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Workshop Report

Workshop on Chemicals Management Policy — What is REACH all about?

Prepared by

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POLLUTION PROBE is a Canadian non-profit environmental organization that works in partnership with all sectors of society to protect health by promoting clean air and clean water. Pollution Probe was established in 1969 following a gathering of 240 students and professors at the University of Toronto campus to discuss a series of disquieting pesticide-related stories that had appeared in the media. Early issues tackled by Pollution Probe included urging the Canadian government to ban DDT for almost all uses and campaigning for the clean-up of the Don River in Toronto.

Since then, the organization has become national in scope. Pollution Probe has expanded its focus to include program work on issues related to climate change, energy, air quality, water pollution and human health. Major initiatives have included a programme to eliminate nonessential uses of mercury and its release from human sources to the environment; working as a contributing member of the Canadian Partnership for Children's Health and Environment (CPCHE) to produce a new vision and strategy to create a healthy environment for children in Canada, entitled *First Steps in Lifelong Health*; and, a joint effort with Environmental Defense Fund in the United States to investigate and report on the strengths and weaknesses of different chemicals management policies in the United States, European Union, and Canada. For more information please visit www.pollutionprobe.org.

THE MINING ASSOCIATION OF CANADA (MAC) is a national organization of the Canadian mining industry. It comprises companies engaged in mineral exploration, mining, smelting, refining and semi-fabrication. MAC's mission is to promote, through the collective action of members, the growth and development of Canada's mining and mineral-processing industry, for the benefit of all Canadians. The Association's broad functions are to promote the interests of the industry nationally and internationally, to work with governments on policies affecting minerals, to inform the public and to promote cooperation between member firms to solve common problems. MAC works closely with provincial and other industry groups across Canada and in other countries.

In 2004, MAC launched *Towards Sustainable Mining (TSM)*, a strategy for improving the mining industry's performance by aligning its actions with the priorities and values of Canadians and a process for finding common ground with our communities of interest, to build a better mining industry today and in the future. TSM aims to sustain the industry's role as a leading economic player by increasing public trust in its ability to manage the environmental and social issues important to Canadians. For more information please visit www.mining.ca.

ENVIRONMENTAL PROFESSIONAL INTERNSHIP (EPI) PROGRAMME was established by Pollution Probe with the goal of building individual and organizational capacity for achieving positive and tangible environmental change. Organizations from the public and private sector with the same goal have joined with Pollution Probe by supporting the advancement of new environmental professionals through the EPI Programme. EPI interns gain professional experience working with three organizations while building a network of contacts. These diverse experiences provide EPI interns with an opportunity to develop professional skills and a broad understanding of a specific aspect of environmental management and policy.

In 2007, Pollution Probe in partnership with Environment Canada, and MAC supported an intern on chemicals management. The internship included a sequence of work assignments at the different host organizations for eight months over a two-year period. MAC placed the intern, Julie Sommerfreund, with the support of the Metals in the Human Environment — Strategic Network, at the European Nickel Industry Association (a sub-unit of the Nickel Institute) in Brussels, Belgium, to contribute to the implementation of Europe's Chemicals Management Regulation — REACH (Registration, Evaluation, Authorization and restriction of Chemicals). The culmination of this internship has resulted in a series of workshops focused on REACH supported by Pollution Probe and the Mining Association of Canada.

March 2009

To: Participants of the Workshop on Chemicals Management Policy — What is REACH all about?

Pollution Probe and the Mining Association of Canada are pleased to publish this report summarizing the presentations and discussions of the Workshop on Chemicals Management Policy, held in January 2009.

Governments and industry around the world are faced with the challenge of managing the impacts of chemicals on the environment and human health. The European Union (EU) has taken an innovative approach to chemicals management with their regulation, REACH (Registration, Evaluation, Authorization and restriction of Chemicals). It should generate significant information and understanding on chemicals throughout the product supply chain.

The interest surrounding REACH stems from its novel approach for dealing with existing and new substances. REACH applies the same set of rules to these two groups and puts the onus on industry to demonstrate the safe use of its substance for both the environment and human health. This means both the testing and the assessment are the responsibility of industry. REACH also includes mechanisms to encourage the substitution of substances of very high concern.

The objective of the workshop was to provide a forum to discuss chemicals management policy, with a focus on the opportunities presented by REACH, and to explore the potential policy implications of REACH as well as lessons learned from the European experience, the use of the emerging data, and the impacts for industries around the world.

This report is the beginning of discussions on chemicals management. Following this, we plan to remain engaged and develop further initiatives relating to chemicals management in the upcoming year.

We wish to express our thanks for your participation in this workshop. Your expert contributions throughout the presentations and discussions helped make this event a success.

Sincerely,

Bob Oliver
Executive Director
Pollution Probe

Justyna Laurie-Lean
Vice-President, Environment and Health
Mining Association of Canada

Acknowledgements

Pollution Probe and the Mining Association of Canada would like to thank the Canadian Environmental Law Association for their assistance in the preparation and development of the workshop.

Pollution Probe and the Mining Association of Canada extend their special thanks to the Metals in the Human Environment Strategic Network and the Nickel Institute for supporting the internship research experience upon which this workshop was based.

We also thank Dina Schwertfeger, and Kathleen Cooper for technical information and/or comments on the report.

This report was written and prepared by Julie Sommerfreund. Pollution Probe staff involved in producing the report included Manisha Pahwa who served as the primary note taker during the workshop, Rebecca Spring and Bob Oliver who served as editors and BoAnne Tran who did editing and layout. Justyna Laurie-Lean from the Mining Association of Canada also served as a reviewer.

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List of Acronyms

BPA	Bisphenol A
CELA	Canadian Environmental Law Association
CEPA 1999	*Canadian Environmental Protection Act 1999*
CMP	Chemicals Management Plan
EU	European Union
ECHA	European Chemicals Agency
EINECS	European Inventory of Existing Commercial Substances
UN GHS	United Nations Globally Harmonized System for classification and labelling
IARC	International Agency for Research on Cancer
MAC	Mining Association of Canada
NGO	Non-governmental Organisation
OEL	Occupational Exposure Limit
PBT	Persistent, Bioaccumulative and Toxic
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
TURA	Proposed Toxics Use Reduction Act
vPvB	Very Persistent and Very Bioaccumulative

Introduction

On January 22, 2009, Pollution Probe and the Mining Association of Canada co-hosted a workshop for non-governmental organizations (focused on environment and public health), labour groups and public health units to learn about and discuss approaches to chemicals management with a particular focus on the European Union's new regulation on chemicals called REACH: Registration, Evaluation, Authorization and restriction of Chemicals.

The workshop lasted a full day. The morning was composed of overview presentations of chemicals management in Canada and Europe, followed by an in-depth discussion on the main processes of REACH. This discussion was enriched by a presentation on the treatment of substances in consumer products, as well as the implications for companies outside of the European Economic Area.

The afternoon agenda was organized into two main sessions. In the first session, perspectives on REACH and corresponding Canadian approaches were presented by the Canadian Environmental Law Association, the Canadian Chemicals Producers' Association and the Mining Association of Canada. This was followed by a break-out session for participants to discuss the advantages and disadvantages of the chemicals management policies that were presented in the morning (see Appendix 2 for Breakout Session I questionnaire).

The second session focused on the specific data and assessment methodologies emerging from REACH. Participants were invited to discuss the ways in which Canadian programs may benefit from the assessments of substances under REACH and how Canada can benefit from the REACH experience in Europe (see Appendix 3 for Breakout Session II questionnaire).

The event concluded with a review of the global implications of REACH and a review of similar approaches under consideration in jurisdictions around the world.

This report constitutes the proceedings of the REACH workshop. It includes brief summaries of the chemical management strategies that were presented at the workshop, as well as questions from the participants and the discussions that followed in the breakout sessions. The contents of this report do not necessarily represent the views of the event sponsors or the participants. Full presentations can be found on Pollution Probe's website at http://www.pollutionprobe.org/Happening/pdfs/REACH-jan09/Agenda.pdf. The report appendices provide more information and clarifications as requested during the workshop.

Overview of Chemicals Management in Canada — Federal, Provincial, Municipal and International Policy

Theresa McClenaghan
Canadian Environmental Law Association

Theresa McClenaghan of the Canadian Environmental Law Association (CELA) began the workshop with an overview of chemicals management in Canada from federal, provincial, municipal and international policy perspectives. She emphasized that to effectively manage chemicals in Canada our policies must be preventive rather than reactive, and, should advocate precaution and prevention. She then gave an overview of the federal Chemicals Management Plan (CMP) launched in December 2006 and identified several challenges facing the government for implementation.

Theresa then focused on Ontario's proposed Toxics Use Reduction Act (TURA), which is focused on the use of toxics and aims to inform stakeholders about their adverse effects. CELA recommends that TURA emphasize substitution for safer alternatives to reduce human exposure to toxics.

Overview of the European Regulation — REACH (Registration, Evaluation, Authorization, and restriction of Chemicals)

Julie Sommerfreund
Pollution Probe and the Mining Association of Canada

Julie Sommerfreund from Pollution Probe and the Mining Association of Canada (MAC) provided an overview of the European Union's new regulation on chemicals: REACH, the Registration, Evaluation, Authorization and restriction of Chemicals. In her presentation, Julie provided some background on the origins of REACH, the main processes comprising REACH and how it will be managed.

REACH is the result of a ten year process that was initiated due to the combination of an increased awareness of the public and regulators on the potential impact of chemicals on the environment and human health, and the lack of comprehensive assessment of many chemicals on the market.

The objectives of REACH are as follows:

- Improve the protection of human health and the environment from the risks that can be posed by chemicals
- Enhance the competitiveness of the EU chemicals industry, a key sector for the economy of the EU
- Ensure the free circulation of substances on the internal market of the EU

In order to achieve these objectives, REACH encompasses new principles and approaches to chemicals management. REACH requires the registration of all substances and eliminates the distinction between new and existing substances. It places the responsibility on industry to demonstrate a safe use of a substance across the entire product supply chain before being granted access to the European Economic Area. REACH employs a risk-based approach, requiring both risk assessment and risk management measures. In addition, it incorporates an assessment of the economic impacts into decision making. Finally, one of the driving principles of REACH is the concept of "No Data, No Market", which denies access to the European market for companies that do not comply with requirements of REACH.

Comments, Questions and Answers

The introductory presentations generated a significant amount of discussion and questions from the participants. The following represents the sequence of the Questions and Answers.

REACH and Canada

Q. Is the REACH approach for classifying a carcinogen comparable to the approach used for the categorization under CEPA 1999 and decisions for CMP or is it broader?

C. The question prompted a discussion among the participants that raised the awareness that there is concern that the approach in Canada is more restricted in its criteria for designation of carcinogen than in the European Union. Participants suggested that REACH is broader and more similar to the classification approach used by the International Agency for Research on Cancer (IARC).

A. In order to provide a more specific answer a review of the guidance documentation from each jurisdiction is required and went beyond the scope of the workshop. Further, this has proven to be challenging given the difficulty in accessing Canadian guidance documents.

Q. Enforcing the proposed Ontario Toxics Reduction Strategy has been identified as a potential challenge due to the lack of specialists who are trained and able to implement it. How was REACH enforced in the European Union?

A. Enforcement of REACH is the responsibility of the Member States, and a regime has been or will be developed for each country.

However, implementation of REACH has been greatly facilitated by the development of the European Chemicals Agency (ECHA). ECHA has developed a website as a single point of entry for all information on REACH, including technical guidance, software tools and help desk material for industry. ECHA will manage the registration, evaluation, authorization and restriction processes for chemical substances to ensure consistency across the European Union. In addition, consulting firms and industry associations have been expanding their programs to assist in this regard. Many environmental scientists are trained in this area and small companies are bringing on new staff to develop their expertise. In the future, Canada could also benefit from this expertise.

Although the lack of specialists has been identified as a potential challenge to the implementation and enforcement of the proposed Ontario Toxics Reduction Strategy, a recent meeting at the Ministry of the Environment was encouraging as it was well-attended by many college and university representatives, demonstrating that there are many researchers working on chemicals management (it also suggested that the capacity exists in Ontario to provide expert oversight and to provide training and development).

Participants commented that while there are multiple mechanisms for research and development in Ontario, there are limited funds for training students and operational development.

Workers' Health

Q. Does REACH protect the health and safety of workers outside of the European Union?

A. REACH requires industries to assess their own production processes and protect the health and safety of workers in their own facilities within the European Union. Responsibilities begin once the substance has entered the Community. Please see Appendix 4 for more information.

Substances Considered Under REACH

Q. How are nanomaterials considered under REACH?

A. In the European Union there have been on-going discussion and debates regarding nanomaterials. Trade Unions have called for a mandatory chemical safety assessment for nanomaterials.[1] The European Commission adopted the "Communication on regulatory aspects of nanomaterials". Based on a regulatory review of EU legislation in relevant sectors, it concluded that the potential health, safety and environmental risks in relation to nanomaterials are "in principle" covered under current EU laws on chemicals, health and safety of workers, different product safety requirements, and the environment.

[1] http://www.euractiv.com/en/science/trade-unions-call-reach-amendment-cover-nanomaterials/article-173791

The position of the European Commission — Enterprise and Industry is copied here.[2]

REACH and Nanomaterials

There are no provisions in REACH referring explicitly to nanomaterials. However, nanomaterials are covered by the "substance" definition in REACH.[3] When an existing chemical substance, already placed on the market as bulk substance, is introduced on the market in a nanomaterial form (nanoform), the registration dossier will have to be updated to include specific properties of the nanoform of that substance. The additional information, including different classification and labelling of the nanoform and additional risk management measures, will need to be included in the registration dossier. The risk management measures and operational conditions will have to be communicated to the supply chain.

In order to address the specific properties, hazards and risks associated with nanomaterials, additional testing or information may be required. To determine specific hazards associated with nanomaterials, current test guidelines may need to be modified. Until specific test guidelines for nanomaterials exist, testing will have to be carried out according to already existing guidelines.

The Commission will carefully monitor the implementation of REACH with respect to nanomaterials. Based on information regarding production and marketing, or new knowledge (e.g., regarding toxicological or physical-chemical properties) current provisions, including quantitative triggers and information requirements, may have to be modified.

Data generated under REACH will serve as input to other regulation, such as worker protection, cosmetics and environmental protection. It complements product legislation (e.g., general product safety) to the extent that this does not cover environmental aspects.

Q. How many substances were pre-registered by the pre-registration deadline of December 1, 2008?

A. The list contains about 150,000 substances which were pre-registered by 65,000 companies (legal entities) between 1 June and 1 December 2008. The list covers the entire European Inventory of Existing Commercial Substances (EINECS) and the number of companies may be slightly inflated due to the pre-registrations (or overzealous activity) on the part of consulting companies and traders.

[2] http://ec.europa.eu/enterprise/reach/reach/more_info/nanomaterials/index_en.htm

[3] Under REACH, manufacturers and importers will have to submit a registration dossier for substances that they manufacture or import at or above 1 tonne per year. At or above 10 tonnes per year, the registrant will be obliged to produce a chemical safety report. Furthermore, if deemed necessary for the evaluation of the substance the European Chemicals Agency can require *any* information on the substance, independent of the minimum information requirements of REACH.

Q. In regards to these 150,000 chemicals pre-registered, how does REACH account for consumer products?

A. Pre-registration only applies to substances, not consumer products.

Q. How do REACH rules apply for polymers, monomers and the implications on importing and manufacturing polymers in Europe?

A. This is currently under discussion in Europe – http://chemicalwatch.com/1713

Q. How did exemptions to REACH arise and how were these collected, particularly with regard to radioactive substances?

A. Most exemptions are for substances already covered by other legislation. For example, radioactive substances are exempt from REACH because there is specific legislation applicable to them.

Q. I am concerned about endocrine disruptors, since industry has not demonstrated an ability to define their effects when they conduct tests.

A. Under the authorization process, member states can nominate substances that meet specific criteria for Substances of Very High Concern for the authorization list. Endocrine disruptors are considered under authorization as substance of similar concern.

REACH Legislative Process

Q. During the period of discussion spanning the drafting of REACH were significant compromises made to weaken the regulation?

A. Some believe that compromises were indeed made. For more information on the perspectives of some non-governmental organizations in Europe on this matter, please refer to Greenpeace *et al* (2007), *Navigating REACH*. http://www.greenpeace.org/raw/content/eu-unit/press-centre/reports/navigating-reach.pdf.

Q. Does REACH have a deadline for review of the various processes?

A. There is a requirement for registrants to update their registration dossier if new data becomes available. The Authorization decisions will include a time period for review, set on a case-by-case basis.

An In–depth Discussion of Registration, Evaluation Authorization and Restriction of Substances Under REACH

Julie Sommerfreund
Pollution Probe and the Mining Association of Canada

The in-depth discussion presentations covered the specific requirements for each process under REACH; specifically Registration, Evaluation, Authorization and Restriction. Here we have provided an overview of each process as described by the European Chemicals Agency (ECHA). For more details see http://guidance.echa.europa.eu/about_reach_en.htm.

Registration
REACH requires manufacturers and importers of chemical substances (greater than or equal to one tonne per year) to obtain information on the physicochemical, health and environmental properties of their substances and use it to determine how these substances can be used safely. Each manufacturer and importer must submit a registration dossier documenting the data and assessments to the Agency.

Evaluation
The Agency will perform dossier evaluation to assess testing proposals made by the registrant or to check that the registration dossiers comply with the requirements. The Agency will also co-ordinate substance evaluation, which will be conducted by the Member States to investigate chemicals of concern.

Authorization
Authorization will be required for the prioritized Substances of Very High Concern (SVHC) that are included in Annex XIV. Companies applying for authorization will have to demonstrate that risks associated with uses of these substances are adequately controlled or that the socio-economic benefits from their use outweigh the risks. Applicants will also have to investigate the possibility of substituting these substances with safer alternatives or technologies, and prepare substitution plans if appropriate.

Restriction
The European Union can impose restrictions and prohibit or set conditions for the manufacture, placing on the market or use of certain dangerous substances or group of substances when unacceptable risks to humans or the environment have been identified.

Communication in the supply chain
Suppliers of substances must pass on information on the health, safety and environmental properties and safe use of their chemicals to their downstream users (via a Safety Data Sheet or other means). Downstream users may only use substances classified as dangerous or which are persistent, bioaccumulative and toxic (PBT) and very persistent and very bioaccumulative (vPvB) if they apply risk management measures identified on the basis of exposure scenarios for their use.

Comments, Questions and Answers

Oversight and Accountability

Q. Is there oversight to ensure that the information submitted by industry is accurate about the safety of their chemicals? How is compliance with REACH monitored?

A. REACH covers many chemicals and thus there is not a third party review of every chemical registered. There are two approaches to evaluation: dossier and substance. The dossier evaluation is a compliance check conducted by the authorities to evaluate whether the registrant has met all the legal requirements and that the data provided is sufficient. The dossier evaluation also evaluates the testing proposals for animal testing. Dossier evaluations must be conducted for a minimum of five per cent of dossiers per registration tonnage band.[4] They will be selected based on specific criteria as well as by random sampling.

The substance evaluation enables authorities to further scrutinize chemicals of particular concern. When the Agency or a Member State has an indication that a substance may pose a risk to human health or the environment, the Agency will include that substance on a list for "substance evaluation". For each substance on this list, one Member State shall evaluate in more detail whether further information is needed and, in that case, the registrant(s) will be requested to provide such information.

Please refer to http://guidance.echa.europa.eu/evaluation_en.htm for more information and specific guidance documents.

One participant suggested that it is in the best interest of companies to comply with the REACH requirements since they will be spending significant amounts of money on testing.

Exposure Scenario

Q. A particular exposure scenario may involve a variety of lead-based paints. Different manufacturers will want to register products that have different downstream users and consequently different exposure scenarios. Do these products need to be registered separately?

[4] Under REACH registration requirements and timelines vary based on tonnage bands and hazard criteria.

A. In REACH a substance is registered (not the paint mixture). In this case, the substance is lead and the other substances used to make the paint. The manufacturer needs to consider paint in the exposure scenario. The criteria being set and the occupational exposure limits (OEL) will be done on a per substance basis. This is part of a comprehensive hazard assessment. However, there is still a need to investigate what the OEL is for many substances.

Authorization and Restriction of REACH Substances

Q. Do countries choose which substances to authorize?

A. The member states or the European Chemicals Agency (ECHA) on behalf of the European Commission can recommend a chemical to be on the list. The public can also contribute to the processes under REACH through commenting.

Q. Why aren't all chemicals on the authorization list?

A. The authorization list is required to be updated at a minimum of every two years by member states or the European Chemicals Agency. To date, only the first candidate lists (October 2008) and prioritization list (January 2009) have been proposed.

The absence of chemicals from the candidate list may be indicative that the substance is better managed under another REACH process, such as a restriction.

Q. There are fifteen substances on the candidate list and only seven on the priority list. Was there much controversy about this?

A. The prioritization list was released on January 14, 2009. A substance that has not been proposed for the prioritization list remains on the candidate list, and can be proposed for prioritization at a later date. The ECHA website provides the information that went into the decision-making process:
http://echa.europa.eu/consultations/authorisation/draft_recommendations_en.asp.

Q. What is the difference between authorization and restriction?

A. Authorization prohibits the placing on the market of a particular substance unless a company is granted authorization for a particular use.

Restriction regulates the manufacture, placing on the market, or use of certain substances within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes.

Q. Previously, there was a Directive restricting the use of IARC I and II carcinogens greater than one per cent in consumer products. Is this Directive still applicable or has REACH replaced it?

A. Any restrictions under previous Directives are carried forward into REACH.

Public Engagement in REACH

Q. Is the REACH data publicly accessible?

A. REACH data will be available on the internet as indicated in Article 119 of REACH.[5]

[5] REACH *Article 119* Electronic public access

1. The following information held by the Agency on substances whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e):
(a) the name in the IUPAC Nomenclature, for dangerous substances within the meaning of Directive 67/548/EEC, without prejudice to paragraph 2(f) and (g);
(b) if applicable, the name of the substance as given in EINECS;
(c) the classification and labelling of the substance;
(d) physicochemical data concerning the substance and on pathways and environmental fate;
(e) the result of each toxicological and ecotoxicological study;
(f) any derived no-effect level (DNEL) or predicted no-effect concentration (PNEC) established in accordance with Annex I;
(g) the guidance on safe use provided in accordance with Sections 4 and 5 of Annex VI;
(h) analytical methods if requested in accordance with Annexes IX or X which make it possible to detect a dangerous substance when discharged into the environment as well as to determine the direct exposure of humans.

2. The following information on substances, whether on their own, in preparations or in articles, shall be made publicly available, free of charge, over the Internet in accordance with Article 77(2)(e) except where a party submitting the information submits a justification in accordance with Article 10(a)(xi), accepted as valid by the Agency, as to why such publication is potentially harmful for the commercial interests of the registrant or any other party concerned:
(a) if essential to classification and labelling, the degree of purity of the substance and the identity of impurities and/or additives which are known to be dangerous;
(b) the total tonnage band (i.e., 1 to 10 tonnes, 10 to 100 tonnes, 100 to 1 000 tonnes or over 1 000 tonnes) within which a particular substance has been registered;
(c) the study summaries or robust study summaries of the information referred to in paragraph 1(d) and (e);
(d) information, other than that listed in paragraph 1, contained in the safety data sheet;
(e) the trade name(s) of the substance;
(f) the name in the IUPAC Nomenclature for non-phase-in substances which are dangerous within the meaning of Directive 67/548/EEC for a period of six years;
(g) the name in the IUPAC Nomenclature for dangerous substances within the meaning of Directive 67/548/EEC that are only used as one or more of the following:
(i) as an intermediate;
(ii) in scientific research and development;
(iii) in product and process orientated research and development.

Q. Processes like REACH in many jurisdictions are often too large for the public and Non-governmental organizations (NGOs) to gauge what is really going on. What is being done to make this information available and communicated/translated effectively? What is the marketing/user-friendliness of REACH?

A. The ECHA website (http://echa.europa.eu/home_en.asp) contains variable levels of information for public consumption. For example, the website provides documents for download that illustrate the justification of ECHA's decisions.

Q. What is the public perception of REACH? Do they recognize that this is a worthwhile effort and support it?

A. Generally speaking, it appears that the public supports REACH but they are reserving judgement until the effectiveness of evaluation is proven. The public is pleased that data gaps that have existed for decades will be filled. For more information, we suggest contacting NGOs in Europe, for example, ChemSec and Greenpeace.

C. One participant noted that environmental organizations were very active in the lead-up to the final regulation, but have since scaled back their activity in this area. The participant noted that, currently, the most active NGO is ChemSec.

Implications of REACH on Chemicals Safety and Management

Q. Has labelling actually improved in the European Union as a result of REACH?

A. Labelling requirements are not included in REACH but fall under a connected (yet separate) Regulation on Classification, Labelling and Packaging of substances and mixtures (CLP) that aligns existing legislation of the European Union with the United Nations Globally Harmonized System (GHS). This was adopted on December 16, 2008 (http://ec.europa.eu/enterprise/reach/ghs/legislation/index_en.htm).

Under REACH, substances of very high concern that have been put on the candidate list for authorization have requirements to provide information upon request to its consumers.

How REACH Addresses Substances in Consumer Products and Promotes Substitution of Substances of Very High Concern

Julie Sommerfreund
Pollution Probe and the Mining Association of Canada

Continuing the overview of REACH, Julie explained how the REACH obligations are applied to substances in consumer products and how REACH encourages substitution through legal obligations and non-legal forces.

Consumer products are considered as preparations or articles under REACH. If two or more substances are mixed together forming a mixture or a solution, the term "preparation" is used. An "article" is the legal term under REACH for any object that has been given a specific shape, surface, or design, so that it can be used for a specific purpose (e.g. manufactured goods such as cars, textiles, electronic chips). The obligations differ according to the type of consumer products. We have included a description from ECHA here (http://guidance.echa.europa.eu/substances_articles_en.htm).

REACH Obligations for Consumer Products

For each substance manufactured or imported in quantities of one tonne or more per year, there is a general obligation for manufacturers and importers to submit a registration to the Agency. This also applies to substances manufactured or imported as part of a preparation.

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, if they are produced or imported in quantities exceeding one tonne per year per producer or importer.

In addition, all substances included in the candidate list that are present in articles above a concentration limit of 0.1 per cent weight by weight, and above one tonne per year must be notified to the Agency.

Such notification is not required however, when exposure to humans and environment can be excluded during normal conditions of use, including disposal. In such cases safety instructions should be provided.

…continued

A notification of a substance in an article consists of sending a dossier to the Agency, containing the identity of the notifier, the identity of the substance, its classification and labelling, a brief description of its use, and the tonnage range.

As a safety net, the Agency can require a registration of a substance in an article at any time if it considers the release of the substance to pose a risk to human health or the environment.

In addition, suppliers of articles containing more than 0.1 per cent of a substance of very high concern that has been identified as being eventually subject to authorization, have to pass on sufficient information to recipients to allow safe use of the substance.

During this presentation, Julie also described the forces that may encourage substitution under REACH. The legal means include a requirement of analysis of alternatives under the Authorization provision and decision criteria for Restriction. Further, during the development of exposure scenarios manufacturers may identify uses that are not appropriate for their substance. As a result, alternatives will be needed to replace these substances.

Comments, Questions and Answers

Substitution of substances in REACH

Q. Is there development of substitution analysis in Europe?

A. Under the authorization process, when a company requests authorization for a particular use of a substance on the authorization list, they are required to do an analysis of alternatives (substitution analysis). If the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining the plan to replace the substance by the alternative. The suitability of available alternatives is assessed taking into account all relevant aspects, including whether the alternative results in reduction of overall risks and is technically and economically feasible. The guidance materials for socio-economic analysis are still under development.

C. One participant noted that there are also competitive drivers to encourage investment in substitution, since companies who produce an alternative can also submit information to the authorization request analysis.

Perspectives

Prior to the breakout discussion, three varying perspectives on REACH and approaches to chemicals management were given. Participants heard presentations from the Canadian Environmental Law Association, the Canadian Chemical Producers Association and the Mining Association of Canada. Please refer to their complete presentations for more details http://www.pollutionprobe.org/Happening/pdfs/REACH-jan09/Agenda.pdf.

Breakout Session I

Participants split into small groups to discuss the advantages and disadvantages of chemicals management policies discussed at the workshop (i.e., REACH, CEPA 1999 and CMP, Ontario TRS) (see Appendix 2). The diverse range of responses are summarized and organized as follows.

1. Data Gathering

Participants were asked to evaluate the advantages and disadvantages of the approaches used in each of three policy options, for gathering data on chemical substances.

REACH	**CEPA 1999 and The Chemicals Management Plan (CMP)**	**Proposed Ontario Toxics Reduction Strategy**
The onus is on industry to demonstrate the safe use of its chemicals throughout the supply chain.	Requires the government to assess all substances currently on the market and request information from industry where necessary.	Relies on assessments done in other jurisdictions to move forward with priorities and requires industry to document its use of certain substances.

Participants identified the following advantages and disadvantages of each approach.

	Advantages	**Disadvantages**
REACH	• Manufacturers/Importers are required to identify data gaps and generate new data • Best practices for risk management will be shared amongst companies • The data generated will include exposure along the entire supply chain • The financial burden of testing will be incurred by industry and not government • Only chemicals identified as dangerous will require an exposure scenario assessment • Occupational exposure is considered as part of the risk assessment • Confidential Business Information is protected regarding formulations • The approach is proactive rather than reactive to demonstrated risk • The data generated will be transparent and publicly available.	• Concerns were raised regarding a companies' ability to conserve their competitive edge • Public confidence in the development of industry data will be tested • Waste is out of scope of registration • REACH does not impact the dumping of substances in other countries • Government is not the active data gatherer • For success government needs to be active in the evaluation of the process; however there are potentially over 150,000 substances to be evaluated • In order to evaluate the success of REACH, long-term monitoring of health outcomes and the environment is required • REACH poses a challenge for major chemicals manufacturing areas like Asia • Decisions are made, to a large extent, on self-regulation of industry • Cumulative exposure of multi-contaminants are not considered in the assessment
CEPA 1999 and Chemicals Management Plan (CMP)	• Under the Industry Challenge of CMP, companies must supply data on exposure and can voluntary provide data on toxicity or other elements relevant to the assessment • Categorization has resulted in more thorough assessment of selected chemicals based on an identification of potential risk and not all substances	• Under CMP and CEPA 1999 there are not any requirements to generate new toxicity data • Occupational exposure is not considered in the assessment • Old exposure data and available literature were used for categorization

…continued	**Advantages**	**Disadvantages**
CEPA 1999 and Chemicals Management Plan (CMP)	• Government plays an active role in evaluation and data gathering	• There is a lack of history and culture of enforcement • The assessment of substances is the responsibility of the government, which requires significant resources and time • The quality of evidence used for categorization is variable
Ontario TRS	• Companies are required to report • As a result of materials accounting, there will be a thorough mapping of processes that use toxics • The provisions are driven by human health and labour concerns.	• There is a current lack of institutional capacity • The approach considers facility-by-facility rather than a life cycle assessment • The decision making is the responsibility of the government • The list of substances included is small • The reporting thresholds will not include small facilities

2. Uncertainty and Action

Participants were asked to consider how the lack of data and information affects decision making and the likely consequences. They were asked to consider the following questions:

How much information is necessary to act? What are the consequences of waiting to fill the data gaps (or moving forward using the incomplete but best available data considering impacts on human health, the environment and industry?

REACH	**Chemicals Management Plan**
Requires the testing of the basic physical chemical properties of the substances. Industry is required to identify and fill the data gaps. Registration for high volume, high hazard substances is required by December 2010.	The CMP categorization efforts were based on the best available literature to-date and modeling in the absence of measured data. For the high priority substances in the Industry Challenge program, risk management measures are being proposed based on this information. The direction for the medium priority substances is unclear.

Participants identified the requisite information to make decisions in regards to chemicals management and suggested that in the absence of that information, protective uncertainty factors are required. Participants agreed that the information required includes the effects on vulnerable populations (particularly children), aggregate exposures, common endpoints (instead of common mode of action), and groups of similar chemicals.

Conventional toxics management approaches have resulted in a lack of information for many important chemicals. Participants suggested that these substances require analysis but cautioned that inaction due to the lack of information often results in "analysis paralysis". This leads to delayed decisions, reinforcing the status quo and undermining innovation. The continued exposure in this situation has economic implications for workers, the public and environmental health. In addition, the legacy of toxins resulting from continued exposure cannot be eliminated from our bodies and environment; in the current paradigm, we have accepted this as the norm.

However, one participant noted that the Government is moving beyond the analysis paralysis in its treatment of high priority substances (identified through Categorization). Under CMP the high priority substance are predisposed to a CEPA toxic designation, allowing the government to regulate the substances.

Others highlighted pesticides and bisphenol A (BPA) as good examples of approaches used in the absence of evidence and felt from these experiences that the ultimate decision-making power should lie with the public. The suggestion was that in order for the public, who are the ultimate consumers of the product, to make effective decisions, better consumer engagement is required. Participants emphasized the need for the public to have access to all the literature presented from all stakeholders, including industry and government. They suggested that leveraging the public voice is needed to facilitate chemicals risk management.

An introduction to the Scientific Information Generated and Risk Assessment Approach Applied Under REACH

Dina Schwertfeger
McGill University

Dina Schwertfeger from McGill University provided the participants with a presentation on the technical data that will emerge from REACH, the risk assessment methodology, and the processes used to evaluate data. Her presentation highlighted the exposure scenario process and toxicological information requirements. Further she shared with the participants the list of data that will be made publicly available under REACH.

Comments, Questions and Answers

Data Foundation of REACH

Q. How does REACH incorporate epidemiology data, if at all?

A. Suppliers, when they are going through the review, include epidemiology data. This information must be provided if it is available. The substance then goes through testing requirements to make sure as much information as possible is included. Dossier development weighs different evidence differently.

Q. Does the exchange of data in the Substance Information Exchange Forum (SIEF) apply only to toxicology and epidemiology data, or does it include other data (biomonitoring, for example)?

A. Biomonitoring data can be considered in the exposure assessment.

Vulnerable Populations and REACH

Q. Are vulnerable populations (e.g., children) considered in exposure and risk assessment calculations?

A. Vulnerable populations are considered in the exposure assessment of substances for sub-populations for particular uses.

Q. How can we measure progress for chemicals management?

A. Biomonitoring represents one way to measure progress. There are currently four ongoing cycles in the United States that will help establish a baseline level of information and will help us understand if there is a drop in exposure over time.

Breakout Session II

Participants discussed the ways in which Canadian Programs may benefit from the assessments of substances under REACH and how, in Canada, we can build on the experience of REACH in the European Union (see Appendix 3).

During the discussion, participants highlighted the need for Canada to obtain the information generated from REACH; however they questioned the utility of the data. Further, they discussed some potential barriers to obtaining the data; although significant amounts will be made publicly available. Some participants questioned if Canada will be able to make a third party agreement with the European Union to gain access to the data and how this will be achieved in the context of the Substance Information Exchange Forum that require cost-sharing mechanisms. Other participants emphasized that Canada should work to gain access to all the European data and incorporate it into the Canadian context as best as possible. It was suggested that the information could be used to promote best practices in Canada. This would also help to avoid duplication testing of substances.

Implications of REACH for Canada and Other Jurisdictions

Julie Sommerfreund
Pollution Probe and the Mining Association of Canada

The event concluded with a look into some of the responses around the world to REACH. REACH is increasingly considered a gold standard for chemicals management worldwide. Subsequently, other jurisdictions are considering replicating it in their own domestic legislation or developing legislation similar to REACH. Julie highlighted the impacts for multi-national companies exporting into the European Union, indicating that Europe's REACH is worldwide.

Workshop Agenda

Objective: *To discuss how chemicals are managed in the European Union and the lessons Canada can learn from REACH (Registration, Evaluation, Authorization and restriction of CHemicals).*

Thursday, Thursday, January 22, 2009

8:30 Morning Refreshments

9:00 **Opening Remarks and Introductions** — Bob Oliver, Pollution Probe

9:15 **Overview of Chemicals Management in Canada** — Theresa McClenaghan, Canadian Environmental Law Association
- CEPA 1999 and the Chemicals Management Plan — Challenge Program
- Proposed Ontario Toxics Reduction Strategy

10:00 **Overview of Registration, Evaluation, Authorization, and restriction of Chemicals (REACH)** — Julie Sommerfreund, Pollution Probe and the Mining Association of Canada

10:30 Question Period

10:45 Health Break

11:00 **An In–depth Discussion of Registration and Evaluation of Substances Under REACH** — Julie Sommerfreund, Pollution Probe and the Mining Association of Canada

11:30 Question Period

11:45 **An In–depth Discussion of Authorization and Restriction of Substances under REACH** — Julie Sommerfreund, Pollution Probe and the Mining Association of Canada

12:00 Question Period

12:15 Lunch

1:00 **How REACH Addresses Substances in Consumer Products (Articles) and Promotes Substitution of Substances of Very High Concern** — Julie Sommerfreund, Pollution Probe and the Mining Association of Canada

1:15 **Perspectives from the Canadian Environmental Law Association —** Kathleen Cooper, Canadian Environmental Law Association

1:30 **Perspectives from the Canadian Chemical Producers Association** — Gordon Lloyd, Canadian Chemical Producers' Association

1:45 **Perspectives from the Mining Association of Canada —** Justyna Laurie–Lean, Mining Association of Canada

2:00 **Breakout Session I** — Participants will be invited to discuss the advantages and disadvantages of chemicals management policies

2:30 **Participant Dialogue** — Discussion of conclusions reached during breakout session I

3:00 Health Break

3:15 **An Introduction to the Scientifi c Information Generated and Risk Assessment Approach Applied Under REACH** — Dina Schwertfeger, McGill University

3:45 **Breakout Session II** — Participants will be invited to discuss the ways in which Canadian Programs may benefit from the assessments of substances under REACH and how we can build on the REACH experience

4:15 **Participant Dialogue** — Discussion of conclusions reached during breakout session II

4:45 **Implications of REACH for Canada and other Jurisdictions —** Julie Sommerfreund, Pollution Probe and the Mining Association of Canada

5:00 **Summary and Conclusions**

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Appendix 1 — Sources of Additional Information

The following is a list of selected sources that participants may wish to consult with:

REACH Guidance Materials

http://guidance.echa.europa.eu/about_reach_en.htm

REACH Responses

Park, DaeYoung, Me-Young Song, Duk-Chan Yoon, Kwi-Ho Lee and Xion Cong. 2008. REACHing Asia: Recent Trends in Chemical Regulations of China, Japan and Korea. http://papers.ssrn.com/sol3/papers.cfm?abstract_id=1121404

Marsden, William. 2008. We're in Chemical Overload Toxic Chemicals: Consumers are the Lab Rats. The Gazette. 20 June 2008. http://www.canada.com/montrealgazette/story.html?id=e4c6d71f-2a6f-4952-98c7-24866f28aa67

Solid State Technology. May 2007. Japan News: EU's REACH extending to Japan. http://www.solid-state.com/display_article/291980/5/ARTCL/none/none/Japan-News:-EU's-REACH-extending-to-Japan/

ICIS news. 2008. US should adopt REACH, Senate leader says. 29 April 2008. http://www.icis.com/Articles/2008/04/29/9120117/us-should-adopt-reach-senate-leader-says.html

Black, Harvey. March 2008. Chemical Reaction: The US Response to REACH, Environmental Health Perspectives; 116(3): A124–A127. http://www.pubmedcentral.nih.gov/articlerender.fcgi?artid=2265068

Greenpeace. 2007. Navigating REACH. http://www.greenpeace.org/raw/content/eu-unit/press-centre/reports/navigating-reach.pdf

Comparison Papers

Wordsworth, Anne, John Jackson, Jessica Ginsburg and Ken Traynor. January 2007. European and Canadian Environmental Law: Best Practices and Opportunities for Co-Operation. Canadian Environmental Law Association. http://www.cela.ca/topical/detail.shtml?x=2916

Denison, Richard. April 2007. Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals. http://www.pollutionprobe.org/Reports/Report_Denison_NotThatInnocent.pdf

CEPA/CMP Background

http://www.chemicalsubstanceschimiques.gc.ca/plan/index_e.html

Ontario Toxics Reduction Strategy

http://www.ene.gov.on.ca/en/toxics/index.php

Appendix 2 — Breakout Session I Questionnaire

Participants are invited to discuss the advantages and disadvantages of chemicals management policies and report back to the group a summary of the discussion.

Discussion Questions

This morning we discussed three chemicals management policy approaches:

- Canadian Environmental Protection Act 1999 (CEPA 1999) and the Chemicals Management Plan (Challenge Program),
- Ontario Toxics Reduction Strategy, and
- the European Union regulation, REACH — Registration, Evaluation, Authorization and restriction of Chemicals

The policies apply different approaches in order to ensure that chemicals are produced and used in ways that minimize significant adverse impacts on the environment and human health.[1]

REACH	CEPA 1999	Proposed Ontario Toxics Reduction Strategy
Strives to improve the protection of human health and the environment from the risks that can be posed by chemicals.	"An Act respecting pollution prevention and the protection of the environment and human health in order to contribute to sustainable development."	Will comprise a new toxic reduction legislation that would reduce pollution, and inform and help protect Ontarians from toxic chemicals in the air, water, land, and consumer products.

The approaches are substantially different, each with their own merits and challenges.

1. Data Gathering

REACH	CEPA 1999	Proposed Ontario Toxics Reduction Strategy
The onus is on industry to demonstrate the safe use of its chemicals throughout the supply chain.	Requires the government to assess all substances currently on the market and request information from industry when necessary.	Benefits from the assessments done in other jurisdictions to move forward with priorities and requires industry to document its use of certain substances.

[1] Strategic Approach to International Chemicals Management http://www.saicm.org/index.php?ql=h&content=home

In practice each seeks to minimize significant adverse impacts of chemicals on the environment and human health. What are the advantages and disadvantages to each approach?

2. Uncertainty and Action

REACH	Chemicals Management Plan
Requires the testing of the basic physical chemical properties of the substances. Industry is required to identify and fill the data gaps. Registration for high volume, high hazard substances is required by December 2010.	The CMP categorization efforts were based on the best available literature to date and modeling in the absence of measured data. For the high priority substances in the Industry Challenge program risk management measures are being proposed based on this information. The direction for the medium priority substances is unclear.

How much information is necessary to act? What are the consequences of waiting to fill the data gaps or moving forward using the best available data considering impacts on human health, the environment and industry?

3. Substitution

REACH	CEPA 1999	Proposed Ontario Toxics Reduction Strategy
Requires a substitution analysis for a request for authorization of a particular Substances of Very High Concern. Substitution is also encouraged through the restriction of certain substances.	Substitution can be encouraged under risk management measures such as pollution prevention plans. Further, the Challenge Questionnaires (under CMP) request information regarding substitution options and barriers to achieving substitution. This information will then be used to identify industrial best practices, in order to set benchmarks for risk management and product stewardship.	Encourages industry to identify opportunities for substitution, to improve the environment and human health, through materials accounting.

What are the advantages and disadvantages to each approach?

4. Consumer Products

REACH requires the notification of substances of very high concern in consumer products and registration for articles that intentionally release products. **Is this approach sufficient? Why, why not?**

5. Chemicals Management Along the Supply Chain

In most jurisdictions substances are managed at each industry level individually, making it difficult to manage substances with wide dispersive uses. REACH requires the manufacturer of a substance to ensure the safe use of its product along the supply chain. **What are the implications for Canadian products?**

Appendix 3 — Breakout Session II Questionnaire

Participants are invited to discuss the ways in which Canadian Programs may benefit from the assessments of substances under REACH and how we can build on the REACH experience.

Discussion Questions

As we heard during this afternoon's discussion, REACH will generate a significant amount of information that will be made publicly available through the worldwide web. Further, REACH provides the EU with the authority to disclose information received under this legislation to third party countries and international organizations, provided that it meets two conditions.[2]

In each of your packages we have provided you with a timeline for each policy.

During this session we invite you to discuss the following questions.

1. Given the information generated from REACH, how can we incorporate it into Canada's current programs?
2. Although REACH applies to the European Economic Area, there are indirect effects for Canadian industry. Companies exporting to the EU must comply with REACH in order to access the European market. How can we take advantage of their participation in order to further chemicals management policy in Canada?
3. REACH, CEPA 1999-CMP Challenge and the Ontario Toxics Reduction Strategy all rely and produce 'Lists'. How can we design policy to take advantage of these lists but ensure they are used appropriately?
4. The CMP Challenge Program will result in proposed risk management measures for the high priority substances based on the currently available information. What processes are available to ensure that these assessments are updated with the new information stemming from REACH over the next few years, as soon as 2010?

[2] Title XII Information Article 120
Notwithstanding Articles 118 and 119, information received by the Agency under this Regulation may be disclosed to any government or national authority of a third country or an international organization in accordance with an agreement concluded between the Community and the third party concerned under Regulation (EC) No 304/2003 of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals1 or under Article 181a (3) of the Treaty, provided that both the following conditions are met:
(a) the purpose of the agreement is cooperation on the implementation or management of legislation concerning chemicals covered by this Regulation;
(b) the third party protects the confidential information as mutually agreed.

Appendix 4 — Post-Workshop Clarifications

During the workshop two points of discussion were raised for future consideration. As follow up, the following clarifications are provided here.

1. Responsibility of Non-EU Manufacturers under REACH

During the workshop, participants raised the question as to whether or not REACH required non-EU manufacturers to adhere to the same safety standards outside the EU. Under REACH, non-EU Manufacturers can appoint an "only representative" based in the EU to undertake their registration duties. In the event that an exposure scenario is required, the exposure scenario shall cover any manufacturer in the Community (European Economic Area) and all identified uses.[3] Responsibilities begin once the substance has entered the Community.

2. Aggregate Exposure[4] and Multi-Contaminant Exposure[5]

During the workshop, participants raised the question as to whether or not the exposure assessment conducted under REACH required an analysis of the aggregate exposure for human health and whether the effects of multi-contaminant exposure were considered. The required exposure assessment under REACH does require an analysis of aggregate exposure. The specific approach is outlined in the guidance materials.

In the case of assessing the impact of exposure to multi-contaminants, known as combined exposure under REACH, the requirements are somewhat more complicated. For the analysis of combined exposure to humans, the following is stated in the guidance material:

> "In special cases, where exposure occurs to a substance as well as to several very closely related and similar acting chemical substances (e.g. different salts of a metal or closely related derivatives of organic substances), the exposure evaluation and risk characterisation should reflect this aspect. If data are available the exposure assessment should also include a scenario concerning this combined exposure. One way to conduct risk characterisation for combined exposure to closely related analogues could be to add exposures and

[3] Registration, Evaluation, Authorization and restriction of Chemicals REGULATION (EC) No 1907/2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL. Annex I s.5.1.1 Development of Exposure Scenarios

[4] Aggregate exposure - potential exposure to a single chemical by multiple routes to individuals in a population.

[5] Multi-contaminant exposure - exposure to an individual of multi-contaminants

> to use a toxicological descriptor from a representative substance among the analogues. If data do not allow for a quantitative assessment, an attempt should be made to address the issue in a qualitative way."[6]

According to the guidance materials for REACH, the assessment of the general population exposure to substances under REACH considers aggregate exposure in the following ways:

1. Risk characterization ratios (RCR) are generated for each exposure route. If exposure is simultaneous the systemic effects are considered through the summation of these RCRs (for simultaneous exposure via three routes) = RCR (oral) + RCR (dermal) + RCR (inhalation) This is especially important when the individual RCRs are just below one, their summation would result in an inability to demonstrate safe use. The calculation has to be performed for chronic effects, and if relevant, separately for acute effects. Separate calculations are performed for the different populations (workers and the general population).[7]

2. If different products result in the release of the same substance, the combined exposure should be calculated in order to estimate the RCR.

Further, when evaluating the exposure to the general population, consumer sub-populations need to be considered (e.g., children) for particular uses.

In addition, the general population exposure must consider exposure from consumer products, exposure as a result of being near where a substance is being used or has been used (including indoor air), and exposure of humans via the environment (e.g., exposure of humans via consumption of food and drinking water, inhalation of air and ingestion of soil, which in turn are directly influenced by the release of the substance into the environmental compartments).

These approaches described in the REACH guidance are not as sophisticated as those described for pesticides in http://www.epa.gov/pesticides/trac/science/, where when quantifying exposure: "the expanded approach will consider consistent spatial, temporal and demographic/behavioural factors as well as linkages among product and overlapping exposures in developing population-based distribution of individual exposure by probabilistically considering these exposures on an individual-by-individual basis, combining these exposures into a population-based distribution, and examining exposures to individuals on a collective basis...".

[6] Concise Guide on CSR – Part E Risk characterisation http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_en.htm

[7] (E.3.5.1 p.27) http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_part_e_en.pdf?vers=20_08_08

However the suggested approach under REACH for evaluating exposure is a tiered approach with the first tier as the reasonable worst-case scenario for each exposure route using the assumptions that the release of the substance is instantaneous and there is no removal.

At the second tier, the more refined approach is used for estimation which allows the specification of some parameters as distribution and a distributed calculation can be performed. The parameter changed is the release of the substance over time. These models are explained in the Appendix of Guidance on information requirements and chemical safety assessment Chapter R.15: Consumer exposure estimation.[8]

In regards to multi-contaminant exposure, REACH is designed on a single substance basis and as such, exposure to multiple contaminants is still not considered. However, it could be argued that REACH is bringing together these multiple contaminant groups through exposure scenario development that could lead to future evaluations and further understanding of what the picture might look like in the case of multiple exposures.

As previously mentioned, there is opportunity in the guidance document to consider multi-contaminant exposure if the data are available for environment and human health — E: 4.5 Combined Environmental Exposure mentions assessment of "similar acting chemicals (e.g., different salts of a metal or closely related derivatives of organic substances)." The overall exposure assessment should reflect this multiple contaminant exposure, at least qualitatively.

[8] http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r15_en.pdf?vers=20_08_08