DSL substances;
- Use restrictions, regulations and enforcement, where warranted;
- Environmental assessment of drugs and personal care products;
- Mandatory ingredient labelling of cosmetics
- Accelerated re-evaluation of older pesticides;
- Biomonitoring, surveillance and research

CMP is Canada's preferred alternative to the
EU REACH program approach

Joyce Borkhoff

4

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- **Phase 1 (High Priorities)**
 - The Challenge – “The Batches”
 - The Petroleum Stream Sector Approach
- **Phase 2 (Medium Priorities)**
 - Targeted Approach for Data Gathering
 - The Domestic Substances List (DSL) Inventory Update
 - The Substance Groupings Initiative (SGI) (~500)
 - Polymer Approach (~600)

- Ongoing
 - Rapid Screening
 - Research and Monitoring
 - International Cooperation

Joyce Borkhoff

5

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- **CMP – 1's Industry 'Challenge'**
 - 195 of the highest-priority substances were divided into 12 “batches” of substances
 - Mandatory surveys (Canada Gazette Notices) & voluntary questionnaires, 3-month intervals
 - Responses required from Canadian manufacturers, importers and users
 - Batched substances were '**predisposed to being declared CEPA Toxic**' (and subject to restriction or prohibition), **unless** responses offered information that proved controls were not needed

Tremendous Burden on Industry

Joyce Borkhoff

6

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- **CMP-2's Targeted Approach for Data Gathering**
 - Government focused mandatory industry surveys on addressing 'essential data needs' for the assessment and potential management of 'substance groupings'
 - Included manufactured items (*i.e.* articles) only where reasonable potential for exposure
 - Refined scope to target uses that are of specific interest
 - Used reporting-concentration thresholds, where appropriate
 - Reduced duplication of requiring information already provided to other Canadian 'partner' programs

Joyce Borkhoff

7

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- Early Stakeholder Engagement enhanced success of targeted approach
 - Helped defined the 'substance groupings' and developed appropriate surveys calling for the 'essential data needs'
- SGI was launched to assess and manage the potential risks of 9 targeted groups of medium-priority substances
 - Groupings identified based on similarities of structure or function
 - Faced challenges where functional groups resulted in range of toxic profiles (*e.g.* Phthalates). Industry and Government worked together to recognize and reflect these differences (workshops)
 - Took into account timing of international activities, risk assessment and risk management efficiencies, potential exposure to sensitive populations, and stakeholder implications

Joyce Borkhoff

8

Industry's perspective and experience with the Chemicals Management Plan

GROUP	Stage				
	1	2	3	4	5
Azo compounds	█	█	█	█	
Substituted diphenylamines	█	█	█		
Cobalt-containing substances	█	█	█	█	
Internationally classified substances	█	█	█	█	
Methylenediphenyl diisocyanates & diamines (MDI/MDA)	█	█	█		
Certain organic flame retardants	█	█	█		
Phthalates	█	█	█		
Selenium-containing substances	█	█	█		
Boron-containing substances	█	█	█		

1. Preliminary Assessment and Stakeholder Engagement
2. Information Gathering (including Section 71 surveys)
3. Draft Assessment & Initial Risk Management Discussions
4. Final Assessment & Risk Management Development
5. Risk Management Actions and CEPA Regulation Timelines

Joyce Borkhoff

9

Industry's perspective and experience with the Chemicals Management Plan

• **Industry Advocacy**

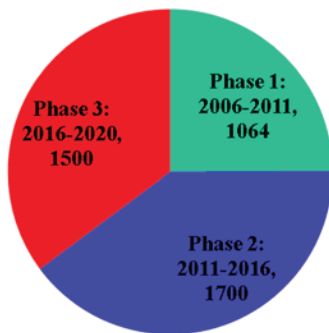
- Industry Associations representing group interests for provision of technical and exposure information
- CMP Stakeholder Advisory Council
- Consultations re proposed Codes of Practice
- Validation of risk assessment and risk management models for certain product categories
- Review of emissions and exposure models associated with assessment for substances of environmental concerns to reflect current realities

Joyce Borkhoff

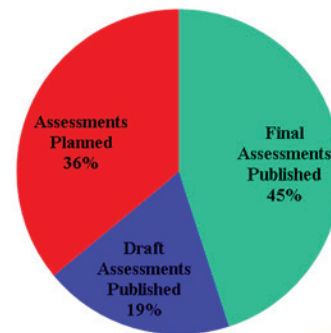
10

Industry's perspective and experience with the Chemicals Management Plan

Priorities Within CMP
~4300 Substances Addressed by 2020



Progress to Date (as of July 25, 2016)

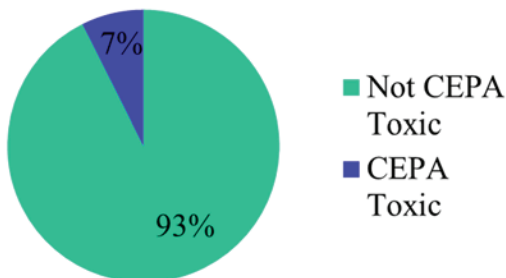


Joyce Borkhoff

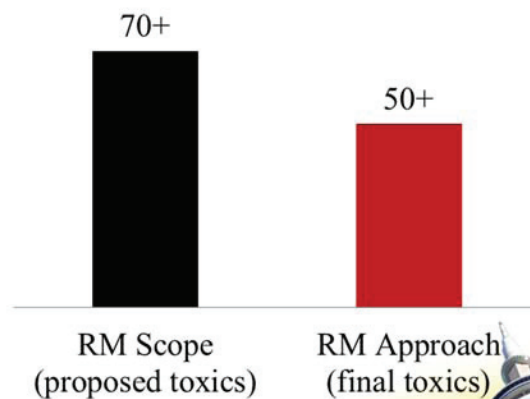
11

Industry's perspective and experience with the Chemicals Management Plan

Risk Assessment Outcome
(~2700 Substances)
Substances



Risk Management Document Progress



Implemented over 180 risk management instruments controlling 132 toxic substances 6 substances with CEPA toxic outcome = Prohibition of Certain Toxic Substances, 2012

Joyce Borkhoff

12

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- **Keys to Success**

- Accelerated Pace
 - More assessments than any other jurisdiction
- Clear, Focussed Priorities (assess what matters)
 - Well communicated
- Ownership of all affected parties through extensive multi-stakeholder activities
 - Government and industry speak same language
 - Data gathering, development and design of risk management instruments

Joyce Borkhoff

13

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- Robustness of stakeholder engagements, science based decisions, weight of evidence approach, decision making process
 - External expert input
 - Polymer approach, analogues, read-across, grouping and sub-grouping
 - Canada / US Regulatory Cooperation Council
 - Changed decisions based on stakeholder input and deeper risk assessment: Challenge substances CEPA Toxic unless otherwise demonstrated → CEPA Toxic decisions reversed

Joyce Borkhoff

14

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

– Practical and ongoing Risk Management
development and amendment

- Robust multi-stakeholder engagement throughout to ensure understanding of current use patterns, existing product stewardship activities and Government's risk management objectives, supports sound decision-making
- Periodic evaluation of progress to measure performance
- Periodic data collection (e.g. mandatory surveys, voluntary surveys, monitoring & surveillance) to evaluate progress and need for additional risk management actions
- Decisions can be adjusted based on new evidence
- Voluntary actions to meet objectives = efficiencies and flexibilities

Joyce Borkhoff

15

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

– Continuous Improvement

- Aligning new and existing substances programs to eliminate redundancy; share approaches, data and operating efficiencies; incorporate what "works"
- Increasing and amending tools for stakeholder outreach and guidance
- Information gathering: Government commitment to incorporate lessons learned and feedback from stakeholders when planning and implementing data gathering activities

Joyce Borkhoff

16

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- Integrated approach to chemical assessment and control
 - Selection of the best placed act to manage the risks associated with a toxic substance
 - CEPA
 - » Pollution Prevention Planning, Environmental Emergency Regulations, Significant New Activity
 - Canada Consumer Product Safety Act (CCPSA)
 - Food and Drugs Act
 - » Cosmetic Ingredient Hotlist
 - » Food Packaging

Joyce Borkhoff

17

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- Strong Communication Plan
 - Transparency re substances being reviewed AND clear indication re why they have been included
 - CSDSL decision tables
 - Substance Profiles of the Challenge
 - Subgrouping Approach and Background Documents of CMP2
 - Published Draft Screening Assessment and Risk Management Scope Document for comment
 - Final Screening Assessments and Risk Management Approach

<http://www.chemicalsubstanceschimiques.gc.ca/index-eng.php>

Joyce Borkhoff

18

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

• **Challenges ahead to ensure continued progress**

- Increase public outreach to raise awareness among general Canadian public re risk management, raise visibility and understanding of the CMP and its successes
- Cumulative risk (combined exposure to chemicals with same toxic mode of action) assessment is critical but complicated
 - Progresses beyond simple “group” assessment where groups are defined by structure
 - Chemicals with similar structures often have similar MoA, but very different toxicological potency
 - More complicated than simple addition, demands transparency
- Biomonitoring
 - Methodology is new, not always simpler, still evolving

Joyce Borkhoff

19

Industry's perspective and experience with
the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

Concluding Remarks

- Tens of thousands of substances in the market and small fraction required further assessment, even smaller fraction had associated risks to be managed
- Outcomes of risk assessment and management are manageable
- Stakeholder engagement has been a strength and is essential to CMP3 based on increased complexity and breadth

Joyce Borkhoff

20

The Chemicals Management Plan Moving Forward

Bio Aikawa, Health Canada



20TH Anniversary CHEMCON  THE AMERICAS 2016 Oct 17th-21st Toronto Canada

The Chemicals Management Plan Moving Forward

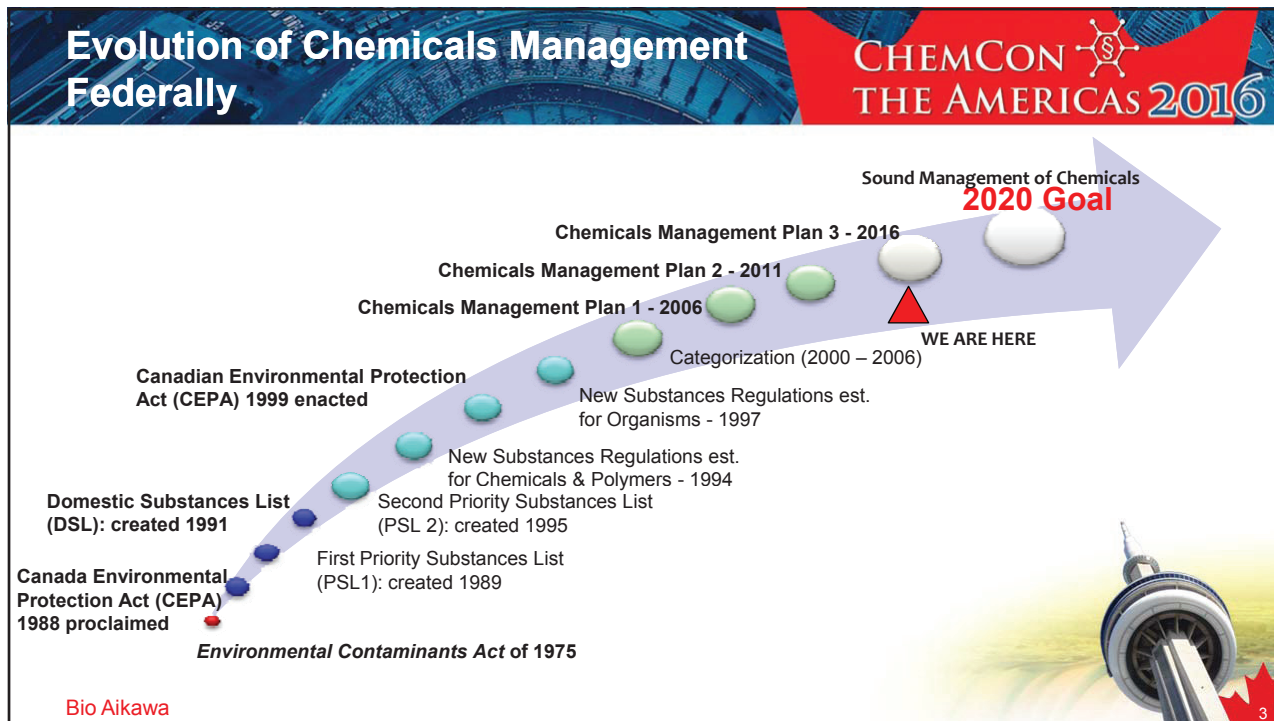
Bio Aikawa
Health Canada

17 October 2016


Outline

CHEMCON 
THE AMERICAS 2016

- Evolution and Continuity of the Chemicals Management Plan (CMP)
- Risk Assessment Approaches and Work Plan
- Risk Management Approaches and Work Plan
- CMP Website and Resources



Continuing on with the Chemicals Management Plan

CHEMCON 
THE AMERICAS 2016

- The current phase of the CMP was launched in May 2016 continuing the goal towards the sound management of chemicals by 2020.
- Key areas of continuity include:
 1. **Integration across the Government of Canada**
 - Continued integration amongst federal programs and the use of the best placed Act.
 2. **Concentration on the importance of stakeholder engagement and public outreach**
 - working closely with stakeholders, delivering workshops and developing communications products
 3. **Transparency and predictability**
 - Timelines and schedules published for risk assessment
 - Work plan for risk management activities
 4. **Focussed on Priorities**
 - Tackling the remaining 1550 substances identified to reach 2020 goal

Bio Aikawa

Continuity: Stakeholder Engagement and Public Outreach

CHEMCON 
THE AMERICAS 2016

Stakeholder engagement remains key to the success of CMP

Engagement opportunities:

Public Comment Periods within risk assessment and management process

Stakeholder Forums:

Renewal of the CMP SAC

Advisory bodies:

Science Committee created to contribute expertise pertaining to scientific considerations moving forward in the CMP

Engagement with Stakeholders:

- On-going dialogue with CEPA ICG and other stakeholders
- Information/Workshop Sessions – face-to-face workshops, webinars, conferences to share information and seek feedback

Outreach and Communications

- [Chemical Substances website](#) - includes email subscription service to "CMP Latest News" (over 1200 subscribers)
- CMP Progress Report - bi-annual publication that reports on results of CMP over the past 6 months and identifying areas for engagement
- Engaging in social media – Facebook, Twitter and Pinterest, house tour/quiz promotion

Bio Aikawa

5

Continuity: Transparency, Predictability and Focused on Priorities

CHEMCON 
THE AMERICAS 2016

- Openness, transparency and predictability remain essential components of the design of CMP.
- Approximately 1550 substances will be addressed and have a wide range of substance complexity, novel approaches will continue to be required.
- Activities include:
 - CMP Phase 3 Substances List
 - An on-going, 'cyclical' process for information gathering initiatives, such as the Inventory Update of the Domestic Substances List
 - Risk assessment publications and the risk management work plan will also allow stakeholders to focus on priorities

Bio Aikawa

6

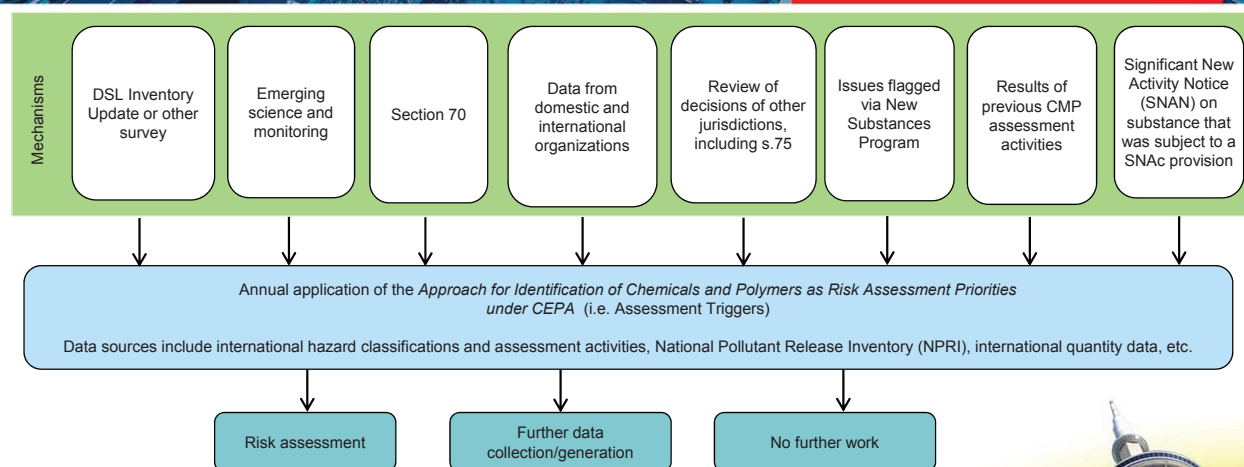
A Look at the Evolution for the Next Phase of CMP

- Improving program design and function as we learn by doing
- Examples of evolution in the next phase of the CMP include:
 - **Enhancing outreach and engagement**
 - Renewed and expanded membership of CMP Stakeholder Advisory Council,
 - Launched a Communications sub-group under the CMP SAC
 - Publications of annual Notices of Intent
 - **Improving openness and transparency**
 - Development of an approach for Confidential Business Information,
 - Increase in publications of New Substances Assessment Summaries

Bio Aikawa

7

Moving Forward: Mechanisms to identify future priorities

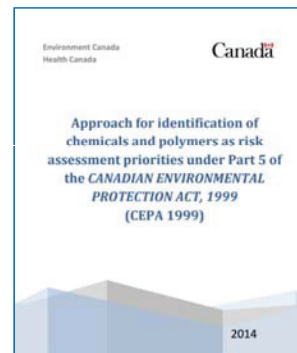


Bio Aikawa

8

Identification of Risk Assessment Priorities

- **Experience To Date and Moving Forward**
 - The Approach for the Identification of Risk Assessment Priorities was published in December 2014
 - Results of the 2015 review published on May 31, 2016
<http://www.chemicalsubstanceschimiques.gc.ca/plan/approche/approche/chem-pol-priori-eng.php>
 - As a result of the 2015 review, 28 non-categorized substances have been identified as risk assessment priorities and more than 100 substances were identified for additional data gathering
 - The scope of substances and data sources considered is anticipated to change with future iterations of review
 - CMP Science Committee topic in November 2016



Bio Aikawa

9

Looking Forward and Beyond 2020

- Canadian Environmental Protection Act (CEPA 1999) Review:
 - Publication of the discussion paper on May 16th which includes possible approaches to address a wide range of issues with the Act.
 - Parliament, including committee proceedings, resumes in September
 - For more information on the CEPA review process:
<http://www.parl.gc.ca/Committees/en/ENVI/>
- Start mapping opportunities for work beyond 2020 and work that will remain from the current phase of the CMP

Bio Aikawa

10

Risk Assessment Toolbox

Type 1 Approach

- Addresses the substance/group with a science-based policy response
- Used when regulatory assessment conclusion under s.64 of CEPA 1999 is not suitable
- Examples include: Referring to a better placed program (e.g., foods); documentation of previous action under CEPA 1999

Type 2 Approach

- Addresses substances using a broad-based approach, often based on low potential for exposure and conservative scenarios
- Substances do not meet criteria under s.64
- Examples include: Rapid Screening; Threshold of Toxicological Concern type approaches

Low

Level of Complexity

High

Type 3 Approach

Type 3-1

- Addresses the substance/group with a reduced amount of effort for streamlined hazard and/or exposure analysis
- Examples include: Use of international hazard characterizations; use of biomonitoring data; qualitative assessment

Type 3-2

- Substance/group requires de novo risk assessment

Type 3-3

- A complex assessment is required for the substance/group that may require cumulative assessment approaches

RM actions for those meeting s.64; additional information gathering and source attribution may be required to inform risk management

Bio Aikawa

11

Risk Assessment Work Plan

- The assessment work plan was developed considering the following factors:
 - Grouping based on chemical structures provide significant efficiencies
 - Distribution of types of assessment approaches across the five years
 - Consideration of timing of monitoring/research data availability
- Schedule of the release of draft assessments for the first 2 years (provided by quarter for year 1, and by half-year for year 2) is available on the website
 - Annual updates will ensure a 2-year rolling publication plan is available
 - In general, final assessments are published one year after the draft
- The following information is also available on the website:
 - A list of substances in each assessment
 - The type of assessment approach to be followed in each assessment (for health and eco)
 - The assessment start date (by quarter) for assessments beginning in the first 2 years
- Key window for stakeholders to provide data :
 - Stakeholders are encouraged to provide additional information for consideration in an assessment before the start date indicated in the Substances List of the next phase of CMP

Canada Gazette Notice published February 6, 2016 indicates types of data that are relevant for most risk assessments

Bio Aikawa

12

Fit-for-Purpose Approaches

- A fit-for-purpose approach ensures the ability to focus efforts on the substances of higher concern and to engage stakeholders on substances as efficiently as possible
- **Experience to Date and Moving Forward**
 - Throughout the CMP, a fit-for-purpose approach has been used (e.g., rapid screening of substances of lower concern, cumulative assessment)
 - The approaches taken may be different for the ecological assessment and the human health assessment
 - The Risk Assessment Toolbox was developed to formalize these approaches

Bio Aikawa

13

Science Approach Documents

- Applies for Type 2 approach with substances that are of low concern for either human health or the environment, but not necessarily both.
- Science Approach Documents (SciADs) outline the approach used to identify substances of low concern (for human health or the environment) and the results of the application of the approach.
- SciADs will clearly indicate when we do not have concern with a substance based on current data, but will not make a formal statement under s.64.
- Assessments concluding on health and environmental risks will be published later in the CMP
 - These SARs will include and consider new information that became available after the publication of the SciAD.
- The publication of SciADs will have an associated 60-day public comment period
- At least 8 SciADs are anticipated moving forward.

Bio Aikawa

14

Two-year Rolling Risk Assessment Publication Plan: Y1

Year 1 April - June 2016	Year 1 July - Sept 2016	Year 1 Oct - Dec 2016	Year 1 Jan - Mar 2017
Monoazo pigments Final Screening Assessment ✓ May 28, 2016	Triclosan Final Screening Assessment	Mitolane, BAPP & Sclareol Final Screening Assessment	Selenium Final Screening Assessment
Aromatic amines and Azo basic dyes Final Screening Assessment ✓ May 28, 2016	Organic Flame Retardants Draft Screening Assessments ✓ Oct 8, 2016	Azo Disperse Dyes Final Screening Assessment	Chloroacetic acids Draft Screening Assessment (2)
Solvent dyes Final Screening Assessment ✓ May 25, 2016	Boron Draft Screening Assessment ✓ Jul 23, 2016	MDI MDA Final Screening Assessment	Phenol, dodecyl-, sulfurized, carbonates, calcium salts, overbased Draft Screening Assessment
Azo acid dyes Final Screening Assessment ✓ Jun 18, 2016	Rapid Screening III Final Screening Assessment ✓ Aug 29, 2016	Phthalates Draft Cumulative Risk Assessment	Acetamide, N-(4-ethoxyphenyl)- Draft Screening Assessment
Ethylbenzene & HCE Final Screening Assessment ✓ April 30, 2016	Approach to Ecological Risk Classification (ERC) of Organic Substances (840) ✓ Jul 30, 2016	Cobalt Final Screening Assessment	Acetic acid, anhydride Draft Screening Assessment
BDTP & Ethene Final Screening Assessment ✓ May 21, 2016	Rapid-screening of low-exposure substances using a TTC-based approach (TBD) ✓ Oct 1, 2016	Liquefied Petroleum Gases Final Screening Assessment	Cyclohexene, 4-ethenyl- Draft Screening Assessment
Internationally Classified Substances Final Screening Assessments ✓ May 28, 2016	Human Health Low Exposure Biomonitoring 1a (3): Vanadium (2), Beryllium(1) ✓ Sep 3, 2016	Chlorhexidine and its Salts Draft Screening Assessment	Ethanol, 2,2'-oxybis-, reaction products with ammonia, morpholine derivs. Residues Draft Screening Assessment
Rapid Screening Polymers Final Screening Assessments ✓ Jun 18, 2016		2-EHA derivatives Draft Screening Assessment (2)	Benzenesulfonamide, 2-methyl- Draft Screening Assessment
Heavy Fuel Oils (HFOs) Final Screening Assessment ✓ Apr 30, 2016		Ethylene Glycol Ethers Draft Screening Assessment (9)	Oils, lard, sulfurized Draft Screening Assessment
Coal Tars and their Distillation Products Draft Screening Assessment ✓ Jun 11, 2016		Formic Acids & formates Draft Screening Assessment (4)	1-Octanol, 3,3,4,4,5,5,6,6,7,7,8,8,8-tridecafluoro- Draft Screening Assessment
Asphalts and Distillate Aromatic Extracts Draft Screening Assessments ✓ Jun 4, 2016		Chloral Hydrate Draft Screening Assessment	Sector-Specific Inorganic UVCBs Draft Screening Assessment (57)
Petrolatum and Waxes Final Screening Assessment ✓ Jun 11, 2016		Alkyl Sulfates and Olefin Sulfonate Draft Screening Assessment (4)	Polymer Rapid Screening 2: Draft Screening Assessment (TBD)
Candida utilis ATCC 9950 and Pseudomonas sp. ATCC 13867 Final Screening Assessment ✓ May 28, 2016		NMP and NEP Draft Screening Assessment (2)	Petroleum substances with no identified product use Draft Screening Assessment (77)
Saccharomyces cerevisiae F53 Draft Screening Assessment ✓ April 19, 2016		Ethane, propane, butane and isobutane Draft Screening Assessment (5)	
		Human Health Early Biomonitoring Equivalent/Biomonitoring (18): Barium (4), Molybdenum (2), Tin (2), Silver (8), Thallium (2)	

Bio Aikawa

15

Two-year Rolling Risk Assessment Publication Plan: Y2

Year 2 Apr - Sept 2017	Year 2 Oct 2017 - March 2018
Thiols Draft Screening Assessment (6)	Aliphatic diesters Draft Screening Assessment (2)
EDTA and salts Draft Screening Assessment (4)	Alkyl/aryl phosphites Draft Screening Assessment (2)
Furan and derivatives Draft Screening Assessment (5)	Carboxylic acid anhydrides Draft Screening Assessment (8)
Heterocycles Draft Screening Assessment (7)	Carboxylic Acids Draft Screening Assessment (4)
Nitrobenzenes Draft Screening Assessment (3)	Benzoates Draft Screening Assessment (10)
Phenol, 2-(1-methylpropyl)-4,6-dinitro- Draft Screening Assessment	Trimellitates Draft Screening Assessment (5)
Arenes Draft Screening Assessment (9)	Fatty Amides Draft Screening Assessment (12)
Acrylates/methylacrylates Draft Screening Assessment (9)	Stilbenes Draft Screening Assessment (4)
Thiocarbamates Draft Screening Assessment (2)	Ketones Draft Screening Assessment (10)
Eugenol and isoeugenol derivatives Draft Screening Assessment (4)	Anthraquinones Draft Screening Assessment (15)
Benzophenone Draft Screening Assessment	Pigments and dyes Draft Screening Assessment (25)
Ethanol Draft Screening Assessment	Triarylmethanes Draft Screening Assessment (7)
Cyanides Draft Screening Assessment (9)	Zinc Draft Screening Assessment (60)
Poly(Phenolics) Draft Screening Assessment (27)	Poly(Phenol-Formaldehyde resin) Draft Screening Assessment (48)
Poly(bios) cellulose-tannin Draft Screening Assessment (40)	Poly(Acrylic-Perfluoro) Draft Screening Assessment (8)
Poly(Siloxanes/Silicones) Draft Screening Assessment (14)	Gas Oils and Kerosenes Draft Screening Assessment (16; and 7 from PSSA)
Poly(Acrylics) Draft Screening Assessment (53)	Base Oils Draft Screening Assessment (2; and 25 from PSSA)
Draft Screening Assessment of Low Concern Organic Substances identified through the ERC and TTC/Health Rapid Screening approaches(TBD)	Used and re-refined oils Draft Screening Assessment (9)
Petroleum substances previously assessed (PRGs (53) and NGCs (2))	
Draft concise assessment covering ten petroleum substances (10)	
Petroleum substances with product use previously assessed (13)	
Health Rapid Screening (TBD)	
Ecological Streamlined Exposure of Inorganic Substances (9), including: Barium (4), Iron (2), Talc (1), Deuterium (1), Silicon carbide (1)	

Bio Aikawa

16

Legend

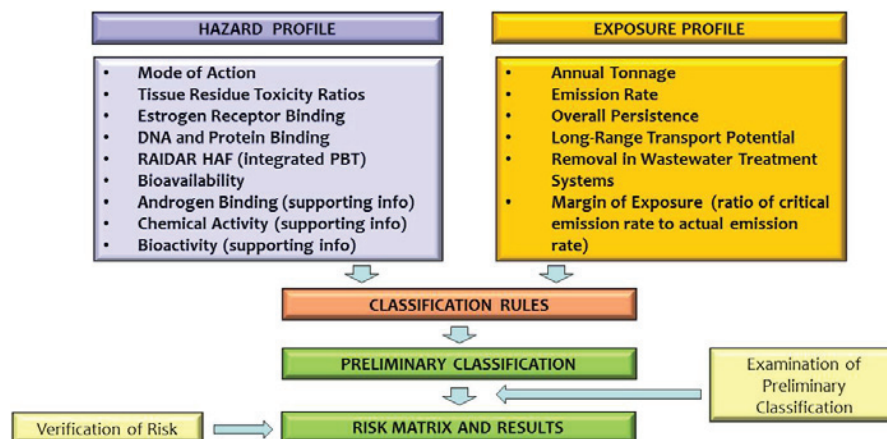
	Draft CMP Screening Assessment Reports presenting information on health and ecological considerations, and where criteria under s. 64 are met, Risk Management Scope documents. Final screening assessment reports are generally published one year after the draft along with a Risk Management Approach document where criteria under s.64 are met. Additional information on timing of Risk Management instrument development and other risk management activities can be found in the Two-Year RM Engagement and Activity Schedule .
	Screening Assessment Reports initiated in earlier phases of CMP, presenting information on health and ecological considerations, and where criteria under s.64 are met, Risk Management Scope/Approach documents. Final screening assessment reports are generally published one year after the draft along with a Risk Management Approach where criteria under s.64 are met. Additional information on timing of Risk Management instrument development and other risk management activities can be found in the Two-Year RM Engagement and Activity Schedule .
	Science Approach Document describing the approach and expected results for health or ecological considerations. Substances considered in Science Approach Documents will be included in Screening Assessment Reports that will be published over the course of the next phase of the CMP. As such, the number of substances indicated in brackets beside the Science Approach Documents overlap with the number of substances indicated in the Screening Assessment Reports.

Bio Aikawa

17

Ecological Risk Classification

- The Ecological Risk Classification (ERC) of organic substances is an example of a fit-for-purpose ecological approach

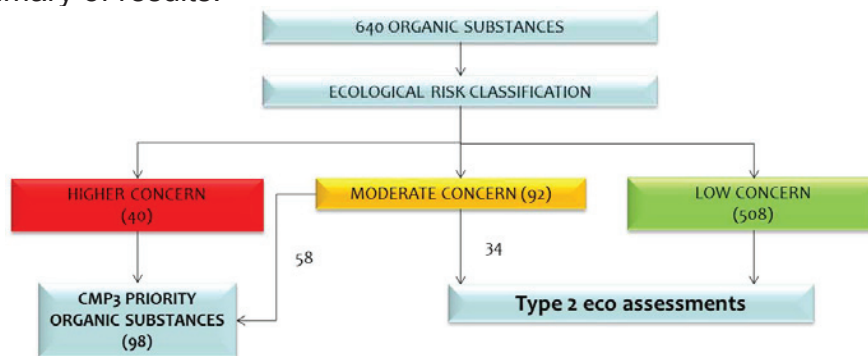


Bio Aikawa

18

ERC Results

- The SciAD for the Ecological Risk Classification of Organic Substances was published on July 29, 2016 for a 60-day public comment period:
<http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/sciad-das-eng.php>
- Summary of results:



Bio Aikawa

19

Threshold of Toxicological Concern

- The Threshold of Toxicological Concern (TTC)-based Approach for Certain Substances is an example of a fit-for-purpose human health approach
 - Applied to substances for which exposure to the general population is expected to be limited
- Based on the principle of establishing human exposure threshold values for chemicals, below which there is a low likelihood of risk to human health (Kroes et al. 2004)
- Threshold values have been established for substances with genotoxic alerts and each of three chemical classes (called "Cramer" classes)

Chemical class	TTC values ($\mu\text{g}/\text{kg bw}/\text{day}$)
Cramer class I	30
Cramer class II	9.0
Cramer class III	1.5
Genotoxic compounds	0.0025

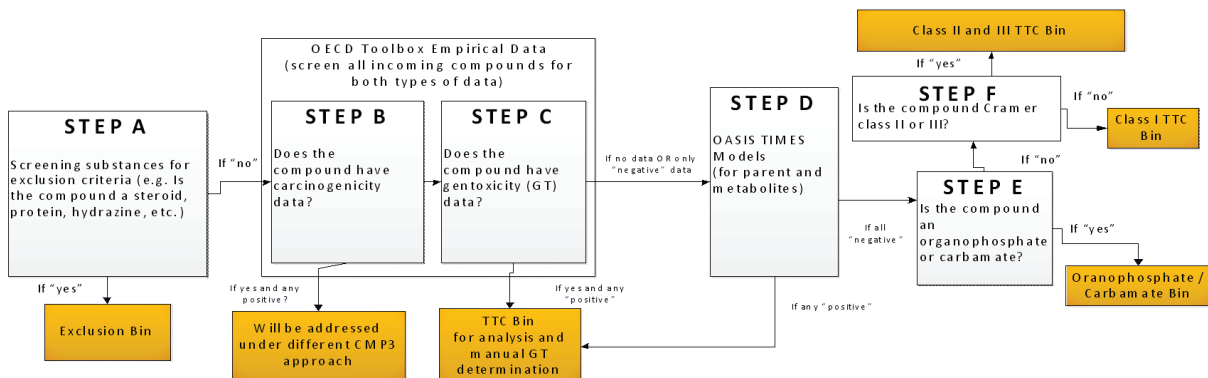
- The TTC is compared to an estimate of human exposure, and substances which have exposure below the assigned TTC value are considered to be of low concern for human health

Bio Aikawa

20

TTC Approach

- The TTC-based Approach for Certain Substances was published on Oct 1, 2016 for a 60-day public comment period: <http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-proche/sciad-das-eng.php>



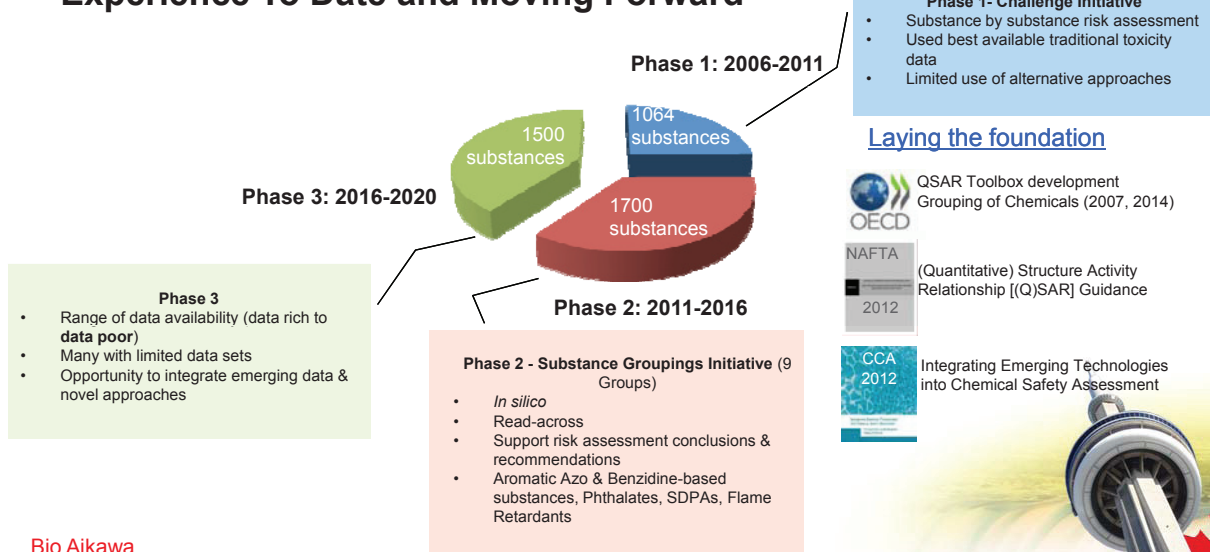
- Substances are screened for relevant empirical/predictive health effects data and classified as potentially genotoxic or as their respective "Cramer" structural class with corresponding threshold value

Bio Aikawa

21

New Approach Methodologies

- Experience To Date and Moving Forward



Bio Aikawa

22

Use of Biomonitoring Data

- **Experience To Date and Moving Forward**
 - Has been used in a number of recent assessments (e.g. boron, selenium)
 - Type 2 approaches will be used in CMP3 Year 1 SciADs
 - Human Health Low Exposure Biomonitoring 1a: Vanadium (2), Beryllium(1)
 - Human Health Early Biomonitoring Equivalent/Biomonitoring : Barium (4), Molybdenum (2), Tin (2), Silver (8), Thallium (2)
 - Access to CHMS cycle 2 biobanks for certain CMP3 metals and trace elements
 - Ongoing work on the development of Biomonitoring Equivalents to interpret BM data
 - Working with international partners (e.g. RCC, OECD, WHO RA network) on approaches for use of HBM data in regulatory risk assessment and development of global database/repository for BM data

Bio Aikawa

23

Risk Assessment Fact Sheets

- ECCC and HC have recently published the first in a series of Risk Assessment Fact Sheets that explain general government approaches to risk assessments:
 - Information Gathering for Risk Assessments
 - Public Comments on Risk Assessment Documents
 - Risk Assessment Toolbox
 - Types of Risk Assessment Documents

<http://www.chemicalsubstanceschimiques.gc.ca/approach-proche/assess-eval-eng.php>

- Additional factsheets addressing complexities and the government's approach to addressing them will be made available in the near future (e.g. How Human Biomonitoring Data is Used, etc.)

Bio Aikawa

24

Risk Management

- Risk management and stakeholder engagement activities for substances managed under the Chemicals Management Plan have been identified and communicated by Health Canada and Environment and Climate Change Canada, through to March 2018
- These activities include:
 - The publication of various risk management Scope and Approach documents for public comment;
 - Information gathering activities to support risk management decision-making;
 - Consultations on risk management instrument development;
 - Publication of proposed and final instruments; and
 - Performance measurement of risk management actions and initiatives

Bio Aikawa

25

Risk Management Work Plan

- Two Year Rolling Risk Management Activities and Consultations Schedule, available at:
<http://www.ec.gc.ca/ese-ees/default.asp?lang=En&n=8727ECCE-1>
- Additional information on risk management activities may be found in the *Chemicals Management Plan Progress Report*, which reports on advances in major initiatives and highlights key activities related to the Government of Canada's recent work under the CMP, available at:
http://chemicalsubstanceschimiques.gc.ca/plan/progress_report-rapport_etape-eng.php

Bio Aikawa

26

Risk Management: Opportunities for Engagement

RM Scope Publication

- Intent is to engage stakeholders as early as possible on potential options for risk management, and obtain feedback to inform the RM Approach

RM Approach Publication

- Intent is to engage stakeholders with more details on proposed risk management and obtain feedback to inform the development of instruments

Post RM Approach Work

- Intent is to design “best” instrument(s) to meet Risk Management Objective
 - Further consultations with Stakeholders

Post-Proposed RM Instrument

- Intent is to review, refine and finalize the proposed RM Instrument to best suit the risk; input from the public consultation process is reviewed and considered.
 - Final consultations with Stakeholders

Risk Management Effectiveness

- RM Effectiveness: Intent is to measure progress, monitor compliance

Bio Aikawa

27

Canada's CMP - Website

www.chemicalsubstances.gc.ca



Bio Aikawa

28

Canada's approach on chemicals

In Canada, every order of government plays a part in protecting against risks from chemical substances: municipalities, the provinces and territories, and the federal government.

The Government of Canada makes regulations and develops guidelines and objectives that apply across the whole country. It also leads in conducting scientific research on human health and environmental issues, and makes agreements with other countries so that our laws provide the same or better level of protection.

The Chemicals Management Plan (CMP) is a Government of Canada initiative aimed at reducing the risks posed by chemicals to Canadians and their environment. The Government of Canada [launched the first phase of the CMP in 2006](#) and [launched the second phase of the CMP in 2011](#). The CMP builds on previous initiatives by assessing chemicals used in Canada and by taking action on chemicals found to be harmful.

Canada's CMP - Resources

Chemical Substances website:

www.chemicalsubstanceschimiques.gc.ca

CMP Progress Reports:

http://www.chemicalsubstanceschimiques.gc.ca/plan/progress_report-rapport_etape-eng.php

Website subscription provides the latest news:

<http://www.chemicalsubstanceschimiques.gc.ca/listserv/index-eng.php>

Substance Groupings Initiative:

<http://www.chemicalsubstanceschimiques.gc.ca/group/index-eng.php>

Polymer Approach:

<http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/polymer-eng.php>

Rapid Screening Approach:

<http://www.chemicalsubstanceschimiques.gc.ca/plan/approach-approche/rapid-eng.php>

Categorization:

<http://www.ec.gc.ca/lcpe-cepa/default.asp?lang=En&n=5F213FA8-1&wsdoc=1695F8D0-5CC4-EDA1-AF63-6F23A94064DD>

Bio Aikawa

29

Thank you!



Questions?



Bio Aikawa

CONTACT

Bio Aikawa

Manager, Information Management Division

Safe Environments Directorate

Healthy Environment and Consumer Safety Branch

Health Canada

613-941-3969

bio.aikawa@hc-sc.gc.ca

30

Information Gathering under the Chemicals Management Plan

Bio Aikawa, Health Canada



20TH Anniversary CHEMCON  THE AMERICAS 2016 Oct 17th-21st Toronto Canada

Information Gathering under the Chemicals Management Plan

Bio Aikawa
Health Canada

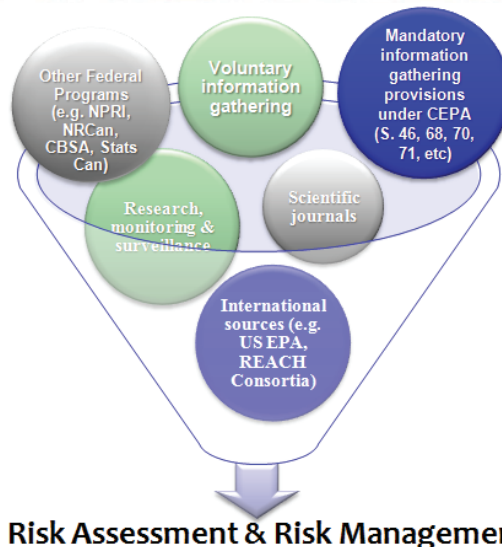
17 October 2016

Outline

CHEMCON 
THE AMERICAS 2016

- Information gathering approaches for the current phase of the Chemicals Management Plan (CMP Phase 3)
- Next Phase of the Inventory Update (IU)
- The Revised In Commerce List (ICL)
- CMP Online reporting system

Information Gathering



NPRI = National Pollutant Release Inventory
NRCAN = Natural Resources Canada
CBSA = Canadian Border Services Agency
Stats Can = Statistics Canada
US EPA = United States Environmental Protection Agency
REACH = Registration Evaluation Authorisation Restriction

Bio Aikawa

3

Notice of Intent

Environment and Climate Change Canada and Health Canada are inviting stakeholders to provide information that will inform the path forward for the current phase of the CMP (2016–2020)

Notice of intent seeks *Early stakeholder engagement to help inform the plan to address the remaining 1550 substances under the CMP*

<http://www.chemicalsubstanceschimiques.gc.ca/>

- Published on February 6, 2016
- Basic information for these substances was collected through the Domestic Substance List Inventory Update in 2012 (DSL IU2), identifying key stakeholders and commercial activity involving these substances.



Bio Aikawa

4

Type of Information Being Sought

Information/data on;

- Composition of Unknown or Variable Composition, Complex Reaction Products, or Biological Materials (UVCBs)
- Releases/the fate of a substance to/in the environment;
- Industrial facility processes, operating conditions and practices, and handling of the substance;
- Controls (e.g., on-site wastewater treatment) relevant to limiting the release of a substance to the environment;
- Products (industrial, commercial or consumer) that contain the substance, as well as the concentration of a substance in a given product; information regarding the function of substance in a product that could influence potential exposures or releases;
- Hazard potential (human health, ecotoxicity)
- Function of the substance (e.g., whether it is consumed in reactions during industrial use; if it is designed to be released to the environment due to its use);
- Migration or release of the substance from products, etc.

Bio Aikawa

5

The current phase of the CMP

- Notice of intent seeks Early stakeholder engagement to help inform the plan to address the remaining 1550 substances under the CMP was published on February 6, 2016
- Notice lists the types of information that will inform assessment work and shape future data-gathering strategies to address the remaining substances
- The current phase of the Chemicals Management Plan launched by the Ministers in the *Canada Gazette* on June 18, 2016, and includes revised substance list
- 2-Year rolling work plan is available online providing publication and start of assessment timing for each substance group, which will be updated annually

Bio Aikawa

6

CMP Phase 3 Information Gathering Approach

- Build on existing information:
 - Information submitted under Domestic Substance List Inventory Updates in 2009 (DSL IU1) and 2012 (DSL IU2)
 - Safety Data Sheets (SDS), databases from other government departments
- Use appropriate mechanisms to address additional data needs, such as:
 - Targeted follow-ups with past notifiers (including voluntary submitters)
 - Coordinated voluntary information gathering
 - Consultations with key stakeholders
 - International data sharing agreements (i.e. Consortia for REACH Dossiers)
- Mandatory information gathering, as required:
 - Outstanding needs after alternative mechanisms used
 - Risk management needs
 - Other needs not addressed by the above

Bio Aikawa

7

CMP Phase 3 Targeted Follow-ups

- Environment and Climate Change Canada and Health Canada have been conducting targeted follow-ups with past notifiers for additional information related to their submissions necessary for assessments
- Typical information being requested include:
 - Updated activity and quantity information
 - Specific information on uses, products, concentrations
 - Facility-based information (e.g. location, types of on-site treatments, effluent flows)
 - Supply-chain information
- Timing of on-going follow-ups are based on the assessment schedule
- Flexibility for efficient data sharing through sector approaches, association-coordinated compilations, supply-chain joint submissions, etc.

Bio Aikawa

8

Supply Chain Compliance Challenges

CHEMCON 
THE AMERICAS 2016

- Compliance challenges identified by industry for past information gathering initiatives include:
 - Large number of products/manufactured items (finished goods) from a large number of suppliers
 - Lack of knowledge or awareness of substances in products / manufactured items
 - Obtaining information from foreign suppliers (e.g. difficult due to confidentiality of information)
 - Obtaining information on substances present at trace concentrations
- Government is working with stakeholders, as well as with key international partners, to address these compliance challenges
 - Participated in Regulatory Cooperative Council sessions

Bio Aikawa

9

What We've Heard

CHEMCON 
THE AMERICAS 2016

The Government has received some feedback on how supply chain awareness and information sharing can be improved:

- Providing more, and better compliance promotion material
- Simplify messaging in outreach materials
- Providing some Q/A's and factsheets specifically designed for upstream, foreign suppliers
- Setting expectations with obligations in plain language in our compliance promotion and outreach materials

Industry has shared some best practices:

- Establishing disclosure conditions within procurement contracts
- Safety Data Sheet component databases
- Sector pooling of component data

Bio Aikawa

10

Inventory Update

- The Inventory Update (IU) is a useful tool to update commercial status of substances of interest
- Moving forward, the IU is proposed to be an on-going, cyclical approach with reporting done every 4 years with the next phase starting in 2016
- Criteria setting the scope of the IU was based on discussions with stakeholders, ensuring scope is practical and relevant to Canadians and CMP priorities
 - For some substances identified through the criteria, separate approaches were deemed more appropriate to address data needs
- Proposed to have a 6-9 month timeframe for responding
- Responses must be provided through the online reporting tool

Bio Aikawa

11

Inventory Update cont'd

- Lessons learned and feedback received to date were taken into consideration in the development of the next phase
 - concentration threshold below which reporting is not required
 - targeting certain categories of manufactured items
 - collecting basic downstream information
 - potential availability of an Excel form upload function
 - revised codes and description, Tiered approach considering reporting challenges and data availability for certain applications (i.e. distribution points, retail, finished goods)
 - Improved guidance wording to increase data quality
 - addressing “snap-shot” challenge of targeting activities based on a single specified calendar year (detailed in next slide)

Bio Aikawa

12

Prioritization of the Revised In Commerce List

- Commitment under Canada's Chemicals Management Plan to complete prioritization of the revised In Commerce List (ICL) by end of March 2016
- Objective to identify those substances that require further review to determine whether they may pose a significant risk to human health or the environment
- Results of Prioritization:
 - 2549 (~ 75%) of the substances on the revised ICL warrant no further consideration in the context of the ICL
 - 884 (~ 25%) of the substances on the revised ICL warrant further consideration
 - contains 272 are active medicinal ingredients

Bio Aikawa

13

ICL Next Steps

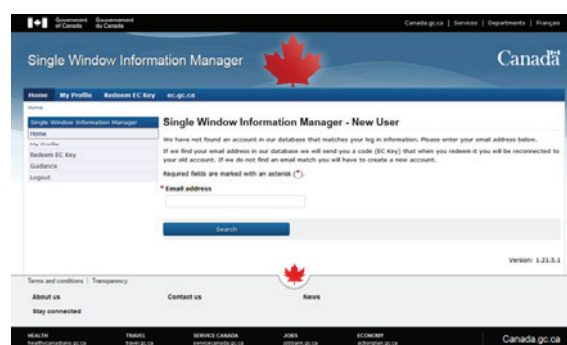
- Update the R-ICL by removing the ~ 800 substances that are also on the DSL – Fall 2016
- Initiate discussions to close R-ICL nomination process
- Share preliminary prioritization results upon request (Sept 2016) indicating:
 - those substances prioritized for further consideration
 - where information is requested on use patterns, status in Canadian commerce, and volumes for those substances identified for further consideration
- Continued discussions with stakeholders on opportunities to provide information to fill other data gaps e.g. biodegradation, ecotoxicity and human health toxicity data

Bio Aikawa

14

CMP Online Reporting System

- Information should be provided using the CMP online reporting system available through Environment Canada's Single Window Information Manager (SWIM): <https://ec.ss.ec.gc.ca/>
- Available for mandatory (e.g., s.71, s.70) and voluntary information (e.g., Declaration of Stakeholder Interest, Declaration of Non-Engagement), New Substances Notification submission, NOI submissions, Follow up on the previous DSL IU submissions, etc.



Bio Aikawa

15

Contact Us

Substances Management Information Line
Chemicals Management Plan
Gatineau, QC K1A 0H3

Telephone: 1-800-567-1999 / 819-938-3232

E-mail: eccc.substances.eccc@ec.gc.ca

Health Canada

Bio Aikawa
Manager, Information Management Division
613-941-3969
bio.aikawa@hc-sc.gc.ca

Environment and Climate Change Canada

Daren Kelland
Manager, Information Management and Data
Collection Section
819-938-5170
daren.kelland@canada.ca

Bio Aikawa

16



Future Events



 CHEMCON
ASIA 2017
★ June 19th - 23rd



 CHEMCON
EUROPE 2018



Speakers

Speakers

- **Bio Aikawa**, *Health Canada*
- **Dan Bastien**, *Environment and Climate Change Canada*
- **Joyce Borkhoff**, *Intertek Scientific & Regulatory Consultancy*

Dr. Bio Aikawa

Health Canada
269 Laurier Ave. W, Ottawa
ON, K1A 0K9, Canada
Tel: 613-941-3969
Email: bio.aikawa@hc-sc.gc.ca



Title / Current Position

Manager, Information Management Division
Existence Substance Risk Assessment Bureau (ESRAB) Safe Environments
Directorate (SED)
Healthy Environments and Consumer Safety Branch (HECSB) Health Canada

Education

- 2001 Ph.D. in Chemistry - Investigation of Catalyzed Hydrodechlorination Reactions of Organochlorines in Supercritical Carbon Dioxide, Carleton University, Ottawa, Canada
- 1996 Bachelor of Science, High Honours in Chemistry

Professional Experience

2015-Current: Manager, Information Management Division, Safe Environments Directorate, Health Canada
2010-2014: Manager, Assessment Division 2, SED, HECSB, Health Canada
2007-2010: Evaluator, Assessment Division 2, SED, HECSB, Health Canada
2006-2007: Evaluator, Human Safety Division, Veterinary Drugs Directorate, Health Canada
2004-2005: Post-doctoral fellow, Environmental and Occupational Toxicology Division, Health Canada
2001-2003: Post-doctoral fellow, Chemistry Research Division, Health Canada



Dan Bastien

Dan Bastien is the Head of the Client Services Unit of the New Substances Division of Environment and Climate Change Canada. He joined the New Substances program in February of 1995.

The Client Services Unit of the New Substances and the evaluation of Existing Substance programs under the Chemical Management Plan, CMP for short, provide advice to Importers and manufacturers of new chemicals, polymers and biotechnology substances under the Canadian Environmental Protection Act, 1999 and supports data collection activities under the CMP. Some of our key activities are:

1. Provides general and technical advice to written and telephone enquiries from potential importers and manufacturers and the general public
2. Drafts public information material including advisory notes, and contribute to writing and editing of regulatory and policy documents
3. Manages an information sharing website.

As well as this, Dan is also responsible for learning solutions to address the competency needs of employees at Environment and Climate Change Canada and help improve the knowledge of industry of the New Substances Regulations and the CMP by putting together training sessions and webinars.



Joyce Borkhoff

Senior Director, Chemicals Group
Intertek Scientific & Regulatory Consultancy¹
2233 Argentia Road, Suite 201 Mississauga, ON
Canada, L5N 2X7
Tel: +1 905-542-2900
Fax: +1 905-542-1011
Email: joyce.borkhoff@intertek.com
www.intertek.com



As a regulatory chemist, Ms. Borkhoff has been employed in senior positions within the chemical industry for over 20 years. Her technical and regulatory acumen and her strong communication and interpersonal skills enabled her to develop and deliver Health, Environment, Safety, Security, and Stewardship programs that addressed all regulatory obligations while contributing to the development and success of corporate business strategies. To support her employers' outreach interests, her leadership and advanced mediation skills enabled her to successfully represent the interests of the chemical industry in bilateral and multi-stakeholder regulatory forums that have tackled the development and evolution of a wide variety of legislative and regulatory amendments.

Ms. Borkhoff is well known for her ability to effectively characterize and communicate the impacts of the regulatory environment on the chemical industry. She is frequently invited to contribute to trade magazines and to present her advice and experience to a wide range of SME and large multi-national audiences. Her technical and regulatory experience and her strong knowledge of the North American Chemical Industry, makes Ms. Borkhoff uniquely qualified to provide practical, best-in-class service to help the NAFTA market understand and meet the requirements of the EU REACH system.

During her career, Ms. Borkhoff has been an active member of the Industry Coordinating Group (ICG) for the Canadian Environmental Protection Act (CEPA), The Canadian Association of Chemical Distributors (CACD), the

1. Cantox Health Sciences Inc., the leading international scientific and regulatory consulting firm established in 1985, was acquired by Intertek Group plc in April 2010, and continues as a wholly owned subsidiary operating as 'Intertek Scientific & Regulatory Consultancy



Joyce Borkhoff (cont'd)

Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), the Color Pigments Manufacturers Association (CPMA), Canadian Paint and Coatings Association (CPCA) and the Canadian Consumer Specialty Products Association (CCSPA).

As an industry expert and advocate, she has participated in numerous industry/government tables and multi-stakeholder consultations regarding such topics as: toxic substance management; the review and re-engineering of the CEPA; the New Substances Notification Regulations (NSNR); the Environmental Assessment Regulations for substances regulated under Food and Drug Act; Categorization and Screening of the Domestic Substances List; and the Canadian Chemical Management Plan (CMP) including the Challenge to Industry, the Substance Groupings Initiative and the DSL Inventory Updates.

At Intertek Scientific & Regulatory Consultancy, Ms. Borkhoff serves as Senior Director of the Chemicals Group, delivering expert advice and direction to clients who seek compliance and understanding of a wide variety of chemical control legislation and regulatory initiatives. She also leads the Chemicals team of regulatory and scientific experts who help clients address challenging regulatory climates and demanding marketplaces, in a timely and cost-effective manner, by successfully using surrogate data, estimation methods, or waiver requests, to meet complex requirements for physical-chemical and toxicological information prescribed under a variety of new and existing chemical notification and assessment programs across the globe.

Ms. Borkhoff has extensive expertise and experience in chemical notification programs, and risk assessment and risk management strategies.

Career Highlights

Ms. Borkhoff has managed the global notification of numerous substances across a broad range of chemical industry sectors including; pigments & dyes; automotive; paints & coatings; plastics; personal care; printing; photo processing; textiles; adhesives & sealants; water treatment; catalysts; intermediates; petrochemicals.



Joyce Borkhoff (cont'd)

She has extensive practical experience in the global management of toxic substances with expertise in the Canadian Chemical Management Plan and the EU REACH system. She has successfully represented companies and industry sectors to ensure product sustainability in North America.

Memberships

- Industry Coordinating Group (ICG) for the Canadian Environmental Protection Act (CEPA) representing the Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers

Educational Background

- B.Sc., Chemistry, McMaster University
- EPA's Sustainable Futures Initiative
- Post-Graduate courses in auditing, business management and organization studies.

