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APPROACHES TO EXPOSURE ASSESSMENT IN OECD MEMBER COUNTRIES: REPORT FROM THE POLICY DIALOGUE ON EXPOSURE ASSESSMENT IN JUNE 2005

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No. 51

APPROACHES TO EXPOSURE ASSESSMENT IN OECD MEMBER COUNTRIES: REPORT FROM THE POLICY DIALOGUE ON EXPOSURE ASSESSMENT IN JUNE 2005

Environment Directorate

ORGANISATION FOR ECONOMIC CO-OPERATION AND DEVELOPMENT

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No. 37, *Detailed Review Document on Classification Systems for Substances Which Pose an Aspiration Hazard (2002)*

No. 38, *Detailed Background Review of the Uterotrophic Assay Summary of the Available Literature in Support of the Project of the OECD Task Force on Endocrine Disrupters Testing and Assessment (EDTA) to Standardise and Validate the Uterotrophic Assay (2003)*

No. 39, *Guidance Document on Acute Inhalation Toxicity Testing (in preparation)*

No. 40, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures Which Cause Respiratory Tract Irritation and Corrosion (2003)*

No. 41, *Detailed Review Document on Classification in OECD Member Countries of Substances and Mixtures which in Contact with Water Release Toxic Gases (2003)*

No. 42, *Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure (2003)*

No. 43, *Draft Guidance Document on Reproductive Toxicity Testing and Assessment (in preparation)*

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The Environment, Health and Safety Division publishes free-of-charge documents in nine different series: **Testing and Assessment**; **Good Laboratory Practice and Compliance Monitoring**; **Pesticides and Biocides**; **Risk Management**; **Harmonisation of Regulatory Oversight in Biotechnology**; **Safety of Novel Foods and Feeds; Chemical Accidents; Pollutant Release and Transfer Registers; and Emission Scenario Documents.** More information about the Environment, Health and Safety Programme and EHS publications is available on the OECD's World Wide Web site (http://www.oecd.org/ehs/).

This publication was produced within the framework of the Inter-Organisation Programme for the Sound Management of Chemicals (IOMC).

The Inter-Organisation Programme for the Sound Management of Chemicals (IOMC) was established in 1995 following recommendations made by the 1992 UN Conference on Environment and Development to strengthen co-operation and increase international co-ordination in the field of chemical safety. The participating organisations are FAO, ILO, OECD, UNEP, UNIDO, UNITAR and WHO. The World Bank and UNDP are observers. The purpose of the IOMC is to promote co-ordination of the policies and activities pursued by the Participating Organisations, jointly or separately, to achieve the sound management of chemicals in relation to human health and the environment.

Foreword

This document summarises the outcome from a Policy Dialogue on Exposure Assessment which was held on 6-7 June 2005 in Paris, in conjunction with the 38th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. This document also includes meeting documents attached as annexes, which were developed from the information received from member countries. This document is a synopsis of current activities regarding exposure assessment for industrial chemicals in a number of OECD member countries and does not necessarily provide a comprehensive description of all activities in all member countries.

This document is published on the responsibility of the Joint Meeting of the Chemicals Group and Management Committee of the Special Programme on the Control of Chemicals of the OECD.

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Executive Summary

One of the goals of the OECD Environment, Health and Safety Programme is the harmonization of approaches for risk assessment of chemicals in member countries. While there is a significant level of sharing of approaches used for hazard characterization for risk assessment, this is not the case for exposure characterization. In order to address the issues associated with exposure assessment, a Policy Dialogue on Exposure Assessment was held on 6-7 June 2005 in Paris, in conjunction with the 38th Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology. The objectives of the dialogue were to:

- Discuss general policy issues associated with exposure assessment including fate assessment.
- Share information, at a policy level, on similarities and differences in how exposure assessment is conducted among OECD members, and identifying major policy issues.
- Identify areas where mutual understanding would lead to more consistency and commonality among countries.

In order to facilitate the dialogue on the issues described above, a set of questions were sent to member countries and the responses to them from Australia, Canada, Japan, the United States and the European Commission were compiled in tables. This exercise was considered particularly helpful in highlighting the similarities and differences in approaches of member countries.

Participants generally recognized that the dialogue had been a very useful initial exchange of information on policy issues relating to exposure assessment. There was general recognition of broad consistency in the overall approaches used by different countries in conducting exposure assessment. However, it was also recognized that there is variation in policy related factors, including the regulatory context for assessment and the way that information is applied, as well as in the types of approaches and tools used.

There was general agreement among participants on a need for further dialogue to better understand commonalities and differences in exposure assessment.

This document summarises the outcome from the dialogue, including meeting documents attached as annexes, which were developed from the information received from member countries. This document is a synopsis of current activities regarding exposure assessment for industrial chemicals in a number of OECD member countries and does not necessarily provide a comprehensive description of all activities in all member countries.

Introduction

Background

1. There have been, and continue to be, significant efforts for standardization of approaches used to characterize the hazard of chemical substances. These include, for example, Test Guidelines for evaluating the toxicity of substances. Given that hazard properties of substances are inherent, results from their testing in any location may be applied in any other location. This is not the case for evaluation of exposure to substances, which is fully dependent on location both in terms of proximity to sources of release of chemicals and in terms of the properties of the environment which affect their dispersion and fate. Nevertheless, there are certain features of exposure assessment common to different countries, such as the types of tools that may be used to measure or estimate the presence of a substance and the types of information needed for such estimations. As an initial step to identify areas where agreement of approaches may be improved, the 37th Joint Meeting in November 2004 agreed, upon a proposal from the Japanese Delegation, to hold a Policy Dialogue on Exposure Assessment back to back with the 38th Joint Meeting.

Objectives and Scope of the Policy Dialogue

2. The Policy Dialogue on Exposure Assessment was held to:

- Discuss general policy issues associated with exposure assessment which should include fate assessment and cover the impacts on both human health and the environment.

- Share information, at a policy level, on similarities and differences in how exposure assessment is conducted among OECD members, and identify major policy issues, their nature and possible approaches to consider them.

- Understand policy factors and conditions to ensure the effectiveness and workability of exposure assessment and to identify areas where mutual understanding would lead to more consistency and commonality among countries.

3. Although technical and policy considerations could be intertwined, the scope of the dialogue would be limited only to policy considerations related to exposure assessment.

Preparation for the Dialogue

4. A steering group, consisting of Australia, Canada, Japan (lead country), the US, the European Commission, IPCS/WHO, BIAC and the Environmental NGOs, was established. Shigetaka Seki representing Japan chaired the Steering Group. The Steering Group developed the agenda of the Dialogue (attached as Annex 2), and an outline paper including a number of specific questions to be addressed at the Dialogue (attached as Annex 3).

5. Prior to the Dialogue, member countries were invited to provide summary descriptions of their national and/or regional approaches on exposure assessment for new/existing industrial chemicals. Six individual countries and the European Commission responded (attached as Annex 6). In addition, these member countries and the Commission also provided responses to a list of detailed questions, developed by the Steering Group, regarding policy considerations and factors related to exposure assessments. The submitted information was then compiled and incorporated into 2 tables (attached as Annexes 4 and 5) for comparative analyses.

Dialogue

Opening

6. The list of participants is attached as Annex 1. Roger Tregunno chaired the Dialogue. Jack de Bruijn (EC), Don Gutzman (Canada), Nhan Nguyen (US) and Eisaku Toda (Japan) acted as rapporteurs. Shigetaka Seki introduced the purpose and scope of the Dialogue.

Session 1: Policy issues related to performing exposure assessments

7. The first session involved discussion of policy issues related to performing exposure assessments. Nhan Nguyen of the US EPA presented a light analysis of the general information submitted by member countries and the European Commission as well as a light analysis of responses to the list of 13 detailed questions (Annexes 4 and 5) pertaining to policy issues on exposure assessment.

8. Some general observations on analyses of policy issues related to performing exposure assessments in the contexts of both new and existing chemicals were provided as follows:

- Regarding evaluation target; most countries consider general population, consumer, occupational and environmental[1] exposure.

- Regarding generic versus site-specific assessment; most countries indicate that site-specific information is used when appropriate. There is variation on how generic and site-specific information are used in combination.

- Regarding measured data versus model estimates; most countries indicate that measured data are preferred if they are of good quality. Modelled data can also be very useful and complementary to monitoring data.

- Regarding tiered approaches; all countries have some form of screening level assessments that can be augmented with more specific assessments; however, assessment approaches vary among countries.

- Regarding life cycle; almost all countries attempt to consider the life-cycle of a chemical. Japan does not consider this for new chemicals and only implicitly for existing chemicals.

- Regarding anticipated uses; all countries except Japan indicated that potential uses should be considered for new chemicals exposure assessments.

9. This introductory presentation was followed by presentations by Chris Money (BIAC), Richard Dennison (Environmental NGO) and Take Fukushima (OECD Secretariat), based on documents attached as Annex 7. IPCS had also submitted a document, but could not attend the Dialogue.

10. The participants were invited to discuss the following issues:

- How does one determine the screening or comprehensive level of exposure assessment and the use of models vs. monitoring data for new chemicals and for existing chemicals?

- What are the major factors for policy decisions regarding this?

[1] Environmental exposure is usually expressed in terms of environmental concentration in air, water, sediment or soil.

- How is the performance of the exposure assessment scheme determined and related to its cost?

- How do the approaches used to conduct exposure assessment account for possible changes in use pattern of the chemical over time?

Session 2: Responsibility

11. Shigetaka Seki presented the summary of the light analysis of the questionnaire.

- For new chemicals, manufacturers are responsible in general for providing required data to the government. The government conducts the assessment and requests additional information from the industry if needed.

- For existing chemicals, all countries use secondary sources to obtain data, and have other mechanisms by which industry may submit information to the government upon request or on a voluntary basis. All countries also require that manufacturers/users submit known information to the government. Types of information and the frequency of submission vary among countries.

12. The participants were invited to discuss the following issues:

- Who has the responsibility to provide exposure information, and how is the appropriate level of information to be provided determined?

- For screening and comprehensive exposure assessments, what is the responsibility of the regulatory body? What is the responsibility of industry/enterprise/applicants?

- What is the role of enforcement in the collecting or reporting of exposure information? Do civil liability issues exist with regard to the submission of exposure information, including its accuracy? If so, what are they?

Session 3: Common and unique factors

13. Nhan Nguyen presented an analysis of the responses of the member countries to questions concerning common and unique factors, identifying the following areas for such factors:

- regulatory context

- jurisdictional background

- required level of evidence

- special hazards or populations of concern (e.g. PBT, children), and

- geographic/demographic.

14. The participants were invited to discuss the following issues:

- Can the information requirements for industry for screening level assessment and comprehensive assessment be influenced by factors unique to individual countries?

- What could be such unique factors?

- What are the common factors?

Major conclusions

Monitoring vs modeling

15. Monitoring data are valuable as confirmatory information for exposure assessment. Monitoring data are also used for evaluation of the effectiveness of management measures, and for identifying future problems. Measured data are generally preferred over model estimates when available.

16. The following are some limitations and challenges of monitoring data:

- They are not typically relevant for new chemicals
- Monitoring is not possible for large numbers of existing chemicals due to cost. Risk screening using model estimation may be needed.
- Consideration for monitoring strategy to ensure temporal and spatial representativeness is needed.

Harmonisation of model approaches

17. There is recognition among the participants that there are different factors and assumptions used in models intended for similar purposes. The OECD Task Force on Environmental Exposure Assessment (TFEEA) has worked on the comparison of default values and assumptions used in different exposure models. The achievement of the Task Force in harmonizing multimedia models for overall persistency and long range transport estimation was noted.

Tiered approaches to exposure assessment

18. All countries have some form of screening level evaluations that can be augmented with more specific assessments. However the actual approaches vary among countries and their legislative contexts.

19. Tiered approaches may be useful for identifying chemicals for collection of more detailed data. Tiered approaches may need to be flexible to allow iteration. Understanding of the triggers and factors that influence different countries to transition from screening level to a more detailed level assessment may provide insight into potential areas for further work.

Targeting and/or tiering the assessments

20. Tierred approaches may also be useful for identifying uses of a substance which may warrant further investigation (i.e. targeting). A screening level assessment that is based on conservative assumptions can provide information on potential risks of the various uses of the chemicals as well as insight on the relative exposure and/or risks of the uses. If no potential risk is identified for all the uses using a screening level assessment, no further work is needed. However, decision and policy makers should be well informed about the criteria used in such a screening assessment. They should be conscious of the possibility that substances that are screened out with having no or low potential risk could in reality still cause concern for areas not or only partly covered in a targeted screening exercise.

21. Member countries may benefit from sharing information on the EU ESR study on success/failures of priority setting decisions (RIVM Report 601504002: Evaluation of EU Risk assessments Existing Chemicals (EC Regulation 793/93)).

Transparency

22. It was recognized and generally agreed by the participants that transparency is an important consideration in preparation of exposure assessments as well as in the reporting of exposure information. Exposure assessments must provide information on how they were done and the factors considered in the risk decision making process. Transparency also enhances public confidence in the outcome of risk assessments.

Information collection and assessment

23. It was suggested that general production volume and use pattern information could be more easily shared among countries. However, detailed information is necessarily collected on a case-by-case basis. Member countries take different approaches for collecting this information e.g. setting conservative default values and inviting more realistic data from industry, peer consultation processes, etc.

Exposure Test guidelines

24. It was agreed that it will be useful to share information and experience on exposure test guidelines. However, this is a new area and it may be difficult to begin developing Guidelines in the short term. A leaching test developed in the Netherlands could provide a basis for a generic test. Bilateral discussion between the US and EU could lead to broader interest in other countries.

Commonalities and differences

25. It was suggested that further policy dialogue should focus on the similarities in approaches among countries, but that we also need to understand the rationale for the differences. Information exchange in these areas could be difficult at the Joint Meeting level; however, case-by-case examples may come up in SIDS[2] Initial Assessment Meetings (SIAM) or TFEEA discussions.

Proposals for future activities

26. The following four activities were proposed:

- Case studies using examples from post-SIDS[3] exposure information, comparing how exposure information is used by different countries in assessments of specific substances. This may be followed up by means of a workshop considering:
  - Different model assumptions
  - Triggers and factors for moving up the tiers of exposure assessment
  - Common or different data elements collected and used for environmental, occupational and consumer exposure assessment.

[2] Screening Information Data Set: The minimum data elements needed for initial assessments of high production volume chemicals (HPV chemicals) under the OECD HPV Chemicals Programme.

[3] Under the HPV Chemicals Programme, only minimum exposure information is required for the initial assessments in order to put the initial hazard assessment into context. If the chemical is considered to warrant further testing and/or assessment beyond the initial hazard assessment or further action related to its management, SIAM will recommend that the chemical is a "candidate for further work" and post-SIDS exposure assessment in follow-up to SIAM will be undertaken nationally (or regionally), according to national/regional priorities, in the majority of cases.

- Noting that monitoring is costly but very useful, a general discussion on national monitoring efforts to understand current and possible common approaches is proposed. The discussion could include biomonitoring of human and possibly non-human organisms. It should be noted that the latter can be complicated as it involves multiple environmental media and a wide range of variables. The Task Force on Environmental Exposure Assessment is already working on guidance related to environmental monitoring, and should continue its work. Guidance should be provided on how to address biomonitoring.

- Exchanging information on approaches used to estimate the cost to industry to respond to government requests for information or data ("reporting burden").

- Consideration of the practicality of doing an overview analysis to compare inventory and exposure information across member countries (production levels and volume trends in different jurisdictions over time).

27. After the Dialogue, the 38th Joint Meeting agreed that this dialogue should continue, with participation of more member countries. The next policy dialogue may be a half-day session back-to-back with the Joint Meeting. Suggested topics for discussion at a future dialogue may include:

- Biomonitoring

- Burden estimation approaches

- Inventory comparison

ANNEX 1: LIST OF PARTICIPANTS

Australia	
Mr. Graeme BARDEN	Director, Department of the Environment and Heritage
Ms. Deborah WILLCOCKS	Team Leader, Existing Chemicals, National Industrial Chemicals Notification and Assessment Scheme (NICNAS)
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European Commission (EC)	
Mr. Bjorn HANSEN	European Commission DG Environment Unit C.3 - Chemicals
Mr. Jack DE BRUIJN	Administrator Joint Research Centre Institute for Health and Consumer Protection European Commission
Business and Industry Advisory Committee (BIAC)	
Mr. Richard HOLT	Regulatory Consultant E.I. DuPont de Nemours
Mr. Chris MONEY	Industrial Hygiene Advisor - Europe Exxon Mobil Petroleum and Chemical
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Environmental NGO	
Mr. Richard DENISON	Senior Scientist Environmental Defense
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ANNEX 2: AGENDA OF THE DIALOGUE

DAY1: SESSION 1/ Policy Issues Related to Performing the Exposure Assessment

Monday, 6 June 2005 (Room 3, starting at 14h00 and ending at 17h10)

Agenda	
Brief Introduction to the Policy Dialogue *(14h00-14h10)*	
1.	**Opening**
	Scope and Objective
Session 1: Policy issues related to performing the exposure assessment *(14h10-17h10)*	
2.	**Introduction *(30 min, 14h10-14h40)*** • *Light Analysis on National/Regional information: Policy issues related on performing exposure assessment.* • *Current activities of IPCS* ***(CANCELLED)*** • *BIAC's perspective and activities* • *Environmental NGO's perspective* • *Current activities of the OECD Task Force on Environmental Exposure Assessment*
3.	**Dialogue *(60 min, 14h40-15h40)***
	Coffee Break (30 min, 15h40-16h10)
3.(cont.)	**Dialogue (cont.) *(60 min, 16h10-17h10)***

DAY2: SESSION 2/ Responsibility and SESSION 3/ Common and Unique Factors

Tuesday, 7 June 2005 (Room 4, starting at 09h30 and ending at 12h30)

Agenda	
Session 2: Responsibility *(09h30-10h30)*	
4.	**Introduction *(5 min, 09h30-09h35)*** • *Light Analysis on National/Regional information: Responsibility*
5.	**Dialogue *(60min, 09h35-10h35)***
	Coffee Break: (20min, 10h35-10h55)
Session 3: Common and unique factors *(10h55-12h00)*	
6.	**Introduction *(5 min, 10h55-11h00)*** • *Light Analysis on National/Regional information: Common and unique factors*
7.	**Dialogue *(60min, 11h00-12h00)***
	Coffee Break: (15min, 12h00-12h15)
CLOSING SESSION *(12h15-12h30)*	
8.	**Chair's summary**
9	**Other business**

ANNEX 3: OUTLINE OF THE POLICY DIALOGUE ON EXPOSURE ASSESSMENT (FEBRUARY 2005)

The Policy Dialogue on Exposure Assessment will be organized in the three following sessions which address important policy issues. The first session is expected to take half a day (afternoon of Monday, 6th June 2005, starting at 14h00) and the other two sessions are expect to take together half a day (morning of Tuesday, 7th June 2005).

Session 1: Policy issues related to performing the exposure assessments

This session will address issues such as:

- How do you determine the screening or comprehensive level of exposure assessment and the use of models vs. monitoring data for new chemicals and for existing chemicals?
- What are the major factors for policy decisions regarding this?
- How is the performance of the exposure assessment scheme determined and related to its cost?
- How do the approaches used to conduct exposure assessment account for possible changes in use pattern of the chemical over time?

Session 2: Responsibility

This session will address issues such as:

- Who has the responsibility to provide exposure information, and how is the appropriate level of information to be provided determined?
- For the screening and comprehensive exposure assessments, what is the responsibility of the regulatory body? What is the responsibility of industry/enterprise/applicants?
- What is the role of the enforcement in the collecting or reporting of exposure information? Do civil liability issues exist with regard to the submission of exposure information including its accuracy? If so, what are they?

Session 3: Common and unique factors

This session will address issues such as:

- Can the information requirements for industry for screening level assessment and comprehensive assessment be influenced by factors unique to individual countries?
- What could be such unique factors?
- What are the common factors?

Detailed questions that may be considered in each session

1/ Policy issues related to performing the exposure assessments

(1) What is the role of model estimation of exposure versus environmental or occupational monitoring data? This includes exposure related data such as emission or biomonitoring and environmental fate data. Which data has priority, and how do they complement each other? What is the role of and approaches to the estimation versus measurement of chemical property data that are used for exposure estimation (e.g. persistence, accumulation, leaching)? What steps are taken to ensure that the sum of measured and modeled/estimated data address and are representative of the full range of actual and potential exposures?

(2) How do you evaluate the data quality and limits of use of submitted data?

(3) What is the role of and approaches to the use of site specific exposure estimation versus fugacity or other generic 'global' models?
(4) What is the policy consideration to identify possible environmental degradation products, metabolites, incineration products and sewage/drinking water treatment transformation products, and to assess their chemical properties and fate?
(5) What is the policy consideration to consider long range transport potential of a substance?
(6) How do you consider to run multimedia models to generate estimates of 'overall' environmental persistence?
(7) What assumptions do you use regarding the use of wastewater treatment prior to release of a substance to the environment and the type and efficiency of the wastewater treatment process?
(8) What assumptions do you use regarding the removal of a substance during drinking water treatment?
(9) Whether and when do you use the on-site release and exposure information from the industry submission or standard, and usually more protective, assumptions and models (e.g., how to deal with submitted release estimates which are much lower than model results, etc.)?
(10) How do you deal with significant data gaps during screening versus comprehensive assessment stages (e.g., inadequate information on: production, formulation and/ or industrial end use; equipment, shipping containers, and process flows; release points or exposure activities; concentrations in formulations; physical states relevant to releases or exposures; media to which the chemical will be released; likelihood and effectiveness of treatment; etc.)? What conservative assumptions do you use in the absence of information on chemical properties, environmental fate data, releases, etc?
(11) Do you consider exposures for likely uses other than the intended use reported by the company? (most relevant to new chemicals).
(12) When potentially relevant data are available for a similarly exposed population or for a similar chemical, to what extent do you apply the data to a similar population or chemical? For example, do you use release data (PRTR) or exposure data for one substance as a surrogate for another substance with expected similar releases, uses, or exposures?
(13) Is the effectiveness of engineering controls or personal protective equipment included in the assessment in all cases, some cases, and, if so, under what circumstances?

2/ Responsibility

(14) What regulatory requirement or voluntary programme exists for the reporting of information related to environmental, occupational and consumer exposure to chemicals (e.g. new chemicals notification, assessment of existing chemicals, periodic reporting)? What types or levels of exposure information are reported by industry, for screening- and detailed-level assessment?
(15) What information is developed by governments (e.g. monitoring and modeling)?
(16) What is the role of governments in estimating and assessing chemical exposure?
(17) When two or more data sets exist, do you prepare multiple assessments and then compare? Do you make an initial determination and rely on one of the data sets? How is this be decided? Do you apply other approaches?

3/ Common and unique factors

(18) While hazard, fate, and physical chemical properties test guidelines have been developed by Member countries and in many cases agreed under OECD procedures, exposure test guidelines are generally not available in the same way. Is there a need for establishing a means for Member countries to share experience in this regard? Given the chemical- or scenario-specific issues presented, do you consider it feasible to develop exposure test guidelines? Would this be a useful step for OECD to consider?

ANNEX 4: LIGHT ANALYSIS – MAIN ISSUES

NOTE: This table is a synopsis of current activities in a number of OECD member countries and does not necessarily provide a comprehensive description of all activities in all member countries.

New Chemicals *Session 1: Performing Exposure Assessments*

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
evaluation target	* workplace * general population (air, drinking water) * consumer * aquatic environment	* general population (air, drinking water) * consumer * ecological (multicompartment approach) * Not occupational (this is addressed under Provincial jurisdiction)	* potential adverse impact on general population through environment * potential adverse impact on eco-system * potential adverse impact on workplace (Industrial Safety and Health Law)	* workplace * general population (air, drinking water, fish ingestion) * consumer * environmental (e.g. to aquatic life)	* workers * general population (exposed via environment) * consumer * environmental (aquatic life, terrestrial environment, air)	* workers * consumer	Exposure of general population via air and drinking water and environmental exposure are common. The US, the EU, Finland, Japan and Australia consider occupational exposures
generic/site-specific	site-specific where possible	available site-specific information (e.g., WWTP removal rate, number of production days) is used with generic emission scenario calculations to produce a quasi site-specific release estimate	assessment is substance based assuming generic conditions.	generally site-specific although generic assessments are used when needed.	* Generic exposure scenarios are applied in the first stage of the exposure assessment where exposure models are used * When more specific information on the emission of a substance is available, it may well be possible to refine the generic or site-specific assessment.	does not specifically address.	In general, site-specific exposure assessments are used when appropriate. Generic exposure assessments are used by the US, the EU and Canada to generally describe exposures to a chemical. These generic assessments are tailored for site-specific applications, when appropriate.
measured data/model estimates	measured data are preferred Model calculations are used when there is insufficient measured data.	Both measured data and model estimates are used in the assessment process of new substances, in general. For exposure assessment, releases must be modeled as no monitoring data exist for chemicals not yet entering the environment.	measured data are required for PMN. Estimates may be used complimentary in the assessment of advanced stage (post-manufactured stage).	measured data are preferred	* Measured data are preferred if they are adequate and representative for the situation that is under scrutiny. * Since measured data are not generally available for new chemicals, estimated data are typically used.	Exposure assessments are based on the modelling and default assumptions as well as on expert judgements, since measured exposure data is very seldom available. In general, measured values are prioritised over the modelling predictions.	Measured data are preferred for site-specific evaluations, however, modeled data are very useful when there aren't monitoring data and also to evaluate spatial and temporal variations of exposure.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
tiered approach	yes	yes; can be iterative	yes	yes	There is no formal differentiation; however, Member states can conduct a screening level assessment to determine if a quantitative assessment is necessary.	Somewhat.	All countries have some form of screening level analysis that can be augmented with a more specific analysis if the screening level results indicate a potential for hazard or exposure.
screening-level	* Based on readily available data, conservative assumptions, and simple models * simple models to estimate most environmental concentrations and human doses * most likely environmental compartments for release * occupational exposure assessment is qualitative * attempts to obtain data from industry	* regulatory decisions are based on the outcome of screening level assessments* see response to "advanced-level".	for PMN * Biodegradability is first assessed. * If a new substance is found not biodegradable, it is subject to bio-accumulation and screening toxicity testing. for the Monitoring Chemical Substances at post-manufacturing stage * exposure assessments for chemicals with potential hazard (the Monitoring Chemical Substances) are conducted. The procedures for the exposure assessment are same as those of existing chemicals.	* based on readily available data * conservative assumptions * simple models * allow for quick prioritization for further work	If there aren't sufficiently detailed information, the assessor may use realistic worst-case assumptions and default values.	*Industry conducts a screening level analysis *The authority can request a more refined or more detailed analysis.	See "tiered approach".
advanced-level	* Rare for new chemicals * Highly toxic chemicals or those being used at single site	The answer to this question depends on the definition of 'detailed'. Most often new substances are short screening-level assessments, but can become quite detailed when required and data are available. This said, the level of detail would not reach that of most Canadian Priority Substance List reports for existing substances.		* rare for new chemicals * requires more data * requires more sophisticated models * uses actual environmental conditions and exposures	* refinement of assessment using a more realistic exposure prediction, where needed and possible.	Advanced exposure models or databases are very rarely used, and measured exposure data are seldom available.	See "tiered approach".
considering life cycle	yes	yes, although there is generally insufficient information to undertake full life cycle analysis	* for PMN, not explicit but evaluation of biodegradability and	yes	yes	Exposure assessment concentrates mainly on the current use pattern.	All but Japan and Finland indicated that life cycle should be considered.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
considering potential use	yes	yes	bioconcentration as indicators of potential exposure is effectively covering the issues of chemicals * for the Monitoring Chemical Substances, not explicit but emphasis on monitoring data are effectively covering the issues of the chemicals	yes	yes (see also answer to question 11)	not addressed.	All but Japan and Finland indicated that potential uses should be considered.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
requiring information	Responsibility of the importer or manufacturer of new chemicals to provide a dossier of all the information required. (according to categories of chemicals. existing, generate, and modeled data associated with the notified chemical or an acceptable analogue.) * chemical identification data * physical and chemical properties * manufacture/import volume * environmental release * environmental fate * toxicity to aquatic organisms * uses * intended disposal options * human exposure * number and category of workers * nature of work done * measures and equipment used for exposure prevention * education and training	Responsibility of the importer or manufacturer of new chemicals to provide all the information required. Canada receives a similar minimum premarketing set of data to that of the EU. In terms of exposure information, this is currently limited to general description of import/manufacture location, use, volumes, release and disposal. Downstream information is often not provided or known. Canada and other countries are working with the OECD to formalize an exposure reporting template for new substances to help fill exposure data gaps. More detailed exposure information can be requested from a Notifier using a template format, if required.	Responsibility of the importer or manufacturer of new chemicals to provide all the information required, and the Authority evaluates the exposure potential and hazard potential with these data. for PMN * chemical identity * biodegradability * planned quantity of manufacture or import * intended use(if not biodegradable) * bioconcentration property * screening toxicity test data to mammal and aquatic organisms for the Monitoring Chemical Substances at post-manufacture stage * shipping volume for production/import per use	Responsibility of the importer or manufacturer of new chemicals to provide all the information required, and EPA conducts a screening level exposure assessment. all available data on * chemical identity * production volume * manufacturing process * byproducts * use * human exposure * environmental release * disposal practices * physical properties * environmental fate	*Responsibility of the importer or manufacturer of new chemicals to provide all the information required * Further information may be supplied in response to requests of the competent authorities as an outcome of the initial assessment. * Member States are requested to submit their unpublished information on the priority chemicals if the information may exist in Member States other than that of the rapporteur.	new chemicals information is submitted by industry: * health hazards * flammability * explosivity Industry has main responsibility for a screening assessment.	In general, it is the manufacturers' responsibility to provide required data to the government. The government conducts the assessment and requests additional information from industry if needed.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
evaluation target	* workplace * general population (air, drinking water) * consumer * environmental	* general population (via environment) * consumer * ecological (multicompartment approach) * Not occupational (this is addressed under Provincial jurisdiction)	* Potential adverse impact on general population through environment * Potential adverse impact on eco-system	* workplace * general population (via environment) * consumer * environmental	* workers * general population (exposed via environment) * consumer * environmental (aquatic life, terrestrial environment, air)	* workers * consumer	Exposure of general population via air and drinking water and environmental exposure are common. The US, the EU, Finland and Australia consider occupational exposures
generic/site-specific	where possible site-specific conditions are considered	* using site-specific information but concluding in a generic way	assessment is substance based assuming generic conditions.	generally site-specific although generic assessments are used when needed	* Generic exposure scenarios are applied in the first stage of the exposure assessment where exposure models are used * When more specific information on the emission of a substance is available, it may well be possible to refine the generic or site-specific assessment.	does not specifically address.	In general, site-specific exposure assessments are used when appropriate. Generic exposure assessments are used by the US, the EU and Canada to generally describe exposures to a chemical. These generic assessments are tailored for site-specific applications, when appropriate. To clarify, monitoring data (which are inherently site-specific) may be used to interpret the range of exposures taking place in Canada to obtain an estimate of realistic worst case conditions. Such information is then used in making a generic conclusion of risk for the substance.
measured data/model estimates	* measured data preferred * use model estimates if insufficient measured data	* both can be used in a weight of evidence context. * they are very complementary .	* measured data preferred * use model estimates if insufficient measured data	measured data preferred.	* Measured data are preferred if they are adequate and representative for the situation that is under scrutiny.	In a case of existing chemicals measured exposure data is often available in open literature and from industry. In some cases consumer organizations may submit exposure information.	Measured data are preferred for site-specific evaluations, however, modeled data are very useful when there aren't monitoring data and also to evaluate spatial and temporal variations of exposure.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
use of monitoring data	worker data	* monitoring data carries significant weight	emphasis on environmental monitoring data in advanced-level exposure assessments	a well-designed monitoring study is desirable	monitoring data are gathered and provide the potential for greater insight into specific steps of the exposure assessment procedure.	Measured data are prioritized over modelled data.	All countries agree that monitoring data are very useful

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
tiered approach	priority setting →screening-level refine	* priority setting, selection→screening-level→PSL assessment. *Regulatory decisions of risk will generally take place at what is called the "screening assessment" stage, although in some cases, it may be deemed desirable to proceed to a PSL assessment. * simple exposure tools are developed for priority setting	in Japanese initiative on investigating existing chemicals * Biodegrability is first assessed. * If an existing substance is found not biodegradable, it is subject to bio-accumulation and screening toxicity test.for the Monitoring Chemical Substances * priority setting (as screening-level) → advanced-level * In priority setting for (advanced) exposure assessment of the Monitoring Chemical Substances, amounts used in a open system are considered as indicators for exposure properties. * Screening of existing chemicals is exposure and toxicity based. If a chemical has risk potential, then the Authority will conduct an advanced-level assessment. all available information on exposure, including environmental monitoring data, PRTR data, and model estimates, is to be considered	level of assessments depends on assessment purposes. Screening level (including priority) --> Advanced-level	level of assessment depends on amount of exposure information available and whether the assessment can be limited to certain protection targets.	Exposure assessment within the EU Existing chemicals regulation is a step-wise procedure. According to the EU Technical Guidance Document and our experiences the steps often include the following:· Uses of the chemical and relevant applications and industrial processes are identified. · All relevant analytical data on the concentration of the chemical in the workplace air, concentration in products, oral intake, skin deposition etc. are obtained. · Conditions and parameters relevant for the identified exposure scenarios are clarified and listed. · When analytical measurements are not available, a suitable modelling tool (e.g. EASE, EUSES, Riskofderm, Consexpo) is selected for the assessment. · In a case when the measured or estimated exposure is close to the critical/harmful level/dose, measurements are made and/or the key parameters are re-examined to avoid any underestimation of the exposure.· The normal and reasonable worst case exposure is reported and used for the risk characterisation. In some cases also peak exposures are considered.	Thoughts of both screening-level and advanced-level are very different among countriesAll countries have some form of screening level analysis that can be advanced to a more specific analysis if the screening level results indicate a potential for hazard or exposure. In Canada, regulatory decisions will generally be taken following what the law refers to as a "screening assessments", which can range from a very simple to quite detailed analysis. A limited number of cases will continue to very detailed assessment as Priority Substances.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
screening-level	* readily available data * conservative assumptions * simple models * most likely environmental compartments for release	* complex exposure tools for human health and ecological assessments * realistic worst-case scenarios (most parameters of significance in the exposure characterization) * regulatory decisions generally based on the outcome of screening assessments * ranging from very simple to quite detailed	See "tiered approach"	*based on readily available data * conservative assumptions * simple models * allows for quick prioritization for further work	If there aren't sufficiently detailed information, the assessor may use realistic worst-case assumptions and default values.	Not explicitly addressed.	See "tiered approach"
advanced-level	* using ESDs * sophisticated validated models for representative local conditions	* Some assessments conducted under our "screening assessment" program can involve quite advanced analysis. *Chemicals nominated to the Priority Substances List (PSL) undergo in-depth assessment, which can require up to 5 years. * PSL assessments may be conducted at conclusion of, or in place of, screening-level assessments although regulatory decisions often taken at screening stage	See "tiered approach"	* requires more data * requires more sophisticated models * uses actual environmental conditions and exposures	* refinement of assessment using a more realistic exposure prediction, where needed and possible.	Not explicitly addressed.	See "tiered approach"
considering life cycle	yes	Yes	not explicit but emphasis on monitoring data are effectively covering the issue of the life cycle of chemicals	yes	yes.	not addressed.	All countries intend to consider the life cycle. of a chemical in conducting an assessment.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
system for data gathering	* attempt to obtain data from industry * calling for environmental exposure information by notice prior to commencing the assessment * PRTR, public literature, industry surveys	* no fixed requirement for the submission of data for purposes of existing substance assessments. * CEPA 1999 provides the authority to carry out industrial surveys and to require companies to supply specified information * Assessments also make use of other sources of information such as PRTR, literature, etc.	* CSCL obligates the manufacturers and importers of the Monitoring Chemical Substances to report shipping volume per use * Other applicable data source on exposure is PRTR data, environmental modeling data by authority.	* variety of regulatory and voluntary approaches with limited exposure reporting * developing and reporting voluntary exposure information and data through informal arrangements or through organized programs	* Responsibility of the importer or manufacturer of priority existing chemicals to provide all the information required. * Rapporteurs of priority existing chemicals should consult published and unpublished data. * Member States are requested to submit their unpublished information on the priority chemicals if the information may exist in Member States other than that of the rapporteur.	Data sources include:- Information from the industry, from reports, reviews and from safety data sheets.- Published articles, data from the industry, unpublished reports	All countries use secondary sources to obtain data for existing chemicals, and have other mechanisms by which industry may submit information to the government upon request or on a voluntary basis.
requiring information	(depending on level of assessment) * uses * manufacture/import volume * number and category of workers * nature of work done * measures and equipment used for exposure prevention * education and training * information or statistics on work-related injuries/disease * atmospheric monitoring data * biological monitoring data * published epidemiological reports	CEPA provides the authority to survey companies and require them to supply information of the following types: * reporting of engagement in an activity involving a specified substance * provision of any information and samples that a person possesses or may reasonably be expected to have access to * conducting toxicological or other specified tests Further, there is a "reverse onus" requirement for companies to submit information on a substance that reasonably supports a conclusion of toxicity to human health or the environment. There is also compulsory annual reporting for about 300 substances to the	manufacturers and importers of the Monitoring Chemical Substances are required to submit annually * shipping volume for production/import per use * If the potential risk of a Monitoring Chemical Substance is found significant based on the result of the advanced assessment, authority may ask the manufacturers and importers of the chemical to conduct toxicity investigation.	Requires reporting every 4 years * production volume * site of manufacture * site-limited status Requires reporting of additional exposure-related information in 2006 including processing and use information for sites producing/importing about 150 tons/year.	* The amount of information that the manufacturer needs to provide obligatory is limited to: - production/import volume, - information on the manufacturing process, and - a description of his own use and the way he knows the substance is used by his customers. * In more advanced stages, the industry gathers more detailed information on - actual emissions and exposure and - on more specific down-stream application of the substance, including for instance concentration in typical formulations and/or consumer products.	*The authority is responsible for preparing the risk assessment. *Industry has an overall responsibility to provide exposure information. However research institutes and other EU member states may provide additional information on exposures. The information is then checked by STTV.	All countries require that manufacturers/users of chemicals submit known information to the government. The countries vary on the type and of information and frequency of submissions that are required.

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
		PRTR.					

Session 3: Common and Unique Factors

	Australia	Canada	Japan	USA	EU	Finland	Comments/Summary
	* Information requirements depend on regulations, significant risk findings, and special hazard concerns. *No difference between information requirements of new and existing chemicals when making decisions about future use. * Overseas data may be used, but actual risk must consider "Australian condition", such as demographic, ecosystem, patterns and conditions of the chemical use in Australia, etc. to determine actual risk posed by a chemical and its management * currently reviewing environmental assessment methods * internationally accepted models are used (e.g. EASE)	* Substance-based assessments (new and existing chemicals) * Consideration of other potential uses (new chemicals) * Allowing regulatory decisions by screening assessments * Utilizing estimation and modeling approaches for chemicals whose data are limited to assess, like PBT chemicals * Regulatory obligation on industries for collection of data * A flexible, weight of evidence framework for evidence consideration and data interpretation * occupational exposure falls under provincial jurisdiction. * PBT characteristics and temporal trends in exposure are considered.	* Conducting exposure assessments for hazardous chemicals on nation-wide basis, as the objective of the law is to prevent long-term and nationwide risks of hazardous chemicals.	* Exposure assessments for new chemicals is based on whether he chemical "may present an unreasonable risk", as opposed to exposure assessments for existing chemicals which are based on whether the chemical "will present an unreasonable risk." * Special consideration on children's exposure	In the TGD in the first stage of the exposure assessment where exposure models are used, generic exposure scenarios (a non-existing model environment) are applied because typographical and climatogical conditions vary among Member States.	In principle, the information requirements for industry for screening level assessment and comprehensive assessment may be influenced by factors unique to individual countries. Maybe the most important reasons are related to "public's attitude and concerns". In addition, national programs etc may have influence.	See below.
			Comments/Summary The purpose of session 3 is to provide an opportunity to discuss and clarify common and unique factors among member countries on policy issues related to exposure assessment. In addition to the common and unique factors identified and discussed in sessions 1 and 2, member countries identified additional factors in response to questions raised in session 3. These additional factors can be grouped into the following categories: 1. Regulatory and jurisdictional related: Regulations within each country can dictate how exposure assessments are done. An example of the former is Japan, where exposure assessments are based on nation-wide information because the law calls for preventing long-term risks of chemicals. An example of the latter is Canada, where occupational exposure falls under provincial jurisdiction. 2. Regulatory requirement for data submission: Also relating to regulatory powers, there is significant variation between countries in the ability to obtain exposure related industrial information, particularly with respect to existing substances. Such legislative ability ranges from required, periodic submission of data on a range of substances, to required submission of data on request to support assessments, to reliance on voluntary agreements for submission. 3. Required level of evidence of risk: Each country has different standards in terms of required level of evidence in exposure assessment. For example, regulatory decisions in Canada are based on "screening assessment" for both new and existing chemicals, recognizing that such assessments may cover a wide range of level of comprehensiveness. In the US, exposure assessments for new chemicals are based on whether the chemical "may present an unreasonable risk" finding whereas those for existing chemicals are based on "will present an unreasonable risk" finding. 4. Special hazard or population of concern: Member countries have varied interests in some categories of chemicals and/or unique populations. For example, Australia has special concerns for PBT chemicals. The US has special concerns for children's exposure. 5. Geographic/demographic: Exposure can vary due to differences in geographic or demographic factors even though the assessments are done using similar exposure scenarios (e.g. manufacturing operation of the same chemical). Overseas data can be used, but actual risk must consider local conditions, such as demographics, ecosystems, and chemical use patterns and conditions in a particular country, to determine actual risk posed by a chemical, and its management. Such variations may occur within a single country or across countries within a regulatory jurisdiction (e.g., the EU).				

ANNEX 5: LIGHT ANALYSIS – DETAILED QUESTIONS

NOTE: This table is a synopsis of current activities in a number of OECD member countries and does not necessarily provide a comprehensive description of all activities in all member countries.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
(1-1) What is the role of model estimation of exposure versus environmental or occupational monitoring data? This includes exposure related data such as emission or biomonitoring and environmental fate data. Which data has priority, and how do they complement each other?	Occupational: Monitoring data is preferable for estimation of potential exposure. However, the reliability of the data and its ability to be representative, are considered in the assessment. Model calculations are used to estimate typical and 'reasonable worst case' exposure levels when no measured data are available. Environmental: Model estimation using 'reasonable worst case' is usually used to fill data gaps as monitoring data are typically not available, even for existing chemicals.	Both monitoring data (when available) and model estimations are considered in characterizing exposure to substances. They are seen as complimentary in the information that they provide. Monitoring provides more accurate data in relation to specific samples, while modeling can be superior in demonstrating spatial and temporal variations. Temporal variations may relate, for example, to release of substances that are used intermittently or in a batch process by a facility. "Averaging periods" for exposure data are also important to consider in appropriate matching with effects threshold concentrations in risk characterization. Environmental fate processes are often only possible to address through modeling. Further, recognizing that monitoring data are not available for new or many of the existing substances that we are compelled to assess, modeling is an essential approach for	In exposure assessments under the law, the authority gives priority to environmental monitoring data, and takes account of the results obtained by model estimation and PRTR emission data complementarily.	Model estimation is usually used to fill data gaps if monitoring data are not available or if data quality is questionable or poor. Monitoring data from appropriate, properly conducted studies would generally be preferred over modeled estimates. The U.S. Environmental Protection Agency, Geological Survey, Center for Disease Control, and other government agencies collect monitoring data on a national scale to characterize exposures to the environment and humans. Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs,	For measured data, the reliability of the available data has to be assessed as a first step. Subsequently, it must be established how representative the data are for the situation that is assessed. For model calculations, the procedure to derive an exposure level should be made transparent. The parameters and default values used for the calculations must be documented. If different models are available to describe an exposure situation, the best model for the specific substance and scenario should be used and the choice should be explained. If a model is chosen which is not described in the TGD, that model should be explained and the choice justified.	In general, measured values, including biomonitoring data, are prioritised over model predictions. However, the measured observations must be collected from a representative situation by using acceptable methods and strategies. Furthermore, the number of samples (exposure measurement) must be reasonable. In addition to measured values and model estimates also expert judgement is widely used.	The US, Finland, Australia, and Japan all state that monitoring data are preferable to modeling data. Canada believes that monitoring and modelling data provide different and complementary information. Canada does not consider occupational exposures, since the responsibility for this is on the provincial level. Canada and Australia note that modeling is most useful for estimating typical and worst case exposures when no monitoring data are available. The US also notes that modeling data are useful when monitoring data are lacking. Canada additionally notes that modeling is useful to calculate temporal and spatial variations of exposure. The EU notes that measured data are preferred, provided they are adequate and

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		filling data gaps in a cost effective manner. Occupational exposure is not considered within the new or existing substances programs at the national level. Rather, individual provinces are responsible for monitoring occupational exposures. A table summarizing some of the monitoring initiatives in Canada has been prepared to accompany the country summary and responses to questions. It provides an overview of major national and international monitoring programs. It also includes examples of other types of sources of monitoring data that are used in conducting risk assessments of existing substances under CEPA. It is worthy of note that the majority of the chemicals routinely monitored by these programs have either already been assessed by the existing substances program at Environment Canada and Health Canada, or are being managed under other programs in the departments. A very low fraction of the chemicals that our existing substances program will be assessing in future are addressed by the monitoring networks. For some substances, data from other sources, such as		including the National Air Quality System, the National Air Toxics Assessment, the Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database. All of these data may be used for site specific data, where available, and may be used to construct exposure models, where appropriate.			representative.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		individual research studies of environmental monitoring or biomonitoring, may be available for consideration in assessments. For a very large number of substances, it is expected that no monitoring data exists.					
(1-2) This includes exposure related data such as emission or biomonitoring and environmental fate data.	No specific answer was provided for this question.	Considered in interpretation of the previous question.	Did not specifically address this question.	Yes.	Considered in interpretation of the previous question.	Considered in interpretation of the previous question.	Canada, the EU, Finland and the US note that their response to question 1 included this consideration.
(1-3) Which data has priority, and how do they complement each other?	Valid measured values have priority. Estimated values are used as a check on the measured values, where appropriate. They also provide a 'ball park' estimate in the absence of measured data.	As representing a specific location and time, monitoring data will generally carry greater weight Reliable monitoring data also serves in determining the validity of modeling results on a case-by-case basis. Modeling can also be used in the planning stage of a monitoring program, when deemed necessary, to help determine appropriate sampling locations, etc. (Note that targeted funding for monitoring is used very infrequently in our programs.) See also answer to the question two above.	Did not specifically address this question.	Valid measured values have priority, and estimated values are used as a check on the measured values, where appropriate.	It may seem that measurements always give more reliable results than model estimations. However, measured concentrations can have a considerable uncertainty associated with them, due to temporal and spatial variations. Both approaches complement each other in the complex interpretation and integration of the data. Therefore, the availability of adequate measured data does not imply that model calculations are unnecessary.	Measured data have priority, as long as they meet quality criteria.	Australia, Finland and the US state that valid measured values have priority over modeled data. Canada believes that monitoring and modelling data provide different and complementary information - monitoring data providing more accurate exposure values at a specific location and time; modelling data providing more information on temporal and spatial variability. Canada states that measured values can provide a check on the accuracy of model values. Canada also notes that modeling can be used to plan sampling programs to collect monitoring data.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
							EU treats data according to the quality and conditions for each data set.
(1-4) What are the role of and approaches to the estimation versus measurement of chemical property data that are used for exposure estimation (e.g. persistence, accumulation, leaching)?	Valid, measured values for hydrolysis, soil sorption, biodegradation (ready, inherent), BCF, etc. are preferred. In the absence of these data, conservative estimations for these endpoints are made using models. In this respect, scientific judgment is important.	Measured data for physical/chemical properties are generally preferred, although suitability of the measurement approaches must be taken into consideration. Measured data are not available for the large majority of existing substances therefore modeling is used extensively to estimate properties. Physical/chemical property data are required data elements for new substances at specific import or manufacture trigger quantities. The data are used to help understand chemical fate	For the evaluation of biodegradability and bioaccumulation, the authority uses actual testing data. If actual data is not available, the authority may use QSAR data to estimate parameters such as Henry's Law constant, Kow, Koc Ozone reaction constant and OH radical rate constant, to be used in model estimation.	Valid, measured values for BCF, biodegradation (ready, inherent) photooxidation, hydrolysis, soil sorption, etc. are preferred. In the absence of these data, the applicability of the estimation method to the specific chemical of interest is evaluated, and if the methods are appropriate, estimations for these endpoints are made using the models.	Not specifically answered.	Did not specifically address this question.	Australia, Canada, and the US state that valid measured chemical property data are preferred; however, in the absence of such data, estimation methods may be used, with careful consideration of the estimation method for a particular chemical. Japan uses measured data for biodegradation and bioaccumulation values. When actual data aren't available, Japan uses QSAR data to estimate input parameters for model estimation of biodegradability and bioaccumulation.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		and behaviour in the environment and potential for human and non-human organism exposure. This can be done qualitatively or using fugacity-based multimedia models. In addition, considerable experience in model use and evaluation of the reliability of estimated properties has been obtained through the process of "categorizing" the 21,800 substances on Canada's domestic substances list. Evaluation of the persistence, bioaccumulation, and inherent toxicity properties for these substances required initially estimating a number of phys/chem properties.					Canada notes that the majority of existing chemicals do not have measured data for these values, and therefore modeled data is significant. Measured phys-chem data are provided for new substances notified at higher volume triggers.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
(1-5) What steps are taken to ensure that the sum of measured and modeled/estimated data address and are representative of the full range of actual and potential exposures?	The relevance of a model to a given chemical is a matter for judgment, but this is often difficult, as Australia mostly does not have access to the databases behind the various models that are used.	Approaches used in new and existing substances assessments attempt to realistically estimate the range of concentrations of exposure in the environment, in particular those concentrations that may represent realistic worst case exposures. This makes use of both available monitoring data and modeled concentrations. Multimedia models are often used to determine relevant exposure media for both human and non-human organisms based on partitioning behaviour of a chemical. This approach attempts to cover the full range of potential or actual exposures expected. Health assessments can also take direct human exposure via products into consideration.	Actual monitoring data is the base for decision making. Complimentarily, various types of model estimations may be used, including those which use the PRTR emission data, according to particular situations of the cases and actual monitoring data of key spots are used to compare the actual and estimated concentration data.	A data characterization step is used to describe how exposures in the assessment may compare to expected actual exposures. The assessor may consult data collected under the various exposure monitoring programs conducted by the U.S. EPA, USGS, CDC or other agencies to determine if exposures calculated in the assessment are reasonable.	In many cases, a range of concentrations from measured data or modelling will be obtained. This range can reflect different conditions during manufacturing and use of the substance, or may be due to assumptions in or limitations of the modelling or measurement procedures.	Did not specifically address this question.	The US describes how the estimated exposures may compare to actual expected exposures. Japan uses measurement data primarily and modeled data in the absence of measurement data. Canada's exposure assessments use both measured and modeled data as available. Approaches used in new and existing substances assessments attempt to realistically estimate the range of concentrations of exposure in the environment, in particular those concentrations that may represent realistic worst case exposures. The EU uses data ranges to encompass ranges of exposure.
(2) How do you evaluate the data quality and limits of use of submitted data?	Data generated in accordance with OECD, US or other available international test guidelines are generally acceptable. (It is to be noted that Australia is currently reviewing its environmental assessment methods, including assessment of data quality). Whether submitted data are measured or estimated can influence the degree of conservatism of the assessment.	Professional judgment is used in evaluating the quality and representativeness of data submitted for new and existing substances, taking into account a variety of factors including measurement/estimation approach, and context under which the data was submitted or obtained. Data submitted to the existing substances program is considered on a case-by-case basis and is used in the assessment as	For the evaluation of biodegradability and bioaccumulation, the authority requests GLP data. Other exposure relating information that the authority requests the industry is the quantity of manufacture or import of the chemical substances and its intended use.	Data quality is evaluated considering the method used and other available background information, particularly applicability or representativeness. Limits of use of submitted data depend on the context of the data, including whether the data are measured or estimated and whether other information is available to make judgments about the applicability or representativeness of the data or estimates. The	There are no rules or guidelines available for evaluation of the quality of exposure data that are submitted by industry. Generally the Member States evaluate these data by expert judgement. Monitoring data, in particular those coming from regular monitoring programmes carried out by authorities, are generally generated under specific guidelines and will therefore in most cases not need further data quality	The quality of exposure data is evaluated by checking that the methodology and strategies used in sample collection and analyses are conducted in accordance with generally accepted standards, methods, guidelines or recommendations. However, there is a very limited number of guides on how to conduct human exposure studies. Furthermore, in the current situation GLP (Good	Australia, Finland and the US evaluate data quality based on the method and applicability of the data. Australia and Canada specifically note that data consistent with OECD, the US or other international guidelines are generally acceptable. Japan asks for GLP for measured biodegradability and bioaccumulation data. Currently, Canada asks for data "consistent with GLP" for new substances and under the revised New

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		part of a weight of evidence in concluding on risk. Typically little measured exposure or release data are available for new substances in Canada. Most releases of new substances are estimated. However, detailed release information can be obtained from a chemical company when needed using exposure template documents developed for new substances. Additionally, assessment reports delineate uncertainty and degree of confidence in relevant data, and take this into account in developing conclusions.		uses of estimated values are generally limited to screening level assessments. Data quality considerations are described in the discussion "Determining the Adequacy of Existing Data" on the HPV Challenge Program web page http://www.epa.gov/chemrtk/datadfin.htm.	checks.	Laboratory Practice) is not applicable to human exposure studies as it is to non-clinical safety studies (e.g. toxicity studies). In many cases expert judgement plays a major role in quality evaluations.	Substances Notification Regulations, will require full GLP studies for toxicity and biodegradation studies. Australian and the US may limit the use of data based on whether it is measured or estimated. The US additionally notes that estimated data are typically limited for use in screening level assessments. The EU currently has no data quality guidelines. The Member States evaluate these data using expert judgement.
(3) What are the role of and approaches to the use of site specific exposure estimation versus fugacity or other generic 'global' models?	Site-specific releases and exposures are estimated only where these are limited to one or a few sites. Conservative assumptions are used unless real data are available to allow refinement of these assumptions. Fugacity models are used alongside specific knowledge to estimate how a chemical partitions in the environment. Estimated concentrations of the chemical in individual environmental compartments can be used to characterize risk.	Ecological assessments of new and existing substances frequently emphasize local exposure. Monitoring and modeling are used to quantify risk to organisms in the area most significantly impacted by substances, which is typically close to the point of release. As pointed out in the summary paper, although site-specific information may be used in realistically estimating the range of exposure to an existing substance in Canada, assessment conclusions are based on generic realistic worst-case scenarios, and are not site-	The objective of the law is to prevent long-term adverse effect, through the environment, of hazardous chemicals and focuses on nation wide risks caused by exposure to such chemicals. Therefore, site specific exposure is not assessed under the law.	The US estimates quantitative site-specific (local) releases and exposures because these are more protective. Site specific or generic assessments using conservative assumptions are used to estimate potential quantitative exposures. Fugacity models, at the present time, are used to supplement our understanding of how a chemical partitions in the environment, its potential persistence, and its potential for long range transport. Estimated concentrations of the	For both the local and the regional environment to which emissions take place standard environmental characteristics have been define in the TGD. The local models for air, water and soil are simple 'dilution models' where concentrations in air, water and soil close to point sources are calculated. Site specific information can be used to override certain, if not all, parameters that are used in these models. The regional model uses a global model similar to a fugacity model which is a nested version with local	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.	Australia and the US use quantitative site-specific data where possible, and conservative assumptions when estimates must be made in lieu of measured data. Canada estimates a combination of local and more general exposure based on both data and assumptions representative of realistic worst case conditions. Fugacity modeling is used by Australia, Canada, and the US to model how a chemical partitions in the environment and the long range transport potential.

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		specific. However, for new substances, generic worst-case scenarios can be site-specific, as discussed in the summary paper. Fugacity modeling is routinely used to help understand chemical fate in the environment, and on occasion in addressing exposure to substances that are released from non-point sources. How to best use fugacity modeling based estimates of overall persistence and long-range transport potential as part of a weight of evidence in assessing risk, is being considered. Human health assessment takes local exposure into account where there is likely to be a significantly sized exposed population locally. Typically, however, assessments are focused on exposure of the general population.		chemical in individual environmental compartments are not currently directly used.	point sources, a regional environment and a continental environment surrounding this. The characteristics of the regional environment are defined as a densely populated, highly industrialised region in Europe, the continental environment reflects the continent of Europe.		Japan notes that site specific exposure is not assessed under the law. The EU uses local and regional models to assess exposures in the European continent. The local models contain simple dilution models, and these may be tailored to site specific conditions.
(4) ***What is the policy consideration to identify possible environmental degradation products, metabolites, incineration products and sewage/drinking water treatment transformation products, and to assess their chemical***	Australia considers these factors on a case-by-case basis.	Assessment of degradation products in the risk assessment of new and existing substances is conducted on a case-by-case basis. This depends on the availability of information on the degradation products and their potential to be more problematic in the environment or to human health than the parent compound. Information from experimental studies (e.g., simulation	If significant amount of degradation products, which are not bio-degradable, are found in the bio-degradation test, those degradation products are subject to bio-accumulation and screening toxicity tests.	Under most circumstances (new and existing chemical programs) policy allows EPA to include known and theoretically possible degradation products resulting from environmental degradation, metabolites, incineration and sewage/drinking water treatment in their assessments. This is largely driven by our understanding of the degradation mechanisms	In the assessments consideration must be given to whether the substance being assessed can be degraded, biotically or abiotically, to give stable and/or toxic degradation products. Where such degradation can occur, the assessment should give due consideration to the properties (including toxic effects) of the products that might arise. For new substances, it is unlikely	The question is not in the scope of the STTV's responsibilities of human health risk evaluations	Australia, Canada, and the US consider degradation products on a case-by-case basis, depending on the availability of information and assessment of the level of concern for the product chemical. Canada additionally conducts separate assessments for particular degradation products of concern, such as dioxin/furans.' Japan conducts bioaccumulation and

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properties and fate?		biodegradation tests) or model simulations (e.g., using CATABOL) is considered. If a metabolite is found to be of more concern than the parent (e.g., more P or B or T), then it is included in the assessment alongside the parent. Risk from possible degradation products can be used in concluding on risk from a "parent" substance within our assessment programs. The level of scientific knowledge relating to the degradation processes is an important consideration in making this decision. Conclusions in the risk assessment can be based solely on the degradation product. Industrial by-products, incineration products, etc. can also be defined as "substances" that require assessment directly (e.g., dioxins and furans). If a degradation product is also directly released to the environment (as opposed to being formed in the environment), or if it is formed by the degradation of a number of different substances, then it is often appropriate to carry out a separate assessment of the degradation product (e.g., ozone precursors; formaldehyde).		and pathways relevant to the processes above and our level of concern for the products. In the event that scientifically supportable concerns for these products were raised, policy would support conducting an assessment on those products.	that information will be available on such degradation products and thus only a qualitative assessment would normally be possible. For existing substances, however, known relevant degradation products should also be subject to risk assessment. Where no information is available, a qualitative description of the degradation pathways can be made.		toxicity tests if the biodegradation test indicates a significant amount of degradation products. The EU states that the assessor should consider whether a substance can be degraded, and if so, should address the toxicity and characterization of the degradation products. For new chemicals the assessor conducts a qualitative evaluation of these products, and for existing chemicals, the assessor will evaluate known degradation products.

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(5) What is the policy consideration to consider long range transport potential of a substance?	Australia does not have a formal PBT policy, but long-range transport potential is considered as issues arise, based on considerations of potential persistence and bioaccumulation.	Evidence of long-range transport of a substance can be used as a means to conclude that a substance is persistent in air in our regulatory context (i.e., will likely have a half-life > 2days in air if it undergoes LRT). Such criteria have played a role in the "categorization" of our Domestic Substances List, where the legal definitions of persistence are critical. As with the US there is no policy in place that requires chemicals to be screened for LRTP in ecological risk assessment. Within our ecological risk assessments, chemical properties that suggest a substance may undergo LRT (e.g., persistence in air, high Kaw) can be used to provide evidence of long-range transport. Multimedia models (e.g., TaPL3) can also be used to simulate LRT. However, currently evidence of LRT is only flagged and only on a case-by-case basis in risk assessment. The information from multimedia models for LRT can be used to determine the scale of exposure and likely target areas or organisms exposed (e.g., Arctic environments). It can also support understanding of	As the risks from long-term exposure to chemical substances via the environment are considered in the law, with a priority to monitoring data in decision making, the transport potential of substance is effectively taken into consideration.	Currently EPA estimates the properties necessary to screen chemicals for long range transport potential (LRTP) but there is no policy in place that requires chemicals to be screened or to incorporate that (LRT) characteristic into our assessments. If however a chemical substance elicits concern relating to its possible PBT (persistence, bioaccumulation and toxicity) properties, it is also more likely to be scrutinized for LRTP. This is based on experience. Even though persistence and LRTP are not equivalent properties, long-range transport is an important issue for many substances precisely because they have PBT characteristics, are subject to LRT, and are also redeposited and subsequently bioaccumulated at sites distant from their release. Examples include hexachlorobenzene and some PCBs.	There is no specific policy in the EU towards the assessment of the long-range transport properties of chemicals. The TGD contains a specific chapter which relates to the assessment of the risks for the marine environment, which contains the criteria for the identification of persistent, bioaccumulating and toxic substances (PBTs). No criteria for long-range transport have been identified but it has been realised that in particular for PBT substances the LRT properties may be important and together with high persistence may contribute to the deposition of substances far away form their sources.	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.	Australia, Canada, the EU and the US do not specifically require a chemical's LRTP to be evaluated; however, if a chemical has PBT properties, then LRTP may be considered. Canada may also consider LRTP for non-PBT substances (specifically when a half-life in air is >2 days). Further, LRTP is a factor in determining whether persistence criteria are met, and can play a role in contributing to conclusions of risk in a weight of evidence context. Japan law requires risks from long-term exposure to be evaluated, and incorporates transport potential as part of this.

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		the degree of exposure owing to release of substances from remote, non-domestic sources.					
(6) How do you consider to run multimedia models to generate estimates of 'overall' environmental persistence?	Australia does not have a policy that requires routine multimedia modeling to estimate 'overall' environmental persistence. When it is done, simpler models are used due to the limited available information and expertise. The need for such a policy is, however, under consideration.	For risk assessment, Canada runs multimedia models at Level III complexity either using EQC, ChemCan, TaPl3 or the Level III model in EPISuite. All of the Level III models provide a measure of overall persistence (Pov). However, currently no regulatory benchmarks exist to compare Pov estimates from models. Consequently, information on Pov is used only in a qualitative manner as it provides information on the relative persistence of a substance in individual media as well as the effect of partitioning on persistence and of persistence on partitioning. Pov cannot be used to categorize substances for persistence as currently regulatory half-life criteria are single media based.	The authority may use fugacity-type models to estimate "overall" environmental persistence. However the authority gives priority to environmental monitoring data.	In EPA a multimedia model is run for all new chemical assessments where there are adequate input data and the model is appropriate for the type of chemical under consideration. This is not based on a policy decision, rather it is because the model exists as part of a set of models that are run together automatically in EPISUITE for all new chemicals. Overall persistence is an output of many level III models. However, currently there is no policy in place that requires calculation of overall persistence or uses this information in our assessments.	In the EU there's no policy or common practice towards the use of multimedia models to generate estimates of 'overall' environmental persistence. Persistence in the context of the PBT assessment (see previous question) is generally assessed though the (bio)degradation half-life values for water, sediment, air and soil based on laboratory or field studies.	The question is not in the scope of the STTV's responsibilities of human health risk evaluations	Australia does not routinely run multimedia modeling due to limited available data. Canada runs Level III multimedia models to determine environmental fate according to the expected modes of entry into the environment, but does not use overall persistence for persistence evaluation as P half-life criteria are single media-based. Japan uses fugacity models to estimate overall persistence. The US runs EPISUITE Level III complexity persistence modeling for all new chemicals that have adequate input data.
(7) What assumptions do you use regarding the use of wastewater treatment prior to release of a substance to the environment and the type and efficiency of the wastewater	If the effectiveness of on-site treatment is known, these are taken into account when estimating the amount of chemical entering STP. Activated sludge treatment is assumed. Removal efficiency is then estimated using an Australia-specific STP model that includes the EU	In the initial (conservative) stage of exposure characterization of existing substances it is usually assumed that there is no removal by a sewage treatment plant. If a potential risk is identified, then one of a number of available models may be applied to refine the release estimation for the	The removal of a chemical substance by the use of water treatment may be considered for detailed exposure assessment. However this factor is not used under the law so far, because this factor is effectively counted when the authority uses limited amount of environmental monitoring data to	Activated sludge treatment is assumed to be the treatment process in place, either at the industrial facility or in the municipality treating wastewater from the industrial site. The removal efficiency for the substance of interest is estimated using the STP model component of	In the risk assessment a proper functioning of waste treatment is assumed. The situation with respect to wastewater treatment at industrial installations is less clear. It may be assumed that many of the larger industrial installations are either connected to a municipal wastewater treatment plant	The question is not in the scope of the STTV's responsibilities of human health risk evaluations	Australia and Canada (new substances) assume activated sludge treatment of wastewater and use a STP model to estimate removal. The US assumes no removal at the screening level. A more refined model may be used if a potential risk is identified,

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treatment process?	SimpleTreat tables. The model estimates removal based on physical and biodegradation processes.	substance. Models may also be used to allow comparison with industry submitted removal efficiency data. Significant work is currently under way to evaluate the validity of STP removal results obtained using a number of different commonly available models. During the ecological exposure assessment of new substances, discharge to waste treatment facilities, either on-site or municipal, is assumed. A similar process to that described above by the US is used. Removal in an STP is either modeled using the fugacity-based STP model or preferentially using data provided by the Notifier. Health assessments of new substances assume no STP removal.	estimate overall exposure.	EPA's EPISUITE estimation models. STP can estimate removal based on physical processes (sorption and volatilization) alone, or using a new method, incorporate biodegradation into the removal estimate. The new method is currently undergoing evaluation. Where properties required as input to the model cannot be estimated, defaults are used based on factors such as chemical class and molecular weight.If a site-specific or industry-specific on-site treatment method other than activated sludge is known to be used, EPA uses estimation methods for those specific treatment types, e.g. oil/water separation.	or have treatment facilities on site. In many cases, these treatment plants are not biological treatment plants but often physico-chemical treatment plants. For a standard regional scale environment (definition see section 2.3.8.1) it is assumed that 80% of the waste water is treated in a biological STP and the remaining 20% released directly into surface waters (although mechanical treatment has some effect on eliminating organic matter, this is neglected because on the other hand stormwater overflows usually result in direct discharges to surface water even in the case of biological treatment. It is assumed that these two adverse effects compensate each other more or less with regard to the pollution of the environment). The degree of removal in a wastewater treatment plant is determined by the physico-chemical and biological properties of the substance (biodegradation, adsorption onto sludge, sedimentation of insoluble material, volatilisation) and the operating conditions of the plant. As the type and amount of data available on degree of removal may vary, the following order of		including the fugacity based STP model or using measured data. Canadian health assessments assume no removal. The EU assumes that wastewater treatment is operating properly, and suggests that removal efficiencies are measured using site-specific data. Where these data are not available, then a wastewater treatment plant model may be used. Japan notes that removal efficiency may be considered for a detailed exposure assessment if data are available. The US assumes zero efficiency for screening level, and uses the STP model in EPISUITE or site-specific information to make more refined estimates. Canada and the US are currently conducting reviews of these methods.

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					preference should be considered. The percentage removal should preferably be based upon measured influent and effluent concentrations. As with measured data from the environment, the measured data from sTPs should be assessed with respect to their adequacy and representativeness. The data may be used provided that certain minimum criteria have been met, e.g., the measurements have been carried out over a longer period of time. If there are no measured data available, the degree of removal can be estimated by means of a wastewater treatment plant model using log Kow (Koc or more specific partition coefficients can also be used; see section 2.3.5). Henry's law constant and the results of biodegradation tests as input parameters.		
(8) What assumptions do you use regarding the removal of a substance during drinking water treatment?	This is outside the remit of the regulatory scheme for industrial chemicals.	As in question7, initially no removal is assumed. If a potentially problematic level of human exposure is noted under this conservative scenario, refinements may be made.	The removal of a chemical substance during drinking water treatment may be considered for detailed exposure assessment. However there has not been such a case so far. The authority may use measured drinking water quality if available. If it is	0 % removal in drinking water treatment is generally assumed for a screening level assessment.	Drinking water is produced from surface water or groundwater, and is modelled as described by Hrubec and Toet (1992). The drinking water module in the present version of the EUSES program which encompasses the models	We may ask the local water company how they process and monitor the water supply. This would then be considered in the exposure assessment. If no data is available on a particular substance in drinking water, then the significance and impact of	Canada and the US assume 0% removal in drinking water treatment, and note that more refined estimates can be modeled as needed. Japan has not encountered this scenario; however, they would use ground water and river water

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			not, measured ground water quality and river water quality may be used as alternative for a consecutive estimation.		included in the TGD, assumes a complete removal of suspended particles from surface water and groundwater. The effects of the treatment processes used for purification of groundwater, which are generally not intended for the removal of organic pollutants, can be neglected. Dependent on the type of storage, two different water treatment systems for surface water can be distinguished: system 1 includes storage in open reservoirs, system 2 includes dune recharge. Removal of the dissolved fraction of a xenobiotic from the surface water is modelled by means of purification factors. For the choice between the two systems and the choice between surface water or groundwater, a worst-case approach is followed. Further details can be found in Appendix II of Chapter 2 of the TGD.	the raw modelling output and the need for possible additional monitoring data would need to be assessed.	quality data to provide a conservative estimate. Australia's drinking water program is outside the scope of the industrial chemicals regulatory scheme. The EU uses the EUSES program to estimate drinking water removals, which assumes a complete removal of suspended solids from surface and ground waters. Then, the type of storage determines additional removal factors that may be used. The EU suggests that the assessor follow a worst-case approach when lacking site-specific information
(9) Whether and when do you use the on-site release and exposure information from the industry submission or standard, and usually more protective, assumptions and models (e.g., how	This is a case-by-case consideration. When a variance does not fit with scientific judgment, the proponent would be asked to make clarifications. Should the variance remain unexplained, conservatism is applied.	There is no fixed standard for making this decision. Professional judgment involving evaluation of all available information (industry data, modeled data, monitoring data) and discussion with industry to try to understand the discrepancy in results support a final decision. For example, industry may be using more advanced	The law does not require manufactures or importers of the chemical substances to submit emission data of chemical substances. However, manufactures or importers of monitoring chemical substances are required to submit the quantity of their products and its intended use. The authority takes into account such data together	If release information in the industry submission is not well substantiated and is significantly lower (e.g. 10 times lower than the standard assumption or model), EPA will use the standard estimate. For consumer exposure, EPA would review the information and make a decision to accept or reject it on a case by case basis.	There are no fixed rules or guidelines defined for taking such decisions. As indicated above the assessments carried out for new and existing substances are normally not addressing specific risks to sites but are intended to assess in general the potential risks to man and the environment from the	If measurements have been conducted under realistic conditions using acceptable methods and standards and the sample size is large enough we prefer measured data.	Australia, Canada and the US review variances on a case-by-case basis and attempt to determine the cause of the variance through clarifications with the manufacturer. If the variance remains unexplained, then the more conservative estimate is used. The E.U. assesses site-

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to deal with submitted release estimates which are much lower than model results, etc.)?		best available technology than was assumed in modeled scenarios.	with available hazard information, monitoring data and estimations to decide if it should issue an order to manufacturer's) or importer's) to provide chronic hazard information of a particular chemical.		marketing and use of these substances. Therefore, in particular for the exposure assessment for downstream uses of a substance, exposure modelling based on generic assumptions plays an important role. This is true for the environmental exposure as well as for the assessment of the workplace. For the actual production of the substances very often the manufacturers are in the position to provide site-specific measurements or emission or exposure information. Generally such data, after checking their quality, are accepted by the authorities and used to override the modelling assumptions.		specific information submitted by industry to evaluate the quality of the data, and then upon data acceptance, will override modeling assumptions with these data. Finland prefers measured data, as long as the data meet quality control criteria. Japan does not request this information from manufacturers.
(10-1) ***How do you deal with significant data gaps during screening versus comprehensive assessment stages (e.g., inadequate information on: production, formulation and/ or industrial end use; equipment, shipping containers, and process flows; release points or exposure activities; concentrations in formulations;***	Industry is obliged by legislation to make a complete data submission, unless granted exemption. Such exemption is scientifically based, so a gap does not arise in these circumstances. When, however, data pertaining to the chemical are not available, the proponent is able to submit data on suitable analogues (with suitability determined early in the assessment process). Another alternative is to provide modeled data. Where data are completely lacking for a given parameter, conservative assumptions	As pointed out in our summary paper, "screening" assessments in Canada can cover a wide range of technical detail, and are intended to routinely lead to regulatory decisions. We do not do "preliminary" assessments as such, although an initial step of our screening assessments may involve the use of highly conservative assumptions to allow rapid identification of less problematic situations. Such conservative assumptions relate to those factors listed in the question, possibly	The authority uses the worst-case assumption that all the amount manufactured or imported for open system use will be released to the environment.	For any assessment stage, EPA generally will make conservative assumptions (e.g. worst-case assumptions of release and exposure scenarios using estimates of releases and exposures that are not expected to be exceeded). More robust data gathering is attempted for the comprehensive stage.	As a matter of principle the generic assessment methodology as described in the TGD can be applied to new chemicals for which a limited amount of information is available to the authorities. The TGD therefore includes a large number of default values and reasonable worst-case assumptions that are needed to carry our the exposure assessment for workers and the environment for the different possible steps in the life-cycle where exposure can occur.	For new substance notifications, the data package is usually sufficient for the estimation of these properties. In other cases, we would ask the industry in question for more details on their processes and their substance. For example, if a powder is assessed, we would assume that it is a dusty powder in case no granulometry data or other information to suggest otherwise is available.	Australia requires industry to submit these data by law. In some cases, similar chemical data or modeled data is used if no data are available. Canada conducts an initial screening assessment using highly conservative estimates to determine whether development of more refined estimates is warranted. Reconsideration of assumptions or soliciting information from industry may be needed to refine these data when a potential risk is identified.

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physical states relevant to releases or exposures; media to which the chemical will be released; likelihood and effectiveness of treatment; etc.)?	are made based on experience to date. Based on the outcome of the environmental hazard and risk assessment, assessment certificates for new industrial chemicals can be withheld/limited/narrowed, effectively preventing or restricting the use of the chemical. For existing chemicals, industry surveys are used to attempt to fill gaps. If necessary, consideration of overseas practices can be used.	supported by other information such as specific data on annual production or import quantities of a substance. If a possible risk is identified, there can be follow-up with affected industries to obtain more realistic data for use in refining the release and exposure estimates. If such data is not forthcoming, the assessment conclusion will be based on these more conservative assumptions.					Japan uses a worst case assumption to make estimates. The US uses the most reasonably conservative assumptions for a screening level, and gathers more refined data for the comprehensive analysis. The EU uses generic scenarios to complete assessments when there are data gaps. Finland requests this information from industry and usually receives a complete data package. If they do not, they request the missing information from the submitter.
(10-2) What conservative assumptions do you use in the absence of information on chemical properties, environmental fate data, releases, etc?	For any assessment stage, Australia would use QSAR to estimate values, to which scientific judgment would be applied. If necessary, worst-case assumptions (e.g., no removal via STP) are made. More robust data gathering is attempted for the comprehensive stage (see above).	For efficiency, first stage exposure characterization is quite conservative with respect to most parameters. If the potential for risk is indicated at that stage, refinement of the characterization involves estimation of parameter values that are believed to be representative of a realistic worst-case scenario. In the absence of empirical information, estimates will tend to be on the more conservative side. There are a number of opportunities for industry to provide comments, and indicate erroneous assumptions	Did not specifically address this question.	EPA models, professional judgment, and information on similar chemicals can provide estimates to fill the chemical properties and environmental fate data gaps in many situations. If EPA is not able to fill the data gaps, conservative assumptions can be made (i.e., higher persistence, lower removal in wastewater treatment and drinking water treatment, etc). For releases, see answer to previous question (10).	Did not specifically address this question.	Did not specifically address this question.	Australia and the US will use data from similar chemicals to make estimates, and if necessary, will use the conservative-end of values to make estimates. Canada uses conservative estimates in the absence of data for a screening level analysis, and will then allow industry to comment on assumptions made if risk is identified.

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		used in our exposure scenarios. These include: discussions with industry during development of the assessment; a science peer review of the assessment, which typically includes technical experts from the affected industry (for ecological assessments of existing substances); and legislated public comment periods associated with publication of the assessment reports (for existing substances). For new substances, an approach similar to that described above by the US is used.					
(11) Do you consider exposures for likely uses other than the intended use reported by the company? (most relevant to new chemicals).	Assessment certificates do not limit the way in which a chemical can be used post-assessment. Secondary Notification conditions can, however, be applied to anticipate significantly changed or increased exposures and assess how they change the risk assessment.	At the present time, existing substance assessments are based on realistic worst case estimates for current known uses only. For new substances, additional likely uses and volumes are forecasted. If a new substance poses no unacceptable risk to humans or the environment, it becomes eligible for listing on the Canadian Domestic Substances List. Once listed it may be used for additional applications at unlimited volumes. Therefore, during the initial assessment, potential other uses and volumes must be forecast and determined to pose no unacceptable risk as well.	Did not specifically address this question.	Sometimes. For example, if other potential use patterns can be identified, EPA may attempt to determine whether those other use patterns may have significantly higher releases and exposures relative to the intended uses. If significantly higher releases and exposures are expected, then EPA may include these other use patterns in the assessment.	Assessments are generally focussed on the intended uses and use conditions indicated by industry. However, in particular for substances used in consumer products, the authorities may also assess the exposure which may results from what is defined as the reasonable foreseeable misuse of these products.	Only the intended use.	Canada (new substances) and the US attempt to predict potential uses and evaluate these as part of an assessment. Australian Assessment Certificates do not consider alternative uses, but Secondary Notification conditions can consider different uses. EU evaluates the intended use of a chemical as well as the reasonable foreseeable "misuse". Finland only considers the intended use.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
(12) When potentially relevant data are available for a similarly exposed population or for a similar chemical, to what extent do you apply the data to a similar population or chemical? For example, do you use release data (PRTR) or exposure data for one substance as a surrogate for another substance with expected similar releases, uses, or exposures?	This would depend on the relevance of the surrogate to the notified chemical, based on scientific judgment.	Emission Scenario Documents (ESD) are developed to allow estimation of release of substances based on their use within an industrial process - in effect using such a surrogate approach. If a suitable ESD is not available, development of such an estimation based on substances having the same known application would be suitable. Use of exposure data in a similar way would have to be considered on a case-by-case basis. Such cases may become more common as we carry out risk assessments of large numbers of lesser known substances identified by the categorization process.	As the authority puts priority on mandatory data, there has not been a case of using the data of similar chemicals in the past. For pre-marketing notification stage the authority dose not request emission related information but information of bio-degradability and bioaccumulation. For the information, information of the chemicals which are considered to have similar properties may be considered by the request of Notifier if appropriate.	EPA will usually use such data to fill data gaps for workplace releases and exposures. EPA sometimes uses consumer exposure data for one substance as a surrogate for another substance with expected similar consumer uses or consumer exposures.	Did not specifically address this question.	This has been applied for existing substances risk assessment. For example, benzene air measurement data during car repair was used for estimating Tert-amyl methyl ether (TAME, additive in gasoline) air concentrations in the same scenario. This could also be valid for new substances, if such data are available.	Australia considers this type of substitution on a case by case basis. Canada, Finland and the US use these data to fill data gaps as is determined to be appropriate. Japan notes that this type of substitution has not been performed previously, however, it would be acceptable to do so if the chemicals had similar properties.
(13) Is the effectiveness of engineering controls or personal protective equipment (PPE) included in the assessment in all cases, some cases, and, if so, under what circumstances?	In all cases, as it is part of the risk assessment (risk mitigation).	Beyond a first stage exposure characterization, engineering controls for which we have information such as sewage treatment plant removal, or stack baghouses would generally be taken into consideration in the release estimation. Occupational exposure is not considered within our programs. Empirical data for the point of release would already account for any controls. However Canada is careful not to limit ourselves to situations where a notifier has gone well above the industry standard in controlling emissions - if	The law does not take into account of engineering control due to the fact that it is not concerned with labor health, which is covered by another law, and focuses on exposure through environment. The other law (Industrial Safety and Health Law) considers occupational exposure.	Engineering controls are usually very difficult to factor into a quantitative assessment and are usually included qualitatively. Personal protective equipment (PPE) is included only when all exposed populations are expected to use PPE (e.g., gloves for corrosive materials, etc.).	Whether or not engineering controls of PPE is included in the assessment is very case dependent. In some cases industry was able to demonstrate convincingly that certain controls are common practice throughout their sector. Similarly, for substances classified as corrosive it is generally assumed that PPE is used. On the other hand there have been cases where it was assumed that PPE was not used (e.g. in the construction sector) despite the labelling of the substance.	For industrial chemicals the exposure estimation is conducted without PPE. In some cases (new or existing substances), the effect of PPE could be taken into account in risk characterization and only when industry has documentation that PPE is always used in that particular exposure scenario. For chemicals in consumer use the estimation is always made without PPE. However, the definition of PPE sometimes seems to be unclear.	Australia and Canada consider engineering controls as part of the risk assessment. The US considers these controls qualitatively. Australia and the US consider PPE, however, the US only considers PPE when all exposed populations are expected to use PPE. The EU considers PPE and engineering controls on a case by case basis. In Canada, occupational exposure is addressed under provincial law.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		we suspect they have, we will assess their approach as well as industry standard					
(14-1) What regulatory requirement or voluntary programme exists for the reporting of information related to environmental, occupational and consumer exposure to chemicals (e.g. new chemicals notification, assessment of existing chemicals, periodic reporting)?	Occupational: Industry is required to provide information relevant to occupational exposure for both new and existing chemical assessment. Typical information required includes information on uses, manufacture/import volume, number and category of workers, nature of work done, measures and equipment used for prevention of worker exposure, education and training on practices and procedures, information or statistics on work-related injuries/diseases, atmospheric monitoring data, biological monitoring data; and published epidemiological or case reports. All this information is taken into consideration during exposure assessment. Consumer: Industry is required to provide information relevant to consumer exposure (to consumer products only) for both new and existing chemical assessment. Environmental: there currently is no requirement to report environmental	Annual reporting of releases of specific substances to the National Pollutant Release Inventory is required. Also, CEPA states that a manufacturer/importer or commercial processor of a substance who obtains information that reasonably supports a (potential) risk associated with a substance must provide this information to the Government. A limited amount of data is collected through this mechanism. There are also fairly broad powers for the collection/generation of data needed for conducting risk assessments, as mentioned in the summary paper. This power has been used to collect information for existing substances assessments. There have also been requests for voluntary submission of data by industry in relation to the categorization initiative. Further, a table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, has been prepared to accompany the country summary and responses to	Under the law, the industry is obliged to report the quantity of the chemicals manufactured or imported if the chemicals are the Classes I-III monitoring chemical substances and the Classes II specified chemical substances. The production and import of the Classes I specified chemical substances are banned. Regarding class II specified chemical substances, industries additionally have to report the amounts of the chemicals planned to be manufactured or imported. The authority conducts a nation wide survey every three years to investigate the amounts of all chemicals which are manufactured in or imported to Japan. Regarding class II specified chemical substances, industries additionally have to report the amounts of the chemicals planned to be manufactured or imported. The authority conducts a nation wide survey every three years to investigate the amounts of all chemicals which are manufactured in or imported to Japan.	These programmes are summarized in the US discussion paper for this dialogue. This paper includes new chemicals, existing chemicals reporting under the inventory update rule (IUR), and the Voluntary Children's Chemical Evaluation Program (VCCEP). In addition to regulatory requirements and voluntary reporting under TSCA, there are several monitoring efforts conducted by the U.S. government. Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System, the National Air Toxics Assessment; Toxic Release Inventory, and	See introduction on the legislative framework above. Other than that there are no EU wide programs to report exposure information. However, in the context of national programs for emission registration (PRTR) there are different initiatives where such information is gathered. Similarly a number of EU Member States have product registers where a lot of information on the use of chemicals in products is gathered on a regular basis.	Under new chemicals notification, the notifier is requested to submit the base set of data. If however, the conditions change significantly, e.g. production volume use or exposure, this needs to be reported to the authorities. Same applies if any new data become available.	Australia requires industry to submit information to describe occupational and consumer exposures for new and existing chemicals. Australia requires reporting of environmental releases under separate legislation, but is considering coordination with industrial chemical legislation. Canadian law states that industry must submit any risk-related data to the Government for both new and existing substances. Canada requires industry to annually report releases to the environment of existing substances specified on the PRTR list. There are also broad powers for requiring submission of requested information. Additionally, Canada provides assessment information to industry and allows comment on assumptions made. There have also been requests for voluntary submission of data. New Substance Notifications must contain certain useful exposure information, but additional data can be requested from the Notifier if necessary.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
	releases except in accordance with PRTR (National Pollutant Inventory) legislation and specific licenses that may or may not be issued by State authorities and which do not directly relate to the regulation of industrial chemicals per se. This matter is the subject of intergovernmental consideration.	questions. Included among the examples of other sources of information is an industry initiative for monitoring and public reporting. Information from such sources is taken into consideration in conducting risk assessments under CEPA. For new substances, all information in the Notifier's possession must be submitted at the time of notification if it relates to one of the information requirements in the New Substance Notification (NSN) Regulations. This would include all exposure related information. Occupational and consumer exposure information is not a requirement under the NSN regulations but can be submitted voluntarily if available.	The industry is required to report to the authority of the new findings of hazard information, if any, on the chemical substances which are included in either the existing or the new chemical substances lists.	through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database.			Japan requires industry to submit production volume information and any new hazard findings for new and existing chemicals. Finland also requires industry to submit exposure information and any new information that would affect the exposure and risk assessment. The US requires industry to provide screening level data on occupational, consumer, and environmental releases. Annually, industry is required to submit data quantifying annual releases of certain chemicals to the environment under TRI and production volume information under IUR. The HPV Challenge program and the VCCEP program request manufacturers to submit more detailed hazard and exposure data. The EU requires assessments to be conducted according to the guidance and directives they have established; however, it is the responsibility of the Member State to conduct the assessment for new chemicals. For existing chemicals, the Member States designate rapporteurs to conduct risk

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
							assessments for priority chemicals. Other than these programs, there is not an EU-wide program requiring report of exposure information.
(14-2) What types or levels of exposure information are reported by industry, for screening- and detailed-level assessment?	Except for certain cosmetics and trial uses, reporting by industry is not required. For existing chemicals, industry is required to provide whatever such information it has.	As discussed in the summary paper and in question 10, there is no formal distinction between the approaches (e.g., level of realism, complexity) used for "screening" and detailed assessments in our programs. For existing substances, there is no predefined reporting requirement. There are predefined information requirements laid out in the New Substance Notification regulations including those for exposure. The NSN regulations have recently been revised, but have not yet been publicly released. More detailed exposure information will be required under the new regulations. The current regulation and NSN reporting guidelines can be found at: http://www.ec.gc.ca/substances/nsb/eng/index_e.htm	The authority requests industries to report the quantity of monitoring chemical substances which are manufactured or imported, and its intended use. These information will be used both for screening- and detailed-level assessment.	See the US discussion paper for a listing of the information reported for these programmes. For new chemicals, the reporting form for new chemicals is available in two parts at http://www.epa.gov/oppt/newchems/pmnpart1.pdf and http://www.epa.gov/oppt/newchems/pmnpart2.pdf. The reporting for new and existing chemicals and the initial tier of VCCEP include primarily screening-level exposure information.	Not specifically addressed.	Finnish Institute of Occupational Health maintains a registry of occupational hygiene measurements and a database on Finnish Job Exposure Matrices (FINJEM) which consists of analytical data evaluated and summarized by experts. Information on chemical releases from products may be received from market surveillance conducted by consumer product agency.	Australia requires industry to provide all data on existing chemicals. Canada does not distinguish between screening and detailed assessment data, and does not define reporting requirements for existing chemicals. For new chemicals, industry will be required to submit some detailed exposure information. Japan requests industry to report production and use information. The US requires industry to submit primarily screening-level exposure information for both new and existing chemicals. Finnish Institute of Occupational Health maintains a registry of occupational hygiene measurements and a database on Finnish Job Exposure Matrices (FINJEM) which consists of analytical data evaluated and summarized by experts. Information on chemical releases from products may be received from market surveillance

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
							conducted by consumer product agency.
(15) What information is developed by governments (e.g. monitoring and modeling)?	Governments have developed some modeling (e.g., removal by STP) but mostly accesses models developed by international regulatory authorities. Monitoring for workplace exposure to hazardous substances is required by Commonwealth legislation. The need for environmental monitoring is under consideration.	Most monitoring data is obtained from the literature or research facilities, many of which are affiliated with Environment Canada. Environment Canada is directly involved in a number of atmospheric, aquatic, terrestrial and wildlife monitoring initiatives. Health Canada has initiatives relating to the monitoring of media of human exposure and levels in biological tissues. A	Other than those mentioned above, the authority have been developing environmental monitoring data, PRTR data including estimation values. And also each ministry has been developing models such as air quality models both for wide area and site specific, Tokyo bay model and models of major rivers as tools for exposure assessment. To help industry to adequately	EPA develops exposure assessments for new chemicals and some limited number of existing chemicals. These assessments use monitoring data, if available in literature, past research, or industry submissions, and using modeling to fill remaining data gaps. The U.S. EPA, USGS, CDC and other agencies conduct exposure	Most EU Member States have national as well as regional programmes for gathering monitoring information on chemicals in different environmental compartments. In terms of the chemicals concerned these programmes are in most cases not directly linked to the EU priority lists for existing substances. Therefore, authorities generally use these data for their EU assessments when	Model predictions and expert judgement estimations. Sometimes the authorities request a monitoring study, which is usually undertaken by the industry.	Australia primarily uses models developed by international regulatory authorities. Canada conducts most modeling within their program using a combination of models developed in-house and those internationally recognized. Each Japanese ministry develops water and air models, and government makes software tools available to industry. The US uses models to fill data gaps.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, such as Provincial and Municipal governments and industry consortia, has been prepared to accompany the country summary and responses to questions. In a very limited number of cases, targeted monitoring or scientific research may be funded by the assessment program. Most modeling is conducted within the program, although external expertise may be engaged for particularly difficult cases.	control chemicals, government provides various tools and information such as soft ware for risk assessment, risk evaluation reports.	monitoring studies in the U.S. (as noted previously). Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System, the National Air Toxics Assessment; Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database.	available and relevant.		Australia requires occupational monitoring. US uses monitoring data published in literature, past research, or industry submissions for new and existing chemicals. Japan did not address occupational monitoring specifically. Australia is considering legislation to require environmental monitoring. Environment Canada conducts environmental monitoring for a variety of existing substances and coordinates or is involved in a number of monitoring programs and networks. Japan and the US didn't not specifically address environmental monitoring. The EU notes that most EU Member States have national as well as regional programmes for gathering monitoring information on chemicals in different environmental compartments. In terms of the chemicals concerned these programmes are in most cases not directly linked to the EU priority lists for existing substances. Therefore, authorities generally use these data for their EU assessments when available and relevant.most governments have their own programs for collecting monitoring programs.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
(16) What is the role of governments in estimating and assessing chemical exposure?	For new chemicals, industry provides an estimation of exposure and the information on which it is based. The government then ultimately estimates and assesses exposure. For existing chemicals, the government estimates and assesses exposure (e.g., by calling for information or conducting industry surveys).	Under CEPA, the government is responsible for conducting risk assessments, which includes exposure characterization. This does not preclude making use of all available sources of information, or in making arrangements with experts (including those in industry, academia, other government departments, etc.) to generate the necessary data. Governments at various levels are involved in monitoring of contaminants. A table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, such as Provincial and Municipal governments and industry consortia, has been prepared to accompany the country summary and responses to questions.	Under the law, the authority is responsible for conducting exposure assessment.	For new chemicals, the government estimates and assesses exposure. For existing chemicals, the government sometimes estimates and assesses exposure (e.g., in some regulatory efforts, such as determining required chemical testing; and in some voluntary efforts, such as chemical substitution comparisons).	See previous answer and answer under sesion 2: responsibility	Finnish competent authorities assess worker, consumer and environmental exposure. Expert judgement is then applied to the modeling output in order to assess its applicability to real life situations. Sometimes site visits are done to support this.	Canadian, Finnish and Japanese governments are responsible for conducting exposure assessment. Australian industries are responsible for conducting exposure assessment on new chemicals, and the government assesses existing chemicals with assistance from industry as needed. US government assesses exposure for all new chemicals, and assesses exposure for some existing chemicals.
(17) When two or more data sets exist, do you prepare multiple assessments and then compare? Do you make an initial determination and rely on one of the data sets? How is this be decided? Do you apply other	All data sets are usually covered within a single assessment. Data of unknown or poor quality may be referenced but not included in the assessment (with reasons stated).	For both new and existing substance assessments all relevant data sets are considered in evaluating risk taking into account the quality of the information in a weight of evidence approach. Experimental data (including close analogues) are preferred over estimated values.	The competent authority gives priority to measured data than estimated value.	EPA has no fixed policy and would handle these issues on a case by case basis. All data sets are usually covered within a single assessment. Data of unknown or poor quality may be referenced but not included in the assessment. A discussion of data comparison is usually included, and the most representative set may be recommended for use in the risk assessment.	There are no specific rules defined for these situations.	If the two data sets were significantly different from one to another, then expert judgement would be used to decide which is the most relevant and applicable. If the data sets are supportive to each other, then they can be used to refine the assessment.	Australia, Canada, and Japan all consider all data sets and select the most appropriate data to use. Data of known quality are preferred, and other data may be references. US makes this judgment on a case-by-case basis, however, notes that the highest quality data will typically be selected for use in the assessment.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
approaches?							EU does not have specific rules to address this situation. Finland notes that given similar quality, measured data will be preferred.
(18-1) While hazard, fate, and physical chemical properties test guidelines have been developed by Member countries and in many cases agreed under OECD procedures, exposure test guidelines are generally not available in the same way. Is there a need for establishing a means for Member countries to share experience in this regard? Given the chemical- or scenario-specific issues presented, do you consider it feasible to develop exposure test guidelines? Would this be a useful step for OECD to consider?	Australia currently has limited exposure assessment options. The dialogue presents an opportunity to understand what other options might be useful, and thus lead to ongoing sharing of experience.	If this question is interpreted in the context of exposure test guidelines relating to the conduct of site-specific assessments, then the relevant factor is that assessments in the existing substances program are not conducted on a site-specific basis. However, more general guidance relating to the collection and interpretation of monitoring data may prove useful. Such guidance would necessarily need to be fairly non-specific, given the variability of situations and of the chemicals themselves. Guidelines considering issues such as the relative significance of modeled versus monitored data may run into difficulties in identifying approaches that are consistent with the legislative requirements and governing policy considerations of the different jurisdictions. Shared development of specific tools and models is, of course, possible, and much of this is currently taking place within the Environmental Exposure Assessment Task Force	Japan considers that the cooperation among the OECD members on exposure assessment should be useful. Although exposure situations vary among countries, commonality and coherence may be found in methodologies for exposure assessments. Further study on the possibility of developing common methodologies or test guidelines should be useful.	Possibly. More discussion would be necessary to determine what types of guidelines could be beneficial and how these should be addressed.	Sharing information and methodologies for assessing exposure information and carrying out exposure assessments could be very useful. We would consider it necessary to discuss further in detail the most efficient way of sharing this experience.	Yes indeed, international guidelines for exposure assessment would help to generate data, which is reliable, comparable and accepted by other countries, when risk assessments from various regulatory programs are shared.	Australia, Canada, Finland, Japan, EU and the US agree that these guidelines may be useful and this warrants further discussion and study.

Question	Australia	Canada	Japan	US	EU	Finland	SUMMARY
		(e.g., emission scenario documents, exposure reporting templates). It would also be ideal to examine exposure assessment approaches in the context of the upcoming international assessment sharing exercise under the New Chemical Task Force - although the current emphasis is on hazard assessment, it will expand to approaches to exposure assessment if OECD wants to move toward full Mutual Acceptance of Notifications					
(18-2) ***Given the chemical- or scenario-specific issues presented, do you consider it feasible to develop exposure test guidelines?***	Yes, however their applicability to the Australian situation, particularly in respect of environmental releases (i.e., STP efficiency, water flows, industry practices) would be an issue.	See answer to previous question. We suggest potential consistency through use of more of a template style for reporting of exposure information.	Did not specifically address this question.	Yes in some cases.	Possibly, this needs further reflection and discussion.	Included in previous answer.	Australia, the EU and the US agree that in some cases, it will be feasible to develop exposure test guidelines. Canada adds that it would be useful to define what is meant by the term "exposure test guidelines".
(18-3) ***Would this be a useful step for OECD to consider?***	Possibly, however relativity to other projects would need to be considered.	Depends on the intended meaning of the earlier question.	Did not specifically address this question.	Possibly.	Possible, this needs further detailed discussion.	Included in previous answer.	Australia, the EU and the US agree that this is possibly a useful step. Canada seeks more discussion and clarity on this issue.

ANNEX 6: COMPILATION OF NATIONAL/REGIONAL INFORMATION

This document provides a compilation of member countries'/region's information on issues and detailed questions as presented in the outline for the Dialogue (Annex 3). The information was provided by Australia, Canada, Japan, the US, the EU and Finland. Belgium provided a brief, which is incorporated in the information under Session 1 (page 70). This material was developed to initiate discussion of policy issues related to exposure assessment for new and exiting industrial chemicals, and does not necessarily provide comprehensive descriptions of the programs in individual countries or jurisdictions.

Issues to be addressed in each session

SESSION 1: Policy issues related to performing the exposure assessment

- How do you determine the screening or comprehensive level of exposure assessment and the use of models vs. monitoring data for new chemicals and for existing chemicals?
- What are the major factors for policy decisions regarding this?
- How is the performance of the exposure assessment scheme determined and related to its cost?
- How do the approaches used to conduct exposure assessment account for possible changes in use pattern of the chemical over time?

Australia	***Introduction*** In Australia, industrial chemicals are regulated through the National Industrial Chemicals Notification and Assessment Scheme (NICNAS). NICNAS assesses industrial chemicals that are new to Australia for their health and environmental effects before they are used and/or released to the environment. NICNAS also assesses those chemicals that are already in use in Australia, known as existing chemicals, on a priority basis in response to specific concerns about potential health and/or environmental effects. Control of the use of industrial chemicals lies with the States and Territories. It should be noted that Australia currently is reviewing its environmental assessment methods (including exposure). It is expected (without prejudice) that Australia will likely develop assessment options based on existing international guidance. ***Performing Exposure Assessment*** For both new and existing chemicals, Australia uses a tiered approach to environmental exposure assessment. Screening-level assessments, based primarily on reported and other readily available data, conservative assumptions and simple models, allow identification of the most likely environmental compartments for release. Where Emission Scenario Documents that are applicable to the Australian experience exist, these can be used to refine the exposure assessment.

Australia ***(cont.)***	When assessing Priority Existing Chemicals, Australia attempts to obtain exposure information from industry, either directly from introducers, or indirectly via user surveys. More sophisticated validated models are used when available and are representative of local Australian conditions. Exposure assessments typically include occupational exposures in the workplace, exposures to the general population (public health exposures) from chemicals in the air, drinking water and through the use of household products, and environmental exposure to aquatic life. These assessments generally cover the lifecycle of the assessed chemical (excluding degradates). Site-specific assessments of release and exposure are undertaken where possible, which is not often in respect of the environment. Important parts of the assessment include determination of chemical properties, fate and release. Measured values generally are preferred over estimated values, but data quality is an important consideration in evaluating experimental data. Australia is currently reviewing its environmental assessment methods (including exposure). Occupational exposure assessments are conducted by establishing the use pattern of the chemical and identifying the sources of occupational exposure. Systemic exposure is then estimated by taking into account the routes of exposure, the frequency and duration of exposure, and measured worker data (for example, atmospheric and/or biological monitoring results). Information is needed for each of the scenarios where workers are potentially exposed to the chemical. The reliability of the measured data, and its ability to be representative, are considered in the assessment. If insufficient measured data are available, then model calculations are used to estimate typical and 'reasonable worst case' exposure levels. Where necessary, default values are used for certain input parameters in the model calculations, for example, inhalation rate, body weight and skin surface area. Internationally accepted methods are used in exposure assessment. For example, a modification of the United Kingdom EASE (Estimation and Assessment of Substance Exposure) model is used for estimating exposure. Where exposure levels have been determined from both measured and modeled data, preference is usually given to measured data provided it is both reliable and representative of the scenarios being considered in the assessment. For new chemicals, the occupational exposure assessment is usually qualitative, as measured data are unlikely to be available and there is insufficient information available to predict reliable quantitative estimates. Data that are required to be provided during assessment of new and existing chemicals include uses, manufacture/import volume, number and category of workers, nature of work done, measures and equipment used for prevention of worker exposure, education and training on practices and procedures, information or statistics on work-related injuries/diseases, atmospheric monitoring data, biological monitoring data; and published epidemiological or case reports. Information is also sourced from published literature, site visits and surveys of end-users. All this information is taken into consideration during exposure assessment. A public health exposure assessment involves identifying the chemical, together with its estimated production or import volume and proposed use, examining the entire life history of the chemical and considering the potential for the public to become exposed at each phase of its lifecycle. This would begin with importation or manufacture and transport within the country, proceed through to reformulation or use in industrial processes and possible use in consumer or industrial goods, and finish with the eventual disposal of the chemical (or products containing it). Public exposure to chemicals most often occurs when they are sold in consumer products, or when products containing them enter the public domain. The extent of public exposure will depend on the concentration of the chemical in products, the sales volume and use pattern of the products, as well as other factors including the physical state of the notified chemical. The number of people likely to be exposed and the likely dose (amount of chemical exposure) to each individual resulting from the product's intended use are differentiated. The possibility of public exposure arising from release into the environment during transport, manufacturing or end-use is also taken into account. Among the most important factors here will be the amount of chemical that might be released, the location of possible discharges or spills, and the chemical's physical state when it enters the environment. These will influence the probability of public contact. Public health assessment methods for existing chemicals are similar to those for new chemical notifications, although the size and complexity of the assessment may be increased, depending on the amount of information available on use.

	For both new and existing chemicals, the data requirements and level of assessment that follows is determined by legislation, which establishes categories of chemicals for which specified data and assessment requirements apply. Australian monitoring requirements are limited to occupational exposures to substances that are defined as 'hazardous' according to hazardous substances legislation. Australia currently does not have (but is considering) environmental monitoring requirements. For new chemicals, descriptions of handling and disposal are coupled with volume and fate information to estimate releases using simple modeling. Existing chemicals assessments may have different purposes that may affect the level of assessment. For example, some existing chemical assessments might be limited to hazard, whereas others might be more comprehensive (risk assessments), leading to regulatory decisions. Assessment certificates for new industrial chemicals can be issued with conditions for secondary notification. These conditions can require, for example, that where an initially limited release of the chemical is expected to become greater (usually above some quantum) through a change in use pattern or increase in use within a given use pattern, additional data be submitted for assessment. The assessment itself would likely be similar to that initially undertaken, with changes to inputs. Based on the outcome of the environmental hazard and risk assessment, assessment certificates for new industrial chemicals can be issued with specific recommendations relating to the environment. Such recommendations to the introducers and users of the new chemical may where relevant include concentration limits for release of the chemical to the environment, specific control measures to minimise environmental exposure, and or particular monitoring to measure environmental release.
Canada	***Framework and Legislative Basis for Assessments*** Assessment activities for new and existing non-pesticidal substances are legislated under the *Canadian Environmental protection Act, 1999* (CEPA 1999). Assessments for potential human health and ecological risks are carried out by Health Canada and Environment Canada, respectively. Assessments of new and existing substances are carried out by different groups within each department, but there is often significant interaction relating to development and standardization of tools and approaches. In Canada, occupational exposure falls under provincial rather than federal jurisdiction, so is not included in human health assessments. CEPA 1999 contains requirements to conduct "screening assessments" of certain substances as well as provision for potentially more in-depth assessments of chemicals nominated to a Priority Substances List (PSL). In general, regulatory decisions are expected to be taken based on the outcomes of screening assessments, although in some cases, a screening assessment may conclude that a PSL assessment should be conducted if it is believed that the legislative framework for such assessments is more suitable. It should be noted that while screening assessments are intended to be more rapid than PSL assessments (which frequently require close to 5 years) and operate under a somewhat less demanding legislative regime, there is latitude for them to be as comprehensive as is felt necessary. As such, screening assessments can range from very simple to quite detailed. All substances that are new to Canada must undergo assessment. The New Substances Program is responsible for assessing substances that are defined, by exclusion, through the original Domestic Substances List (DSL). Substances that are "new" to Canadian commerce fall under the purview of Parts 5 and 6 of the CEPA, 1999. New substances that are chemicals, polymers and inanimate products of biotechnology are covered in Part 5 of the CEPA, 1999, whereas Part 6 of the CEPA, 1999 deals with new substances that are animate products of biotechnology. Substances to be assessed are identified based on input from a number of different sources. Some of these are mandated under CEPA including industry submissions of information on potentially problematic substances, and consideration of international regulatory activities and of substances nominated by the public. Other factors, such as emerging science also play an important role in identifying candidates. The largest number of substances are being identified through a process known as "categorization" of the approximately 21,800 substances on Canada's DSL. This

Canada *(cont.)*	process, which will be completed by Environment Canada and Health Canada in September 2006, identifies those existing substances that: o are inherently toxic and (persistent and/or bioaccumulative), or o have the greatest potential for human exposure. Substances identified by this activity must undergo screening assessment. It is worthy of note that very limited data (particularly monitoring) will be available for a large fraction of these substances. Assessments of existing substances under CEPA 1999 are "substance-based" (as opposed to site-based), although "substance" is broadly defined and can include categories of chemicals, effluents from a specific industrial sector, or chemicals used in a specific application. Assessments of new substances are also "substance-based", however, a conclusion on risk can be, and often is, made for specific locations, relating to the notifier of the substance. When a risk is identified, risk management actions are taken on these facilities. Assessment activities under CEPA 1999 are based on evaluating whether the substance is "toxic" as defined under the Act. A substance is "toxic" if it is entering or may enter the environment in a quantity or concentration or under conditions that (a) have or may have an immediate or long-term harmful effect on the environment or its biological diversity; (b) constitute or may constitute a danger to the environment on which life depends; or (c) constitute or may constitute a danger in Canada to human life or health. Cost is generally not a consideration in deciding whether to conduct an assessment, as most assessments are required under legislation. Costs can be a factor in deciding how to do an assessment, for example by using existing or modelled information as opposed to generating new monitoring -data. Targeted funding of research or monitoring is used for a very limited number of assessments. ***Conducting assessments*** CEPA 1999 requires that a weight-of-evidence approach be used in conducting assessments. Therefore, in ecological risk assessments, aside from standard quantitative estimates of risk, factors such as PBT characteristics and temporal trends in exposure are considered in concluding an assessment. In particular, greater caution is used in assessing risk from substances that are persistent and bioaccumulative and inherently toxic. In human health assessments, the weight of evidence approach is applied in the identification of hazard properties of substances. Assessments of substances are, in principle, conducted on a "cradle to grave" basis. They may consider potential exposure scenarios from manufacture or importation, through transportation and use to ultimate disposal. The availability of data and estimation approaches make exposure assessment more feasible and reliable at some life-cycle stages than at others. Although site-specific information may be used to obtain a realistic estimate of the range of exposure to a substance that is taking place in Canada, existing substance assessments interpret this information and conclude in a generic way, as opposed to making site-specific conclusions. However, for new substances, information specific to one location may be used to conduct the exposure assessment and derive predicted environmental concentrations in addition to generic non-site-specific scenarios. Realistic worst-case scenarios are the basis for estimating the range of potential exposure in Canada in order to determine whether substances are likely to pose a risk to human health or to the environment. Within an ecological assessment, a tiered approach to exposure characterization can be used to more rapidly decide at what point further refinement is not warranted. This typically begins by assuming worst-case conditions for most parameters of significance in the exposure characterization. Such "tiers" are not formalized, and only reflect a practical approach for improving efficiency. For human health, the "simple" and "complex" exposure tools

Canada *(cont.)*	developed for priority setting and screening assessments have incorporated a tiered approach in their design. Both monitoring data and estimation techniques such as modeling can be used in exposure assessments. Each of these approaches has strengths and weaknesses. For new and existing substances, exposure assessments can be based on release, mitigation and dispersion estimation approaches such as Emission Scenario Documents, dilution factors, etc. For existing substances, monitoring data may also be available and carries significant weight for assessment purposes. Ideally, both monitoring and modelling data are available for consideration, as they are very complimentary, the combination providing significantly greater information than either on its own. Modelling provides flexibility in evaluating a range of scenarios, such as temporal and spatial variability. Monitoring provides specific examples of "real" exposure concentrations, as well as a basis for "ground truthing" modelled results. Both can be used, in a weight of evidence context, in concluding an assessment, the age and quality of monitoring data and the reliability of the modeling approaches being taken into consideration. Cost-benefit analysis related to potential management actions does not play a role in making an assessment conclusion, but is considered when developing risk management strategies. Assessments of existing substances are based on current use and release patterns, but as mentioned above, they can also take into account exposure trend data. In some cases significant changes in use pattern may result in a reassessment, particularly if usage of a substance or its environmental release increases substantially. However, such changes are not currently anticipated when conducting exposure characterization of an existing substance. The possibility of accounting for anticipated changes in use patterns in some assessments is being considered – for example, in assessing risk of existing substances that are potential replacements for other substances that are being restricted. The exposure assessment of new substances considers the potential for additional use patterns (in terms of both increased use quantities and alternative applications) because a new substance posing no unacceptable risk to the environment or human health is eligible for listing on the Canadian DSL where it may be used for other purposes at unrestricted volumes.
Japan	***Introduction*** In order to prevent adverse effects on human health and living organisms in the environment caused by chemical substances, the Chemical Substances Control Law (the Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture. etc.) is intended to assess potential risks of the chemicals and to regulate manufacture, import and use of chemical substances when necessary. The law was introduced in response to the environmental pollution problem caused by PCB whose property is persistent, highly bioaccumulative, and toxic. Exposure is considered at various stages of the law implementation. ***The exposure consideration and policy aspects of exposure assessment under the Chemical Substances Control law*** ***(Pre-manufacturing Evaluation)*** All new chemicals should be notified before manufacturing or import except for those that is used for research and development. As the objective of the law is to prevent long-term adverse effect, through the environment, of hazardous chemicals, the law focuses on chemicals which are likely to exist in the environment for significant time period at significant concentration. The exposure potential is considered by its properties (biodegradability and bioaccumulation) and the potential amount of the chemicals to be released to the environment. When the planned amount of a new chemical to be produced or imported is less than 1 ton, the company needs not to provide testing data but to notify. Such notification is necessary for the authority to confirm if the planned production and import will not exceed 1 ton nationwide.

Japan ***(cont.)***	A new chemical, which is used as intermediate and is not expected to be released to the environment, is also subject to exemption of the submission of testing data. Application for the exemption is necessary so that the authority can confirm if the chemical will not be released to the environment. A new chemical for export only is also exempt from submission of testing data. Regarding a new chemical regarded as persistent (not biodegradable), the manufacturer or the importer has to conduct bioaccumulation test. If a chemical has both persistent and bioaccumulative properties, chronic toxicity testing needs to be conducted. If a chemical is regarded as persistent, bioaccumulative and also toxic, it shall be categorized as the Class I Specified Chemical Substances and shall be under the strict control--effectively, not be allowed to produce or import. If a new chemical is found persistent but not bioaccumulative, it will be subject to screening toxicity (to human and ecosystem) testing unless it is planned to be produced less than 10 tons. If the chemical turns out to be potentially toxic as the result of the screening testing, it will be categorized as the Type II monitored chemical substances (potential of toxicity to human health) or the Type III monitored chemical substances (potential of eco-toxicity). ***(Existing Chemicals)*** If an existing chemical is found persistent and bioaccumulative but not defined toxic as yet, it is categorized as the Type I monitoring chemical substances. The manufacturers and the importers of the Type I monitoring chemicals have to report to the authority of the actual quantity of production or import together with the information on use. A chemical in the Type I monitoring chemical is subject to further risk assessment. The assessment starts first by identifying the potential of exposure considering the production/import volume and the use, and other relevant information. If the chemical is likely to possess exposure potential, the authority will conduct a preliminary hazard assessment. The authority may issue an instruction or advice on the risk reduction measures in case a certain potential of risk be found. The authority ay issue an order to the manufacturer or the importer to provide chronic toxicity test data on condition that the chemical is considered to pose significant risk despite the risk reduction measures above mentioned. If the chemical is found to possess chronic toxicity, it shall be categorized as the Class I Specified Chemical Substances and thus subject to strict control. If an existing chemical is found persistent but not bioaccumulative, and potentially toxic as the results of screening toxicity (to humans or eco-system), it will be categorized as the Types II and III monitored chemical substances. ***(Risk assessment of chemicals in the Types II and III Groups)*** If a chemical is categorized as the Types II or III substance, it shall be subject for monitoring of production/import quantity and the use. The law imposes the obligation on manufactures or importers of the chemicals in the Types II and III Chemicals to report the actual quantities of the chemicals manufactured or imported as well as their use. For a chemical of the Types II and III, the authority may issue an order to the manufacturer or importer to conduct toxicity investigation. The authority determines a candidate chemical substance considering the quantity of manufacturing or import, the results of the screening toxicity test and whether it is used in an open system. The authority prioritizes them, and conducts exposure assessment according to the priority in order to decide whether it should issue an order of toxicity investigation or not. All available information on exposure at the time, including environmental monitoring data, PRTR data, and the results of the modeling, is to be considered in this process. According to the level of the concern, appropriate level of toxicity data will be requested to the manufacturer or the importer. Once hazardous properties, such as chronic toxicity on human health, of a chemical are confirmed

Japan ***(cont.)***	by the survey, the chemical will be designated as the Class II Specified Chemicals. The manufacturers or importers of the Class II Specified Chemicals are obliged to report the planned and actual quantities of manufacture or import and their intended use. In addition, they have to put appropriate labels on the chemicals as required by the law. The authority may instruct them to change the planned quantities of manufacture or import, if necessary.
US	***Introduction*** EPA has broad authority to identify and control substances that may pose a threat to human health or to the environment. EPA evaluates chemical substances as either "existing" chemicals or "new" chemicals. EPA's new chemical program, which is primarily regulatory in nature, has prescribed requirements for industry reporting of exposure-related information and supplements the reported information with estimates or scenarios to develop EPA's screening-level exposure assessment. EPA's existing chemical program has a variety of regulatory and voluntary approaches with limited exposure reporting requirements and exposure assessment development, although more exposure information will be reported under required reporting starting in 2006. This paper discusses some exposure-related reporting requirements, policies, and assessment issues that are applicable to new chemicals, existing chemicals, or both in the U.S. ***Performing Exposure Assessments*** For both new and existing chemicals, EPA uses a tiered approach to exposure assessment. Screening-level assessments, based primarily on reported and other readily available data, conservative assumptions and simple models, allow a quick prioritization of exposures for further work. Advanced assessments which focus on higher priority exposures attempt to represent actual environmental conditions and exposures; these assessments require more data and make use of more sophisticated models or ideally, for existing chemicals, a well-designed monitoring study. Exposure assessments typically include occupational exposures in the workplace, exposures to the general population from chemicals in the air and drinking water, consumer exposure through the household use of products, and environmental exposure to aquatic life. These assessments generally cover the lifecycle of the assessed chemical and are site-specific for releases and exposures. Important parts of the assessment include determination of chemical properties, fate, and releases. Measured values are generally preferred over estimated values, but data quality is an important consideration in evaluating experimental data. EPA makes use of a number of existing guidance documents, including Guidelines for Exposure Assessment (US Federal Register, Vol. 57, No. 104, p.22888) in generating its exposure assessments. For both new and existing chemicals, the level of assessment and the use of models versus monitoring data are determined by a combination of regulatory authority, significant risk findings (sometimes involving technical and policy judgments), and economics (cost versus benefits) for each chemical case. Existing chemicals assessments may have different purposes that may affect the level of assessment. For example, some existing chemical projects may be aimed at informing a particular industry sector and the public of options for improving environmental performance rather than for making a regulatory decision. Regarding measuring performance of the exposure assessment schemes to justify costs, EPA has begun exploring such measurements for the US, but we are not at a point to make final determinations. Cost justification can be a difficult issue due to the subjective nature of assigning absolute monetary values to some environmental improvements. Regarding possible use pattern changes over time, EPA may attempt to determine other use patterns than those currently intended and may include other use patterns in the assessment.
EU	***Legislative background*** In the European Union risk assessments for new and existing substances are carried out under Council Directive 67/548/EEC (as amended for the seventh time by Directive 92/32/EEC) and Council Regulation (EEC) No. 793/93 on the evaluation and control of existing substances. For new chemicals, the competent authority of the Member State in which it is manufactured or into which it will be imported carries out an assessment of the risks of the substance to man and the environment in accordance with the principles set out in Commission Directive 93/67/EEC on

EU ***(cont.)***	risk assessment for new notified substances. For existing substances the risk assessments are carried out by competent authorities designated by the responsible Member States to act as rapporteurs for priority substances in accordance with the principles laid down in Commission Regulation (EC) No. 1488/94 on risk assessment for existing substances. Detailed guidance on how to perform risk assessments on the context of these legal frameworks is laid down in the Technical Guidance Documents on risk assessment for new and existing substances and biocides, the so-called TGD. This guidance which has been produced with the assistance and endorsement of Member States, provides supplementary technical detail. The guidance is not legally binding, and the competent authorities may use other methods or approaches if they are more appropriate, provided that they are scientifically justified and compatible with the general principles laid down in Directive 93/67/EEC, Regulation 1488/94 or Directive 98/8/EC. When other methods are used, the methods, including any assumptions, uncertainties and calculations, should be clearly described and justified. The exposure assessment carried out for new and existing substances generally comprises the estimation of the concentrations/doses to which human populations (i.e. workers, consumers and man exposed indirectly via the environment) or environmental compartments (aquatic environment, terrestrial environment and air) are or may be exposed. The risk assessment should as a matter of principle cover all stages in the life-cycle of the substance i.e. starting from production or import, through, where relevant, formulation, professional and consumer use and finally the recycling or waste steps. In practice, however, information on in particular the last phases is often missing and therefore these phases are omitted or only qualitatively reviewed. ***Policy issues related to performing the exposure assessments*** Within the legislative framework described above there is no formal differentiation in screening or comprehensive risk assessments. Generally the risk assessments, and likewise the exposure assessments are based on all information that is available to the authorities. In practice, however, due to the amount of exposure information that is available, the level of detail in the exposure assessments varies tremendously. For new chemicals for instance, the information provided in the notification dossiers is generally limited to a description of the Industry and use Category to which the use of the substance belongs. On request by the authorities further actual use and/or exposure information may be provided. Whereas specific exposure information at the manufacturing site may in some case be available to allow site-specific assessment of the risks to workers at the site or the environment surrounding it, such exposure information is generally not available for down-stream use of the substance. Therefore the exposure assessment of downstream use is almost always based on modelling approaches. The question of whether screening or comprehensive exposure assessments are carried out can also be related to whether the assessments can be limited to certain protection targets. Member States can decide to carry out a first **screening** step in the exposure assessment in which they evaluate the likelihood of exposure to the substance under consideration. If in the screening step it is indicated that exposure to one of more of the human populations or the environment does not occur or when the expected exposure is so low that it can be neglected further in the risk characterisation phase, no further assessment is needed and the conclusion can be mentioned in the risk assessment report. If actual or potential exposure has been identified a **quantitative** exposure assessment is necessary. The exposure assessment should be based on representative measured data and/or model calculations. The availability of representative and reliable measured data and/or the amount and detail of the information necessary to derive realistic exposure levels by modelling, in particular at later stages in the life cycle of a substance, will vary a lot. Generally measured data, provided they are adequate and representative for the situation that is under scrutiny, are preferred in the assessment. In most cases however, expert judgement is used to decide whether the measured or model data are used in the risk characterisation. If appropriate, available information on

EU *(cont.)*	substances with analogous use and exposure patterns or analogous properties can be taken into account. In order to ensure that the predicted environmental concentrations are realistic, all available exposure-related information on the substance should be used. When detailed information on the use patterns, release into the environment and elimination, including information on the downstream uses of the substance is provided, the exposure assessment will be more realistic. A general rule for predicting the environmental concentration is that the best and most realistic information available should be given preference. However, it may often be useful to initially conduct an exposure assessment based on realistic worst-case assumptions, and using default values when model calculations are applied. Such an approach can also be used in the absence of sufficiently detailed data. If the outcome of the risk characterisation based on worst-case assumptions for the exposure is that the substance is not "of concern", authorities can stop the risk assessment for that substance with regard to the compartment considered. If, in contrast, the outcome is that a substance is "of concern", the assessment must, if possible, be refined using a more realistic exposure prediction. Similar considerations apply to the exposure estimation for workers or for consumers where also an initial realistic worst-case assessment can be carried out followed by more extensive assessments, where needed. The environment may be exposed to chemical substances during all stages of their life cycle from production to disposal or recovery. For each environmental compartment (air, soil, water, sediment) potentially exposed, the exposure concentrations should be derived. The assessment procedure should in principle consider the following stages of the life cycle of a substance: • Production; • Transport and storage; • Formulation (blending and mixing of substances in preparations); • Industrial/Professional use (large scale use including processing (industry) and/or small scale use (trade)); • Private or consumer use; • Service life of articles; • Waste disposal (including waste treatment, landfill and recovery). No measured environmental concentrations will normally be available for new substances. Therefore, concentrations of a substance in the environment must be estimated. In contrast, the exposure assessment of existing substances does not always depend upon modelling. Data on measured levels in various environmental compartments have been gathered for a number of existing substances. They can provide the potential for greater insight into specific steps of the exposure assessment procedure (e.g. concentration in industrial emissions, "background" concentrations in specific compartments, characterisation of distribution behaviour).
Belgium	For new and existing chemicals, Belgium uses generic exposure scenarios due to insufficient expertise, practical experience and data, with respect to the chemicals that are assessed. It is not yet possible to provide information on the strategy for exposure assessment under the future EU legislation (REACH). *[Note: The original text was provided in French and translated by the Secretariat.]*
Finland	***General issues*** National Product Control Agency (STTV) is responsible for ensuring that human health is protected from the adverse health effects of chemicals. STTV is a competent authority for the notification of new substances and the health risk assessment of existing chemicals. Thus, STTV is responsible for preparing exposure assessment for workers and consumers. The agency's functions are based on the national chemicals act, derived from European Community legislation. The environmental issues are not covered in this paper. ***Policy issues related to performing the exposure assessments*** ***(New substances)*** Finland has taken part in the notification of new substances in EU since joining the European Economic Area (EEA) in 1994 and as a full EU member since 1995. The notification information

Finland ***(cont.)***	is submitted by industry and it involves information about health hazards or other dangerous properties such as flammability or explosivity of the substances. A risk assessment is prepared to estimate the potential health effects for workers or consumers via all significant exposure routes. The exposure assessment is predominantly based on the modelling and default assumptions as well as on expert judgements, since measured exposure data is very seldom available. Currently, the most commonly used model is EASE 2.0. More advanced exposure models or databases are very rarely used. The competent authority may request additional data or information if a potential health concern arises or if the exposure levels are not satisfactorily estimated. Additional information can be measured data but in some cases a more detailed process or substance handling description may be enough. If a substance is manufactured or used in a chemical process in Finland, then site visits could also be considered. In general, measured values are prioritised over the modelling predictions. Whenever exposure measurements are available, samples must be collected from a representative situation, most preferably from a process similar to that in the notification. Measurements from analogous processes can also be acceptable (expert judgement). It is checked that sample collection and analysis methods correspond to the current practices, standards, guidelines or recommendations. The conduct of exposure assessment scheme is defined by the industry. Generally, this leads to a selection of methods with minimal costs, e.g., the use of an exposure model and judgement. Also screening assessment is used. Industry has main responsibility for screening. As stated above the authority (STTV) may request additional data or information if there are unclear issues (for instance in the extension of screening). We try to avoid any unnecessary costs, but no cost benefit calculations are conducted. The exposure assessment concentrates mainly on the current use pattern (processes, time budgets etc.). Industry is required to inform the competent authority about any changes in use pattern. This may lead to a revision of a risk assessment. ***(Existing substances)*** STTV is responsible for preparing the risk assessment parts that concern the physico-chemical properties of the chemical and health risks posed by the chemical. The risk assessment is prepared to estimate the potential health risks to workers and consumers, including human exposure via environment. Risk assessment work is prepared together with research institutes, such as the Finnish Institute of Occupational Health (FIOH). In a case of existing chemicals measured exposure data is often available in open literature and from industry. In some cases consumer organizations may submit exposure information. Sometimes EASE-model estimations can be utilized, either without or together with measured observations. Measured values are in general prioritized over model predictions. However the expert judgement plays a key role both in evaluation of measurements and model estimates. Co-operation with industry is one of the important elements in exposure assessment process. During the assessment industry may also make changes to reduce risk. The samples (including biomonitoring) must be collected from a representative situation, most preferably from a similar process that is under assessment. Sometimes measurements from analogous processes can be acceptable (expert judgement). The sample collection and analysis methods are checked that they correspond to the current practices, standards or guidelines. However, sometimes exposure measurements can be relatively old and not conducted according to current standards. The acceptance of this existing data is evaluated by expert judgement. Exposure assessment within the EU Existing chemicals regulation is a step-wise procedure. According to the EU Technical Guidance Document and our experiences the steps often include the following:

Finland *(cont.)*	• **Uses of the chemical** and relevant applications and industrial processes are identified. (These are referred as "exposure scenarios" in the current legislation. The definition of terms will change along with the implementation of the REACH). Information from the industry, from reports, reviews and from safety data sheets are used in this phase. • **All relevant analytical data** on the concentration of the chemical in the workplace air, concentration in products, oral intake, skin deposition etc. are obtained. Published articles, data from the industry, unpublished reports etc. are the relevant sources of data. This information is reviewed for reliability and coverage regarding the exposure scenarios identified. • **Conditions and parameters** relevant for the identified exposure scenarios are clarified and listed. The key parameters are e.g.: typical amount used in a process/application, use levels of consumer products, process type manual: open, semi-closed, closed, breached, etc., temperature, ventilation, vapour pressure, particle size distribution. • When analytical measurements are not available, a suitable modelling tool (e.g. EASE, EUSES, Riskofderm, Consexpo) is selected for the assessment. If information on **modelling** parameters are missing, measurements are made or expert judgement is used to acquire the necessary data. • In a case when the measured or estimated exposure is close to the critical/harmful level/dose, measurements are made and/or the key parameters are re-examined to avoid any underestimation of the exposure. • The normal and reasonable worst case exposure is reported and used for the risk characterisation. In some cases also peak exposures are considered.

SESSION 2: Responsibility

- Who has the responsibility to provide exposure information, and how is the appropriate level of information to be provided determined?
- For the screening and comprehensive exposure assessments, what is the responsibility of the regulatory body? What is the responsibility of industry/enterprise/applicants?
- What is the role of the enforcement in the collecting or reporting of exposure information? Do civil liability issues exist with regard to the submission of exposure information including its accuracy? If so, what they are?

Australia	Legislation requires that new chemical submissions from industry be accompanied by specific scheduled data requirements according to the nature (or 'category') of the chemical. The different chemical assessment categories require different levels of assessment to be undertaken. There are five main categories relating to notification for a new chemical assessment, with each category depending on the type of chemical, the amount being introduced and the period of use required. In general, the amount of information that is required for the assessment of new chemicals increases in accordance with the introduction volume of the new chemical and the associated hazards, use, handling and disposal of the chemical. The volume of a chemical to be introduced and the hazards of the chemical are significant factors in determining the risk posed to human health and the environment. For example, a "standard notification" of a new chemical has greater data requirements for assessment than a polymer that meets the legislated definition of a "polymer of low concern". The schedule information generally required for an assessment of the potential environmental impact includes chemical identification data, certain physical and chemical data (including water solubility, hydrolysis, partition coefficient, dissociation and adsorption/desorption), volume of import and/or manufacture, environmental release, environmental fate (biodegradability and bioaccumulation potential), and the toxicity to aquatic organisms. In addition, the submitted data generally include information on intended disposal option(s) and human exposure. It is the responsibility of the importer and/or manufacturer (i.e. the notifier) of the new industrial chemical to provide a technical dossier containing all the information required for the assessment. In conducting an environmental assessment, the extent of the potential environmental exposure is based on information supplied by the notifier along with local and literature sources. The environmental effects of the chemical are also measured by the degree of toxicity to aquatic organisms. The potential hazard of the chemical to the environment and its fate are then evaluated. The environmental fate and toxicity information are only required for standard assessments, although such information should be provided if available for the other categories. Industry is required to provide existing data, generate data or provide modeled data. In each case, the data may be associated with the notified chemical or an acceptable analogue (although the former is strongly preferred). From these data most environmental concentrations and human dose estimates are generated (by simple models). Advanced exposure assessments are rare for new chemicals. When they do occur, it is usually for highly toxic chemicals or those being used at single sites. NICNAS may require that additional data be provided in the event that release exceeds a level of concern or exposure to a new compartment is intended. Reporting of environmental exposure information is not required for certain low hazard /low risk chemicals (including cosmetics) except where the use exceeds specified volume or concentration restrictions. Environmental exposure information is, however, called for by notice prior to commencing the assessment of existing chemicals selected for review. Additional environmental exposure information is variously sourced from the National Pollutant Inventory (PRTR), the public literature and industry surveys. As mentioned previously, data for existing chemicals may be generated as a result of other regulatory requirements, such as workplace monitoring for worker exposure to hazardous substances. Failure to submit legally required data could be an offence under the Industrial Chemicals (Notification & Assessments) Act. Other legislation governs the giving of false or misleading information.
Canada	For new substances, companies must submit a prescribed set of information before they can manufacture or import the substance. This information requirement prescribes only basic

Canada ***(cont.)***	exposure-related information, such as intended use, annual amounts to be imported or manufactured and location of import or manufacture. The type and quality of information submitted varies, often requiring the assessor to seek greater detail from the Notifier in order to estimate releases to the environment or exposure to humans. More stringent exposure data requirements are currently proposed for the revised New Substance Notification Regulations which will be released to the public in the near future. There is no fixed requirement for the submission of data for use in assessments of existing substances. CEPA 1999, however, does provide the authority to carry out industrial surveys and to require companies to supply specified information relating to substances that are under assessment. This can include requirements for: a) reporting of engagement in an activity involving a specified substance; b) provision of any information and samples that a person possesses or may reasonably be expected to have access to, and c) conducting toxicological or other specified tests. Use of part c) is limited to situations where the Ministers already have reason to suspect that a substance poses a risk. CEPA 1999 also includes a "reverse onus" clause, whereby industry is required to submit information on a substance that reasonably supports a conclusion of toxic to human health or the environment. Literature searches and contact with established monitoring networks can also provide exposure related data and information on existing substances. Environment Canada operates or is involved in a number of networks including, for example, the National Air Pollution Surveillance (NAPS) network. As already mentioned, for a very limited number of cases, the assessment program may provide targeted funding for the generation of monitoring or other scientific data. In some cases there is also the option of entering into voluntary agreements with outside parties, including industry, for the provision of existing information or generation of new data. Companies meeting certain triggers of use quantity and company size are required to annually submit release data to Canada's National Pollutant Release Inventory (a PRTR). This is only applicable to approximately 300 specified substances. Individuals who, either knowingly or negligently, provide false or misleading information, results or samples in responding to a legal request made under CEPA 1999 are liable for fines (maxima ranging from C$200k to C$1M) or imprisonment (maxima ranging from 6 months to 3 years).
Japan	Under the law, the authority is responsible for undertaking risk assessment of chemical substances, while manufacturers or importers of chemical substances are responsible for providing necessary information to the authority. The authority conducts environmental monitoring for exposure assessments, measuring concentration of chemical substances in the environmental media including in the atmosphere, water, and soil. The data which manufacturers or importers of the chemical substances should submit for pre-manufacturing evaluation includes physico-chemical properties, the planned quantity of manufacture or import and the intended use. For monitoring chemical substances, manufactures or importers should submit actual quantity of manufactured or imported chemical substance and its use. If manufacturers or importers of the monitoring chemical substances do not submit a report or deliberately make a false report to the authority, they would be fined. The fine is 500 thousands yen for a violation of the reporting requirements on the Class I monitoring chemical substances, 300 thousands yen for a violation of the reporting requirements on the Classes II and III monitoring substances.
US	New chemical submissions require industry to report all available data on chemical identity, production volume, manufacturing process, byproducts, use, human exposure, environmental release, disposal practices, physical chemical properties, and environmental fate. Because the new chemical assessment is done prior to its manufacture, limited amounts of the data requested

US *(cont.)*	may exist; in these cases, EPA will estimate those inputs necessary for the assessment. EPA generates the screening-level assessment, and most environmental concentration and human dose estimates are generated by simple models. Advanced exposure assessments are rare for new chemicals. EPA may require exposure information or data as part of the terms and conditions for the manufacture of the new chemical substance. Regarding existing chemicals, industry has been required to report limited exposure information (including production volume, site of manufacture, and site-limited status) on all non-polymeric organic chemicals produced at above approximately 5 tons/yr at a site; this has occurred every 4 years since 1988. Under a revision of this regulation taking effect for reporting in 2006 and beyond [40 CFR Part 710; see http://www.epa.gov/opptintr/iur/amendment.htm], the reporting trigger volume has been revised upward, additional exposure information is required, and reporting has been extended to inorganic chemicals. Reporting elements under the revised regulation are site-specific and are as follows: - above approximately 10 tons/yr at a site ("known to or reasonably ascertainable by''): number of exposed workers at the site of manufacture or import; physical form(s), associated percent production volume, and maximum concentration leaving the site; - additional reporting above approximately 150 tons/yr at a site (''readily obtainable''): North American Industrial Classification System (NAICS) codes for sites that use or process the substance; industrial functions of the chemical substance; numbers of processing and use sites; numbers of exposed workers at all use and processing sites; commercial and consumer uses; maximum concentration in each commercial and consumer product category; and estimated percentages of the submitter's production volume in each industrial function category and commercial and consumer product category. "Known to or reasonably ascertainable by" the submitter means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. "Readily obtainable" means information that is ``readily obtainable" by the submitter's management and supervisory employees responsible for manufacturing, processing, distributing, technical services, and marketing of the reportable chemical substance. Extensive file searches are not required, yet sufficiently precise processing and use information will be provided for screening level reviews. In addition, EPA can by notice and comment regulation require reporting of basic exposure information on specific chemicals. Additional existing chemical exposure information is obtained by EPA by literature searches; where data are lacking, EPA may enter into voluntary reporting arrangements such as Memoranda of Understanding (MOU) (e.g., MOU for sampling and environmental monitoring for perfluorooctanoic acid (PFOA) at fluoropolymer manufacturing facilities as part of the PFOA effort). Unlike for health and environmental hazard test data, OECD or EPA test guidelines for development of exposure test data are generally not available. Because of this limitation, development of new exposure test data generally occurs through negotiated procedures producing enforceable or voluntary exposure testing agreements. Enforceable Consent Agreements (ECAs) are negotiated among interested parties and produce testing requirements that are met by chemical manufacturers or processors; these ECAs specify the test procedure (e.g., incineration byproducts, monitoring, etc.) for developing needed exposure information (e.g., source and pathway data for PFOA) according to an enforceable schedule. Voluntary exposure information and data can be developed and reported through informal arrangements or through organized programs such as the Voluntary Children's Chemical Evaluation Program (VCCEP). For Tier 1 of VCCEP, sponsors develop a screening level assessment of readily available exposure information, including, to the extent possible, data on exposures outside the chain of commerce. The Tier 1 assessment (includes population groups exposed, sources of the exposure, as well as frequencies, levels, and routes of exposure) puts the totality of exposures into context, so that a judgment can

US *(cont.)*	be made as to whether the risks a chemical may pose to children have been adequately characterized and hence whether a chemical should proceed to a higher VCCEP Tier. At Tiers 2 and 3, sponsors conduct progressively more detailed/ comprehensive exposure studies needed to characterize the extent and magnitude of exposure and develop more sophisticated exposure assessments addressing outside the chain of commerce exposures. Data or estimates may be generated due to various regulations involving multimedia (e.g., for new chemicals consent orders, for US Toxics Release Inventory (PRTR)), media-specific (e.g., air and water regulations), and workplace (e.g., for new chemicals consent orders) monitoring and/ or reporting. Some of these monitoring data or estimates may be generated due to compliance or enforcement efforts. EPA sometimes uses these monitoring data or estimates for its exposure assessments. Failure to submit legally required data, or submission of false or misleading data, can be a violation of the Toxic Substances Control Act (TSCA) and its regulations. For example, in the pre-manufacture notification (PMN) rule, 40 CFR 720.50 may require submission of exposure data, and 40 CFR 720.120(f) states that "[p]ersons who submit materially misleading or false information in connection with the requirements of any provision of this rule may be subject to penalties calculated as if they never filed their notices." Under section 16 of TSCA (15 U.S.C. 2615), there is potential civil and criminal enforcement liability for violations of TSCA and its regulations. Penalties can reach $27,500 per violation per day, and up to one year imprisonment for knowing and willful criminal violations. There is also criminal liability under 18 U.S.C. 1001 for intentional fraud with potential incarceration up to five years.
EU	***Who has the responsibility to provide exposure information, and how is the appropriate level of information to be provided determined?*** For new substances an initial assessment of risk is made at the time of the first notification using the information on exposure which is delivered by industry. This assessment is re-addressed and may be revised in the light of any further information on the properties of the substance and/or on exposure, whenever such information becomes available. Further information may be supplied in response to requests of the competent authorities as an outcome of the risk assessment; or it may be supplied when the next tonnage threshold is reached. The risk assessment of priority existing substances is based on the information on the substance submitted by the manufacturers and importers in accordance with Regulation 793/93 and on other available information gained by the rapporteur. The amount of information that the manufacturer needs to provide obligatory is limited to production/import volume, information on the manufacturing process and a description of his own use and the way he knows the substance is used by his customers. Often this use information is limited to the generic industry and use categories. Often, in more advances stages of the risk assessment, the industry gathers more detailed information on actual emissions and exposures and on more specific down-stream application of the substance, inclusing for instance concentrations in typical formulations and/or consumer products. In order to ensure that all relevant data for a risk assessment are available, the rapporteurs should conduct their own literature research and should also use non-published data for the risk assessment, where relevant. Sources of this type of data include: (national) product registers, data banks containing exposure data collected in the context of legislation on consumer products, data banks of poison control centres, results of governmental monitoring programmes or governmental testing programmes. Data not publicly available may also exist in Member States other than that of the rapporteur. Therefore all Member States are requested to submit their unpublished information on the priority substances to the rapporteurs as early as possible. In future according to the REACH proposal for a new chemicals legislation the manufacturers and

EU ***(cont.)***	importers of substances will need to provide information on use and exposure in their registrations dossiers. For hazardous substances marketed or imported in volumes above 10 tonnes per year the registrant will also need to carry out a chemical assessment through which he needs to demonstrate that he uses the substance in a safe manner and in which he needs to describe the risk management measures that his customers need to implement in order adequately control the risks of the substance. ***For the screening and comprehensive exposure assessments, what is the responsibility of the regulatory body? What is the responsibility of industry/enterprise/applicants?*** See also the answer to the previous question. In practice during the first review of a comprehensive risk assessment on a priority existing substance the major gaps in the exposure information are identified by the experts of the Member States. Subsequently it is decided what additional information needs to be gathered, by who and at what timeframe. In general, most of these requests are related to information that is only available to industry which automatically makes them the responsible for generating the data. However, in some cases, (e.g. when access to existing monitoring data needs to be obtained) the request may also be addressed towards the authorities. Under the current legislation, requests for further information can only be made towards the manufacturers and/or importers of substances and not to the users. Hence, exposure information from downstream users is usually supplied on a voluntary basis. ***What is the role of the enforcement in the collecting or reporting of exposure information? Do civil liability issues exist with regard to the submission of exposure information including its accuracy? If so, what they are?*** Enforcement is the responsibility of the EU Member States. We have no specific information of cases where enforcement authorities have been involved in the collection or reporting of exposure information.
Finland	***New substances*** The industry has an overall responsibility to provide exposure information of the new substances. This information is then checked by STTV. The dossier is checked in a general level i.e. all required elements are included, for example, all use scenarios are estimated. The general requirements are defined in Finnish Chemicals Act 744/1989. Then the level and the quality of the assessment (for example the methods used) are evaluated and it is decided if any additional information is needed. STTV do not currently have any specific screening assessment protocol, instructions or demands. The screening is in principle conducted by industry. ***Existing Chemicals*** As in the case of new chemicals industry has an overall responsibility to provide exposure information. However research institutes and other EU member states may provide additional information on exposures. The information is then checked by STTV.

SESSION 3: Common and unique factors

- Can the information requirements for industry for screening level assessment and comprehensive assessment be influenced by factors unique to individual countries?
- What could be such unique factors?
- What are the common factors?

Australia	For both new and existing chemicals, information requirements are influenced by a number of factors, including regulations, findings of significant risk and special hazard concerns (*e.g.*, PBTs, carcinogenicity), as well as quality and uncertainties within the data or modeled estimates. There is no difference between new or existing chemicals when making recommendations about their future use. While the use of overseas hazard assessment reports is supported and encouraged, the actual risk posed by a chemical, and hence its management, must be determined by taking into account Australian conditions - that is, our demographics, unique environmental ecosystems and the patterns and conditions of the chemical's use in this country. Regarding environmental exposure, Australia is reviewing its entire environmental assessment method and framework for regulating the release of chemicals into the environment.
Canada	There are a number of factors that have been raised in the above discussion that, while perhaps not unique to Canada, are likely to vary considerably between legislations in different countries and jurisdictions. Some of these include: • Substance-based (rather than site-based) assessments of existing substances that conclude on risk in a generic way. • Consideration of other potential use patterns and annual volumes for new substances. • Defining screening assessments in a manner that allows regulatory decisions to be based on their outcome, taking into account identified uncertainties, rather than as "preliminary" assessments. • Factors used in identification of substances for assessment. This includes: 1) that cost does not play a role in deciding whether to assess a substance, and; 2) recognition that many substances that will be required to undergo assessment have been identified on the basis of PBT properties, may have very limited data available, and therefore will be more reliant on estimation and modelling approaches. • Legislation that does not include specific requirements for reporting of data for existing substances, but which does include provision for collection of data as needed. • A flexible framework that allows weight of evidence considerations, and open interpretation of both monitoring and modelling data, to take best advantage of the two.
Japan	Japanese authority puts priority on monitoring data in assessing the exposure potential of chemicals. It intends to use the PRTR data for exposure assessment although the data submission started rather recently. As the objective of the law is to prevent long-term and nation wide risks of hazardous chemicals, only nation wide exposure assessments are conducted.
US	For both new and existing chemicals, information requirements are influenced by a number of factors, including regulations, findings of significant risk, special populations (e.g., children), special hazard concerns (e.g., PBTs, carcinogenicity, etc.), and quality and uncertainties in the data or model estimates. New chemical regulation in the US requires a "may present an unreasonable risk", while existing chemical regulation requires a "will present an unreasonable risk". This distinction affects the exposure assessments. Also, a special population of concern in the US has been for children, and the VCCEP program was created to address this concern. Exposure assessment in the VCCEP program focuses on children's exposure. The OECD has developed internationally-harmonized formats and guidance for the reporting of summary exposure information for consumer exposure, environmental exposure, and occupational exposure. This unclassified monograph, GD No. 42 in the OECD's Series on Testing and Assessment [ENV/JM/MONO(2003)16; December 18, 2003; 66 pp.], is expected to

	be useful for VCCEP and other existing chemical programs.
EU	The risk assessments that have to be carried out according to Regulations 793/93 and 1488/94 for existing substances, Directives 67/548 and 93/67 for new substances and Directive 98/8 for active substances and substances of concern in a biocidal product, are in principle valid for all countries in the European Union. It is recognised, however, that exposure estimation, for example, is subject to variation due to topographical and climatological variability. Therefore, in the TGD in the first stage of the exposure assessment where exposure models are used, so-called generic exposure scenarios are applied. These assume that substances are emitted into a non-existing model environment with predefined agreed environmental characteristics. These environmental characteristics can be average values or reasonable worst-case values depending on the parameter in question. Generic exposure scenarios have been defined for local emissions from a point source and for emissions into a larger region. In these generic scenarios emissions to lakes are not assessed. When more specific information on the emission of a substance is available, it may well be possible to refine the generic or site-specific assessment. This generic model environment is also applied for the assessment of the exposure of man via the environment.
Finland	In principle, the information requirements for industry for screening level assessment and comprehensive assessment may be influenced by factors unique to individual countries. Maybe the most important reasons are related to "public's attitude and concerns". In addition, national programs etc may have influence.

Detailed questions that may be considered in each session

1/ Policy issues related to performing the exposure assessments

(1) (a)What is the role of model estimation of exposure versus environmental or occupational monitoring data? (b)This includes exposure related data such as emission or biomonitoring and environmental fate data. (c) Which data has priority, and how do they complement each other? (d)What is the role of and approaches to the estimation versus measurement of chemical property data that are used for exposure estimation (e.g. persistence, accumulation, leaching)? (e)What steps are taken to ensure that the sum of measured and modeled/estimated data address and are representative of the full range of actual and potential exposures?

Australia	(a) , (b) Occupational: Monitoring data is preferable for estimation of potential exposure. However, the reliability of the data and its ability to be representative, are considered in the assessment. Model calculations are used to estimate typical and 'reasonable worst case' exposure levels when no measured data are available. Environmental: Model estimation using 'reasonable worst case' is usually used to fill data gaps as monitoring data are typically not available, even for existing chemicals. (c) Valid measured values have priority. Estimated values are used as a check on the measured values, where appropriate. They also provide a 'ball park' estimate in the absence of measured data. (d) Valid, measured values for hydrolysis, soil sorption, biodegradation (ready, inherent), BCF, etc. are preferred. In the absence of these data, conservative estimations for these endpoints are made using models. In this respect, scientific judgement is important. (e) The relevance of a model to a given chemical is a matter for judgement, but this is often difficult, as Australia mostly does not have access to the databases behind the various models that are used.
Canada	(a) Both monitoring data (when available) and model estimations are considered in characterizing exposure to substances. They are seen as complimentary in the information that they provide. Monitoring provides more accurate data in relation to specific samples, while modeling can be superior in demonstrating spatial and temporal variations. Temporal variations may relate, for example, to release of substances that are used intermittently or in a batch process by a facility. "Averaging periods" for exposure data are also important to consider in appropriate matching with effects threshold concentrations in risk characterization. Environmental fate processes are often only possible to address through modeling. Further, recognizing that monitoring data are not available for new or many of the existing substances that we are compelled to assess, modeling is an essential approach for filling data gaps in a cost effective manner. Occupational exposure is not considered within the new or existing substances programs at the national level. Rather, individual provinces are responsible for monitoring occupational exposures. A table summarizing some of the monitoring initiatives in Canada has been prepared to accompany the country summary and responses to questions (page 111-112). It provides an overview of major national and international monitoring programs. It also includes examples of other types of sources of monitoring data that are used in conducting risk assessments of existing substances under CEPA. It is worthy of note that the majority of the chemicals routinely monitored by these programs have either already been assessed by the existing substances program at Environment Canada and Health Canada, or are being managed under other programs in the departments. A very low fraction of the chemicals that our existing substances program will be assessing in future are addressed by the monitoring networks. For some substances, data from other sources, such as individual research studies of environmental monitoring or biomonitoring, may be available for consideration in assessments. For a very large number of substances, it is expected that no monitoring data exists.

Canada *(cont.)*	(b) Considered in interpretation of the previous question. (c) As representing a specific location and time, monitoring data will generally carry greater weight Reliable monitoring data also serves in determining the validity of modeling results on a case-by-case basis. Modeling can also be used in the planning stage of a monitoring program, when deemed necessary, to help determine appropriate sampling locations, etc. (Note that targeted funding for monitoring is used very infrequently in our programs.) See also answer to the question two above. (d) Measured data for physical/chemical properties are generally preferred, although suitability of the measurement approaches must be taken into consideration. Measured data are not available for the large majority of existing substances therefore modeling is used extensively to estimate properties. Physical/chemical property data are required data elements for new substances at specific import or manufacture trigger quantities. The data are used to help understand chemical fate and behaviour in the environment and potential for human and non-human organism exposure. This can be done qualitatively or using fugacity-based multimedia models. In addition, considerable experience in model use and evaluation of the reliability of estimated properties has been obtained through the process of "categorizing" the 21,800 substances on Canada's domestic substances list. Evaluation of the persistence, bioaccumulation, and inherent toxicity properties for these substances required initially estimating a number of phys/chem properties. (e) Approaches used in new and existing substances assessments attempt to realistically estimate the range of concentrations of exposure in the environment, in particular those concentrations that may represent realistic worst case exposures. This makes use of both available monitoring data and modeled concentrations. Multimedia models are often used to determine relevant exposure media for both human and non-human organisms based on partitioning behaviour of a chemical. This approach attempts to cover the full range of potential or actual exposures expected. Health assessments can also take direct human exposure via products into consideration.
Japan	(a), (b), (c) In exposure assessments under the law, the authority gives priority to environmental monitoring data, and takes account of the results obtained by model estimation and PRTR emission data complementarily. (d) For the evaluation of biodegradability and bioaccumulation, the authority uses actual testing data. If actual data is not available, the authority may use QSAR data to estimate parameters such as Henry's Law constant, Kow, Koc Ozone reaction constant and OH radical rate constant, to be used in model estimation. (e) Actual monitoring data is the base for decision making. Complimentarily, various types of model estimations may be used, including those which use the PRTR emission data, according to particular situations of the cases and actual monitoring data of key spots are used to compare the actual and estimated concentration data.
US	(a) Model estimation is usually used to fill data gaps if monitoring data are not available or if data quality is questionable or poor. Monitoring data from appropriate, properly conducted studies would generally be preferred over model estimates. The U.S. Environmental Protection Agency, Geological Survey, Center for Disease Control, and other government agencies collect monitoring data on a national scale to characterize exposures to the environment and humans. Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System,

US *(cont.)*	the National Air Toxics Assessment, the Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's. (b) Yes. (c) Valid measured values have priority, and estimated values are used as a check on the measured values, where appropriate. (d) Valid, measured values for BCF, biodegradation (ready, inherent) photooxidation, hydrolysis, soil sorption, etc. are preferred. In the absence of these data, the applicability of the estimation method to the specific chemical of interest is evaluated, and if the methods are appropriate, estimations for these endpoints are made using the models. (e) A data characterization step is used to describe how exposures in the assessment may compare to expected actual exposures.
EU	For measured data, the reliability of the available data has to be assessed as a first step. Subsequently, it must be established how representative the data are for the situation that is assessed. For model calculations, the procedure to derive an exposure level should be made transparent. The parameters and default values used for the calculations must be documented. If different models are available to describe an exposure situation, the best model for the specific substance and scenario should be used and the choice should be explained. If a model is chosen which is not described in the TGD, that model should be explained and the choice justified. In many cases, a range of concentrations from measured data or modelling will be obtained. This range can reflect different conditions during manufacturing and use of the substance, or may be due to assumptions in or limitations of the modelling or measurement procedures. It may seem that measurements always give more reliable results than model estimations. However, measured concentrations can have a considerable uncertainty associated with them, due to temporal and spatial variations. Both approaches complement each other in the complex interpretation and integration of the data. Therefore, the availability of adequate measured data does not imply that model calculations are unnecessary.
Finland	In general, measured values, including biomonitoring data, are prioritised over model predictions. However, the measured observations must be collected from a representative situation by using acceptable methods and strategies. Furthermore, the number of samples (exposure measurement) must be reasonable. In addition to measured values and model estimates also expert judgement is widely used.

(2) How do you evaluate the data quality and limits of use of submitted data?

Australia	Data generated in accordance with OECD, US or other available international test guidelines are generally acceptable. (It is to be noted that Australia is currently reviewing its environmental assessment methods, including assessment of data quality). Whether submitted data are measured or estimated can influence the degree of conservatism of the assessment.
Canada	Professional judgment is used in evaluating the quality and representativeness of data submitted for new and existing substances, taking into account a variety of factors including measurement/estimation approach, and context under which the data was submitted or obtained. Data submitted to the existing substances program is considered on a case-by-case basis and is used in the assessment as part of a weight of evidence in concluding on risk. Typically little measured exposure or release data are available for new substances in Canada. Most releases of new substances are estimated. However, detailed release information can be obtained from a chemical company when needed using exposure template documents developed for new substances. Additionally, assessment reports delineate uncertainty and degree of confidence in relevant data, and take this into account in developing conclusions.
Japan	In exposure assessments under the law, the authority gives priority to environmental monitoring data, and takes account of the results obtained by model estimation and PRTR emission data complementarily. For the evaluation of biodegradability and bioaccumulation, the authority uses actual testing data. If actual data is not available, the authority may use QSAR data to estimate parameters such as Henry's Law constant, Kow, Koc Ozone reaction constant and OH radical rate constant, to be used in model estimation. Actual monitoring data is the base for decision making. Complimentarily, various types of model estimations may be used, including those which use the PRTR emission data, according to particular situations of the cases and actual monitoring data of key spots are used to compare the actual and estimated concentration data.
US	Data quality is evaluated considering the method used and other available background information, particularly applicability or representativeness. Limits of use of submitted data depend on the context of the data, including whether the data are measured or estimated and whether other information is available to make judgments about the applicability or representativeness of the data or estimates. The uses of estimated values are generally limited to screening level assessments. Data quality considerations are described in the discussion "Determining the Adequacy of Existing Data" on the HPV Challenge Program web page http://www.epa.gov/chemrtk/datadfin.htm.
EU	There are no rules or guidelines available for evaluation of the quality of exposure data that are submitted by industry. Generally the Member States evaluate these data by expert judgement. Monitoring data, in particular those coming from regular monitoring programmes carried out by authorities, are generally generated under specific guidelines and will therefore in most cases not need further data quality checks.
Finland	The quality of exposure data is evaluated by checking that the methodology and strategies used in sample collection and analyses are conducted in accordance with generally accepted standards, methods, guidelines or recommendations. However, there is a very limited number of guides on how to conduct human exposure studies. Furthermore, in the current situation GLP (Good Laboratory Practice) is not applicable to human exposure studies as it is to non-clinical safety studies (e.g. toxicity studies). In many cases expert judgement plays a major role in quality evaluations.

(3) What is the role of and approaches to the use of site specific exposure estimation versus fugacity or other generic 'global' models?

Australia	Site-specific releases and exposures are estimated only where these are limited to one or a few sites. Conservative assumptions are used unless real data are available to allow refinement of these assumptions. Fugacity models are used alongside specific knowledge to estimate how a chemical partitions in the environment. Estimated concentrations of the chemical in individual environmental compartments can be used to characterise risk.
Canada	Ecological assessments of new and existing substances frequently emphasize local exposure. Monitoring and modeling are used to quantify risk to organisms in the area most significantly impacted by substances, which is typically close to the point of release. As pointed out in the summary paper, although site-specific information may be used in realistically estimating the range of exposure to an existing substance in Canada, assessment conclusions are based on generic realistic worst-case scenarios, and are not site-specific. However, for new substances, generic worst-case scenarios can be site-specific, as discussed in the summary paper. Fugacity modeling is routinely used to help understand chemical fate in the environment, and on occasion in addressing exposure to substances that are released from non-point sources. How to best use fugacity modeling based estimates of overall persistence and long-range transport potential as part of a weight of evidence in assessing risk, is being considered. Human health assessment takes local exposure into account where there is likely to be a significantly sized exposed population locally. Typically, however, assessments are focused on exposure of the general population.
Japan	The objective of the law is to prevent long-term adverse effect, through the environment, of hazardous chemicals and focuses on nation wide risks caused by exposure to such chemicals. Therefore, site specific exposure is not assessed under the law.
US	The US estimates quantitative site-specific (local) releases and exposures because these are more protective. Site specific or generic assessments using conservative assumptions are used to estimate potential quantitative exposures. Fugacity models, at the present time, are used to supplement our understanding of how a chemical partitions in the environment, its potential persistence, and its potential for long range transport. Estimated concentrations of the chemical in individual environmental compartments are not currently directly used.
EU	For both the local and the regional environment to which emissions take place standard environmental characteristics have been define in the TGD. The local modesl for air, water and soil are simple 'dilution models' where concentrations in air, water and soil close to point sources are calculated. Site specific information can be used to override certain, if not all, parameters that are used in these models. The regional model uses a global model similar to a fugacity model which is a nested version with local point sources, a regional environment and a continental environment surrounding this. The characteristics of the regional environment are defined as a densely populated, highly industrialised region in Europe, the continental environment reflects the continent of Europe.
Finland	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.

(4) What is the policy consideration to identify possible environmental degradation products, metabolites, incineration products and sewage/drinking water treatment transformation products, and to assess their chemical properties and fate?

Australia	Australia considers these factors on a case-by-case basis.
Canada	Assessment of degradation products in the risk assessment of new and existing substances is conducted on a case-by-case basis. This depends on the availability of information on the degradation products and their potential to be more problematic in the environment or to human health than the parent compound. Information from experimental studies (e.g., simulation biodegradation tests) or model simulations (e.g., using CATABOL) is considered. If a metabolite is found to be of more concern than the parent (e.g., more P or B or T), then it is included in the assessment alongside the parent. Risk from possible degradation products can be used in concluding on risk from a "parent" substance within our assessment programs. The level of scientific knowledge relating to the degradation processes is an important consideration in making this decision. Conclusions in the risk assessment can be based solely on the degradation product. Industrial by-products, incineration products, etc. can also be defined as "substances" that require assessment directly (e.g., dioxins and furans). If a degradation product is also directly released to the environment (as opposed to being formed in the environment), or if it is formed by the degradation of a number of different substances, then it is often appropriate to carry out a separate assessment of the degradation product (e.g., ozone precursors; formaldehyde).
Japan	If significant amount of degradation products, which are not bio-degradable, are found in the bio-degradation test, those degradation products are subject to bio-accumulation and screening toxicity tests.
US	Under most circumstances (new and existing chemical programs) policy allows EPA to include known and theoretically possible degradation products resulting from environmental degradation, metabolites, incineration and sewage/drinking water treatment in their assessments. This is largely driven by our understanding of the degradation mechanisms and pathways relevant to the processes above and our level of concern for the products. In the event that scientifically supportable concerns for these products were raised, policy would support conducting an assessment on those products.
EU	In the assessments consideration must be given to whether the substance being assessed can be degraded, biotically or abiotically, to give stable and/or toxic degradation products. Where such degradation can occur, the assessment should give due consideration to the properties (including toxic effects) of the products that might arise. For new substances, it is unlikely that information will be available on such degradation products and thus only a qualitative assessment would normally be possible. For existing substances, however, known relevant degradation products should also be subject to risk assessment. Where no information is available, a qualitative description of the degradation pathways can be made.
Finland	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.

(5) What is the policy consideration to consider long range transport potential of a substance?

Australia	Australia does not have a formal PBT policy, but long-range transport potential is considered as issues arise, based on considerations of potential persistence and bioaccumulation.
Canada	Evidence of long-range transport of a substance can be used as a means to conclude that a substance is persistent in air in our regulatory context (i.e., will likely have a half-life > 2days in air if it undergoes LRT). Such criteria have played a role in the "categorization" of our Domestic Substances List, where the legal definitions of persistence are critical. As with the US there is no policy in place that requires chemicals to be screened for LRTP in ecological risk assessment. Within our ecological risk assessments, chemical properties that suggest a substance may undergo LRT (e.g., persistence in air, high K_{aw}) can be used to provide evidence of long-range transport. Multimedia models (e.g., TaPL3) can also be used to simulate LRT. However, currently evidence of LRT is only flagged and only on a case-by-case basis in risk assessment. The information from multimedia models for LRT can be used to determine the scale of exposure and likely target areas or organisms exposed (e.g., Arctic environments). It can also support understanding of the degree of exposure owing to release of substances from remote, non-domestic sources.
Japan	As the risks from long-term exposure to chemical substances via the environment are considered in the law, with a priority to monitoring data in decision making, the transport potential of substance is effectively taken into consideration.
US	Currently EPA estimates the properties necessary to screen chemicals for long range transport potential (LRTP) but there is no policy in place that requires chemicals to be screened or to incorporate that (LRT) characteristic into our assessments. If however a chemical substance elicits concern relating to its possible PBT (persistence, bioaccumulation and toxicity) properties, it is also more likely to be scrutinized for LRTP. This is based on experience. Even though persistence and LRTP are not equivalent properties, long-range transport is an important issue for many substances precisely because they have PBT characteristics, are subject to LRT, and are also redeposited and subsequently bioaccumulated at sites distant from their release. Examples include hexachlorobenzene and some PCBs.
EU	There is no specific policy in the EU towards the assessment of the long-range transport properties of chemicals. The TGD contains a specific chapter which relates to the assessment of the risks for the marine environment, which contains the criteria for the identification of Persistent, bioaccumulating and toxic substances (PBTs). No criteria for long-range transport have been identified but it has been realised that in particular for PBT substances the LRT properties may be important and together with high persistence may contribute to the deposition of substances far away form their sources.
Finland	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.

(6) How do you consider to run multimedia models to generate estimates of 'overall' environmental persistence?

Australia	Australia does not have a policy that requires routine multimedia modelling to estimate 'overall' environmental persistence. When it is done, simpler models are used due to the limited available information and expertise. The need for such a policy is, however, under consideration.
Canada	For risk assessment, Canada runs multimedia models at Level III complexity either using EQC, ChemCan, TaPl3 or the Level III model in EPISuite. All of the Level III models provide a measure of overall persistence (P_{ov}). However, currently no regulatory benchmarks exist to compare P_{ov} estimates from models. Consequently, information on P_{ov} is used only in a qualitative manner as it provides information on the relative persistence of a substance in individual media as well as the effect of partitioning on persistence and of persistence on partitioning. P_{ov} cannot be used to categorize substances for persistence as currently regulatory half-life criteria are single media based.
Japan	The authority may use fugacity-type models to estimate "overall" environmental persistence. However the authority gives priority to environmental monitoring data.
US	In EPA a multimedia model is run for all new chemical assessments where there are adequate input data and the model is appropriate for the type of chemical under consideration. This is not based on a policy decision, rather it is because the model exists as part of a set of models that are run together automatically in EPISUITE for all new chemicals. Overall persistence is an output of many level III models. However, currently there is no policy in place that requires calculation of overall persistence or uses this information in our assessments.
EU	In the EU there's no policy or common practice towards the use of multimedia models to generate estimates of 'overall' environmental persistence. Persistence in the context of the PBT assessment (see previous question) is generally assessed though the (bio)degradation half-life values for water, sediment, air and soil based on laboratory or field studies.
Finland	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.

(7) What assumptions do you use regarding the use of wastewater treatment prior to release of a substance to the environment and the type and efficiency of the wastewater treatment process?

Australia	If the effectiveness of on-site treatment is known, these are taken into account when estimating the amount of chemical entering STP. Activated sludge treatment is assumed. Removal efficiency is then estimated using an Australia-specific STP model that includes the EU SimpleTreat tables. The model estimates removal based on physical and biodegradation processes.
Canada	In the initial (conservative) stage of exposure characterization of existing substances it is usually assumed that there is no removal by a sewage treatment plant. If a potential risk is identified, then one of a number of available models may be applied to refine the release estimation for the substance. Models may also be used to allow comparison with industry submitted removal efficiency data. Significant work is currently under way to evaluate the validity of STP removal results obtained using a number of different commonly available models. During the ecological exposure assessment of new substances, discharge to waste treatment facilities, either on-site or municipal, is assumed. A similar process to that described above by the US is used. Removal in an STP is either modeled using the fugacity-based STP model or preferentially using data provided by the Notifier. Health assessments of new substances assume no STP removal.
Japan	The removal of a chemical substance by the use of water treatment may be considered for detailed exposure assessment. However this factor is not used under the law so far, because this factor is effectively counted when the authority uses limited amount of environmental monitoring data to estimate overall exposure.
US	Activated sludge treatment is assumed to be the treatment process in place, either at the industrial facility or in the municipality treating wastewater from the industrial site. The removal efficiency for the substance of interest is estimated using the STP model component of EPA's EPISUITE estimation models. STP can estimate removal based on physical processes (sorption and volatilization) alone, or using a new method, incorporate biodegradation into the removal estimate. The new method is currently undergoing evaluation. Where properties required as input to the model cannot be estimated, defaults are used based on factors such as chemical class and molecular weight.
EU	In the risk assessment a proper functioning of waste treatment is assumed. The situation with respect to wastewater treatment at industrial installations is less clear. It may be assumed that many of the larger industrial installations are either connected to a municipal wastewater treatment plant or have treatment facilities on site. In many cases, these treatment plants are not biological treatment plants but often physico-chemical treatment plants. For a standard regional scale environment (definition see section 2.3.8.1) it is assumed that 80% of the waste water is treated in a biological STP and the remaining 20% released directly into surface waters (although mechanical treatment has some effect on eliminating organic matter, this is neglected because on the other hand stormwater overflows usually result in direct discharges to surface water even in the case of biological treatment. It is assumed that these two adverse effects compensate each other more or less with regard to the pollution of the environment). The degree of removal in a wastewater treatment plant is determined by the physico-chemical and biological properties of the substance (biodegradation, adsorption onto sludge, sedimentation of insoluble material, volatilisation) and the operating conditions of the plant. As the type and amount of data available on degree of removal may vary, the following order of preference should be considered. The percentage removal should preferably be based upon measured influent and effluent concentrations. As with measured data from the environment, the measured data from STPs should be assessed with respect to their adequacy and representativeness. The data may be used provided that certain minimum criteria have been met, e.g. the measurements have been carried

EU ***(cont.)***	out over a longer period of time. If there are no measured data available, the degree of removal can be estimated by means of a wastewater treatment plant model using log Kow (Koc or more specific partition coefficients can also be used; see section 2.3.5), Henry's Law constant and the results of biodegradation tests as input parameters.
Finland	The question is not in the scope of the STTV's responsibilities of human health risk evaluations.

(8) What assumptions do you use regarding the removal of a substance during drinking water treatment?

Australia	This is outside the remit of the regulatory scheme for industrial chemicals.
Canada	As in question7, initially no removal is assumed. If a potentially problematic level of human exposure is noted under this conservative scenario, refinements may be made.
Japan	The removal of a chemical substance during drinking water treatment may be considered for detailed exposure assessment. However there has not been such a case so far. The authority may use measured drinking water quality if available. If it is not, measured ground water quality and river water quality may be used as alternative for a consecutive estimation.
US	0 % removal in drinking water treatment is generally assumed for a screening level assessment.
EU	Drinking water is produced from surface water or groundwater, and is modelled as described by Hrubec and Toet (1992). The drinking water module in the present version of the EUSES program which encompasses the models included in the TGD, assumes a complete removal of suspended particles from surface water and groundwater. The effects of the treatment processes used for purification of groundwater, which are generally not intended for the removal of organic pollutants, can be neglected. Dependent on the type of storage, two different water treatment systems for surface water can be distinguished: system 1 includes storage in open reservoirs, system 2 includes dune recharge. Removal of the dissolved fraction of a xenobiotic from the surface water is modelled by means of purification factors. For the choice between the two systems and the choice between surface water or groundwater, a worst-case approach is followed. Further details can be found in Appendix II of Chapter 2 of the TGD.
Finland	We may ask the local water company how they process and monitor the water supply. This would then be considered in the exposure assessment. If no data is available on a particular substance in drinking water, then the significance and impact of the raw modelling output and the need for possible additional monitoring data would need to be assessed.

(9) Whether and when do you use the on-site release and exposure information from the industry submission or standard, and usually more protective, assumptions and models (e.g., how to deal with submitted release estimates which are much lower than model results, etc.)?

Australia	This is a case-by-case consideration. When a variance does not fit with scientific judgement, the proponent would be asked to make clarifications. Should the variance remain unexplained, conservatism is applied.
Canada	There is no fixed standard for making this decision. Professional judgment involving evaluation of all available information (industry data, modeled data, monitoring data) and discussion with industry to try to understand the discrepancy in results support a final decision. For example, industry may be using more advanced best available technology than was assumed in modeled scenarios.
Japan	The law does not require manufactures or importers of the chemical substances to submit emission data of chemical substances. However, manufactures or importers of monitoring chemical substances are required to submit the quantity of their products and its intended use. The authority takes into account such data together with available hazard information, monitoring data and estimations to decide if it should issue an order to manufacturer(s) or importer(s) to provide chronic hazard information of a particular chemical.
US	If release information in the industry submission is not well substantiated and is significantly lower (e.g. 10 times lower than the standard assumption or model), EPA will use the standard estimate. For consumer exposure, EPA would review the information and make a decision to accept or reject it on a case by case basis.
EU	There are no fixes rules or guidelines defined for taking such decisions. As indicated above the assessments carried out for new and existing substances are normally not addressing specific risks to sites but are intended to assess in general the potential risks to man and the environment from the marketing and use of these substances. Therefore, in particular for the exposure assessment for downstream uses of a substance, exposure modelling based on generic assumptions plays an important role. This is true for the environmental exposure as well as for the assessment of the workplace. For the actual production of the substances very often the manufacturers are in the position to provide site-specific measurements or emission or exposure information. Generally such data, after checking their quality, are accepted by the authorities and used to override the modelling assumptions.
Finland	If measurements have been conducted under realistic conditions using acceptable methods and standards and the sample size is large enough we prefer measured data.

(10) (a)How do you deal with significant data gaps during screening versus comprehensive assessment stages (e.g., inadequate information on: production, formulation and/ or industrial end use; equipment, shipping containers, and process flows; release points or exposure activities; concentrations in formulations; physical states relevant to releases or exposures; media to which the chemical will be released; likelihood and effectiveness of treatment; etc.)? (b)What conservative assumptions do you use in the absence of information on chemical properties, environmental fate data, releases, etc?

Australia	(a) Industry is obliged by legislation to make a complete data submission, unless granted exemption. Such exemption is scientifically based, so a gap does not arise in these circumstances. When, however, data pertaining to the chemical are not available, the proponent is able to submit data on suitable analogues (with suitability determined early in the assessment process). Another alternative is to provide modelled data. Where data are completely lacking for a given parameter, conservative assumptions are made based on experience to date. Based on the outcome of the environmental hazard and risk assessment, assessment certificates for new industrial chemicals can be withheld/limited/narrowed, effectively preventing or restricting the use of the chemical. For existing chemicals, industry surveys are used to attempt to fill gaps. If necessary, consideration of overseas practices can be used. (b) For any assessment stage, Australia would use QSAR to estimate values, to which scientific judgement would be applied. If necessary, worst-case assumptions (e.g., no removal via STP) are made. More robust data gathering is attempted for the comprehensive stage (see above).
Canada	(a) As pointed out in our summary paper, "screening" assessments in Canada can cover a wide range of technical detail, and are intended to routinely lead to regulatory decisions. We do not do "preliminary" assessments as such, although an initial step of our screening assessments may involve the use of highly conservative assumptions to allow rapid identification of less problematic situations. Such conservative assumptions relate to those factors listed in the question, possibly supported by other information such as specific data on annual production or import quantities of a substance. If a possible risk is identified, there can be follow-up with affected industries to obtain more realistic data for use in refining the release and exposure estimates. If such data is not forthcoming, the assessment conclusion will be based on these more conservative assumptions. (b) For efficiency, first stage exposure characterization is quite conservative with respect to most parameters. If the potential for risk is indicated at that stage, refinement of the characterization involves estimation of parameter values that are believed to be representative of a realistic worst-case scenario. In the absence of empirical information, estimates will tend to be on the more conservative side. There are a number of opportunities for industry to provide comments, and indicate erroneous assumptions used in our exposure scenarios. These include: discussions with industry during development of the assessment; a science peer review of the assessment, which typically includes technical experts from the affected industry (for ecological assessments of existing substances); and legislated public comment periods associated with publication of the assessment reports (for existing substances). For new substances, an approach similar to that described by the US is used.
Japan	(a), (b) The authority uses the worst-case assumption that all the amount manufactured or imported for open system use will be released to the environment.
US	(a) For any assessment stage, EPA generally will make conservative assumptions (e.g. worst-case assumptions of release and exposure scenarios using estimates of releases and exposures that are not expected to be exceeded). More robust data gathering is attempted for the comprehensive stage.

US *(cont.)*	(b) EPA models, professional judgment, and information on similar chemicals can provide estimates to fill the chemical properties and environmental fate data gaps in many situations. If EPA is not able to fill the data gaps, conservative assumptions can be made (i.e., higher persistence, lower removal in wastewater treatment and drinking water treatment, etc). For releases, see answer to previous question (10).
EU	As a matter of principle the generic assessment methodology as described in the TGD can be applied to new chemicals for which a limited amount of information is available to the authorities. The TGD therefore includes a large number of default values and reasonable worst-case assumptions that are needed to carry our the exposure assessment for workers and the environment for the different possible steps in the life-cycle where exposure can occur.
Finland	For new substance notifications, the data package is usually sufficient for the estimation of these properties. In other cases, we would ask the industry in question for more details on their processes and their substance. For example, if a powder is assessed, we would assume that it is a dusty powder in case no granulometry data or other information to suggest otherwise is available.

(11) Do you consider exposures for likely uses other than the intended use reported by the company? (most relevant to new chemicals).

Australia	Assessment certificates do not limit the way in which a chemical can be used post-assessment. Secondary Notification conditions can, however, be applied to anticipate significantly changed or increased exposures and assess how they change the risk assessment.
Canada	At the present time, existing substance assessments are based on realistic worst case estimates for current known uses only. For new substances, additional likely uses and volumes are forecasted. If a new substance poses no unacceptable risk to humans or the environment, it becomes eligible for listing on the Canadian Domestic Substances List. Once listed it may be used for additional applications at unlimited volumes. Therefore, during the initial assessment, potential other uses and volumes must be forecast and determined to pose no unacceptable risk as well.
Japan	The authority uses the worst-case assumption that all the amount manufactured or imported for open system use will be released to the environment.
US	Sometimes. For example, if other potential use patterns can be identified, EPA may attempt to determine whether those other use patterns may have significantly higher releases and exposures relative to the intended uses. If significantly higher releases and exposures are expected, then EPA may include these other use patterns in the assessment.
EU	Assessments are generally focussed on the intended uses and use conditions indicated by industry. However, in particular for substances used in consumer products, the authorities may also assess the exposure which may results from what is defined as the reasonable foreseeable misuse of these products.
Finland	Only the intended use.

(12) When potentially relevant data are available for a similarly exposed population or for a similar chemical, to what extent do you apply the data to a similar population or chemical? For example, do you use release data (PRTR) or exposure data for one substance as a surrogate for another substance with expected similar releases, uses, or exposures?

Australia	This would depend on the relevance of the surrogate to the notified chemical, based on scientific judgement.
Canada	Emission Scenario Documents (ESD) are developed to allow estimation of release of substances based on their use within an industrial process – in effect using such a surrogate approach. If a suitable ESD is not available, development of such an estimation based on substances having the same known application would be suitable. Use of exposure data in a similar way would have to be considered on a case-by-case basis. Such cases may become more common as we carry out risk assessments of large numbers of lesser known substances identified by the categorization process.
Japan	As the authority puts priority on mandatory data, there has not been a case of using the data of similar chemicals in the past. For pre-marketing notification stage the authority dose not request emission related information but information of bio-degradability and bioaccumulation. For the information, information of the chemicals which are considered to have similar properties may be considered by the request of notifier if appropriate.
US	EPA will usually use such data to fill data gaps for workplace releases and exposures. EPA sometimes uses consumer exposure data for one substance as a surrogate for another substance with expected similar consumer uses or consumer exposures.
EU	(Blank)
Finland	This has been applied for existing substances risk assessment. For example, benzene air measurement data during car repair was used for estimating Tert-amyl methyl ether (TAME, additive in gasoline) air concentrations in the same scenario. This could also be valid for new substances, if such data are available.

(13) Is the effectiveness of engineering controls or personal protective equipment included in the assessment in all cases, some cases, and, if so, under what circumstances?

Australia	In all cases, as it is part of the risk assessment (risk mitigation).
Canada	Beyond a first stage exposure characterization, engineering controls for which we have information such as sewage treatment plant removal, or stack baghouses would generally be taken into consideration in the release estimation. Occupational exposure is not considered within our programs as it is addressed under Provincial law. Empirical data for the point of release would already account for any controls. However Canada is careful not to limit ourselves to situations where a notifier has gone well above the industry standard in controlling emissions – if we suspect they have, we will assess their approach as well as industry standard]
Japan	The law does not take into account of engineering control due to the fact that it is not concerned with labor health, which is covered by another law, and focuses on exposure through environment.
US	Engineering controls are usually very difficult to factor into a quantitative assessment and are usually included qualitatively. Personal protective equipment (PPE) is included only when all exposed populations are expected to use PPE (e.g., gloves for corrosive materials, etc.).
EU	Whether or not engineering controls of PPE is included in the assessment is very case dependent. In some cases industry was able to demonstrate convincingly that certain controls are common practice throughout their sector. Similarly, for substances classified as corrosive it is generally assumed that PPE is used. On the other hand there have been cases where it was assumed that PPE was not used (e.g. in the construction sector) despite the labelling of the substance.
Finland	For industrial chemicals the exposure estimation is conducted without PPE. In some cases (new or existing substances), the effect of PPE could be taken into account in risk characterization and only when industry has documentation that PPE is always used in that particular exposure scenario. For chemicals in consumer use the estimation is always made without PPE. However, the definition of PPE sometimes seems to be unclear.

2/ Responsibility

(14) (a)What regulatory requirement or voluntary programme exists for the reporting of information related to environmental, occupational and consumer exposure to chemicals (e.g. new chemicals notification, assessment of existing chemicals, periodic reporting)? (b)What types or levels of exposure information are reported by industry, for screening- and detailed-level assessment?

Australia	(a) Occupational: Industry is required to provide information relevant to occupational exposure for both new and existing chemical assessment. Typical information required includes information on uses, manufacture/import volume, number and category of workers, nature of work done, measures and equipment used for prevention of worker exposure, education and training on practices and procedures, information or statistics on work-related injuries/diseases, atmospheric monitoring data, biological monitoring data; and published epidemiological or case reports. All this information is taken into consideration during exposure assessment. Consumer: Industry is required to provide information relevant to consumer exposure (to consumer products only) for both new and existing chemical assessment. Environmental: there currently is no requirement to report environmental releases except in accordance with PRTR (National Pollutant Inventory) legislation and specific licences that may or may not be issued by State authorities and which do not directly relate to the regulation of industrial chemicals per se. This matter is the subject of intergovernmental consideration. (b) Except for certain cosmetics and trial uses, reporting by industry is not required. For existing chemicals, industry is required to provide whatever such information it has.
Canada	(a) Annual reporting of releases of specific substances to the National Pollutant Release Inventory is required. Also, CEPA states that a manufacturer/importer or commercial processor of a substance who obtains information that reasonably supports a (potential) risk associated with a substance must provide this information to the Government. A limited amount of data is collected through this mechanism. There are also fairly broad powers for the collection/generation of data needed for conducting risk assessments, as mentioned in the summary paper. This power has been used to collect information for existing substances assessments. There have also been requests for voluntary submission of data by industry in relation to the categorization initiative. Further, a table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, has been prepared to accompany the country summary and responses to questions (page111-112). Included among the examples of other sources of information is an industry initiative for monitoring and public reporting. Information from such sources is taken into consideration in conducting risk assessments under CEPA. For new substances, all information in the Notifier's possession must be submitted at the time of notification if it relates to one of the information requirements in the New Substance Notification Regulations. This would include all exposure related information. Occupational and consumer exposure information is not a requirement under the NSN regulations but can be submitted voluntarily if available. (b) As discussed in the summary paper and in question 10, there is no formal distinction between the approaches (e.g., level of realism, complexity) used for "screening" and detailed assessments in our programs. For existing substances, there is no predefined reporting requirement. There are predefined information requirements laid out in the New Substance Notification regulations including those for exposure. The NSN regulations have recently been revised, but have not yet been publicly released. More detailed exposure information will be required under the new regulations. The current regulation and NSN reporting guidelines can be found at: http://www.ec.gc.ca/substances/nsb/eng/index_e.htm
Japan	(a) Under the law, the industry is obliged to report the quantity of the chemicals manufactured or

Japan ***(cont.)***	imported if the chemicals are the Classes I-III monitoring chemical substances and the Classes II specified chemical substances. The production and import of the Classes I specified chemical substances are banned. Regarding class II specified chemical substances, industries additionally have to report the amounts of the chemicals planned to be manufactured or imported. The authority conducts a nation wide survey every three years to investigate the amounts of all chemicals which are manufactured in or imported to Japan. The industry is required to report to the authority of the new findings of hazard information, if any, on the chemical substances which are included in either the existing or the new chemical substances lists. (b) The authority requests industries to report the quantity of monitoring chemical substances which are manufactured or imported, and its intended use. These information will be used both for screening- and detailed-level assessment.
US	(a) These programmes are summarized in the US discussion paper for this dialogue. This paper includes new chemicals, existing chemicals reporting under the inventory update rule (IUR), and the Voluntary Children's Chemical Evaluation Program (VCCEP). In addition to regulatory requirements and voluntary reporting under TSCA, there are several monitoring efforts conducted by the U.S. government. Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System, the National Air Toxics Assessment; Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database. (b) See the US discussion paper for a listing of the information reported for these programmes. For new chemicals, the reporting form for new chemicals is available in two parts at http://www.epa.gov/oppt/newchems/pmnpart1.pdf and http://www.epa.gov/oppt/newchems/pmnpart2.pdf . The reporting for new and existing chemicals and the initial tier of VCCEP include primarily screening-level exposure information.
EU	See introduction on the legislative framework above. Other than that there are no EU wide programs to report exposure information. However, in the context of national programs for emission registration (PRTR) there are different initiatives where such information is gathered. Similarly a number of EU Member States have product registers where a lot of information on the use of chemicals in products is gathered on a regular basis.
Finland	Under new chemicals notification, the notifier is requested to submit the base set of data. If however, the conditions change significantly, e.g. production volume use or exposure, this needs to be reported to the authorities. Same applies if any new data become available. Finnish Institute of Occupational Health maintains a registry of occupational hygiene measurements and a database on Finnish Job Exposure Matrices (FINJEM) which consists of analytical data evaluated and summarized by experts. Information on chemical releases from products may be received from market surveillance conducted by consumer product agency.

(15) What information is developed by governments (e.g. monitoring and modeling)?

Australia	Governments have developed some modelling (e.g., removal by STP) but mostly accesses models developed by international regulatory authorities. Monitoring for workplace exposure to hazardous substances is required by Commonwealth legislation. The need for environmental monitoring is under consideration.
Canada	Most monitoring data is obtained from the literature or research facilities, many of which are affiliated with Environment Canada. Environment Canada is directly involved in a number of atmospheric, aquatic, terrestrial and wildlife monitoring initiatives. Health Canada has initiatives relating to the monitoring of media of human exposure and levels in biological tissues. A table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, such as Provincial and Municipal governments and industry consortia, has been prepared to accompany the country summary and responses to questions (page 111-112). In a very limited number of cases, targeted monitoring or scientific research may be funded by the assessment program. Most modeling is conducted within the program, although external expertise may be engaged for particularly difficult cases.
Japan	The authority requests industries to report the quantity of monitoring chemical substances which are manufactured or imported, and its intended use. These information will be used both for screening- and detailed-level assessment. Other than those mentioned above, the authority have been developing environmental monitoring data, PRTR data including estimation values. And also each ministry has been developing models such as air quality models both for wide area and site specific, Tokyo bay model and models of major rivers as tools for exposure assessment. To help industry to adequately control chemicals, government provides various tools and information such as soft ware for risk assessment, risk evaluation reports.
US	EPA develops exposure assessments for new chemicals and some limited number of existing chemicals. These assessments use monitoring data, if available in literature, past research, or industry submissions, and using modeling to fill remaining data gaps. The U.S. EPA, USGS, CDC and other agencies conduct exposure montoring studies in the U.S. (as noted previously). Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and he National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System, the National Air Toxics Assessment; Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database.
EU	Most EU Member States have national as well as regional programmes for gathering monitoring information on chemicals in different environmental compartments. In terms of the chemicals concerned these programmes are in most cases not directly linked to the EU priority lists for existing substances. Therefore, authorities generally use these data for their EU assessments when available and relevant.
Finland	Model predictions and expert judgement estimations. Sometimes the authorities request a monitoring study, which is usually undertaken by the industry.

(16) What is the role of governments in estimating and assessing chemical exposure?

Australia	For new chemicals, industry provides an estimation of exposure and the information on which it is based. The government then ultimately estimates and assesses exposure. For existing chemicals, the government estimates and assesses exposure (e.g., by calling for information or conducting industry surveys).
Canada	Under CEPA, the government is responsible for conducting risk assessments, which includes exposure characterization. This does not preclude making use of all available sources of information, or in making arrangements with experts (including those in industry, academia, other government departments, etc.) to generate the necessary data. Governments at various levels are involved in monitoring of contaminants. A table summarizing some of the Federal monitoring programs and providing examples of other types of monitoring data sources, such as Provincial and Municipal governments and industry consortia, has been prepared to accompany the country summary and responses to questions (page 111-112).
Japan	Under the law, the authority is responsible for conducting exposure assessment.
US	For new chemicals, the government estimates and assesses exposure. For existing chemicals, the government sometimes estimates and assesses exposure (e.g., in some regulatory efforts, such as determining required chemical testing; and in some voluntary efforts, such as chemical substitution comparisons). The U.S. EPA, USGS, CDC and other agencies conduct exposure mentoring studies in the U.S. (as noted previously). Biomonitoring data have been collected under the NHANES, NHATS, NHEXAS, and TEAM studies for chemicals found in humans and through the National Fish Tissue Study, the National Sediment Inventory Tissue Data, and the National Water Quality Assessment Program for non-human organisms. Environmental monitoring data are available from EPA monitoring and data collection programs, including the National Air Quality System, the National Air Toxics Assessment; Toxic Release Inventory, and through EPA's STORET database. Monitoring data on chemicals found in drinking water sources are stored in EPA's NCOD database and USGS's NASQAN database.
EU	See answer under session 2: responsibility
Finland	The Finnish competent authorities assess worker, consumer and environmental exposure. Expert judgement is then applied to the modeling output in order to assess its applicability to real life situations. Sometimes site visits are done to support this.

(17) When two or more data sets exist, do you prepare multiple assessments and then compare? Do you make an initial determination and rely on one of the data sets? How is this be decided? Do you apply other approaches?

Australia	All data sets are usually covered within a single assessment. Data of unknown or poor quality may be referenced but not included in the assessment (with reasons stated).
Canada	For both new and existing substance assessments all relevant data sets are considered in evaluating risk taking into account the quality of the information in a weight of evidence approach. Experimental data (including close analogues) are preferred over estimated values.
Japan	The competent authority gives priority to measured data than estimated value.
US	EPA has no fixed policy and would handle these issues on a case by case basis. All data sets are usually covered within a single assessment. Data of unknown or poor quality may be referenced but not included in the assessment. A discussion of data comparison is usually included, and the most representative set may be recommended for use in the risk assessment.
EU	There are no specific rules defined for these situations.
Finland	If the two data sets were significantly different from one to another, then expert judgement would be used to decide which is the most relevant and applicable. If the data sets are supportive to each other, then they can be used to refine the assessment.

3/ Common and unique factors

(18) (a)While hazard, fate, and physical chemical properties test guidelines have been developed by Member countries and in many cases agreed under OECD procedures, exposure test guidelines are generally not available in the same way. Is there a need for establishing a means for Member countries to share experience in this regard? (b)Given the chemical- or scenario-specific issues presented, do you consider it feasible to develop exposure test guidelines? (c)Would this be a useful step for OECD to consider?

Australia	(a) Australia currently has limited exposure assessment options. The dialogue presents an opportunity to understand what other options might be useful, and thus lead to ongoing sharing of experience. (b) Yes, however their applicability to the Australian situation, particularly in respect of environmental releases (i.e., STP efficiency, water flows, industry practices) would be an issue. (c) Possibly, however relativity to other projects would need to be considered.
Canada	(a) If this question is interpreted in the context of exposure test guidelines relating to the conduct of site-specific assessments, then the relevant factor is that assessments in the existing substances program are not conducted on a site-specific basis. However, more general guidance relating to the collection and interpretation of monitoring data may prove useful. Such guidance would necessarily need to be fairly non-specific, given the variability of situations and of the chemicals themselves. Guidelines considering issues such as the relative significance of modeled versus monitored data may run into difficulties in identifying approaches that are consistent with the legislative requirements and governing policy considerations of the different jurisdictions. Shared development of specific tools and models is, of course, possible, and much of this is currently taking place within the Environmental Exposure Assessment Task Force (e.g., emission scenario documents, exposure reporting templates). It would also be ideal to examine exposure assessment approaches in the context of the upcoming international assessment sharing exercise under the New Chemical Task Force – although the current emphasis is on hazard assessment, it will expand to approaches to exposure assessment if OECD wants to move toward full Mutual Acceptance of Notifications] (b) See answer to previous question. We suggest potential consistency through use of more of a template style for reporting of exposure information. (c) Depends on the intended meaning of the earlier question.
Japan	Japan considers that the cooperation among the OECD members on exposure assessment should be useful. Although exposure situations vary among countries, commonality and coherence may be found in methodologies for exposure assessments. Further study on the possibility of developing common methodologies or test guidelines should be useful.
US	(a) Possibly. More discussion would be necessary to determine what types of guidelines could be beneficial and how these should be addressed. (b) Yes in some cases. (c) Possibly.
EU	(a) Sharing information and methodologies for assessing exposure information and carrying out exposure assessments could be very useful. We would consider it necessary to discuss further in

EU *(cont.)*	detail the most efficient way of sharing this experience. (b) Possibly, this needs further reflection and discussion. (c) Possible, this needs further detailed discussion.
Finland	Yes indeed, international guidelines for exposure assessment would help to generate data, which is reliable, comparable and accepted by other countries, when risk assessments from various regulatory programs are shared.

ANNEX 7: PAPER FROM IPCS, BIAC, NGO AND OECD

(1) IPCS

15 April 2005

Dear Dr Visser,

OECD Policy Dialogue on Exposure Assessment (Industrial Chemicals)

Thank you for inviting IPCS to provide brief information on policy issues related to exposure assessment for new and existing industrial chemicals, for consideration by the OECD Policy Dialogue on Exposure Assessment.

IPCS is involved in a range of activities on exposure assessment, including developing globally harmonized methodologies for conducting exposure assessment, the generation of actual exposure assessments in its chemical assessment work, the development of information/training materials on exposure assessment, a project on mechanisms and guidance for collecting human exposure assessment and work on integrated risk (including exposure) assessment.

IPCS is pleased to provide information on a selection of these activities, in order to facilitate cooperation between OECD and IPCS in this area. In relation to the policy dialogue aims, IPCS is particularly interested in topics that relate to Data Quality, and the issue of "common and unique factors". In relation to the former, we have work underway to develop guidance that specifically relates to the quality of exposure data. With respect to the latter, if there is potential to identify common factors that would be common for a broader range of countries (i.e. non-OECD countries), then it would be a valuable contribution to OECD's outreach programme, as the collection, analysis and interpretation of exposure data is beyond the capacity of many non-OECD countries.

Thank you for the opportunity to make this submission.

Yours sincerely,

Tim Meredith,
Coordinator, IPCS

1. **Experience from Conducting Exposure Assessments of Specific Chemicals**. IPCS's chemical assessment programme is largely delivered through its Concise International Chemical Assessment Documents (CICADs). The CICADs aim mainly to hazard characterization, and as a result thereof, usually give as the bottom-line tolerable concentrations (in the air), or tolerable daily intakes (for oral exposure). In order to do this meaningfully, a general assessment of patterns and scenarios of exposure are investigated and reported. However, CICADs only report a sample risk characterization for a specific exposure scenario, i.e., ambient air concentrations in the source country, or dietary or drinking water exposure, again within a specific region or a country. For these exposure scenarios, information on exposure is collected, but it is not meant to be that elsewhere the exposure were quantitatively similar. No effort is made to be all-inclusive in the exposure assessment. For the specific exposure scenario chosen for the sample risk characterization, measured data, but also modelled data are used. When modelled data are used, the basic assumptions of the model are described, and the uncertainties in the assessment (both as to data and model) are described in the section on uncertainties. Published data on exposure tend to be random and scattered, mostly collected for purposes other than to describe typical exposures, and in addition, often are quite old. Therefore, they are seldom very useful for the characterization of prevailing risks. IPCS thus uses also unpublished information from industrial sources and as a policy, welcomes and encourages participation of industrial organizations in the CICAD process.

2. **Data quality in exposure assessment.** This activity is developing a paper on a harmonized approach to data quality principles for exposure assessment. It will be a short stand-alone document that aims at informing those responsible for collecting and using exposure data why quality considerations are important. The document would describe the principles of data quality and include brief illustrative examples that highlight the importance of the key principles. It will be circulated for wide peer review and OECD input would be welcome.

3. **IPCS Glossary of Exposure Terminology.** This terminology is a product of the IPCS Harmonization Project and reflects wide consultation with exposure assessors. It is published on the IPCS website. IPCS website harmonization page: http://www.who.int/ipcs/methods/harmonization/en/. It has been accepted by the International Society of Exposure Analysis. OECD countries are encourage to adopt the terminology.

4. **Principles of characterizing and applying human exposure models.** This draft document is currently undergoing revision after international peer review. The report has been developed for risk assessors, who need to use exposure models and model results in their work, as well as model developers, to help them communicate openly and effectively with each other. Ten principles are recommended for characterizing, evaluating and using exposure models in order to help model users select and apply the most appropriate models. The report also discusses issues such as validation, input data needs, time resolution and extrapolation of the model results to different populations and scenarios. Uptake and use of the ten principles by OECD countries would facilitate harmonization, in that they impact on model data acceptance.

5. **Harmonized guidance on characterizing and communicating uncertainty in exposure assessment.** This activity is developing a harmonized set of principles for the treatment of uncertainty in exposure assessments. It will include the treatment of uncertainty in tiered assessment approaches.

6. **Aggregate/Cumulative Risk Assessment.** A scoping scientific workshop will be convened to produce a report including an internationally agreed framework for further work by IPCS and others, e.g. what can be achieved in the near/medium/longer term, what the harmonization issues are. It is anticipated that work could commence in the area of aggregate/cumulative exposure assessment.

7. **Integrated exposure assessment.** Historically, human health and environmental risk assessment methodologies have generally developed independently. Regulatory agencies often use a chemical-by-chemical approach, focusing on a single media, a single source, and a single toxic endpoint. Many international and national organizations have expressed a need for an integrated, holistic approach to risk assessment that addresses real life situations of multichemical, multimedia, multiroute, and multispecies exposures. In response to this need, IPCS convened a group of international scientific experts to develop approaches for a framework for integrated risk assessment. The report, which includes consideration of integrated exposure assessment is at: http://www.who.int/ipcs/methods/risk_assessment/en/

8. **Exposure Assessment and Human Data** Existing sources of human data can be found in many forms e.g. case reports, poisons centre records, health surveillance results. Much data is gathered as part of routine clinical and occupational practices but this is often not available or used for risk assessment. Data is typically not recorded with the needs of risk assessment in mind. Aggregation of data from various ad-hoc sources is not commonly undertaken and null-data is not well regarded. Poorly recorded exposure data is most frequently the reason why human data is not used with the highest confidence in risk assessment. Improvements in the collection and recording of exposures associated with human data could lead for new opportunities and uses for this data at the screening stage of risk assessment for example:

    - including development of intelligent test plans
    - Identification and refinement of exposure scenarios so that the circumstances by which humans are commonly exposed are taken into account
    - alerting of actual exposure circumstances causing concern with feedback to effective risk management actions

9. At the more detailed stage of risk assessment, further use of human data including biomonitoring data could be used to refine the weight-of-evidence considerations given during risk characterization processes.

10. In October 2003, at the fourth session of the Inter Governmental Forum on Chemical Safety (IFCS) held in Bangkok, 450 participants including 129 governments, 11 IGOs, and 13 NGOs recommended that **IPCS take the lead in the development of guidance on and mechanisms for collecting, disseminating and utilizing clinical and exposure data from human observations**.

11. **IPCS Workshop on Collection, Reporting and Use of Human Data.** In February 2004, IPCS held a Workshop on the Collection, Reporting and Use of Human Data (Cardiff, UK) to identify and discuss work needing to be undertaken to address the invitation from the IFCS. The Workshop discussed explored possibilities to build synergies and alliances between work on the development and harmonization of risk assessment methodology, poisons information, prevention and management and chemical incident alert, surveillance and response.

12. **In a parallel to this meeting the European Centre for Ecotoxicology and Toxicology** (ECETOC) held a workshop on the Use of Human Data in Risk Assessment. The key recommendations of the ECETOC Workshop focused on the need for good quality exposure data from humans and a clear framework for assessing the quality of human data form different sources.

13. Following these two workshops a one day meeting of the chairs and co-chairs of the Cardiff Workshop met together to consider the recommendations of the two Workshops and to develop an action plan as a response to the IFCS recommendation. This action plan is focusing on:

⇒ mechanisms for collecting comparable human data (in collaboration with the IPCS INTOX project and work being developed in the European Union, DG Health)
⇒ identifying priority areas where human data will help reduce uncertainties in risk assessment (in collaboration with IPCS RASG and HSG, OECD and EU JRC)
⇒ issues where use of human data could maximise effective risk management actions.

1. Planned activities over the next 12-18 months

Over the next 12-18 months projects being undertaken include:

⇒ A prospective study collecting data from poisons centres to illustrate the value of this underused data source among risk assessors)
⇒ A Workshop on Burden of Disease Methodologies, which would identify the exposure data needed to improve estimates of injury and disease due to chemicals exposures.
⇒ Specific work on the quality criteria and data formats for reporting human exposures
⇒ Role of human data in the risk assessment of consumer chemicals
⇒ Work to elaborate a framework on the use of null epidemiological data

(2) BIAC

June 2005

BIAC: OECD Policy Dialogue on Exposure Assessment

BIAC considers that within the context of the Policy Dialogue on Exposure Assessment, a number of core elements require particular attention, and should be incorporated into any follow-on work proposed within the context of the OECD dialogue:

- Exposure assessment is key to risk-based decision-making. BIAC strongly supports the improved use of exposure assessment (EA), when integrated with hazard information and assessment, to enable soundly-based judgements to be reached and for any necessary risk management and risk communication

- The extent and depth to which exposure information is required is dependent on the circumstances in which the information is to be applied. As such, the process for gathering the information should necessarily be efficient and account for these circumstances and the audience that is expected to participate in helping to ensure its success (recognising that this audience is rarely homogeneous). Specifically it should
  - Be obtained and applied in targeted, tiered and iterative processes
  - Recognise issues of data quality and business sensitive confidentiality
  - Avoid unnecessary complications in risk communications to enhance understanding by non-experts

- OECD should work to develop proportionate policies that, where appropriate, lead to the harmonisation and coordination of EA activities across stakeholders, recognizing regional differences in actual human and environmental use and exposure patterns.

- OECD is a recognized leader in the development of technical tools and guidance, including relevant projects in the field of EA. However, in practice the utility of this work is somewhat constrained by differing approaches to the adoption and implementation of these tools. BIAC therefore urges consideration and documentation of the scientific reasons for differing approaches.

- Data provided by biomonitoring have a particular role and value in EA when these result from the use of validated methodologies and are applied within accepted scientific frameworks for the evaluation of exposure and risk.

(3) Environmental NGO

Environmental Defense's perspective on policy issues related to exposure assessment

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April 2005

While both hazard and exposure are clearly relevant in determining chemical risks, there are critical differences between our ability to assess hazard and exposure that have implications for the development and application of exposure assessment policies. And real-world experience in chemical assessment programs that have attempted to rely on exposure information to prioritize chemicals also offers lessons for exposure assessment. In this paper I first address these issues, and then discuss their implications for exposure assessment policies.

Critical differences between assessing hazard and exposure

Approaches to integrating exposure assessment into regulatory decision-making need to acknowledge and account for a number of critical differences between the nature of hazard and exposure information and their relative extent of availability. While both hazard and exposure are clearly relevant in determining risk, certain characteristics of exposure information pose serious challenges to sound decision-making:

1. Hazard is largely inherent to a chemical, and doesn't fundamentally change over space or time, whereas any exposure information necessarily represents only a "snapshot" in both space and time.

A chemical's ***hazard*** is relatively intrinsic, largely or entirely independent of how the chemical is used, where or how it enters the environment, or other factors that vary with time and place. Hazard data are therefore relevant (i.e., necessary though not sufficient) in characterizing risk whatever the use of a chemical, and hence are useful in understanding any and all potential uses of or exposures to a chemical -- and what kind of exposure-reducing efforts may need to be taken.

Just the opposite is true for ***exposure***, the potential for which changes depending on how a chemical is produced, used, transported and discarded. Conditions that determine exposure can and often do differ enormously for every setting and point in time that a chemical is present. And even if a "snapshot" of current exposure were able to be assembled, the next new use or activity leading to a release would alter the exposure picture.

The variable nature of exposure poses a major challenge to exposure (and risk) assessment: It means that exposure assessment must be an ongoing activity, with the scope and frequency of its measurement sufficient to characterize the *variation* in as well as *magnitude* of exposure.

2. Voluntary and regulatory mechanisms for generating and collecting exposure information are undeveloped relative to those for hazard information.

Extensive international consensus exists as to how to test a chemical for most hazardous properties. Detailed government-sanctioned procedures, guidelines, criteria and standards are already in place for conducting hazard tests, for assuring the quality and reliability of the results, and for determining whether

[1] Participant in the Policy Dialogue on Exposure Assessment nominated by the EEB.

the results constitute evidence of a particular hazard. Moreover, these measures allow that results are reproducible and can be independently verified.

In contrast, virtually none of these mechanisms are in place to assure that exposure information is complete and accurate. Debates over what constitutes adequate exposure assessment and how to address the "moving target" nature of such information are far from resolved. Government-sanctioned procedures for generating, evaluating the adequacy of and interpreting exposure data have yet to be developed or validated, including testing and measurement standards, guidance, methods and tools.

Even use and exposure information reported in sufficiently qualitative terms or sufficiently aggregated form so as to eliminate any confidential business information (CBI, see next bullet) concern is rarely systematically collected and made public. For the first time, beginning in 2006, USEPA will begin to require the reporting of basic information relevant to understanding uses of and exposure to chemicals, although it will be limited to several thousand chemicals, and will be collected only once every five years – despite enormous documented variability in these chemicals' production volumes[2] that presumably reflects changes in their underlying use patterns.

3. Differential access to both exposure data and the means to generate them severely limit the "reproducibility" of such data.

In addition to the variability and absence of agreed-upon procedures noted above, other factors limit "reproducibility," that is, the ability to readily and independently measure or verify exposure data. Most exposure data and the means to generate them reside virtually exclusively with industry. It must be acknowledged that industry has a strong interest in maintaining that exposure to its products is low, so the ability to independently measure and verify exposure data is critical. Yet physical access to many exposure "settings" (e.g., workplaces) is very limited and infrequent at best, even for government officials.

Broader access to exposure-relevant information is even more restricted: Wide latitude is typically provided to claim chemical use and exposure information as CBI, preventing even its review outside government; this situation is often in contrast to that applying to hazard data, which is more likely to be deemed ineligible from designation as CBI.

Finally, even chemical manufacturers have incomplete access to and information on their customers and how their chemicals are used. Intermediaries (vendors, brokers, distributors) are a formidable information flow bottleneck, as is the often-proprietary nature of information concerning downstream use and competition among suppliers. These factors serve to impede information-sharing even within supply chains, which in turn affects the extent and accuracy of exposure-relevant information that any one entity in a supply chain can provide if asked or required to do so.

For all of these reasons, we believe that exposure assessment at this time is simply too uncertain and unreliable for it to serve as a basis for deciding for which chemicals hazard data should be developed. While ultimate decisions concerning risk identification and management need to account for exposure as well as hazard, in all but the most exceptional cases, chemical prioritization approaches should be hazard-, not exposure-driven.

[2] Environmental Defense analysis of production volume data reported under the Toxic Substances Control Act Inventory Updated Rule, comparison of data for 1986, 1990, 1994, 1998 and 2002. Available on request. Analysis shows that from one reporting cycle to the next one four years later, the production volume of about 40-50% of reported chemicals changed significantly, likely by one or more orders of magnitude.

Difficulty of using exposure information in chemical priority-setting: OECD experience as a real-world example

The ongoing work of the OECD Existing Chemicals Program vividly illustrates the limitations to available exposure information – and to efforts to prioritize chemicals based on such information. In that program, chemical-by-chemical assessments of high-production volume (HPV) chemicals are conducted. Typically, industry collects existing information and conducts any testing needed to fill gaps in the required set of hazard information. Industry then prepares draft assessment documents, which are reviewed by health and environmental agency officials in member countries. While the primary emphasis is on hazard assessment, program procedures currently allow for exposure information to be included to "place the hazard information into context." As we have documented in detail elsewhere,[3] in practice this exposure information is routinely being used to decide that chemicals that have been identified as possessing clearly hazardous properties are nevertheless low priorities for further work based on "anticipated low exposure."

Unfortunately, the exposure information typically being relied upon has truly massive deficiencies with respect to scope, quality and completeness.[4] Such information typically is:

- very limited in scope, and hence incomplete or even haphazard in its coverage of potential exposures, because it:
  - covers only a portion of known production and use;
  - covers only a subset of relevant activities, e.g., production, transport, storage, processing, use by customers, use in consumer products, product disposal, waste management;
  - covers only a subset of exposed entities, e.g., workers, consumers, the general population, sensitive populations, and wildlife;
  - addresses only a subset of relevant routes of exposure, e.g., by inhalation, ingestion or dermal contact; through food, water, air;
  - rarely is based on ongoing or sufficiently frequent measurement to address variation or changing conditions;
- unverified, unpublished, rarely peer-reviewed and of uncertain or undetermined quality;
- frequently based on judgment or speculation, rather than on actual measurements, monitoring or validated methods of exposure modeling.

Some of these deficiencies are related to the limited requirements under the program governing what exposure information is to be provided. However, others reflect the fundamental characteristics of exposure information described in the first section of this paper, as well as limitations on the extent and quality of information actually available and the capacity for effective review, and the lack of agreed-upon measures of scope, quality and completeness.

The Existing Chemicals Program has wrestled repeatedly with this problem over its history. Indeed, because of what many saw as an over-reliance on exposure-related considerations in the absence of an agreed-upon approach, the program went through a major refocusing to return to a primary focus on hazard characteristics as the primary driver for the program. However, despite the refocusing effort, inconsistent

[3] Denison, R. and Silbergeld, E., memorandum to the Task Force on Existing Chemicals for its 12th meeting, "Environmental Defense's concerns regarding use of exposure information in making recommendations regarding further work on HPV chemicals," 15 August 2003; Denison, R., addendum to memorandum to the Task Force on Existing Chemicals for its 12th meeting, "Statistics for all chemicals with SIAPs reviewed for SIAMs 15-16 and to be reviewed at SIAM 17 regarding use of exposure information in making recommendations regarding further work on HPV chemicals," 26 September 2004; Denison, R., memorandum to the Task Force on Existing Chemicals for its 13th meeting, "Further Proposal Re Use of Exposure Information in SIAM Recommendations," 17 September 2004.

[4] See prior footnote.

and insufficient exposure-related information – more than any other factor – drives the recommendation process for chemicals being assessed through the program.

Implications for exposure assessment policy

All of the factors discussed above mean that assembling a complete and reliable exposure picture even for a single point in time faces obstacles and has proven exceedingly difficult in practice. So how should exposure assessment policies – and practices – address these current realities?

Guidelines development: We continue to strongly support the development of comprehensive guidelines for collection, analysis, validation and presentation of exposure information, as the much-needed foundation of any exposure assessment policy and practice. In our view, the OECD program needs to invest at least the same effort in developing a process for exposure assessment as was invested in developing the SIDS. There remain a number of substantial obstacles that must be solved in order to ensure that adequately robust data on exposure can be gathered. Resolving these challenges will not be easy. These obstacles include:

- lack of agreement as to what exposure information is relevant and needed;
- lack of consensus as to the framework and methodologies needed to conduct an exposure assessment;
- limited availability of and access to internationally accepted, comprehensive measured exposure information or models for predicting exposure; and
- limited information available on all uses and other exposure pathways of chemicals.

Guidelines need to ensure that the measured and modeled or estimated data address and are representative of the full range of actual and potential exposures that can or do occur. Procedures are needed to govern, for example, the minimum number of samples, the frequency of sampling, and other parameters so as to ensure that the results of any exposure measurements are both statistically meaningful and representative of the spatial and temporal variations present in the sampled environment. Quality assurance/quality control procedures to ensure data quality are needed. Where data are available for only a subset of production sites/release points/exposure sources, procedures are needed to determine whether and if so how extrapolations from available data can be used to characterize exposures arising from the missing sources.

Adequate expert review: Policies need to provide for thorough review of exposure information. This starts with ensuring exposure-related expertise among reviewers is sufficiently diverse to address each of the various relevant exposure settings (workplace, consumer, environmental), and data generated through direct measurement as well as modeling. The review process should yield an explicit assessment of the **scope, completeness and quality** of the exposure information, in which any conclusions are qualified to accurately reflect the actual extent and nature of exposure information provided and hence the degree of associated uncertainty. Specific factors to be assessed should include:

- **Scope and Completeness**: geographic, temporal extent of applicability and associated limitations; to what fraction of total production and use, to what uses, and to which specific facilities, processes, activities and products the provided information applies; which activities associated with the chemical's full lifecycle (production, processing, storage, transport, use and disposal) are covered; whether information on releases and exposures relate to workers, consumers, public or the environment; whether information is based on measurements, modeling, judgment, extrapolation.
- **Quality**: extent of documentation provided/cited; reference to/description of procedures used; representativeness of sampling underlying any measured data; validation of any model used; peer review and extent of access to underlying data; assignment of measures of reliability; reproducibility.

Accounting for the variable nature of exposure: Policies need to acknowledge and account for the inherent variability in exposure over time as well as space. For example:

- For new chemicals, the nature or extent of production, use and exposure needs to be tracked and revisited/reassessed over time, not only as a chemical enters commerce but as its production level and range of uses change. During the initial review/approval process, conditions should be included that require reporting of any changes in the nature and extent of production and use and other exposure-relevant factors, and such reports should trigger a reassessment of exposure potential.
- For existing chemicals, policies should also be responsive to changes in the production level or use profile of a chemical. One recent illustration of this need in the U.S. is the change that has accompanied the phase-out of pentabromodiphenyl ether and its replacement with a different chemical, the production and use of which has increased dramatically as a result.

Data verification and model validation: To the extent data from industry are relied on, policies need to incorporate mechanisms to ensure and demonstrate that such data are accurate and representative, and wherever possible, to be able to independently verify such data.

To the extent that modeled as opposed to measured data are relied on to provide exposure estimates, policies need to outline procedures to be employed to validate the models, provide public access to the models and their underlying data sets. Just as for measured data, policies also need to ensure that models effectively account for variation in exposure over time.

Differential access: The differential access to exposure-related information (as discussed above) is a serious barrier to public confidence in both industry- and government-derived exposure assessment. In addition to adopting and abiding by comprehensive guidelines covering all aspects of exposure assessment, government needs to develop and implement mechanisms to demonstrate that it can independently verify the reliability of industry-generated exposure information; and industry needs to be encouraged or required to implement its own measures to increase confidence in the information it provides, including routine third-party review and a commitment to make information public whether exculpatory or not.

In addition, policies need to consider means to break through the supply-chain bottlenecks that effectively prevent development of a full understanding of chemical processing and use. In our view, one of the key innovations offered by the European Union's REACH proposal is its intent to compel information-sharing up and down the chemical supply chain.

Finally, in our view, serious reconsideration of the currently overbroad broad allowances for CBI claims related to exposure-relevant information is warranted.

Transparency: Policies should ensure that any descriptions of exposure information are clear and transparent in describing the scope and nature of the information and its limitations, including by addressing all of the elements specified above under Scope and Completeness and Quality.[5]

Policies should require that conclusions or recommendations be carefully written and explicitly qualified so as to limit their perceived and actual applicability to those settings for which information has been provided and deemed sufficient to warrant the conclusion or recommendation. Furthermore, the degree of uncertainty associated with a conclusion or recommendation should be stated and should reflect the extent

[5] Revisions proposed at SIAM20 to the *Manual for Investigation of HPV Chemicals* incorporate many of these suggestions, and are an excellent starting point for consideration of clarity and transparency in reporting exposure information.

of exposure information available. Lastly, policies should ensure that in the absence of good exposure information, exposure should be assumed possible or likely.

Additional challenges

Cumulative and aggregate exposures: A common limitation of exposure assessments in practice is to examine exposures only to single chemicals at single points in time, or from single sources or products, as if they occur in isolation from other exposures that are in fact relevant to understanding the true nature and magnitude of exposure. While understandable given the complexity involved in going further, this frequent failure to consider or even acknowledge the need to ultimately examine cumulative and aggregate exposures undermines the credibility of an exposure assessment. Policies, therefore, need to ensure that an accurate context is provided within which to judge a particular exposure assessment, one that accounts for factors such as:

- production, processing and use of the same chemical by multiple entities;
- multiple uses of the chemical leading to actual or potential exposures;
- multiple routes of exposure (direct, indirect) to a chemical;
- continuous or periodic release of or exposure to a chemical; and
- exposure to multiple chemicals producing the same/similar effects and/or acting by the same/similar mechanism(s)

Biomonitoring/environmental monitoring/health tracking: The ultimate arbiter of the value of exposure assessment is the extent to which its findings comport with reality. It is relatively rare for extensive data from actual environmental and biomonitoring to be available, and rarer still for health tracking statistics to be available that can be linked to particular exposures. Nonetheless, exposure assessment policies should ensure that such data are examined and incorporated where available, and should encourage the development of and public access to such data.

Susceptible subpopulations: In addition to variation over time and space, exposure to a chemical or the effects arising from such exposure may differ among particular subsets of human or ecological populations. This variation may be due any number of factors, such as inherent differences in the subpopulations themselves (e.g., children's respiratory rates are higher than those of adults), differences with respect to proximity to, or reliance on activities associated with, particular sources of exposure (e.g., occupational exposure, dependence on a diet high in fish or groundwater as a drinking water source), or differences in sensitivity to a substance (e.g., sensitization, genetic susceptibilities). (Less understood at present are the analogous differences in ecological subpopulations.) Policies need to account for such variations and ensure protection of the most susceptible and sensitive sectors of potential exposed populations.

(4) OECD Secretariat

Current Activities of the OECD Task Force on Environmental Exposure Assessment (June 2005)

1. In 1995, the OECD Task Force on Environmental Exposure Assessment was established in order to contribute to risk assessment activities, focusing on the improvement in the methods for estimation of releases of chemicals to the environment, modeling of environmental fate and pathways, and use of monitoring data in exposure assessment. Australia, Austria, Canada, Denmark, Finland, France, Germany, Ireland, Italy, Japan, Korea, the Netherlands, Poland, Slovak Republic, Spain, Sweden, the United Kingdom, the United States, European Commission, UNEP and BIAC regularly participate in the meeting of the Task Force in recent years.

2. The current Work Programme of the Task Force consists of the following four work areas.
- Improvement of release estimates for exposure assessment
- Harmonization and further development of exposure models
- Improved use of monitoring data
- Reporting summary exposure information.

Release Estimates

3. The core activity of the Task Force on Environmental Exposure Assessment is the development of emission scenario documents (ESDs), which describe sources, pathways, production and use patterns that quantify the emissions (or releases) of chemicals, with respect to specific industry categories and types of the use of chemicals. ESDs are used in risk assessment of chemicals to establish the conditions on use and releases of chemicals, which are the bases for estimating the concentration of chemicals in the environment. ESDs are already widely used in national and regional contexts. The Technical Guidance Document for EU Risk Assessment includes a number of ESDs, so that the information in these documents be used instead of more general default emission factors. The USEPA has developed a number of generic scenarios to be used as default release scenarios in risk assessment.

4. The OECD Task Force on Environmental Exposure Assessment is developing ESDs at the OECD level, in order to make it possible to reflect conditions on production, use etc. that are different between countries, and to avoid duplicative efforts by Member countries and industry in gathering exposure information. The following ESDs were published.
- Wood preservatives (February 2003. Joint project with the OECD Task Force on Biocides)
- Plastic Additives (June 2004)
- Water Treatment Chemicals (June 2004)
- Photographic Industry (June 2004)
- Rubber Additives (June 2004)
- Textile Finishing (June 2004)
- Leather Processing (June 2004)
- Photoresist Use in Semiconductor Manufacturing (June 2004)
- Lubricants and Lubricant Additives (December 2004)
- Automotive spray application (December 2004)
- Metal finishing (December 2004)
- Antifoulants (April 2005. Task Force on Biocides)

Published and draft ESDs are publicly available on the EHS website and users are encouraged to provide updated information regarding the estimation of chemical emission from these industry/use categories to the OECD Secretariat. The Task Force reviews the comments received and considers the revision of ESDs.

5. The Task Force is currently working on the following ESDs:

- Industrial surfactants (lead country: UK).
- Printing industry (lead country: Germany).
- Pulp and paper manufacturing (lead country: Canada).
- Paper recycling (lead country: UK).
- Coatings industry: paints, lacquers and varnishes (lead country: UK).
- Chemical industry (lead country: the Netherlands).
- Blending of fragrance oils into consumer and commercial products (lead country: US).
- Formulation of adhesives (lead country: US).
- Insecticides for stables and manures (Task Force on Biocides).
- Insecticides for households (Task Force on Biocides).

6. Several projects to enhance the development and use of ESDs are under way, including the revision of the Guidance Document on developing ESDs, the development of a Guidance Document to cover the emission during the service life of products and articles in ESDs, the development of a matrix of the coverage by ESDs of industry categories, use categories and life-cycle stages of chemicals ("Matrix Project"), and the development of a document on comparison of emission estimation methods used in PRTRs and ESDs.

Exposure Models

7. As follow-up activities to the OECD/UNEP Workshop on the Use of Multimedia Models for Estimating Environmental Persistence and Long-range Transport in the Context of POPs and PBTs Assessment (Ottawa, October 2001),

- "Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-Range Transport" was published in March 2004; and
- a hands-on training workshop on application of multimedia models for identification of POPs will be held in August 2005, in co-operation with UNEP (lead countries: Switzerland and Germany).

Use of Monitoring Data

8. After the Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals, held in Berlin in May 1998, the activities of the Task Force on this issue have stayed minimal, limited to exchange of information among Member countries and other organizations. In March 2005, at the teleconference of the Task Force, Japan proposed a preliminary study aiming at presenting methodologies and experiences on environmental exposure assessment using monitoring data, for guidance to member states, by summarizing experiences and ideas including outcomes from Berlin Workshop.

Reporting Exposure Information

9. The "Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure" was published in December 2003. This document provides formats for reporting summary information on exposure to chemicals, which are designed to be flexible enough to cover any kind of chemicals, variety of exposure scenarios, and various international or national chemical assessment programmes. Formats will contribute to the post-SIDS exposure information collection and also to other programmes related to exposure assessment.

ANNEX 8: NATIONAL MONITORING PROGRAMS/STUDIES OF MEMBER COUNTRIES/REGIONS

(1) AUSTRALIA

Australian Government National Exposure and Environmental Related Monitoring Data

Program/Study	Description
Environmental Monitoring	
National Pollutant Inventory (NPI)	The NPI contains monitoring data on 90 substances emitted to the environment by industrial sources. The NPI also records estimate emissions of these substances from diffuse sources, such as transportation, lawn mowing etc. The substances reported to the NPI have been identified as important because of their possible health and environmental effects. The NPI is publicly available and can be viewed at: http://www.npi.gov.au/index.html
Ambient Air Toxics National Environment Protection Measure (NEPM)	The Air Toxics NEPM establishes a national framework for monitoring and reporting ambient air toxics. The Measure is primarily concerned with the collection of data on ambient levels of formaldehyde, toluene, xylene, benzene and polycyclic aromatic hydrocarbons at locations where elevated levels are expected to occur and there is a likelihood that significant population exposure could occur. http://www.ephc.gov.au/nepms/air/air_toxics.html
Ambient Air Quality NEPM	Each jurisdiction has developed a monitoring plan to measure its performance against the ambient air quality standards set forth in this Measure. Note: this measure does not set standards for indoor air quality. http://www.ephc.gov.au/nepms/air/air_nepm.html
Waterwatch	Waterwatch is a national community water quality-monitoring network that encourages volunteers to undertake a variety of biological & habitat assessments and physical & chemical tests to determine the environmental health of their waterways and catchments. There are 3000 Waterwatch groups undertaking regular monitoring at approximately 5,000 sites nationally. http://www.waterwatch.org.au
Human Biomonitoring	
The Australian Total Diet Survey administered by Food Standards Australia New Zealand (FSANZ)	The Australian Total Diet Survey is a 2 yearly assessment of consumers' dietary exposure to pesticide residues, contaminants and other substances. In conducting the survey, FSANZ tests food samples representative of the total diet and provides estimates of the level of dietary exposure to the Australian population to a range of residues and contaminants. http://www.foodstandards.gov.au
National Residues Survey (NRS)	The NRS monitors and reports on the level of contaminants in food, inputs to production and the environment. The NRS provides estimates on the occurrence of residues in products and confirms (or otherwise) that residues in products are within limits set forth by the Australian New Zealand Food Standards Code. The NRS alerts responsible government authorities and industry of incidences when limits are exceeded so that corrective action can be taken. http://www.affa.gov.au/content/output.cfm?ObjectID=D2C48F86-BA1A-11A1-A2200060B0A05746
National Survey of Lead in Children	Unit record survey data of blood lead levels in a representative sample of Australian children aged 1 to 4 years (inclusive). Information collected includes blood lead level and environmental data (tap water, paint specimens, dust samples). The data collection contains health outcomes and risk factor information.
Ecological Biomonitoring	
NRS	The NRS monitors and reports on the level of contaminants entering the environment to determine whether or not contaminants and residue in various forms of biota exceed Australian standards. See information and website link above for more information.
Monitoring Chemicals in Drinking Water	
Australian Drinking Water Guidelines, administered by the National Health and Medical Research Council (NHMRC).	Although not legally enforceable, the Australian Drinking Water Guidelines provide the Australian community and the water supply industry with guideline values for a wide range of chemical and radiological substances and physical properties which affect water quality, to ensure that drinking water does not pose a health risk to the consumer. The guidelines assist industry in developing monitoring programs, procedures for assessing performance of a water supply system and advice on reporting performance to the public and to health authorities. http://www7.health.gov.au/nhmrc/publications/synopses/eh19syn.htm

(2) CANADA

Canadian National Exposure and Environmental Related Monitoring Data

Program/Study	Description
Food and Diet Monitoring	
Canadian Total Diet Study Health Canada	Since 1969, Health Canada has conducted Total Diet Studies in five different periods of time to estimate the levels of chemicals to which Canadians in different age-sex groups are exposed through the food supply. http://www.hc-sc.gc.ca/food-aliment/cs-ipc/fr-ra/e_tds_concentration.html
Canadian Food Consumption Statistics Canada	Annual statistics on food consumption in Canada on a per capita basis. All food commodities consumed by Canadians are included in this program. The sources of data are from Provincial and Federal government departments, growers' associations and marketing board. This program has been administered by Statistics Canada since 1960. http://www.statcan.ca/english/Pgdb/famil102d.htm
Environmental Monitoring	
National Air Pollution Surveillance Network (NAPS) Environment Canada	NAPS is a joint program of Environment Canada and provincial governments to monitor and assess the quality of the ambient air in Canadian urban centres. Air quality data for SO_2, CO, NO_2, O_3 and total suspended particulates are measured at over 152 stations in 55 cities. A number of other monitoring activities to support priority national air issues can also be carried by this group. http://www.etc-cte.ec.gc.ca/naps/index_e.html
Canadian Air and Precipitation Monitoring Network (CAPMoN) Environment Canada	CAPMoN is operated by the Meteorological Service of Environment Canada in order to study the regional patterns and trends of acid rain, air and precipitation chemistry. It measures both wet deposition (through rain or snow) and (inferential) dry deposition, as well as the ambient concentrations of acid forming gases and particles. http://www.msc-smc.ec.gc.ca/natchem/particles/n_capmon_e.html
Arctic Monitoring and Assessment Program (AMAP)	One of the 5 working groups of the Arctic Council, AMAP measures levels and assesses the effects of anthropogenic pollutants in all compartments of the Arctic environment, including humans; documents trends of pollution, sources and pathways of pollutants. Eight Arctic countries (Canada, Denmark/Greenland, Finland, Iceland, Norway, Russia, Sweden and USA) contribute to the program. http://www.amap.no/. Associated with this program is the Northern Contaminants Program, coordinated by Indian and Northern Affairs Canada, which measures contaminant concentrations in the environment and people in the Canadian North. http://www.ainc-inac.gc.ca/ncp/index_e.html
Integrated Atmospheric Deposition Network (IADN)US EPA and Environment Canada	IADN was established by the United States and Canada for conducting air and precipitation monitoring in the Great Lakes Basin. IADN's objectives are to determine the atmospheric loadings and trends of priority toxic chemicals to the Great Lakes and its basin and acquire air and precipitation concentration measurements and help determine the sources of the continuing input of those chemicals. http://www.msc-smc.ec.gc.ca/iadn/
Great Lakes Water Quality Surveillance Program Environment Canada	Set up to fulfill Canada's obligations under the Canada-United States Great Lakes Water Quality Agreement. The surveillance program monitors nutrients, major ions, organic contaminants, biological and physical parameters. All data are stored at Canada Centre for Inland Waters, in the STAR database. http://www.on.ec.gc.ca/monitoring/water-quality/greatlakes-e.html
St. Lawrence Action Plan	This comprehensive multistakeholder program for the St. Lawrence river includes monitoring of contaminants, drinking water and ecological indicators. http://www.slv2000.qc.ca/index_a.htm
Canadian National Atmospheric Chemistry Database and Analysis System (NAtChem) Environment Canada	Operated by the Meteorological Service of Environment Canada, the NAtChem Database contains air and precipitation chemistry data from many major regional-scale networks in North America. It consists of 4 smaller databases: Particulate Matter Database, Precipitation Chemistry Database, Air Toxics Database and CORE Database. http://www.msc.ec.gc.ca/natchem/index_e.html
ENVIRODAT Environment Canada	A repository of water quality information including chemical, physical, biological, and selected hydrometric data which are stored for surface, groundwater, wastewater, precipitation and various other water types. Data are obtained from a wide range of sources, and the data bases are managed on a regional basis.
National Pollutant Release Inventory (NPRI) Environment Canada	The NPRI is a publicly available database that contains information on releases to air, water, land and disposal or recycling from all sectors. Annual reporting to Environment Canada is compulsory for facilities meeting the criteria relating to the approximately 300 substances listed in this Priority Release and Transfer Registry (PRTR). http://www.ec.gc.ca/pdb/npri/npri_home_e.cfm
Inventory of Toxic Air Emissions Great Lakes Commission	This database provides data for emissions from point, area, on-road and off-road sources for 82 toxic air pollutants in the Province of Ontario and the eight Great Lake states. http://www.glc.org/air/inventory/2001/
Ecological Biomonitoring	
Ecological Monitoring and Assessment Network (EMAN)	EMAN is a cooperative partnership of federal, provincial and municipal governments, academic institutions, aboriginal communities and organizations, industry, environmental non-government organizations and other groups/individuals involved in ecological monitoring, to better detect, describe and report on ecosystem changes across Canada. http://www.eman-rese.ca/eman/
Environmental Effects Monitoring (EEM) Environment Canada	EEM is facility specific monitoring of the effects of effluent on fish, fish habitat and the use of fisheries resources. It consists of biological monitoring and effluent and water quality monitoring. EEM is currently a requirement for regulated pulp and paper mills and metal mines. http://www.ec.gc.ca/eem/english/default.cfm

Monitoring Chemicals in Drinking Water	
Provincial-Regional monitoring programs	Monitoring of drinking water is conducted by Provincial and in some cases Municipal authorities. The water quality reports for the largest regions in Canada are available. Some of these reports are very detailed including many organic chemicals, while others provide only the provincially required information. A limited number of reports are available online. Examples include: http://winnipeg.ca/waterandwaste/water/ http://watersupply.london.ca/water_reports.htm http://www.region.waterloo.on.ca/web/region.nsf/DocID/0DFF011F5AA7DB2085256C130069922E?OpenDocument&Section=LIV&bc=Living%3E%20Water%20Services http://www.regional.niagara.on.ca/living/water/decew.aspx http://www.hrwc.ns.ca/about_us/annual_report_2003.pdf
Following are several examples of other types of monitoring information sources that are often of importance to national risk assessment activities. These include programs under direction of Provinces and large Municipalities, as well as both individual and consortia of industries.	
Clean Air Strategic Alliance (CASA) Data Warehouse Province of Alberta	The CASA Data Warehouse contains archived air quality data from monitoring stations operated by Alberta Environment, the West Central Airshed Society, the Wood Buffalo Environmental Association, the Parkland Airshed Management Zone, the Strathcona Industrial Association and Environment Canada. http://www.casadata.org/
Ministry of the Environment of Ontario (MOE) Air Quality Province of Ontario	Based on data from its network of air monitoring stations, the Ontario Ministry of the Environment reports an Air Quality Index for many communities across the Province. Six key air pollutants are monitored by the ministry: sulphur dioxide, ozone, nitrogen dioxide, total reduced sulphur compounds, carbon monoxide, fine particulate matter. http://www.airqualityontario.com
Municipal/Industrial Strategy for Abatement (MISA) Province of Ontario	MISA program is a provincial program for addressing levels of persistent toxic substances in industrial direct discharges entering Ontario's waterways. The MISA program, by focusing on nine industrial sectors, covers the major toxic polluters, which have monitoring and reporting requirements. http://www.ene.gov.on.ca/envision/water/misa/
Greater Vancouver Regional District (GVRD) City of Vancouver	The network is run in co-operation with the Fraser Valley Regional District, Environment Canada and other partners and consists of more than 25 stations in the Lower Fraser Valley region. Levels of common air contaminants such as ammonia, carbon monoxide, fine particulate, inhalable particulate, nitrogen dioxide, ozone, sulphur dioxide and volatile organic compounds are monitored. http://www.gvrd.bc.ca/air/monitoring.htm
Association industrielle de l'est de Montréal (AIEM) Association of Industries of Montreal East	This local monitoring network is operated by an association of 10 industries located near an urban area. Monitoring of atmospheric contaminants includes SO2, H2S, and particulate matter and its components. http://www.aiem.qc.ca/content/view/93/63/

(3) JAPAN

Ministry of the Environment of Japan: National Exposure and Environmental Related Monitoring Data

Program/Study	Description
Initial environmental survey	As a part of the Survey Programs on Chemicals in the Environment, the Ministry of the Environment, in co-operation with local authorities, measures the level of chemicals selected from the type II monitoring chemicals of the Chemicals Management Law, PRTR candidate substances, etc. In FY 2004, 22 substances were measured. The media are selected from air, water, sediment and biota in accordance of the fate properties of the chemicals.
Advanced environmental survey	As a part of the Survey Programs on Chemicals in the Environment, the Ministry of the Environment starts detailed surveys in FY 2005 in order to evaluate the environmental level of chemicals that have been frequently detected in initial environmental surveys in the past.
Environmental survey for exposure study	As a part of the Survey Programs on Chemicals in the Environment, the Ministry of the Environment, in co-operation with local authorities, carries out extensive survey of chemicals in ambient air, indoor air, water, sediment, biota and food. The purpose of this survey is to obtain data for exposure assessment. In FY2004, 5 substances were measured at 41 water monitoring sites, 21 air monitoring sits, food in 50 families and 12 indoor air monitoring sites.
Monitoring investigation	As a part of the Survey Programs on Chemicals in the Environment, the Ministry of the Environment, in co-operation with local authorities, carries out continuous monitoring of POPs and other substances of concern. Currently 8 POP substances and 3 other substances are monitored at 39 water monitoring sites, 63 sediment monitoring sites, 22 biota monitoring sites and 37 air monitoring sites.
Environmental survey for human biological samples	As a part of the Survey Programs on Chemicals in the Environment, the Ministry of the Environment starts in FY 2005 measurements of chemicals concentration in breast milk, blood and umbiblical blood.
Other environmental surveys	The Ministry of the Environment, in co-operation with local authorities, continuously monitors the environmental levels of pollutants in air, water and soil.
Pollutant Release and Transfer Register	Currently PRTR data from individual facilities and estimated releases and transfers from non-point sources in 2001, 2002 and 2003 are stored in a database and disclosed to the public upon request.

(4) US

U.S. EPA National Exposure and Environmental Related Monitoring Data

Program/Study	Description
Environmental Monitoring	
National Air Quality System (AQS) U.S. EPA Office of Air and Radiation	The National Air Monitoring System and the State and Local Air Monitoring System measure ambient concentrations of six criteria air pollutants. Data are collected by thousands of monitoring stations operated by EPA, national, state and local agencies. http://www.epa.gov/aqspubl1/select.html
National Air Toxics Assessment U.S. EPA Office of Air and Radiation	EPA's ongoing comprehensive evaluation of air toxics in the U.S. These activities include expansion of air toxics monitoring, improving and periodically updating emission inventories, improving national- and local-scale modeling, continued research on health effects and exposures to both ambient and indoor air, and improvement of assessment tools. http://www.epa.gov/ttn/atw/nata/
National Status and Trends Program (NSTP) National Oceanic and Atmospheric Administration	Assesses the contamination of estuarine and coastal waters of the U.S. by analyzing bivalves, fish livers and sediment collected by the Mussel Watch and Benthic Surveillance Programs. http://nsandt.noaa.gov/nsandt_overview.htm
National Water Quality Assessment (NAWQA) Program USGS.	Systematically collecting chemical, biological, and physical water quality data from 42 study units (basins) across the nation. http://infotrek.er.usgs.gov/servlet/page?_pageid=543&_dad=portal30&_schema=PORTAL30
STORET and STORET Legacy Data Center (LDC) U.S. EPA Office of Water	The LDC contains historical water quality data dating back to the early part of the 20th century and collected up to the end of 1998. STORET contains data collected beginning in 1999, along with older data that has been properly documented and migrated from the LDC. Both systems contain raw biological, chemical, and physical data on surface and ground water collected by federal, state and local agencies, Indian Tribes, volunteer groups, academics, and others. http://www.epa.gov/storet/
Toxic Release Inventory (TRI) U.S. EPA	The Toxics Release Inventory (TRI) is a publicly available EPA database that contains information on toxic chemical releases and other waste management activities reported annually by certain covered industry groups as well as federal facilities http://www.epa.gov/tri/
Human Biomonitoring	
National Health and Nutrition Examination Survey (NHANES) Center for Disease Control	Exposure data for 116 chemicals, as well as lead, mercury, cadmium, and other metals; dialkyl phosphate metabolites of organo-phosphate pesticides; cotinine; and phthalates; Polycyclic aromatic hydrocarbons (PAHs); Dioxins, furans, and coplanar polychlorinated biphenyls (PCBs); Non-coplanar PCBs; Phytoestrogens; Selected organophosphate pesticides; Organochlorine pesticides; Carbamate pesticides; Herbicides; and Pest repellents and disinfectants. http://www.cdc.gov/nchs/nhanes.htm
National Human Adipose Tissue Survey (NHATS) U.S. EPA Office of Pollution Prevention and Toxics	NHATS analyzed human adipose tissue specimens in order to monitor human exposure to potentially toxic chemicals. These data are from the 1980's and have not been updated. http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55204
National Human Exposure Assessment Survey (NHEXAS) U.S. EPA National Exposure Research Laboratory	Survey evaluated comprehensive human exposure to multiple chemicals from multiple routes on both a community and regional scale, as well as the association between exposure, environmental concentrations, and personal activities. http://www.epa.gov/heasd/edrb/nhexas.htm
Total Exposure Assessment Methodology (TEAM) U.S. EPA.	Studies that measured personal exposures to pollutants. These studies monitored more than 3,000 participants, in 18 U.S. urban and suburban cities and one Canadian province, for exposure to volatile organic compounds (VOCs), pesticides, carbon monoxide, particles, phthalates (plasticizers) and polycyclic aromatic compounds (PAHs), among other pollutants.
Ecological Biomonitoring	
Contaminant Exposure and Effects-Terrestrial Vertebrates database (CEE-TV)	Contains contaminant exposure and effects information for terrestrial vertebrates (birds, mammals, amphibians and reptiles) that reside in estuarine and coastal habitats along the Atlantic, Gulf and Pacific Coasts including Alaska and Hawaii and in the Great Lakes Region. http://www.pwrc.usgs.gov/contaminants-online/pages/CEETV/CEETVintro.htm
National Fish Tissue Study U.S. EPA Office of Science and Technology	A screening-level study to estimate the national distribution of selected persistent, bioaccumulative and toxic chemical residues in fish tissue from lakes and reservoirs of the continental United States. http://www.epa.gov/waterscience/fishstudy/overview.htm
National Sediment Inventory (NSI) Tissue Data U.S. EPA Office of Water	Designed to compile sediment quality information from available electronic databases into one centralized, easily accessible location. The NSI database includes approximately 4.6 million records for more than 50,000 monitoring stations http://www.epa.gov/waterscience/cs/nsidbase.html
National Water Quality Assessment (NAWQA) Program USGS.	Systematically collecting chemical, biological, and physical water quality data from 42 study units (basins) across the nation. http://infotrek.er.usgs.gov/servlet/page?_pageid=543&_dad=portal30&_schema=PORTAL30

Monitoring Chemicals in Drinking Water	
National Contaminant Occurrence Database (NCOD) U.S. EPA	The database contains physical, chemical, microbial and radiological information for monitored contaminants in drinking water. http://www.epa.gov/safewater/data/ncod.html
National Stream Quality Accounting Network (NASQAN) Surface Water and Sediment Data U.S.G.S.	Monitoring the water quality of four of the nation's largest river systems: the Mississippi, the Columbia, the Colorado, and the Rio Grande. http://water.usgs.gov/nasqan/progdocs/wri014255/results/data.htm

(5) EU

Program/Study	Description
Chemical Inventory	Collection of metadata on chemical monitoring activities in the 31 EEA member countries. The project was finalised end 2004 and the final report as well as the resulting database and the report from a chemicals workshop organised last year are available under: http://eea.eionet.eu.int/Public/irc/eionet-circle/chemicals/library Note: The overview still is not comprehensive for all media in all MS as the response rate was not optimal from all countries. Some member countries also indicated that they are still working to compile additional information (which would be included at a later stage).
Database on Reporting Obligations (ROD)	ROD is the EEA's reporting obligations database that can be found under the following link: http://rod.eionet.eu.int/index.html It contains records describing environmental reporting obligations that countries have towards international organisations. A search on 'chemicals' returned 66 reporting obligations. Though some of these obligations only refer to information if and how European legislation has been implemented on national level there are others that request more detailed parameters to be monitored (and reported to the Commission).
European Pollutant Emission Register (EPER)	EPER is the European-wide register of industrial emissions into air and water which gives access to information on the annual emissions of approx. 10000 industrial facilities in the 16 Member States of the EU as well as Norway – mostly from the year 2001. http://eper.cec.eu.int/eper/default.asp

ANNEX 9: ADDITIONAL SOUSES OF EXPOSURE ASSESSMENT INFORMATION

(1) OECD Publications on Exposure Assessment

General

- Report of the OECD Workshop on Environmental Hazard/Risk Assessment (1995, Testing and Assessment Series No. 4) http://www.olis.oecd.org/olis/1995doc.nsf/LinkTo/ocde-gd(95)134

The following documents include comparisons of exposure assessment approaches among member countries, but the first two documents were published in 1990's and are old in content.

- Occupational and Consumer Exposure Assessment (1993, Environment Monograph No. 70)
  http://www.olis.oecd.org/olis/1993doc.nsf/LinkTo/ocde-gd(93)128
- Environmental Exposure Assessment Strategies for Existing Industrial Chemicals in OECD Member Countries (1999, Testing and Assessment Series No.17)
  http://www.olis.oecd.org/olis/1999doc.nsf/LinkTo/env-jm-mono(99)10
- New Chemical Assessment comparisons and implications for Work Sharing (2004, Testing and Assessment Series No.48. Chapter on Exposure Assessment: page 23-25)
  http://www.olis.oecd.org/olis/2004doc.nsf/LinkTo/env-jm-mono(2004)27

Emission Scenario Documents (ESDs)

- Guidance Document on Emission Scenario Documents (2000, Series on Emission Scenario Documents No.1)
  http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/env-jm-mono(2000)12
- Series on ESDs
  http://www.oecd.org/document/46/0,2340,en_2649_34373_2412462_1_1_1_1,00.html
  Wood preservatives (2003), Plastic Additives (2004), Water Treatment Chemicals (2004), Photographic Industry (2004), Rubber Additives (2004), Textile Finishing (2004), Leather Processing (2004), Photoresist Use in Semiconductor Manufacturing (2004), Lubricants and Lubricant Additives (2004), Automotive spray application (2004), Metal finishing (2004), Antifoulants (2005)

Exposure Models

- Report of the OECD/UNEP Workshop on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-range Transport in the Context of PBTs/POPs Assessment (2002, Testing and Assessment Series No. 36)
  http://www.olis.oecd.org/olis/2002doc.nsf/LinkTo/env-jm-mono(2002)15
- Guidance Document on the Use of Multimedia Models for Estimating Overall Environmental Persistence and Long-Range Transport (2004, Testing and Assessment Series No. 45)
  http://appli1.oecd.org/olis/2004doc.nsf/linkto/env-jm-mono(2004)5

Use of Monitoring Data

- Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial chemicals (2000, Testing and Assessment Series No.18)
  http://www.olis.oecd.org/olis/2000doc.nsf/LinkTo/env-jm-mono(2000)2

Reporting Exposure Information

- Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure (2003, Testing and Assessment Series No. 42)
  http://www.oecd.org/document/39/0,2340,en_2649_34373_22826727_1_1_1_1,00.html

(2) IPCS Publications on Exposure Assessment

- IPCS Risk Assessment Terminology Part 1: IPCS/OECD Key Generic Terms used in Chemical Hazard/Risk Assessment, Part 2: IPCS Glossary of Key Exposure Assessment Terminology (2004, Harmonization Project Document No. 1)
  http://www.who.int/ipcs/methods/harmonization/en/
- Integrated exposure assessment (2001)
  http://www.who.int/ipcs/methods/risk_assessment/en/

(3) BIAC Publications on Exposure Assessment

- Targeted Risk Assessment (ECETOC Technical Report No 93, December 2004)
  (For abstract and order, see www.ecetoc.org)

(4) Member Countries' Publications on Exposure Assessment

CANADA

- Environmental Assessments of Priority Substances Under the Canadian Environmental Protection Act, Guidance Manual Version 1.0, Environment Canada, March 1997. Hard copies may be ordered from www.ec.gc.ca/publications (search = priority substances). Electronic copies are available on request by contacting either ESB.DSE@ec.gc.ca or DSL.SURVEYCO@ec.gc.ca.
- Human Health Risk Assessment of Priority Substances, Health Canada, 1994. Electronic copies are available on request from EXSD@hc-sc.gc.ca.
- Exposure Factors for Assessing Total Daily Intake of Priority Substances by the General Population of Canada, Priority Substances, Bureau of Chemical Hazards, Environmental Health Directorate, Health Canada , 1998 Draft. Electronic copies are available on request from EXSD@hc-sc.gc.ca.

US

- Guidelines for Exposure Assessment. US Federal Register, vol. 57, no. 104, p. 22888.
- US EPA's Office of Pollution Prevention and Toxics' Exposure Assessment Tools and Models website. The website contains several exposure assessment methods, databases and downloadable, predictive models to help in evaluating: 1) what happens to chemicals when they are used and released to the environment, and 2) how workers, the general public and consumers and the aquatic ecosystems may be exposed to chemicals. The URL for the website is:
  http://www.epa.gov/oppt/exposure