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GUIDANCE DOCUMENT FOR EXPOSURE ASSESSMENT BASED ON ENVIRONMENTAL  
MONITORING

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No. 185

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**OECD Environment, Health and Safety Publications**  
**Series on Testing and Assessment**

**No. 185**

**GUIDANCE DOCUMENT FOR EXPOSURE ASSESSMENT BASED ON ENVIRONMENTAL  
MONITORING**

**IOMC**

**INTER-ORGANIZATION PROGRAMME FOR THE SOUND MANAGEMENT OF CHEMICALS**

A cooperative agreement among **FAO, ILO, UNDP, UNEP, UNIDO, UNITAR, WHO, World Bank and OECD**

**Environment Directorate**

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Paris 2013

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## FOREWORD

This document provides guidance for performing an exposure assessment – for humans and the environment – based on environmental monitoring data. It covers topics such as environmental levels and distribution of contaminants, ways of using monitoring data in exposure assessments for differing purposes, the collection of data, quality of monitoring activities, as well as several examples of data compilation in member countries and their use in exposure assessment.

OECD's work on the use of monitoring data in exposure assessments began with a workshop on *Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals* in Berlin, Germany, from 13 to 15 May 1998. As a follow-up to the workshop, the Task Force on Environmental Exposure Assessment, later renamed the Task Force on Exposure Assessment, has developed this guidance under Japan's leadership. The guidance was reviewed and approved by the Task Force on Exposure Assessment in October 2011. The Joint Meeting declassified the document on March 29, 2013.

This document is published under the responsibility of the Joint Meeting of the Chemicals Committee and the Working Party on Chemicals, Pesticides and Biotechnology of the OECD.

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## LIST OF ACRONYMS AND ABBREVIATIONS

ADI	acceptable daily intake
APCL	Air Pollution Control Law
BASE	Building Assessment Survey and Evaluation
bw	body weight
CDR	Chemical Data Reporting
C-FERST	Community-Focused Exposure and Risk Screening Tool
CSCL	Chemical Substances Control Law
DDT	dichlorodiphenyltrichloroethane
DL-PCBs	dioxin-like polychlorinated biphenyls
DOC	dissolved organic carbon
EA	Environment Agency
EAFUS	Everything Added to Food in the United States
ECD	electron capture detector
GC	gas chromatography
GIS	geographic information system
GRAS	generally recognised as safe
HAP	hazardous air pollutant
HPV	High Production Volume
HPVIS	High Production Volume Information System
HRGC	high-resolution gas chromatography
HRMS	high-resolution mass spectrometry
ICP	inductively coupled plasma
ICP-AES	inductively coupled plasma–atomic emission spectrometry
ICP-MS	inductively coupled plasma–mass spectrometry
ICP-OES	inductively coupled plasma–optical emission spectroscopy
ISO/DIN	International Standards Organization / Deutsches Institut für Normung
IUCLID	International Uniform Chemical Information Database
IUR	Inventory Update Reporting
LC	liquid chromatography
LOD	limit of detection
LOQ	limit of quantification
LRMS	low-resolution mass spectrometry
MEC	measured environmental concentration
MOE	Ministry of the Environment
MS	mass spectrometry
MS/MS	tandem mass spectrometry
ng	nanogram
NAPS	National Air Pollution Surveillance
ND	non-detect
NHANES	National Health and Nutrition Examination Survey
NHATS	National Human Adipose Tissue Survey

NHEXAS	National Human Exposure Assessment Survey
NPRI	National Pollutant Release Inventory
OC	organic carbon
OECD	Organisation for Economic Co-operation and Development
OHT	OECD's Harmonised Templates for Reporting Chemical Test Summaries
PBDD	polybrominated dibenzo- <i>p</i> -dioxin
PBDF	polybrominated dibenzofuran
PCB	polychlorinated biphenyl
PCDD	polychlorinated dibenzo- <i>p</i> -dioxin
PCDF	polychlorinated dibenzofuran
PEC	predicted environmental concentration
pg	picogram
PNEC	predicted no-effect concentration
PRTR	Pollutant Release and Transfer Register
QA	quality assurance
QC	quality control
RMC	representative media concentration
RSEI	Risk Screening Environmental Indicators
TDI	tolerable daily intake
TEQ	toxic equivalent
TOF	time of flight
TRI	Toxics Release Inventory
TSCA	Toxic Substances Control Act
US EPA	United States Environmental Protection Agency
US FDA	United States Food and Drug Administration

## EXECUTIVE SUMMARY

This document describes the basic methodology used to conduct an exposure assessment based on environmental monitoring data, summarising the main facts and issues to be considered. Although there are fundamental differences between human and environmental exposure assessment methodologies, there are still common approaches for using monitoring data, and these constitute the main focus of this document.

This document also gives an example of how monitoring data could be used in an exposure assessment, and discusses the possible links between the use of monitoring data and an approach that uses modelling results. The nature of the monitoring data, properties of the measurements, and characteristics of the concentration distributions are discussed from the perspective of their application in exposure assessment. The key issues for the use of monitoring data in exposure assessment are:

- General considerations when using environmental monitoring data for the purpose of exposure assessment
- Fundamental properties of monitoring data
- Analytical methods: selectivity and sensitivity
- Representativeness of monitoring data in the spatial and temporal distribution of environmental concentrations
- Consistency of monitoring and modelling approaches, temporal variation of environmental concentrations, and density of sampling points for specific assessment purposes
- Statistical data analysis and metric selection

Guidance is provided on how to deal with these issues, illustrated with examples.

## 1. INTRODUCTION

### 1.1 Purpose of the document

OECD's work on the use of monitoring data in exposure assessments began with a workshop in Berlin in 1998: *Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals* (referred to in this document as the "Berlin workshop"). The workshop discussed the use of monitoring data in terms of 1) sharing information; 2) sharing experiences of using measured data; 3) identifying ways to improve monitoring programmes; 4) identifying ways in which existing monitoring data can be used to calibrate and validate exposure models; and 5) recommending further work (OECD, 2000).

The Berlin workshop summarised the basic issues in designing a monitoring programme and the data management requirements for sharing and using model validation. However, it did not make specific recommendations for the direct use of monitoring data in exposure assessments of chemicals in environmental media. This document fills that gap by providing guidance on how monitoring data could be used in an exposure assessment. It discusses the basic and common concepts, methodology, considerations, and examples of exposure assessments based on environmental monitoring data. Although there are substantial differences between the methodologies used for human and environmental exposure assessment, there are common approaches for using monitoring data in both. The guidance can be applied to both type of exposure assessment. It also discusses the links in exposure assessment between the use of monitoring data and approaches that use modelling results. Finally it concludes with several annexes containing examples of exposure assessments and frameworks from Japan, the United States, Europe and Canada.

### 1.2 Use of monitoring data for exposure assessment

Exposure of mammals or other living organisms to chemicals via environmental media (such as soil, water, or air) can generally be described by the following equation:

$$\text{Exposure} = \text{Representative media concentration (RMC)} \times \text{Intake rate of the media}$$

The general objective of an exposure assessment is to derive the representative media concentration (RMC) using modelling, monitoring or other appropriate approaches. As the intake rate of the media generally comes from human or biological data sources, this document focuses on how to derive the RMC using monitoring data for exposure assessment purposes.

One previously established method is to derive the RMC from the predicted environmental concentration (PEC). The representative concentration derived from monitoring data could also be obtained in another way, such as the measured environmental concentration (MEC). Although the term PEC originated from the modelling approach, this document will also use the term PEC for the RMC derived from monitoring data to highlight clearly the comparability of

the different approaches. The following distinguishes between the two methods for deriving the RMC:

RMC = PEC (using a modelling approach)

or PEC (using a monitoring approach)

This document describes how to obtain the RMC using a monitoring approach, and uses some examples to illustrate.

### **References**

OECD (2000), “Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals”, Report of the OECD workshop, Berlin, Germany, 13–15 May 1998, *OECD Series on Testing and Assessment*, No. 18, OECD, Paris.

## 2. GENERAL CONSIDERATIONS

### 2.1 Fundamental properties of monitoring data

Monitoring data consist of numerical data and associated information, often referred to as meta-data. Table 2.1, taken from the output of the Berlin workshop, lists the fundamental meta-data required to support the monitoring data.

The meta-data include the target chemical, analytical method and performance information for the analysis; sampling protocol; sampling location and time; information on the nature of the sample; and other relevant information. The identification of the target chemical – which is sometimes only operationally defined by the analytical method used (see Chapter 3) – limit of detection (LOD), limit of quantification (LOQ), sampling location and sampling time, are key elements for using the data for exposure assessment confidently. It is recommended that these meta-data elements are collected when comparing data compiled from different sources.

**Table 2.1: What minimum meta-data do we need to back up existing monitoring data?**

Criteria	Ideal set	Minimum set for exposure assessment
Objective of the programme	✓	
What has been analysed? (e.g. pure water, bulk, water column) <sup>1</sup>	✓	✓
Analytical method <sup>2</sup>	✓	✓
Unit	✓	✓
Limit of quantification (LOQ) <sup>3</sup>	✓	✓
Blank concentration <sup>4</sup>	✓	
Recovery <sup>5</sup>	✓	
Accuracy <sup>6</sup>	✓	
Reproducibility <sup>7</sup>	✓	
Sampling protocol (e.g. grab samples, continuous sampling, duration, filtered/unfiltered, sampling frequency and pattern) <sup>8</sup>	✓	(see statistical evaluation below)
One shot or mean <sup>9</sup>		✓
Location <sup>10</sup>	✓	✓
Date of sampling (dd/mm/yy) <sup>11</sup>	✓	Minimum required is sample year
Time	✓	
Matrix characteristics (e.g. organic carbon (OC)-content, dissolved organic carbon (DOC), hardness, pH, major ions, size and age of organisms)	✓	
Proximity and influence of sources <sup>12</sup>	✓	✓
Discharge emission pattern and volume <sup>13</sup>	✓	
Flow and dilution or application rate of water body sampled	✓	✓

Explanation of value assigned to non-detect values if used in a mean <sup>14</sup>	✓	✓
Description of statistical evaluation of results	✓	Minimum required is whether one-shot or mean

*Source:* OECD (2000), “Report of the OECD Workshop on Improving the Use of Monitoring Data in the Exposure Assessment of Industrial Chemicals”, *Health and Safety Publications Series on Testing and Assessment* No.18, ENV/JM/MONO(2000)2, OECD, Paris.

#### Notes

1. It should be clear precisely what has been analysed. There should be details of the sample preparation, including for example whether the analysis was of the dissolved fraction, the suspended matter (*i.e.* adsorbed fraction) or the total (aqueous and adsorbed).
2. The analytical method should be given in detail or the scientific publication (*e.g.* the relevant ISO/DIN<sup>1</sup> method or standard operating procedure) should be referenced.
3. The limit of detection (LOD) and details of possible interfering substances should be quoted. There is normally a fixed relation between the LOD and the limit of quantification (LOQ), so the LOQ may be calculated from the LOD.
4. Concentrations in system blanks should be given to support the minimum level of detection.
5. Recovery of laboratory and field standard additions (spikes) should be quoted.
6. The relationship between the measured concentration and the LOD should be given. Results should be provided of standard “reference samples” analyses containing a known quantity of the substance. Accuracy depends on the analytical method and the matrix.
7. The degree of confidence and standard deviation in the results from repeat analyses should be given. Reproducibility also depends on the analytical method and the matrix.
8. Whether the sampling frequency and pattern relate to the emission pattern, or whether they allow for other influences, such as seasonal variations, need to be considered.
9. The assessor needs to know how the data have been treated, *e.g.* whether the values reported are single values, means, 90th percentile, etc.
10. The monitoring site should be representative of the location and scenario chosen. If data represent temporal means, the time period over which concentrations were averaged should also be given.
11. The time, day, month and year may all be important depending upon the release pattern of the chemicals. For some modelling and trend analysis, the year of sampling will be the minimum requirement.
12. For the aqueous environment, detailed information is needed on the distance from and influence of other sources, in addition to qualitative information on flow and dilution (see “Flow and dilution or application rate of water body sampled”).
13. Consider whether there is a constant and continuous discharge, or whether the chemical under study is released as a discontinuous emission showing variations in both volume and concentration with time.
14. Non-detect (ND) data values are those quantities of a substance found to be below the limit of detection (LOD) value.

#### 2.1.1 Numerical data

Generally the output of monitoring data is shown as numerical data with units such as 10 ng/L. The volume or weight basis of the numerical data should be clear, so that the basis of the data is clearly understood. It is often difficult to transform data based on weight to data based on volume, and *vice versa*, because this generally requires knowledge of related parameters such as moisture content, lipid content or some other variable – such information is often not reported in general data sources.

The average value should be accompanied by information on the number of repetitions and samples, and on the type of mean (e.g. arithmetic or geometric), and on how non-detect data (see note 14 under Table 2.1) and outlier values are characterised in the data set.

### **2.1.2 Data quality**

Quality assurance and quality control (QA/QC) are important for high quality monitoring data. According to guidance from the United Nations Environment Programme (UNEP), the key elements in assuring the quality of monitoring data are: (1) utilising reference materials; (2) conducting inter-laboratory studies; and (3) reporting the QA procedures used in collecting the data (UNEP, 2004 and UNEP, 2007). These are each described in more detail below.

It is important to analyse reference materials, and any appropriate quality control processes (such as quality control charts) which arise from them, to ensure the quality of the monitoring data used for exposure assessment. Reference materials are available from various organisations, such as the National Institute of Standards and Technology (NIST)<sup>2</sup> in the US, the Institute of Reference Materials and Measurements (IRMM)<sup>3</sup> in Europe, Japan's National Institute for Environmental Studies (NIES)<sup>4</sup>, and the National Metrology Institute of Japan (NMIJ).<sup>5</sup>

Inter-laboratory studies have been conducted for various chemicals and matrices. An example of effective practice in inter-laboratory studies is discussed in UNEP's guidance document for a global monitoring programme of persistent organic pollutants (POPs) (UNEP, 2004). If there are no certified reference materials or inter-laboratory studies available, analytical performance should be demonstrated by regular blank analysis, spiked samples, duplicates and confirmatory analyses. These are described by the International Union for Pure and Applied Chemistry (Thompson *et al.*, 2002) and UNEP (2004).

Internal QA/QC practices in each analytical laboratory are pre-requisites for ensuring high quality monitoring data. Important quality assurance components include sampling protocols (e.g. method, number, size and representativity), LOD/LOQ, concentrations in blanks, recoveries, duplicates, calibration, QA of co-factors (e.g. lipid, organic carbon and moisture contents) and confirmatory tests (e.g. use of second gas chromatography, column or another detection system). The essential components may differ from one programme to another, depending on the purpose or specific conditions of the exposure assessment.

There are many national and international programmes for accrediting analytical or sampling laboratories<sup>6</sup>. These accreditation programmes generally certify all or some of the elements discussed above, depending on the type of analyte, environmental media or matrices, and the characteristics of each programme. It is important for the QA and QC of the exposure assessment to know which accreditation programme controls the quality of the monitoring data.

## **2.2 Harmonising data collection**

Effective QC, compilation of QA and QC information as property data elements, and the use of a properly accredited laboratory (if possible) are all good practices for ensuring the collection of high-quality monitoring data. Another good practice element is to use a format for collecting data that can be easily harmonised with other systems. The OECD's Harmonised Templates for Reporting Chemical Test Summaries (OHT) are standard data formats for reporting studies done on chemicals to determine their properties or effects on human health and the environment.<sup>7</sup> The following established OHTs may be useful for reporting environmental monitoring data for use in exposure assessments.<sup>8</sup>



- OECD Template #38: Monitoring data
- OECD Template #39: Field studies
- OECD Template #83: Exposure related observations in humans: other data
- OECD Template #85-6: Expected exposure and proposed acceptable residues
- OECD Template #87: Analytical methods

For example, IUCLID 5, the International Uniform Chemical Information Database developed by the European Commission, entirely implements the OECD Harmonised Templates (European Commission, 2007). Information compiled in IUCLID 5<sup>9</sup> can be exchanged with other databases that use the same templates or XML schemas, including the templates listed above. The *Guidance Document on Reporting Summary Information on Environmental, Occupational and Consumer Exposure* (OECD, 2003) is another example of the reporting of summary exposure information in a consistent and transparent manner. In any case, a well-designed data collection format is important for the proper and effective use of monitoring data for exposure assessment.

## References

European Commission (EC) (2007), IUCLID 5, the International Uniform Chemical Information Database, <http://iuclid.eu/index.php?fuseaction=home.iuclidHome>, accessed 6 December 2011.

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UNEP (United Nations Environmental Programme) (2004), *Guidance for a Global Monitoring Program on Persistent Organic Pollutants*, 1<sup>st</sup> Ed., UNEP, Geneva, available at [www.chem.unep.ch/gmn/guidancegpm.pdf](http://www.chem.unep.ch/gmn/guidancegpm.pdf).

UNEP (2007), Guidance on the Global Monitoring Plan for Persistent Organic Pollutants, Preliminary version, UNEP, Geneva, February 2007, amended in May 2007, [www.pops.int/documents/meetings/effeval/POPS-COP3-22\\_Rev1.doc](http://www.pops.int/documents/meetings/effeval/POPS-COP3-22_Rev1.doc).

## Notes

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<sup>1</sup> International Standards Organization / Deutsches Institut für Normung

<sup>2</sup> [www.nist.gov](http://www.nist.gov)

<sup>3</sup> [irmm.jrc.ec.europa.eu](http://irmm.jrc.ec.europa.eu)

<sup>4</sup> [www.nies.go.jp/gaiyo](http://www.nies.go.jp/gaiyo)

<sup>5</sup> [www.nmij.jp/english](http://www.nmij.jp/english)

<sup>6</sup> One example is Good Laboratory Practice (GLP) which is a quality system concerned with the organisational processing process and conditions under which non-clinical health and environmental safety studies are planned, performed, monitored, recorded, archived and reported. OECD developed the OECD Principles of GLP to ensure the generation of high quality and reliable test data related to the safety of industrial chemical substances and preparations in the framework of harmonising testing procedures for the Mutual Acceptance of Data (MAD).

<sup>7</sup> For more information, please access to [www.oecd.org/ehs/templates/introductiontooecdharmonisedtemplates.htm](http://www.oecd.org/ehs/templates/introductiontooecdharmonisedtemplates.htm).

<sup>8</sup> The templates are all listed at [www.oecd.org/ehs/templates/templates.htm](http://www.oecd.org/ehs/templates/templates.htm).

<sup>9</sup> IUCLID 5.4 is available in 2012.

### **3. FUNDAMENTAL PROPERTIES OF MONITORING DATA**

#### **3.1 Identifying the target chemical**

The target chemical should be clearly defined. Of course, the identification of the target compound often depends on the sampling and analytical methods used in the monitoring process.

Where a group of target compounds is being analysed, each component in the group should also be clearly identified. Again, the composition of the group analysed may depend on the analytical method used.

A surrogate may also be used as the analyte (the substance being analysed) to ensure quality of monitoring which requires high sensitivity. In this case, the target chemical group can only be operationally defined by the analytical method employed. To ensure the comparability of the analytical results for the surrogate analyte, it is essential to harmonise the analytical methods. Practical difficulties can arise from the analyte, the sample properties and the application of the surrogate analyte in the monitoring system in each country or region.

Analytical results derived from different methods may not be comparable (Box 3.1), and sometimes it may be difficult to describe the comparability in a quantitative manner, especially for the analysis of samples where the target analyte exists within a complex matrix.

**Box 3.1 How the choice of analysis method can influence results**

There are several very different methods used to analyse polychlorinated biphenyls (PCBs). The most sophisticated analysis uses high-resolution gas chromatography-high-resolution mass spectrometry (HRGC-HRMS) operated under more than 10 000 mass resolution, after extensive clean-up steps. The results from this method are the most reliable and show the content of each true single PCB congener. However, the HRGC-HRMS method is often difficult to use because of its high cost and time requirements; low-resolution mass spectrometry (LRMS) is often used for the analysis instead. In this case, there is a higher possibility of interference from other unknown chemicals. These can overlap with the signals from the target analytes, making it difficult to distinguish the true congeners from these other chemicals. In other cases, the electron-capture detector (ECD) method is used. However, this can also be affected by unknown interferences, again making it difficult to clearly distinguish the interference from the target analytes. This example shows that the analytical results obtained by the HRGC-HRMS method, the GC-LRMS method and the GC-ECD method may not be equivalent. This is why it is important to include information on the analysis method for proper interpretation of the results.

There are many other examples of how the choice of sampling, analytical methods and data manipulation (such as surrogate selection) affects the results. This suggests that the analytical method should be chosen carefully, especially if one is going to use monitoring data from different data sources.

**3.2 Analytical methods and selectivity*****3.2.1 Analytical methods for inorganic chemicals***

Table 3.1 provides some examples of analytical methods used for inorganic chemicals. Applicable analyte species, sensitivity, selectivity (see Box 3.2) and requirements for the pre-treatment of the sample differ depending on the analytical method. Different levels of sensitivity and selectivity should be noted when monitoring data are used in the exposure assessment.

## Box 3.2: Technical terms

**Sensitivity:** The slope of the calibration curve. If the curve is in fact a 'curve', rather than a straight line, then of course sensitivity will be a function of analyte concentration or amount. If sensitivity is to be a unique performance characteristic, it must depend only on the chemical measurement process, not upon scale factors.

**Selectivity:** (qualitative): The extent to which other substances interfere with the determination of a substance according to a given procedure. (quantitative): A term used in conjunction with another substantive (e.g. constant, coefficient, index, factor, number) for the quantitative characterization of interferences.

**Matrix:** The components of the sample other than the analyte.

**Isomers:** One of several species (or molecular entities) that have the same atomic composition (molecular formula) but different line formulae or different stereochemical formulae and hence different physical and/or chemical properties.

*Source:* IUPAC (International Union of Pure and Applied Chemistry) (2005-2012), *Compendium of Chemical Terminology - the Gold Book*, available at <http://goldbook.iupac.org/index.html>, accessed on 11<sup>th</sup> January, 2013.

Samples with a chemical matrix may need pre-treatment – such as dilution, digestion, or extraction using an organic solvent – to enhance their sensitivity and selectivity. As these pre-treatments may significantly alter the results, it is necessary to check the analytical procedures, including the pre-treatment process used, to ensure that proper analytical results were obtained for the purposes of developing the exposure assessment.

**Table 3.1: Examples of analytical methods for inorganic chemicals**

<b>Method</b>	<b>Analyte</b>	<b>Sensitivity</b>	<b>Selectivity</b>
Atomic absorption	Major metal species	Low to high	High: sometimes spectrophotometric and matrix interferences
Inductively coupled plasma (ICP) <sup>1</sup> - atomic emission spectrometry (ICP-AES) or optical emission spectroscopy (ICP-OES)	Wide range of elements	Medium	High: sometimes spectrophotometric interference and/or matrix effects: wide dynamic range
Inductively coupled plasma - mass spectrometry <sup>2</sup> (ICP-MS)	Wide range of elements	High	High: sometimes mass-spectrometric interference and/or matrix effects: wide dynamic range

### ***3.2.2 Analytical methods for organic chemicals***

Table 3.2 provides some examples of analytical methods for organic chemicals, although many other analytical methods may be used. Again, the analyte, sensitivity, selectivity and requirements for the pre-treatment of the sample will differ depending on the analytical method. Different levels of sensitivity and selectivity should be noted when monitoring data are used for exposure assessment.

Organic chemical analysis generally requires pre-treatment of the chemical, including extraction, clean-up and concentration, before final instrumental analysis. The clean-up step often determines the selectivity of the target chemical from the sample matrix and related isomers, but it is difficult to quantify the selectivity. Therefore, method validation, inter-laboratory comparison, round-robin studies and other QC procedures are especially important to derive comparable data for exposure assessment purposes.

**Table 3.2: Examples of analytical methods for organic chemicals**

<b>Method</b>	<b>Analyte</b>	<b>Sensitivity</b>	<b>Selectivity</b>
Gas chromatography (GC)	Volatile to semi-volatile, mainly hydrophobic	Depending on the detector and analyte	Generally high, but depends on detector and analyte
Liquid chromatography (LC)	Hydrophilic compounds or non-volatiles.	Medium to high	Generally enough, but sometimes significant interference depending on detector and analyte
Gas chromatography-mass spectrometry (GC-MS)	Volatile to semi-volatile, mainly hydrophobic	High	High
Liquid chromatography-mass spectrometry (LC-MS)	Hydrophilic compounds or non-volatiles.	Medium to high	High, especially when using detectors such as tandem MS (MS/MS) or time of flight (TOF) MS

### 3.3 Sensitivity

#### 3.3.1 Required sensitivity

Section 1.2 proposed the following general equation for calculating exposure:

$$\text{Exposure} = \text{Representative media concentration (RMC)} \times \text{Intake rate of the media}$$

Based on this equation, exposure calculations using monitoring data can generally be further developed as shown in the following equation:

$$\text{Exposure} = \text{Concentration in media} \times \text{Intake rate by population}$$

From this equation, the required sensitivity of the monitoring data can be derived based on:

- the relevant exposure threshold (e.g. the “tolerable daily intake” (TDI)<sup>3</sup>, the “acceptable daily intake” (ADI)<sup>4</sup>, or other measure of exposure threshold); and
- the rate of intake by the population for which the exposure assessment is being conducted. For ecological or environmental exposure assessments, information on intake rate is not very clear, so the threshold concentration in media is often

directly determined from an eco-toxicity threshold concentration, such as “predicted no-effect concentration” (PNEC), without reference to intake rate.

The use of sufficiently sensitive analytical technique is essential to develop an effective exposure assessment based on monitoring data. Analytical results below the required sensitivity for exposure calculations are generally unsatisfactory for the purposes of developing an exposure assessment.

### ***3.3.2 “Limit of detection” and “limit of quantification”***

The definition of the LOD and LOQ should follow general guidance for QC and/or analytical protocols.

The accuracy of the data may decrease at levels close to the LOD of the analytical procedure. Possible issues that may need to be addressed include data reported as non-detect values, non-linearity of concentrations in the lower concentration range, and quantifying data that are close to or below the LOD.



## References

IUPAC (International Union of Pure and Applied Chemistry) (2005-2012), *Compendium of Chemical Terminology - the Gold Book*, available at <http://goldbook.iupac.org/index.html>, accessed on 11<sup>th</sup> January, 2013.

## Notes

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<sup>1</sup> Inductively coupled plasma (ICP) is a type of plasma source in which the energy is supplied by electrical currents produced by electromagnetic induction; that is by time-varying magnetic fields. ICP is widely used in analytical instruments for inorganic elements.

<sup>2</sup> Mass spectrometry (MS) is an analytical technique for determining the elemental composition of a sample or molecule. It is widely used in analytical instruments for organic contaminants, often coupled with gas chromatography or other separation methodologies.

<sup>3</sup> The TDI is an estimate of the quantity of a chemical contaminant in food or water that can be ingested daily over a lifetime without posing a significant risk to health. “Contaminants” are different from “residues” in this context: a contaminant is a chemical whose presence in food or water does not serve, and never has served, any useful purpose, whereas “residues” refer to chemicals that have been deliberately added to a product, such as pesticide sprays or antifungal agents. The TDI is thus distinct from the acceptable daily intake (ADI), which relates to residues.

<sup>4</sup> The ADI is a measure of the quantity of a particular chemical in food that, it is believed, can be consumed on a daily basis over a lifetime without harm. Data for the calculation of an ADI may be derived from a variety of sources; often direct observation of human eating habits is used, but laboratory tests may also be appropriate.

## 4. USE OF MONITORING DATA FOR EXPOSURE ASSESSMENT

### 4.1 How representative is the monitoring data?

For many exposure assessments, the goal is to establish the most appropriate representative environmental concentration of a target chemical from existing modelling, monitoring or other relevant data. This issue of “representativeness” has two aspects, described in detail in this section:

- 1) the specific placement of the selected target or reference concentration in the distribution of the data; and
- 2) representativeness in the scale of spatial and temporal distributions of environmental concentrations and exposures.

World Health Organisation (2008) provides a broader view on uncertainty issues including “representativeness”.

#### *4.1.1 Placement of the data in the distribution*

How the target or reference concentration is described depends on the purpose of the exposure assessment. The data can be described as a distribution. Therefore, it can be described using percentiles, median, maximum or minimum, or as the “realistic point estimate” of exposure. For a screening-level assessment, the upper end of the distribution tends to be estimated to obtain conservative (or protective) estimates. This allows exposure scenarios to be set that may not need further analysis unless the exposure changes. Thus while screening-level assessments are useful, they are often biased towards these conservative estimates. In other types of exposure assessment, the concentration at a specific location on the distribution is clearly stated. For example, a statement that the concentration at the 95<sup>th</sup> percentile of the distribution is “X” means that 95% of the population or ecosystem considered would be expected to be at or below that concentration. Each type of exposure assessment may require a different type of placement in the distribution.

The placement in the distribution may not necessarily be clearly stated in a traditional exposure assessment, often due to the limited availability of information. The concept of the realistic point estimate of exposure implies placement in the distribution in accordance with the goal of the assessment, although it may not be very clear whether the placement is, for example, close to the 95<sup>th</sup> percentile or near the maximum. However, it is important to understand the placement in the distribution for the purposes of the exposure assessment’s main goals, and this should be clearly stated in the assessment where possible.

#### *4.1.2 Representativeness in the scale of spatial and temporal distributions*

Representativeness in the scale of spatial and temporal data distribution refers to how much confidence we can have in corresponding to the required placement in the distribution. Limited knowledge or limited available data may mean we do not know the real data distribution in the

environment when using monitoring or modelling methodologies. On the other hand, when proper mathematical modelling methodology is used with sufficient representative data, the distribution can closely reflect the actual placement in the data distribution of target substances in the environment. In addition, when extensive monitoring data are analysed with proper statistical methodologies, the real placement in the data distribution in the environment can be more accurately described.

Ideally, the representativeness of monitoring data in at least the spatial and temporal distribution should be established. Annex A provides examples to illustrate this issue.

#### 4.2 Consistency of monitoring and modelling approaches

The RMC can be derived using both modelling and monitoring approaches. Consistency between the two different approaches should be evaluated; how comparable are the exposure estimations using monitoring and modelling?

As discussed in Section 4.1, consistency between the different approaches can be investigated using the data distribution, and representativeness of the selected RMC in the distribution.

The placement in the distribution is used to select the RMC from the data distribution, as discussed in Section 4.1. This placement should be determined based on the purposes of the exposure assessment (*e.g.* screening, reasonable worst case<sup>1</sup>).

If the placement in the distribution is specified to be the 95<sup>th</sup> percentile, the RMC from the monitoring data should be selected to represent the 95<sup>th</sup> percentile concentration within the data distribution. This is accomplished through, for example, the selection of sampling locations and strategies, the selection of data, the statistical treatment of measured data or some other means proven to extract the true 95<sup>th</sup> percentile value from the real-world data distribution. The RMC from the modelling approach could be selected by procedures such as input data selection to represent the specified percentile level, Monte Carlo simulation<sup>2</sup> to estimate the 95<sup>th</sup> percentile in the data distribution, or some other means proven to represent the true 95<sup>th</sup> percentile value. The example given in Annex B provides a general background.

It is often difficult to establish both the placement in the distribution and the representativeness in the data distribution using the available data or assessment framework. Although it may be difficult, the approach discussed above should ideally be used to establish consistent exposure estimation from both monitoring and modelling approaches.

Table 4.1 summarises the issues discussed in Sections 4.1 and 4.2.

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<sup>1</sup> It is the case in which a person or population is expected to be exposed the most. It does not consider every parameter to be in its most unfavourable state (worst case), but it presents a reasonable case in which a person or population is most exposed.

<sup>2</sup> The Monte Carlo method provides approximate solutions to a variety of mathematical problems by performing statistical sampling experiments on a computer.

**Table 4.1: Examples of placement in the data distribution, representativeness, and consistency of monitoring-based exposure assessment**

<b>Example of placement in the data distribution</b>	<b>How to confirm representativeness in the scale of distributions</b>	<b>How to prove consistency between modelling and monitoring approaches</b>
<p>Statistical: Mean, median, percentiles (95<sup>th</sup> percentile, etc)</p>	<p>Statistical examination based on highly spatially resolved fate model output  Statistical analysis of monitoring data</p>	<p>Compare derived percentiles on the basis of highly resolved fate models;  Compare derived percentiles on the basis of monitoring data</p>
<p>Conceptual: Reasonable worst case, background, average...</p>	<p>Conceptual case study based on the conceptual definition of “reasonable”, “worst case”, etc.  Expert judgement of the average level</p>	<p>Compare conceptual terminology on the basis of data derivation</p>
<p>Measurement basis: Maximum, minimum, detectable ...</p>	<p>Data management after precise QC and quality management</p>	<p>Expert judgement on the representativeness of the real geographical distribution</p>
<p>Modelling basis: Hypothetical percentiles obtained from Monte Carlo or random simulation</p>	<p>Statistical examination on the selection of data distribution</p>	<p>Compare model-based and monitoring-based values for given percentiles</p>

### 4.3 Temporal variation in environmental concentrations

The temporal variation of environmental concentrations is another matter for discussion. The scale of temporal variation can differ – often from a few hours to many years – depending on the contaminant and the environment.

How to consider temporal variation depends on the type of hazard posed by the target chemical. For chemicals for which acute toxicity is the main concern, shorter temporal variations will be considered in the exposure assessment. For chemicals for which chronic toxicity is the main concern, longer temporal variations will be considered in the exposure assessment. In the latter case, the temporal variation of exposure may not be explicitly addressed within the exposure assessment. However, temporal variation may still be important for those chemicals, and the assessor should be aware of this.

Considering temporal variation in the exposure assessment may be essential for some chemicals, such as endocrine disrupting chemicals, which may have specific windows of exposure that are particularly sensitive. In that case, the ideal would be to carry out the exposure assessment at the time or the life stage specified. However, in reality this type of ideal assessment requires monitoring data at the specific time or life stage indicated and may be difficult to achieve.

Pesticides are sometimes used only for a short period, such as a few days in the year. It is not always clear whether these temporal environmental exposures should be assessed on an acute or chronic toxicity basis. Although the nature of the hazard presented by the substance is not the focus of the exposure assessment, these temporal variations are worth considering in order to integrate the exposure assessment into the final risk evaluation. These temporal variations may be useful since they may relate to the mode of hazard impact.

### 4.4 Density of sampling points for specific assessment purposes

To be sufficiently confident in the representativeness of the sample, the density and/or number of sampling points should be considered. These depend on the exposure assessment's purpose.

The spatial or geographical density could be considered in relation to the spatial distribution discussed in Section 4.1.

Another issue to consider is the transport potential of the chemicals. The long-range transport potential in assessments of persistent organic pollutants is well-known. The sampling density should reflect the absolute distance of the sampling points in the context of the scale of the chemical's transport potential. The sampling density should reflect the relative distance in the scale of demographic distribution over the geographical scale.

However, as it can be costly to collect a large number of samples, the actual density and/or number of sampling locations may be based on feasibility. More sophisticated methodology, such as spatial statistics, may be used in the future.

## Reference

WHO (World Health Organization) (2008), *Uncertainties and data quality in exposure assessment*, World Health Organization, Geneva, Switzerland

## 5. STATISTICAL DATA ANALYSIS

### 5.1 Data distribution from a statistical viewpoint

Calculating the representative media concentration (RMC) is one of the primary targets of the exposure assessment. The RMC can be assigned from both location and dispersion information (*e.g.* to protect 95% of the population). “Location” and “dispersion” are statistical notions that characterise the data distribution, and can be established by statistical data analysis:

- “Location” often represents the central tendency, “typical value” or the upper end of a data distribution (*e.g.* average, median).
- “Dispersion” represents the spread, variability, or scale of a data distribution (*e.g.* standard deviation, interquartile range).

The location and the dispersion of the concentrations of specific chemicals in environmental media must be known in order to characterise the exposure’s data distribution of the exposure as described in calculate the exposure formula:

Exposure = Representative media concentration (RMC) x Intake rate of the media.

The same applies to estimating intake rates of the population; however, for the sake of simplicity this chapter focuses on the concentrations in environmental media.

Statistics are most useful when the underlying assumptions are understood. Thus statistics representing the location or dispersion should be accompanied by any underlying assumptions. For example, the mean – plus or minus one standard deviation – contains about 68% of the data when the distribution is normal, but not when a normal distribution does not apply. This does not exclude the application of statistics that are based on normal distribution assumptions to data that do not follow the normal distribution; but those statistics should be applied and properly characterised while recognising the associated extent of uncertainties due to non-normality.

The population<sup>1</sup> distributions of the concentrations of chemicals in environmental media are often assumed to follow some specific patterns, but the basis for this assumption is not always sound. It has been pointed out that the concentrations of various measured substances in different environmental fields have frequency distributions that are tailed to the higher end and may be approximated as logarithm-normal. Mechanisms generating these (near) log-normal distributions have been proposed (Koch 1966, 1969; Ott 1990). However, it can be argued that fitting the data to some population distribution is not advisable. When the number of data points is small, it is difficult to determine the shape or function of the population distribution anyway; when the number of data is large, fitting the data to any specific population distribution may be rejected due to the nature of statistical testing. In addition one cannot always expect a single-peak distribution in the real world. There can be two or multiple-peak data distributions due to multiple sources or transport. If this is the case it should be mentioned, and the method used to handle these types of observed distributions should be briefly described.

It is always important to check the data distribution visually before conducting any statistical analysis. For example, it may be useful to make scatter plots, box plots and other exploratory statistical techniques to illustrate the data distribution of the samples. There are also problems raised by so-called “outliers” (*i.e.* data which “out lies” or is numerically distant from the rest of the data). There are a variety of causes of outlying data, including errors in handling the data (*e.g.* inappropriate unit conversion) or in handling the samples (*e.g.* a mix-up in transportation). Statistical procedures may be useful in identifying potential outliers, but exclusion of outliers based solely on a statistical basis may not be justified because the stochastic, or intrinsically random, nature of the environment does produce some data that only appear to be outliers.

Depending of the type of the data, parametric statistics or non-parametric statistics can be used. The other approaches are available to help use these statistics.

## 5.2 Parametric statistics

Parametric statistics are so called because the population probability distribution is assumed to be determined by the parameters in a certain equation (distribution function). Therefore, it is noteworthy that the general form of distribution (as a distribution function) is determined prior to a parametric statistical analysis of the data. The uncertainty due to this implicit choice of a distribution function is not usually discussed, but should not be neglected.

The most popular distribution is the normal distribution and the related *t*-distribution. One major reason for the popular use of the normal distribution is the Central Limit Theorem, which states that the distribution of the sample mean of size *n* random samples from almost any population of a population mean  $\mu$  and a population standard deviation  $\sigma$  comes closer as *n* increases to the normal distribution of a mean  $\mu$  and a standard deviation of  $\sigma n^{-1/2}$ .

## 5.3 Non-parametric statistics

Non-parametric statistics were developed in the late 1930s (Conover, 1999), although they are younger than parametric statistics. Many of these statistics are characterised by the distribution-free property – in other words, no assumption of the underlying population distribution is applying for this statistics (Hollander and Wolfe, 1999). This property could make such statistical methods suitable for analysing the measured concentrations in environmental media, because of the inherent difficulties in assuming their population distribution discussed above. Non-parametric statistics provide counterparts to most of the frequently used parametric statistics or statistical tests. These include the Wilcoxon-Mann-Whitney methods, the associated confidence interval of Hodges-Lehmann estimator to the *t*-tests and the associated confidence intervals of mean difference. Related distribution-free confidence intervals or multiple comparison procedures are also available. Most of the calculations required for these non-parametric statistics are currently available in software for personal computers. The proposed advantages of these non-parametric methods are described in textbooks (*e.g.* Conover, 1999; Hollander and Wolfe, 1999) and should be summarised if these methods are used in an assessment.

## 5.4 Other approaches

Resampling methods, such as “jackknife” and “bootstrap” (Efron, 1982), enable non-parametric approaches to be used in many complicated situations where the distribution theory needed to support parametric methods is intractable (Hollander and Wolfe, 1999). The bootstrap method is closely related, in the way in which it obtains estimates, to the Monte Carlo method. The Monte Carlo method provides approximate solutions to a variety of mathematical problems by performing statistical sampling experiments on a computer. This method may be used in the process of exposure assessment, such as combining the distributions of concentrations of chemicals in exposure media and of intake rates of these media.

## References

- Conover, W.L. (1999), *Practical Nonparametric Statistics*, 3rd ed. Wiley, Hoboken, New Jersey.
- Efron, B. (1982), “The Jackknife, the Bootstrap and Other Resampling Plans”, *CBMS-NSF Monographs* 38, Society for Industrial and Applied Mathematics, Philadelphia, Pennsylvania.
- Hollander, M. and D.A. Wolfe, (1999), *Nonparametric Statistical Methods*, 2nd ed. Wiley, Washington, DC.
- Koch, A.L. (1966), “The Logarithm in Biology, I. Mechanisms generating the log-normal distribution exactly”, *Journal of Theoretical Biology*, No. 12, Elsevier, Amsterdam, pp. 276–290.
- Koch, A.L. (1969), “The Logarithm in Biology, II. Distributions simulating the log-normal”, *Journal of Theoretical Biology*, No. 23, Elsevier, Amsterdam, pp. 251–268.
- Ott, W.R. (1990), “A Physical Explanation of the Lognormality of Pollutant Concentrations”, *Journal of the Air & Waste Management Association* No. 40, Air & Waste Management Association, Pittsburgh, pp. 1378–1383.

## Notes

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<sup>1</sup> “Population” here is a statistical notion that represents a hypothetical collection of entities (e.g. in this case, measurements) from which samples are drawn.



## **ANNEX A: GUIDANCE FOR SCREENING EXPOSURE ASSESSMENT (USING MONITORING DATA) IN JAPAN<sup>1</sup>**

This annex summarises and translates Japan's guidance for screening exposure assessment as a part of "Guidelines for initial assessment of environmental risk of chemical substances" (Ministry of the Environment Japan, 2006), used for screening exposure assessment in Japan. The exposure assessment in this scheme is mainly based on monitoring data available in Japan, and the assessment protocol involved selecting appropriate monitoring data, mainly government based, with which to perform consistent and effective exposure assessments. The annex describes the exposure assessment protocol for humans and aquatic organisms as examples.

These guidelines outline the steps involved in an initial assessment of the risk to human health and living organisms presented by chemical substances in the environment. They include separate guidelines for exposure assessment, initial assessment of health risk, and initial assessment of ecological risk. The description of these guidelines will be revised to take into consideration international trends in assessment methods for environmental risk as appropriate.

1. Exposure assessment. This initial exposure assessment assesses both the health and ecological risks posed by chemical substances.
2. Initial assessment of health risk. After hazard assessment of chemical substances towards human health, a screening assessment is then conducted of the human health risk posed by exposure to chemical substances from environmental sources.
3. Initial assessment of ecological risk. This screening assesses the risk to aquatic organisms of exposure to chemical substances from aquatic sources after assessing the ecological toxicity of chemical substances to these aquatic organisms.<sup>2</sup>

### **A1. Overview of assessment methods**

Exposure assessments required for the initial assessment of both the health risk and ecological risk of chemical substances are conducted by taking actual measurements of the concentrations of chemical substances in the environment.

#### ***A1.1 Exposure assessment for an initial assessment of health risk***

The health risk posed by chemical substances is initially assessed by answering the question, "How much exposure to chemical substances does an average Japanese citizen have?" This initial assessment focuses on people's exposure to chemical substances in their typical day-to-day living environments. To obtain a conservative exposure estimate, a human exposure assessment is carried out using high value concentration data that cover the majority of the population. To ascertain the overall exposure of humans to

chemical substances, diet is also assessed. Measurement data in the vicinity of emission sources are assessed, while taking into account actual residential conditions in the surrounding areas.<sup>3</sup>

### ***A1.1 Predicted environmental concentration (PEC) assessment for an initial assessment of ecological risk***

An initial assessment is made of the ecological risk posed by chemical substances in aquatic environments to ensure the existence and growth of aquatic organisms. To obtain a conservative estimate, the PEC assessment is carried out using high value concentration data that cover the majority of such areas. Measurement data in the vicinity of sources of release are assessed, to take into account conditions of aquatic environments in the surrounding areas.

## **A2. Procedures for exposure assessment**

### ***A2.1 Basic data regarding substances***

#### *A2.1.1 Gather general data*

A2.1.1.1 Molecular formula, molecular weight, structural formula, including:

- Substance name (and any other names)
- Chemical Abstracts Service (CAS) number; notification number in Law Concerning the Evaluation of Chemical Substances and Regulation of their Manufacture, etc. (also known as Chemical Substances Control Law); Pollutant Release and Transfer Registers (PRTR) Law Cabinet Order Number (Type I and Type II Designated Chemical Substances); Registry of Toxic Effects of Chemical Substances (RTECS) number
- Molecular formula, molecular weight, conversion factor, structural formula

A2.1.1.1.2 Physicochemical properties:

- Melting point, boiling point, density and specific gravity, vapour pressure
- Potential for transport by soil or water: partition coefficient (1-octanol/water) (log Kow), dissociation constant (pKa), water solubility

A2.1.1.1.3 Basic data on movement and transformation of substances in the environment (environmental fate)

- Biodegradability: Aerobic degradation (including designation under Chemical Substances Control Law), anaerobic degradation
- Chemical degradability: reactivity with OH radicals (in atmosphere), reactivity with ozone (in atmosphere), reactivity with nitrate radicals (in atmosphere), hydrolysability
- Bioconcentration properties: bioaccumulation factor (BAF), bioconcentration factor (BCF)<sup>4</sup>
- Soil adsorption properties: soil adsorption coefficient (Koc)

A2.1.1.1.4 Production, import and uses of substances

- Production quantity and/or import quantity
- Application of substances

#### A2.1.1.1.5 Environmental policy

Specify how the substances are treated by environmental policy including: the environmental standards of the Basic Environment Law. Chemical substances stipulated in the Chemical Substances Control Law, designated substances in the PRTR Law, substances requiring priority action as hazardous air pollutants, substances suspected of being hazardous air pollutants, substances requiring observation under the Water Pollution Control Law, and substances requiring investigation for water environment preservation measures and substances requiring priority investigation for developing water quality targets for the preservation of aquatic organisms.

#### A2.1.2 Information sources

##### A2.1.2.1 Publications

Refer to the following handbooks, taking into account that they are intended for general, widespread use over a prolonged period and evaluating the reliability of several reported values.

#### **Handbooks on physicochemical properties and environmental fate include:**

- CRC Handbook of Chemistry and Physics
- The Merck Index
- Exploring QSAR Hydrophobic, Electronic, and Steric Constants
- Handbook of Physical Properties of Organic Chemicals
- Handbook of Environmental Data on Organic Chemicals
- Handbook of Aqueous Solubility Data
- Handbook of Environmental Degradation Rates

#### **Publications on production, imports, and uses include:**

- Notified quantity as an observed chemical substance stipulated in the Chemical Substances Control Law
- Chemical Industry Statistics Annual
- Factual surveys on production and import quantities of chemical substances
- Production and import quantities reported to the OECD
- PRTR Law production and import quantity categories

Obtain as many of the original papers listed in these handbooks as possible, and adopt the values for properties that can be verified as the most reliable. Once reliability has been verified, use the original paper as the cited literature. If the original papers cannot be verified and if the property value cannot be narrowed down to a single value, include multiple values.

##### A2.1.2.2 Values estimated from models

Where actual measured values for properties cannot be obtained, values estimated from models can be considered. The name of the model used can then be cited when using a calculated value. The following are examples of models used in the field of environmental policy by government organisations in various countries, and marketed and used widely elsewhere.

- EPI Suite (Estimation Programs Interface Suite) is provided by the US Environmental Protection Agency (US EPA)'s Office of Pollution Prevention and Toxics (OPPT). This suite of Windows programmes for predicting physicochemical properties and environmental dynamic states comprises sub-programmes such as KOWWIN (1-octanol/water partition coefficient), AOPWIN

(atmospheric reaction rates with OH radicals and ozone), and BCFWIN (bioconcentration coefficients)

- ClogP, provided by BioByte Corp, is a predictive programme for 1-octanol/water partition coefficients

#### A2.1.2.3 Databases

Refer to databases such as the Hazardous Substances Data Bank (<http://toxnet.nlm.nih.gov/cgi-bin/sis/htmlgen?HSDB>) for property values, and, wherever possible, obtain the original paper referred to in the database and verify its reliability. Once reliability has been verified, use the original paper as the cited literature. For values whose reliability is difficult to verify, lower their order of priority in relation to information from other sources.

### **A2.2 Conducting exposure assessment**

#### *A2.2.1 Ascertain emissions of chemical substances*

- For chemical substances designated as Type 1 under the PRTR Law, ascertain the emissions and migration based on the latest officially-announced PRTR data.
- For emissions data that are not broken down into separate media (*i.e.* water, atmosphere, or soil) in the officially announced PRTR data, refer to “Details of Estimation Methods, etc., for Emissions Not Reported in PRTR”.<sup>5</sup> The target substances’ emissions to the environment by individual medium can be calculated by apportioning summarised total emissions into individual media.

#### *A2.2.2 Predict allocation ratios for individual media*

- Use as parameters the property data collected and compiled in the section above (“Gather general data”), and the Mackay Level III multimedia model, to predict how target substances will be apportioned by individual media. Taking into account the precision of the model, calculate the final mass ratios apportioned to environmental media, including the atmosphere and water.
- For PRTR Law Type 1 Designated Chemical Substances for which PRTR data can be obtained, predict the distribution ratios for emissions to the environment by individual media for the target substances identified in the section above on “Ascertaining emissions of chemical substances” The “internal environment” of spatially-nested multimedia models (the target region for prediction) is the Japan prefectures where PRTR emissions are highest, together with the prefectures where emissions to each medium are highest; “the external environment” is the difference between the whole of Japan and the internal environment.
- In cases where PRTR data cannot be obtained, predict emissions to the environment for the three cases where 1 000 kg/h are emitted to the atmosphere, water or soil, and the case where 1 000 kg/h are emitted simultaneously to each of the three media (total of four cases).

#### *A2.2.3 Summarise measured environmental levels in each medium*

##### A2.2.3.1 Collect measured environmental data from the following sources

### **Surveys by governmental organizations**

#### Databases

*Ministry of the Environment databases*

- Survey of Chemical Substances in the Environment (Chemical Substances and the Environment)
- Survey of Endocrine Disrupting Chemical Substances in the Environment
- Water quality surveys (including groundwater)
  - Public water quality surveys (environmental standard categories)
  - Surveys of categories requiring monitoring
  - Surveys of presence of items requiring monitoring in aquatic environments
- Atmospheric surveys
  - Monitoring studies of noxious atmospheric pollutants

*Other organisations' databases*

- Ministry of Health, Labour and Welfare: Waterworks Statistics, Water Quality Edition
- Ministry of Land, Infrastructure and Transport: Factual Survey on Endocrine Disruptors in the Water Environment
- Data independently measured by local governments

## Collection requirements

Data must have been measured within the past 10 years. If such data are unavailable, collect the next most recently measured data. When surveys are conducted regularly, adopt measure data of the most recent three years.

**Existing information**

## Data sources

- Japan Science and Technology Agency: JDreamII (<http://pr.jst.go.jp/jdream2/>, academic database for searching papers written in Japanese, available in Japanese)
- Internet searches

## Collection requirements

Give preference to Japanese literature published within the last 10 years. If this cannot be obtained, use the next most recently published Japanese literature, followed by foreign research.

## A2.2.3.2 Inspect quality

Closely inspect the survey locations, measurement and analytical methods of the data obtained, and verify their reliability for use in an exposure assessment.

A2.2.3.3 Compile substance presences in each environmental medium<sup>6</sup>

For each target substance, compile a table showing the concentration data for each medium to summarise the presence of target chemicals in each medium. The environmental concentrations (minimum value, maximum value, arithmetic mean value, geometric mean value, etc.) in the table are calculated from data from single locations.

## Summarising the environmental concentrations at each sampling location

The first step in establishing the location-specific environmental concentration is to summarise the monitoring data at each sampling location. Some data are measured only at intervals of once a year or less, but other data may be measured several times a year or more. The steps below show the procedure for using different temporal data in your exposure assessment:

### **Locations where measurements are conducted once a year**

- Single measurement data are taken as the location-specific environmental concentration data if measurements are conducted only once per year. When the period of target chemical emission is expected to be limited, such as in the case of agricultural chemicals, take into account whether the timing of measurement could be considered to represent the realistic environmental concentration, considering the expected timing of emission or other relevant issues.

### **Locations where measurements are conducted several times (twice or more) a year**

- For cases where measurements are taken at the same location several times per year, values less than the lower limit of detection are taken to be half the lower limit of detection, and the arithmetic means of the measurement data are taken as location-specific data.
- If location-specific data are found to be less than the lower detection limit, the data are designated as “not detected”.

### **Set representative environmental concentrations in each medium**

#### Designating lower detection limit values

A “unified detection limit value” may be set for a survey (a uniform or single detection limit set for all measurements under consideration). Sometimes the detection limit is different from one measurement to another. The procedure for the latter case is described in the next paragraph. In this case, location-specific data that are found to be below this limit are designated as “not detected data”. However, the data should still be noted so that the trace status can be identified.

#### Selecting the minimum value

- When the target chemical is detected in all locations, the smallest value is taken as the minimum value.
- When both “not detected” and “detected” data coexist, compare the not detected data of the lowest lower detection limit with the lowest value of the detected data, and take the smallest one as the minimum value.
- When no detected data whatsoever are obtained, the not detected data of the lowest lower detection limit is taken as the minimum value.

#### Selecting the maximum value

- When detected data are obtained for all samples, the highest value is taken as the maximum value.
- When both not detected and detected data coexist, in principle the highest value from among the detected data is taken as the maximum value. However, for locations where the lower detection limit of not detected data exceeds the maximum detected concentration, in cases where there is a possibility that a concentration exists that is higher than the maximum detected concentration due to the existence of a specific emission source, for example, a value less than the lower detection limit is taken as the maximum value.
- When no detected data whatsoever are obtained, the undetected data of the largest lower detection limit are taken as the maximum value.

#### Calculating arithmetic and geometric mean values

- Taking not detected data as half of the lower detection limit, arithmetic and geometric mean values are calculated from all location-specific data.
- When the arithmetic and geometric means are less than the highest lower detection limit, the average value is taken as less than the lower detection limit.

- When no detected data whatsoever are obtained, the not detected data of the highest lower detection limit are used as the average value.

#### *A2.2.4 Estimate concentration and exposure*

##### A2.2.4.1 How to record values

Take this into account the number of location-specific data that can be collected is limited and record values.

##### **Recording the number of data points**

- More than 100 data points: note the actual number
- 6-100 data points: record as “ca. N” (N = number)
- 3-5 data points: record as “generally N” (N = number)
- 1-2 data points: record as “Data that could stand up to assessment were not obtained” or “There are N reports” (N = number)
- No data: record as “No data could be obtained”

##### **Spatial bias**

- In the case of location-specific data for the entire country, record the actual numerical value.
- Data for certain regions only: record as “N for limited regions” (N = numerical value)
- For data in the vicinity of emission sources or from other countries, introduce case studies and record in the form of “The report [REPORT TITLE] contains data regarding the vicinity of [NAME] plant” or “The report [REPORT TITLE] contains data regarding [COUNTRY NAME]”, for example.

##### **Time of measurement**

- Where data are more than 10 years old, and if it is likely that emissions of chemical substances at that time were not significantly different from current emissions: note “While these are past data, ...”
- Where data are more than 10 years old and if it is likely that emissions of chemical substances at that time vary from current emissions: note them as past data.
- Where data are more than 10 years old and records of chemical substance emissions are lacking, making it difficult to compare that time with the current situation: note that “Data that could stand up to assessment could not be obtained.”

##### A2.2.4.2 Estimate human exposure (maximum estimated daily exposure)

##### **Set concentrations for each medium**

Set concentration based on actual measured values. To err on the safe side and favour assessments based on data on the high concentration side, for the time being, use the maximum concentrations once data reliability has been verified for assessment. Compile as average values and maximum values.

##### **Calculate daily exposure**

Calculate daily exposures based on the above concentrations as follows.

Daily exposure calculation media include: atmosphere, drinking water and groundwater, soil and food. If drinking water and groundwater data cannot be obtained, use public water and freshwater data.

Formulae for daily exposure:

- Atmospheric exposure  
(concentration  $\mu\text{g}/\text{m}^3$ )<sup>7</sup>  $\times$  (Daily quantity inhaled:  $15\text{m}^3/\text{day}$ )  $\div$  (body mass: 50 kg)
- Exposure from potable water  
(concentration  $\mu\text{g}/\text{L}$ )  $\times$  (Daily quantity drunk: 2 L/day)  $\div$  (body mass: 50 kg)
- Exposure from soil  
(concentration  $\mu\text{g}/\text{g}$ )  $\times$  (Daily quantity taken in: 0.15 g/day)  $\div$  (body mass: 50 kg)
- Exposure from food  
(concentration  $\mu\text{g}/\text{g}$ )  $\times$  (Daily food quantity: 2 000 g/day)  $\div$  (body mass: 50 kg)

The daily quantity of air inhaled and the daily quantity of drinking water drunk used here are values usually adopted for various administrative estimates in Japan. The daily quantity taken in from soil (0.15 g/day) is the average daily amount for adults and children taken from the “Initial Report of Dioxins in Soil Study Group” (Ministry of the Environment, July 1999, in Japanese). A daily food intake of 2 000 g/day was determined based on the mass records from a Japanese national nutrition survey (Ministry of Health, Labour and Welfare, in Japanese, accessed 17 January, 2013) , including water drunk during meals.

### Assess exposure

In cases where exposure cannot be calculated or where reliable values cannot be obtained, exposure is assessed by taking into account emissions of the substance, physical properties, and the ratios of apportionment to each medium. For media where actual measurement data are deemed necessary, the evidence for such measurements is also recorded.

A2.2.4.3 Estimate exposure of aquatic organisms (predicted environmental concentration (PEC) related to water)

### Set concentration for each medium

Set concentration of each medium based on actual measurement values. The setting philosophy is the same as in the above section on “Set representative concentrations for each medium”.

### Assessment of predicted no-effect concentration

Assess predicted no-effect concentration (PNEC). The predicted environmental concentration is set based on an understanding of nationwide distribution; for cases where the number of data points is low or there is a geographical bias, records are made in accordance with the recording method described above (“Setting representative concentration for each medium”).

### A2.2.5 Consider monitoring

#### A2.2.5.1 Consider necessity of monitoring

In cases where information related to the concentration and exposure of target substances cannot be obtained from a literature survey, consider whether monitoring is needed, taking into account the following:

- The possibility that the chemical substance has accumulated in the environment (inferences based on target substance properties and estimation of apportionment between media)
- Production, import and emission quantities of chemical substances



- The possibility of attaining a lower detection limit value sufficient for ascertaining a concentration equivalent to 1/1 000 of the no-observed-adverse-effect level (NOAEL), obtained from mammalian oral exposure experiments
- The possibility of attaining a lower detection limit value sufficient for ascertaining a concentration equivalent to 1/10th of the PNEC, obtained from toxicity experiments for aquatic organisms
- The validity of the measurement and analytical techniques.

#### A2.2.5.2 Monitoring after the consideration above

- When monitoring of concentration is deemed necessary: consider the validity of the measurement and analytical techniques.
- When measurement of concentration is deemed unnecessary: clearly state the basis upon which it is deemed unnecessary.

## References

Ministry of the Environment, Japan (1999), *Initial Report of Dioxins in Soil Study Group*, Ministry of the Environment Japan, Tokyo. (in Japanese), [www.env.go.jp/chemi/dioxin/kento/dojo-fr.html](http://www.env.go.jp/chemi/dioxin/kento/dojo-fr.html), accessed 17 January 2013.

Ministry of Health, Labour and Welfare (n.d.), *National nutrition survey*, Ministry of the Environment Japan, Tokyo. (in Japanese), [www.mhlw.go.jp/bunya/kenkou/kenkou\\_eiyou\\_chousa.html](http://www.mhlw.go.jp/bunya/kenkou/kenkou_eiyou_chousa.html), accessed 17 January 2013.

Ministry of the Environment, Japan (2006), *Initial risk assessment of chemicals*, Vol.5, Ministry of the Environment Japan, Tokyo. (in Japanese) [www.env.go.jp/chemi/report/h18-12/index.html](http://www.env.go.jp/chemi/report/h18-12/index.html), accessed 18 November 2011.

## Notes

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<sup>1</sup> Provisional translation of the guidance document. It has been edited by the OECD Secretariat for use in this document.

<sup>2</sup> This document does not discuss naturally occurring chemicals such as metals.

<sup>3</sup> Measurement data are to be assessed to ascertain the characteristics of the site. This statement shows one example of how data from the vicinity of emission sources are characterised, according to the purpose of the assessment.

<sup>4</sup> Although bioconcentration factor (BCF) is mentioned in the original document, a more general example including bioaccumulation is given for this general guidance.

<sup>5</sup> Published by the Ministry of Economy, Trade and Industry and Ministry of the Environment, in Japanese

<sup>6</sup> The sampling and analytical methods used in each monitoring situation often have different detection limits. Also, measurement data often contain a significant proportion of values below the detection limit, depending on the detection limit determined by each sampling or analysis. These two issues can raise practical difficulties and confusion in establishing the representative media concentration. Therefore the following section provides some pointers for dealing with these difficulties.

<sup>7</sup> µg: microgram

## **ANNEX B: THE USE OF MONITORING DATA FOR EXPOSURE ASSESSMENT: DIOXINS IN JAPAN**

In this annex we use the example of an exposure assessment using monitoring data to set environmental standards for dioxins in Japan (Japan Ministry of the Environment, 1999)).

### **B1 Compilation of existing monitoring data**

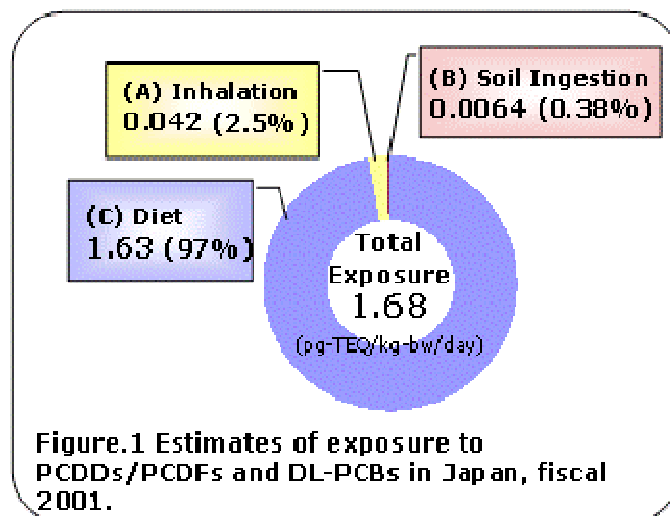
At the time of the assessment, only a limited monitoring programme had been carried out and data were limited. There was also a limited amount of information on concentrations of dioxins in food and fish. One robust data set available was a national monitoring programme for new chemicals in the atmosphere. Several other data sets were found in other monitoring programmes, but many of them contained a substantial number of non-detect (ND) data because of insufficient analytical sensitivity,<sup>1</sup> and they were therefore omitted from this exposure assessment. Food data from a government survey especially were insufficient because of the insufficient analytical sensitivity.

The primary source for the assessment was therefore the scientific literature. Re-processing of laboratory data as well as a new monitoring campaign was also carried out to obtain enough data to confidently estimate exposure. The detection limit was set at about one-tenth of the expected tolerable daily intake (TDI) values for humans from fish and the other food (considered to be the major exposure pathway).

### **B2. Exposure assessment**

An assessment of exposure from various environmental pathways and food items was carried out based on the reference/representative concentration derived from the above sources of monitoring data. The assessment was performed annually after the first exposure assessment and the current results are shown in Figure B.1.

Figure B.1: Exposure estimation example using monitoring data, 2001



Notes: bw: body weight; DL-PCBs: dioxin-like polychlorinated biphenyls; PCDDs: polychlorinated dibenzo-*p*-dioxins; PCDFs: polychlorinated dibenzofurans; pg: picogram (0.001 nanogram); TEQ: toxic equivalents

Source: Suzuki, N. *et al* (2003). "Human Exposure to PCDDs, PCDFs and Co-PCBs in Japan, 2000" *Organohalogen Compounds*, No. 64, pp. 67-70.

### **Special scenarios for higher exposure cases**

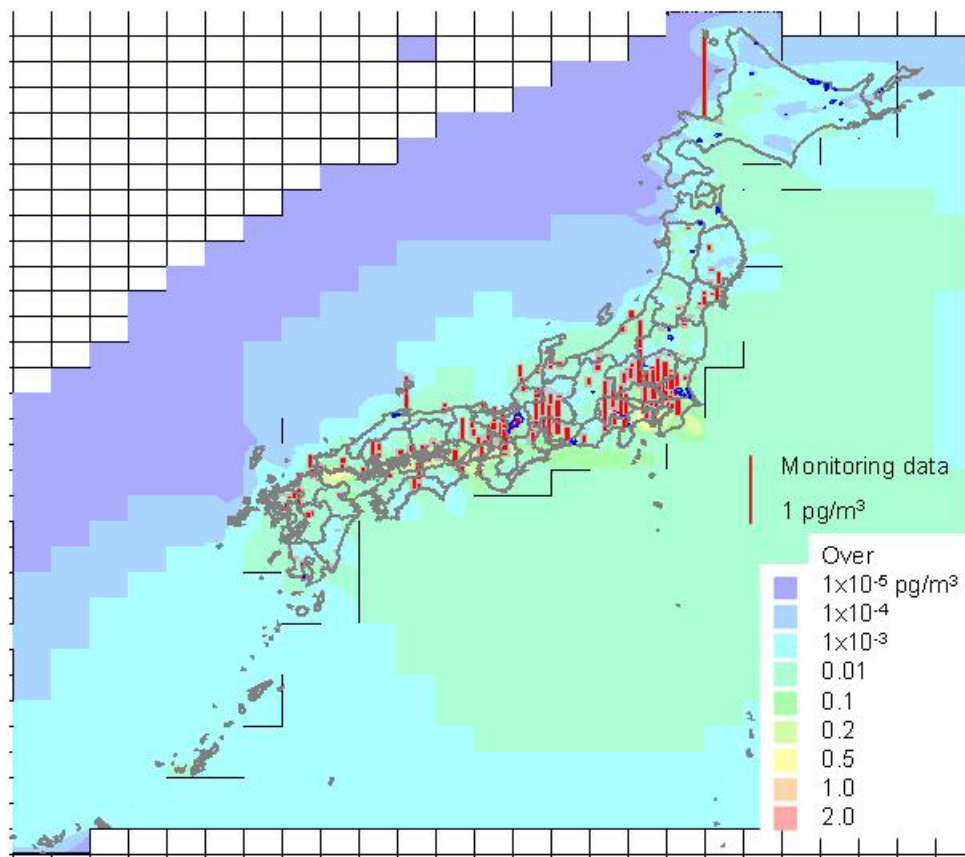
Two special exposure scenarios were calculated – for higher fish intake and residents in the vicinity of emission sources – based mainly on available monitoring data. Some of the data were based on the modelling methodology that was calibrated to this monitoring data.

### **Ensuring representativeness of the exposure estimation**

The spatial distribution of contaminant concentrations can vary significantly. It is essential to take into account the geographical variability of monitoring data before establishing a reference concentration of a contaminant. It is essential to establish the relationship between the geographical distribution of concentrations in the real world and monitoring data obtained at a finite number of sampling locations. As we could not know the real-world distribution of environmental concentrations, simulation outputs from a spatially resolved fate model study were assumed to reflect the real-world geographical distribution, and the simulation results were compared with the real monitoring data in the same region.

Figure B.2 shows the simulated concentration of dioxins in air, based on a fate model of Japan at 5 km × 5 km resolution. This result is assumed to represent the real geographical distribution of environmental concentrations in Japan, including for locations that have no real monitoring data. The results of extensive monitoring of dioxins at about 400 sampling locations throughout the country are compiled and compared with the modelling outputs on a point-by-point basis. The model result covers the whole area of Japan evenly at 5 km × 5 km resolution, and the outputs were validated to show a good correlation with monitoring data on a point-by-point basis (Suzuki *et al.*, 2004). A generic model calculation was also done based on the same geographical/environmental/chemical set-up, but assuming a single-box compartment according to the generic framework. Results of monitoring data were compiled and compared with the location-specific modelling outputs at each of the 400 locations. The data are summarised in statistical format in Figure B.3.

**Figure B.2: Simulated concentrations of dioxins in air, based on the multimedia fate model G-CIEMS at 5 km × 5 km resolution, Japan**

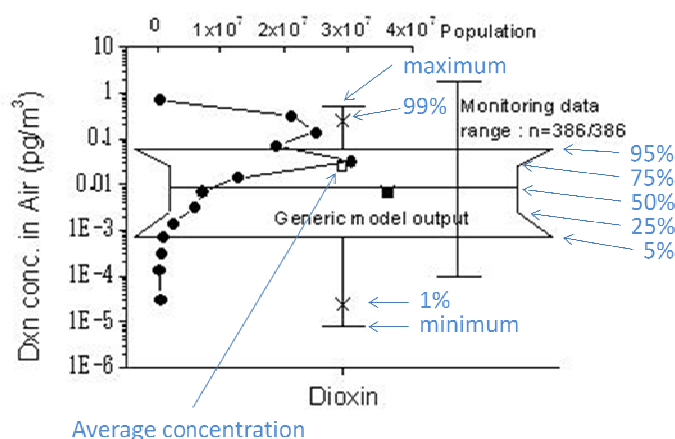


Notes: Colours indicate the simulated concentrations in the air, and bars indicate the measured concentrations. The simulated results consist of approximately 40 000 data points, and extensive monitoring data consist of approximately 400 data points.

1 pg<sup>1</sup> (picogram) = 0.001 nanogram

Source: Suzuki *et al.* (2004), “Geo-referenced Multimedia Environmental Fate Model (G-CIEMS). Model formulation and comparison to the generic model and monitoring approaches”, *Environmental Science & Technology*, No. 38, Washington, DC, pp. 5682-5693.

**Figure B.3: Results of simulated outputs from 5 km × 5 km resolution and generic model domain, range of monitoring data and demographic distribution.**



Notes: This Box-and-Whisker plot shows maximum, 99th, 95th, 75th, 50th, 25th, fifth and first percentiles and minimum respectively, from upper to lower end of box-whisker presentation. An open-box bullet shows the averaged concentration of all data.

Source: Suzuki *et al.* (2004), “Geo-referenced Multimedia Environmental Fate Model (G-CIEMS). Model formulation and comparison to the generic model and monitoring approaches”, *Environmental Science & Technology*, No. 38, Washington, DC, pp. 5682-5693.

Figure B.3 shows the simulated result of the fate model calculation, showing the maximum, 99<sup>th</sup> percentile, 75<sup>th</sup> percentile, 50<sup>th</sup> percentile, 25<sup>th</sup> percentile, fifth percentile, first percentile and minimum data points in the plot. A generic model output for air is plotted in the same figure as the filled-box bullet labelled “Generic model output”.

The plot reveals that the generic model output gives nearly 50<sup>th</sup> percentile (median) of the spatially-resolved modelling outputs on the same regional/chemical set-up.

Monitoring data outputs are shown as the range in the same figure. This shows that the range of monitoring data significantly overlapped the major range of simulated outputs.

The circle and line plot shows the population that lives in the area of the specified air concentration.

Figure B.3 gives several insights into the spatial distribution and exposure estimation:

- The range of spatial distribution of dioxin concentrations occupied 6 orders of magnitude over the country from maximum to minimum. The range is about 4 orders of magnitude when restricting data between the 5<sup>th</sup> and 95<sup>th</sup> percentiles.
- The output of extensive monitoring data over the country shows a similar range of spatial distribution to the simulated results. This suggests that, in this case, there is no substantial discrepancy between measured and simulated outputs in terms of environmental concentrations.
- The generic model gives a median estimation of the whole range of spatial distribution when assuming a single-box domain over the country.

- People live in the regions with relatively high concentrations of dioxins in the air. The densest population is found in the region with a concentration around the 75<sup>th</sup> percentile, and the majority of the population lives in the region with a concentration range between the 75<sup>th</sup> and 99<sup>th</sup> percentiles.

This information gives an insight into the realistic spatial distribution of contaminant concentrations, the distribution of measured data from extensive monitoring programmes, estimation from a generic model framework and linkage to the exposure estimation for real populations.

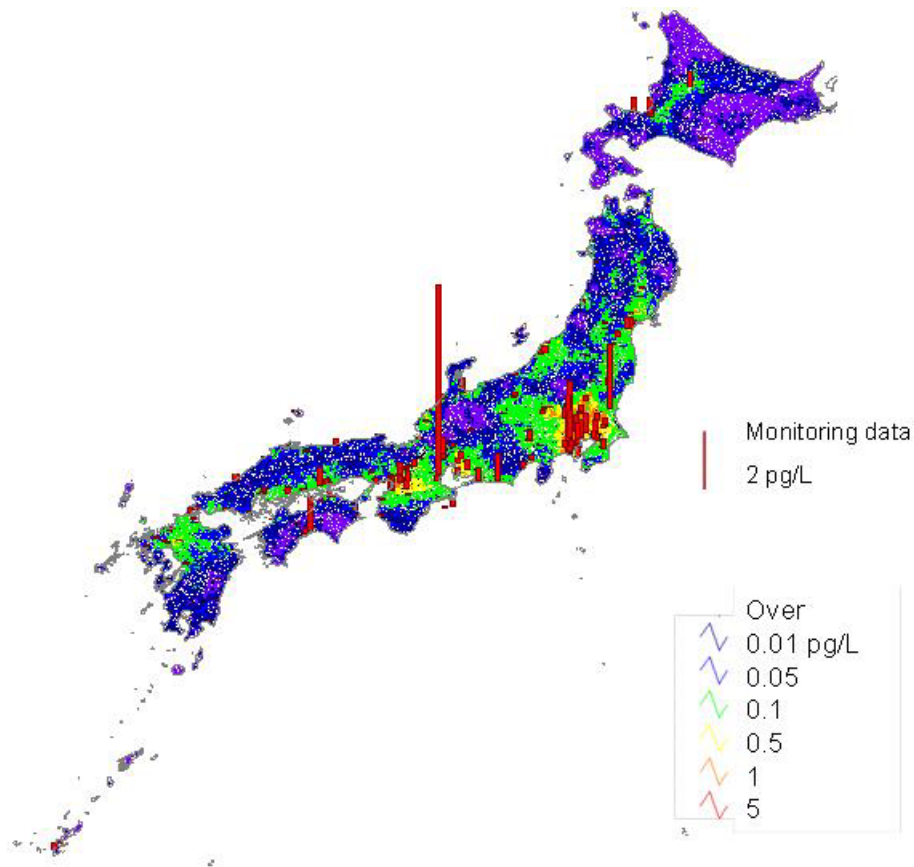
The representativeness of monitoring data for the purpose of exposure assessment can be compared with the example given in this section.

#### **Consistency/discrepancy between monitoring data-based exposure estimation and model-based exposure estimation**

As indicated in the previous section, monitoring-based exposure estimation could be assumed to be consistent, to capture nearly the whole range of spatial distribution in the real world. However, when a limited number of monitoring data are available, such as in screening-level assessment, it is not apparent if or how monitoring-based, model-based and real-world estimations can be compared.

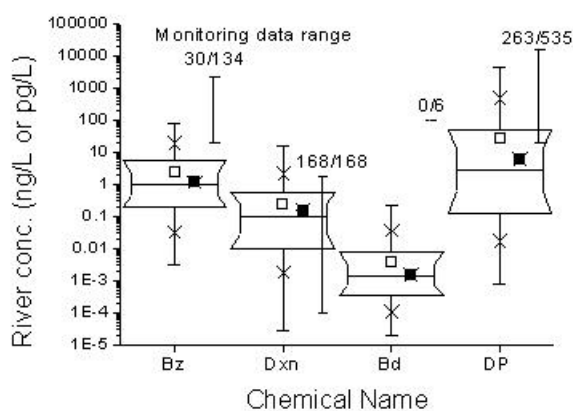
Figure B.4 shows concentrations of dioxins in river water, derived in the same way as for dioxin concentrations in the air. The model simulated the concentrations of dioxins in river water based on the river network structure across the country, consisting of approximately 35 000 river segments. The average length of river segments is about 5.7 km, which is the basic geographical resolution of the data shown in Figure B.4. The results of the simulation were also validated against the available monitoring data (Suzuki *et al.*, 2004). Results in Figure B.4 for dioxins are summarised in statistical format in Figure B.5, together with similar simulation outputs for benzene, butadiene and di-(2-ethylhexyl) phthalate.

**Figure B.4: Simulated concentrations of dioxins in river water, based on the multimedia fate model G-CIEMS, Japan**



*Notes:* Colours indicate the simulated concentrations in water, and bars indicate the measured concentrations. The simulated results consist of approximately 35 000 data points and the monitoring data consist of approximately 170 data points.

*Source:* Suzuki *et al.* (2004), "Geo-referenced Multimedia Environmental Fate Model (G-CIEMS). Model formulation and comparison to the generic model and monitoring approaches", *Environmental Science & Technology*, No. 38, Washington, DC, pp. 5682-5693.

**Figure B.5: Simulated outputs for river water with approximately 5.7 km river segment resolution over Japan.**

Notes: Bd, butadiene; Bz, benzene; DP, di-(2-ethylhexyl) phthalate; Dxn, dioxins

Source: Suzuki *et al.* (2004), "Geo-referenced Multimedia Environmental Fate Model (G-CIEMS). Model formulation and comparison to the generic model and monitoring approaches", *Environmental Science & Technology*, No. 38, Washington, DC, pp. 5682-5693.

The legends in Figure B.5 are similar to those of Figure B.3. Because of the different level of validation of the model results (and related input data including emission estimation), the relationships between the range of modelling (Box-and-Whisker plots) and range of monitoring data (bars) are different for each chemical. For benzene, the range of monitoring data is around the maximum or higher range of modelled outputs. For dioxins, the range of monitoring and modelling outputs is within a similar geographical distribution. For butadiene, the number of monitoring data is very limited, and all data are below non-detect levels, although the limit of detection for this analyte is already much higher than the range of modelling outputs. For di-(2-ethylhexyl) phthalate, the monitoring data range is around the higher end of the modelling outputs.

Although we cannot draw any conclusions from the above discussion, the monitoring data obtained under normal sampling practices in Japan tend to suggest the higher region of geographical distribution. This means that reference environmental concentrations by limited monitoring outputs in Japan might suggest the 90<sup>th</sup>, 95<sup>th</sup> or 99<sup>th</sup> percentiles of the whole geographical distribution of environmental concentrations.

### Impact of non-detect data on exposure estimates

Non-detect (ND) data create significant difficulties in the use of monitoring data for exposure assessments. ND data means neither zero, nor some of the arbitrarily determined values, like the ND level of analytical methods.

An ND value or value below the detection limit means that the value was not able to be distinguished from blank signals from an analytical chemistry point of view, and therefore no specific value was reported. In other words, an ND value means an unknown value between zero and the detection limit (when the blank was subtracted) or uncertainty due to a low concentration in the sample in terms of analytical chemistry (including all related factors, such as sampling and sample properties).



It is important to bear in mind that ND values cannot be neglected in the analysis of a dataset. They tell us that those values are smaller than a certain value (detection limit). Removing ND values thus introduces a bias in higher location statistics, for example. Statistics based on rank are robust to the presence of ND values, to some extent. For example, the median can be calculated when the proportion of ND value is less than 0.5, and the inter-quartile range can be calculated when the proportion of ND value is less than 0.25.

The major problem in dealing with ND values lies in the fact that they are without point estimates; that is, only the range (from zero to the detection limit) is given. Because the ND value is not a specific value, its treatment becomes complicated, especially when dealing with a sum of concentrations or, more generally, a linear combination of concentrations. For example, in the case of dioxin concentrations in a sample, the former would be a sum of the concentrations of all the dioxin compounds, and the latter would be a toxic equivalent (TEQ). These values are determined from individual compounds, assuming that the detection limits are the same ( $a$ ) for all the  $n$  compounds, for simplicity. When the concentrations ( $x_i$ ) of all the compounds are below the detection limits, *i.e.*  $0 \leq x_i < a$ , we know that the sum concentration is  $0 \leq S = \sum x_i < na$ . When only one compound has the concentration ( $c$ ) above the detection limit, then we know that  $c \leq S < c + (n-1)a$ . These ranges (without point estimates) can introduce uncertainty due to ND values. This uncertainty is usually negligible, but may sometimes affect the exposure estimates.

## References

Ministry of the Environment, Japan (1999), “Results of Intensive National Monitoring on Dioxins” (in Japanese) [www.env.go.jp/press/press.php?serial=1908](http://www.env.go.jp/press/press.php?serial=1908), accessed 18 November 2011.

Suzuki, N. *et al* (2003). “Human Exposure to PCDDs, PCDFs and Co-PCBs in Japan, 2000” *Organohalogen Compounds*, No. 64, pp. 67-70.

Suzuki, N. *et al*. (2004), “Geo-referenced Multimedia Environmental Fate Model (G-CIEMS). Model formulation and comparison to the generic model and monitoring approaches”, *Environmental Science & Technology*, No. 38, Washington, DC, pp. 5682-5693.

## Notes

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<sup>1</sup> Because the lower detection limit of the analysis was set at a relatively high level.

## ANNEX C: MONITORING PROGRAMMES IN THE UNITED STATES

In the United States, concentrations of chemicals in environmental media and assessment of exposure or dose are monitored through a variety of programmes. Environmental monitoring may be conducted by the Federal Government, state and local authorities, and private industry. It may be conducted to determine compliance with regulatory standards, to improve environmental conditions or public health and welfare, or for research and investigation.

The US Environmental Protection Agency (US EPA) has developed Envirofacts<sup>25</sup>, a data warehouse that provides access to several US EPA databases containing monitoring information on environmental activities that have been conducted for air, water and land anywhere in the United States. Envirofacts enables individuals to generate maps of environmental information for a specific location. Many databases developed by the US EPA, the US Geological Survey and other agencies include a geospatial component that allows users to display data geographically. Some states, such as Oregon and Washington, have established extensive databases. Oregon has many databases containing environmental monitoring information, such as: the Air Quality Index, Environmental Cleanup Site Information, Laboratory Analytical Storage and Retrieval, Pacific Northwest Water Quality Data Exchange, Wastewater Permit Reports, Wastewater Permit Search and Longitude Latitude Identification. Washington also has environmental information in the following databases: Columbia River Main Stem-Water Resources Information System, Polluted Waters-303 (d) Listing, Water Resources Explorer and Facility/Site Identification System.

### *Air*

The current focus for air pollution monitoring programmes in the United States is on a set of six criteria air pollutants and 187 hazardous or toxic air pollutants that have been identified by the US EPA. The criteria air pollutants are common throughout the United States and include carbon monoxide, lead, nitrogen dioxide, ozone, particulate matter and sulphur dioxide. Hazardous or toxic air pollutants are those that cause or may cause serious health effects. The US EPA is required to manage 187 hazardous air pollutants. States are required to conduct monitoring for the criteria air pollutants and to provide a summary of the results to the US EPA. Each year the US EPA examines trends in air pollution for the six criteria air pollutants and prepares a National Air Quality and Emissions Trends Report that summarises changes in air pollution over time and the current air pollution status.

In addition, the US EPA has programmes that address acid rain, climate change, ozone depletion, radiation, indoor air and new sources of air pollution. Air monitoring data for the entire United States are available in the AirData database<sup>26</sup> and can be displayed geospatially. Data on the sources and emissions of the criteria and hazardous air pollutants are available via the National Emissions Inventory Database.<sup>27</sup> More information on the US EPA air monitoring programmes and databases can be found on their Air and Radiation website.<sup>28</sup>

### *Water*

Waters are monitored throughout the US by state, federal and local agencies, universities, dischargers and volunteers. Section 106 (e) (1) of the Clean Water Act provides for the US EPA to award eligible states funding in order to monitor, compile and analyse data on the quality of navigable waters; to update

the data annually; and to include the data in a report under section 305 (b) of the Clean Water Act. Water quality data are primarily collected by the states, dischargers and the federal government and used by the federal and state governments to characterise waters, identify trends over time, identify emerging problems, determine whether pollution control programmes are working, help direct pollution control efforts to where they are most needed and respond to emergencies such as floods and spills. The US EPA and the states conduct monitoring to protect surface water, groundwater, waters flowing over the ground and water used for drinking. In addition, the US EPA and the states promote effective and responsible water use, treatment, disposal and management.

The US EPA has established a list of drinking water contaminants and maximum contaminant levels for microorganisms, disinfectants, disinfection by-products, organic and inorganic chemicals, and radionuclides, and collects data on unregulated contaminants. The US EPA also issues permits for the discharge of pollutants into surface water and requires water systems to test to ensure that drinking water is safe. The US EPA's national regulatory compliance database for the drinking water programme – Safe Drinking Water Information System (federal version) – includes information on the nation's 160 000 public water systems, as well as violations of drinking water regulations. The US EPA's primary database for storing and maintaining water quality data is STORET<sup>29</sup> (short for STORage and RETrieval), a data warehouse repository for water quality, biological and physical data. The US EPA has instructed the states to make all their water quality data compliant with the STORET format by the end of 2013 so that federal and state data can be merged.

The US EPA, states and tribes are conducting a national quality assurance programme designed to yield unbiased, statistically representative estimates of the condition of the whole water resource (*e.g.* rivers and streams, lakes, ponds, reservoirs, wetlands). A range of surveys can be accessed at the US EPA's National Aquatic Resource Surveys website,<sup>30</sup> as well as information on the US EPA's drinking water monitoring programmes and databases.<sup>31</sup> The US EPA also makes information and data available on:

- Groundwater<sup>32</sup>
- Wastewater<sup>33</sup>
- Watersheds<sup>34</sup>
- Stormwater<sup>35</sup>
- Lakes<sup>36</sup>
- Rivers and streams<sup>37</sup>
- Oceans, coasts, estuaries and beaches<sup>38</sup>
- Wetlands<sup>39</sup>

Water monitoring data and other information are also available for specific regions or areas.<sup>40</sup> Finally, the US EPA has conducted a national screening-level survey of chemical residues in fish tissue from lakes and reservoirs in the country.

The US EPA has other responsibilities related to monitoring and analysing data on water quality for US waters. Some of those responsibilities are to report on water quality conditions throughout the United States, and assemble those results in the following reports:

- National Aquatic Resource Surveys (statistical surveys of the quality of US waters)<sup>41</sup>
- US EPA's WATERS database (mapping and displaying water quality information)<sup>42</sup>
- Water Quality Conditions Report by the States (ATTAINS database)<sup>43</sup>
- Monitoring, Assessment and Reporting Guidelines (for states)<sup>44</sup>
- Assessing the Biological Condition of Waters<sup>45</sup>

The US Geological Survey also implements programmes that collect water monitoring data, including the National Stream Quality Accounting Network,<sup>46</sup> which reports on the concentrations and loads of selected constituents delivered by major rivers to the coastal waters of the United States. The National Water-Quality Assessment Program<sup>47</sup> provides an understanding of water quality conditions: whether conditions are getting better or worse over time, and how natural features and human activities affect those conditions.

### ***Sediment and soil***

Contaminated sediment and soil may be addressed through other monitoring programmes. Contaminated sediments may impair water bodies and require fish consumption advisories. The US EPA has developed guidance for cleaning up contaminated sediments (available on its Superfund Sediment Resource Center website)<sup>48</sup> and screening guidance to assist in site cleanup.<sup>49</sup>

### ***Biomonitoring and exposure-related information***

The National Health and Nutrition Examination Survey (NHANES)<sup>50</sup> is a programme of studies designed to assess the health and nutritional status of adults and children in the United States. NHANES is managed by the Centers for Disease Control and Prevention (CDC). Findings are used to determine the prevalence of major diseases and risk factors for diseases.

The National Human Exposure Assessment Survey (NHEXAS)<sup>51</sup> was implemented in the 1990s by the US EPA to provide critical information about the distribution of multi-pathway, multimedia population exposures to chemical classes.

The National Human Adipose Tissue Survey (NHATS) was an annual survey conducted from 1970 to 1989 by the US EPA to collect and chemically analyse human adipose tissue specimens for the presence of toxic chemicals. Additional information about NHATS can be found via the EPA's Environmental Assessment web pages.<sup>52</sup>

The Toxic Substances Control Act (TSCA) Inventory Update Reporting (IUR) rule allows the US EPA to collect public information on manufacturing, processing, and use of commercial chemicals, including current information on volumes of chemical production, manufacturing facility data and how the chemicals are used. This information helps the agency determine whether chemicals may be dangerous to people or the environment. The IUR rule, promulgated under TSCA section 8(a), requires manufacturers (including importers) of certain chemical substances on the TSCA Chemical Substance Inventory (TSCA Inventory) to report information about the manufacturing (including import), processing and use of those chemical substances. This information is made available to the public, to the maximum extent possible due to confidentiality concerns, at the EPA's Chemical Data Reporting / Inventory Update Reporting web pages.<sup>53</sup>

The Toxics Release Inventory (TRI) programme compiles TRI data on toxic chemical releases and waste management activities reported annually by certain industries, as well as federal facilities, and makes the data available through data files and database tools. The goal of the TRI programme is to provide communities with information about toxic chemical releases and waste management activities, and to support informed decision-making at all levels by industry, government, non-governmental organisations, and the public. TRI information is available at the EPA's Toxics Release Inventory web pages.<sup>54</sup>

The High Production Volume (HPV) Challenge Program is designed to allow companies that produce high volumes (1 000 000 pounds (453.6 tonnes) per year or more) of certain toxic chemicals to report on a designated set of characteristics about those chemicals and environmental monitoring data available to the company from their manufacturing, processing or disposal of those chemicals. As of June 2007, companies sponsored more than 2 200 HPV chemicals, with approximately 1 400 chemicals sponsored directly through the HPV Challenge Program and over 860 chemicals sponsored indirectly through international efforts. Access to HPV chemical information enables the public to participate in environmental decision-making at all levels - federal, state and local. The HPV Challenge website<sup>55</sup> provides information about the HPV programme in the following areas: 1) summary of the programme and its background; 2) health and environmental effects data collected by the programme in a database that allows users to refine searches of and queries on chemical data; 3) the US EPA review of chemical data and characterisation provided by the company; 4) discussion of how the voluntary chemical sponsorship portion of the programme was established; and 5) list of HPV chemicals that were not sponsored in the volunteer portion of the programme, and information on the US EPA regulatory actions to collect data for those chemicals.

The US Food and Drug Administration (FDA) Center for Food Safety and Applied Nutrition (CFSAN), under a programme known as the Priority-based Assessment of Food Additives (PAFA), generates the Everything Added to Food in the United States (EAFUS) list of substances. This is a database that contains ingredients added to food directly and that have been approved as “generally recognised as safe” (GRAS) by the US FDA. This database contains only a partial list of all food ingredients that may in fact be lawfully added to food, because under federal law, some ingredients may be added to food under a GRAS determination made independently from the US FDA. The list contains many, but not all, of the substances subject to independent GRAS determinations. Information about the GRAS notification programme can be found at the GRAS notice inventory web pages.<sup>56</sup>

In addition, there are several databases that contain exposure-related data and information, which are useful in developing exposure assessments in the United States. These databases include the IUR, which is now Chemical Data Reporting (CDR), the High Production Volume Information System (HPVIS), the BASE, and other information on indoor air monitoring in buildings.

The purpose of the CDR programme is to collect high-quality screening-level, exposure-related information on chemical substances and to make that information available for use by the US EPA and to the public to the furthest extent possible, due to data confidentiality claims.<sup>57</sup> The CDR data are used to support risk screening, assessment, priority setting and management activities and constitute the most comprehensive source of basic screening-level exposure-related information on chemicals available to the US EPA. CDR and IUR data can be accessed at the CDR/IDR section of the Chemical Data Reporting / Inventory Update Reporting web pages.<sup>58</sup>

The HPVIS is a database that provides access to physical/chemical property, environmental fate and transport, and health and environmental effects information obtained through the High Production Volume (HPV) Challenge Program described above. The HPVIS and related data are available at the High Production Volume Information System web pages.<sup>59</sup>

The US EPA conducted the Building Assessment Survey and Evaluation (BASE) study to provide information on baseline indoor air quality in typical buildings in the United States. The BASE study used a standardised protocol to collect extensive indoor air quality data from 100 randomly selected public and commercial office buildings in 37 cities and 25 states. The BASE study results are accessible at the Building Assessment Survey and Evaluation Study web pages.<sup>60</sup> Additional information on indoor air quality can be found at the EPA’s Indoor Air Quality web pages.<sup>61</sup>

### ***Existing and potential uses of exposure assessments***

Exposure assessment is commonly used in many programmes in the United States, especially in those that use risk assessment, such as under the Toxic Substances Control Act. Many US programmes implement legislation that is based on a risk assessment context; others are based on meeting technological standards or other findings. Both regulatory and voluntary programmes are implemented within the United States. Exposure assessment may be conducted by the Federal Government, state and local authorities, and private industry.

The US EPA has developed policy and guidance for conducting human and environmental exposure assessments and has established databases and tools used by the US EPA programme offices in implementing agency policy within their programmes. In addition, the US EPA's Office of Research and Development conducts exposure assessment research in support of the Agency's mission. The relevant Agency policy and guidance include: *Guidelines for Exposure Assessment*, *Exposure Factors Handbook*, *Child-Specific Exposure Factors Handbook*, *Dermal Exposure Assessment: A Summary of EPA Approaches*, *Guidance Document on the Development, Evaluation and Application of Environmental Models*, *Guidance for Quality Assurance Project Plans for Modelling* and *Peer Review Handbook* (all publications available from the Environmental Protection Agency).

In addition, the US EPA develops information, data and tools for use by others. For example, it has developed the National Air Toxics Assessments as a state-of-the-science screening tool for state, local and tribal agencies to prioritise pollutants, emission sources and locations of interest for further study in order to gain a better understanding of risks (available at the National Air Toxic Assessments web pages).<sup>62</sup>

Finally, the US EPA has developed data, information and tools that are specifically designed for use by communities in prioritising chemicals of potential concern and better understanding exposure. Two such models are the Community-Focused Exposure and Risk Screening Tool (C-FERST)<sup>63</sup> and the Risk Screening Environmental Indicators (RSEI). C-FERST is a web-based tool to assist communities with the challenge of identifying and prioritising decisions about exposures and risks within their community. RSEI<sup>64</sup> is a computer-based screening tool that analyses risk factors to put TRI data into a chronic health context. RSEI is often used by government regulators, communities, journalists, industry and others to examine trends, identify important emission situations for follow-up, support community-based projects, and initially screen potential impacts of emissions.

## Notes

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- <sup>25</sup> [www.epa.gov/enviro/](http://www.epa.gov/enviro/)
- <sup>26</sup> [www.epa.gov/airdata](http://www.epa.gov/airdata)
- <sup>27</sup> [www.epa.gov/ttn/chief/net/2008inventory.html](http://www.epa.gov/ttn/chief/net/2008inventory.html)
- <sup>28</sup> [www.epa.gov/air](http://www.epa.gov/air)
- <sup>29</sup> STORET can be accessed at [www.epa.gov/storet](http://www.epa.gov/storet).
- <sup>30</sup> <http://water.epa.gov/type/watersheds/monitoring/nationalsurveys.cfm>
- <sup>31</sup> <http://water.epa.gov/drink/index.cfm>
- <sup>32</sup> <http://water.epa.gov/type/groundwater/index.cfm>
- <sup>33</sup> <http://water.epa.gov/aboutow/owm/index.cfm>
- <sup>34</sup> <http://water.epa.gov/type/watersheds/index.cfm>
- <sup>35</sup> [http://cfpub.epa.gov/npdes/home.cfm?program\\_id=6](http://cfpub.epa.gov/npdes/home.cfm?program_id=6)
- <sup>36</sup> <http://water.epa.gov/type/lakes/index.cfm>
- <sup>37</sup> <http://water.epa.gov/type/rsl/index.cfm>
- <sup>38</sup> <http://water.epa.gov/type/oceb/index.cfm>
- <sup>39</sup> <http://water.epa.gov/type/wetlands/index.cfm>
- <sup>40</sup> <http://water.epa.gov/type/location/index.cfm>
- <sup>41</sup> [http://water.epa.gov/type/watersheds/monitoring/aquaticsurvey\\_index.cfm](http://water.epa.gov/type/watersheds/monitoring/aquaticsurvey_index.cfm)
- <sup>42</sup> [www.epa.gov/waters](http://www.epa.gov/waters)
- <sup>43</sup> [www.epa.gov/waters/ir/](http://www.epa.gov/waters/ir/)
- <sup>44</sup> <http://water.epa.gov/type/watersheds/monitoring/repguid.cfm>
- <sup>45</sup> <http://water.epa.gov/type/watersheds/monitoring/bioassess.cfm>
- <sup>46</sup> <http://water.usgs.gov/nasqan>
- <sup>47</sup> <http://water.usgs.gov/nawqa>
- <sup>48</sup> [www.epa.gov/superfund/health/conmedia/sediment/ssrc.htm](http://www.epa.gov/superfund/health/conmedia/sediment/ssrc.htm)
- <sup>49</sup> [www.epa.gov/superfund/health/conmedia/soil/index.htm](http://www.epa.gov/superfund/health/conmedia/soil/index.htm)

<sup>50</sup> [www.cdc.gov/nchs/nhanes.htm](http://www.cdc.gov/nchs/nhanes.htm)

<sup>51</sup> [www.epa.gov/nerl/research/nhexas/nhexas.htm](http://www.epa.gov/nerl/research/nhexas/nhexas.htm)

<sup>52</sup> <http://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=55204>

<sup>53</sup> [www.epa.gov/iur](http://www.epa.gov/iur)

<sup>54</sup> [www.epa.gov/tri](http://www.epa.gov/tri)

<sup>55</sup> [www.EPA.gov/hpv](http://www.EPA.gov/hpv)

<sup>56</sup> [www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm](http://www.fda.gov/Food/FoodIngredientsPackaging/GenerallyRecognizedasSafeGRAS/GRASListings/default.htm)

<sup>57</sup> [www.epa.gov/iur/pubs/guidance/confidentiality.html](http://www.epa.gov/iur/pubs/guidance/confidentiality.html)

<sup>58</sup> [www.epa.gov/iur/tools/data/index.html](http://www.epa.gov/iur/tools/data/index.html)

<sup>59</sup> [www.epa.gov/hpvis/index.html](http://www.epa.gov/hpvis/index.html)

<sup>60</sup> [www.epa.gov/iaq/base](http://www.epa.gov/iaq/base)

<sup>61</sup> [www.epa.gov/iaq](http://www.epa.gov/iaq)

<sup>62</sup> [www.epa.gov/ttn/atw/natamain/](http://www.epa.gov/ttn/atw/natamain/)

<sup>63</sup> [www.epa.gov/head/c-ferst](http://www.epa.gov/head/c-ferst)

<sup>64</sup> [www.epa.gov/oppt/rsei](http://www.epa.gov/oppt/rsei)



**ANNEX D: MONITORING PROGRAMMES IN THE EUROPEAN UNION**

The data centres of the European Environment Agency compile various environmental data, including monitoring data for air pollution, water and wastes (Figure D.1). They are comprehensive compilations of various monitoring data collections, not necessarily relating to chemical contaminants.

The data portal site of the Institute of Environment and Sustainability of the European Commission's Joint Research Centre has compiled other environmental data sources covering a variety of monitoring data, including pollutants (Figure D.2). Through those compilations, various monitoring data in the European Union can be accessed.

Figure D.1: European data centres under the responsibility of the European Environment Agency

**Data and maps**

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- » Indicators
- » Data providers and partners
- » **European data centres**

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## European data centres

The Environmental data centre website is the coordinated entry point for European data relevant to the selected theme and products related to the indicators. It provides users with easy searching, viewing and download functions. It also gives links to involved partners and supporting documents.

### European data centres under responsibility of EEA

- European air pollution data centre**  
The air pollution data centre provides access to data and information related to the amount of air pollutants emitted into the atmosphere from different anthropogenic (human-made) sources as well as measured ambient air pollution at monitoring stations across Europe. The air pollution data centre also provides access to related products for air pollution indicators and assessments. Priority is given to policy-relevant data and information for European and national institutions, professionals, researchers and the public.
- European biodiversity data centre**  
The biodiversity data centre provides the coordinated entry point for data on species, habitat types and sites of European interest. The data and information maintained here are used in biodiversity indicators and assessments. Priority is given to policy-relevant data and information for European and national institutions, professionals, researchers and the public.
- European climate change data centre**  
The climate change data centre provides access to data and information on greenhouse gas emissions, climate change impacts, vulnerability and adaptation in Europe. Priority is given to policy-relevant data and information for European and national policy makers, influencers (such as NGOs, business, media and scientists) and the general public.
- Environmental data centre for land use**  
The environmental data centre for land use provides data to understand the relationship between land use and environmental impacts. Information is provided at different scales combining European coverage with global and *in situ* survey data. The core of data centre activities is related to dissemination of operational services in connection with key land cover/land use datasets, relevant indicators and derived products based on spatial analysis and change detection.
- European water data centre**  
The water data centre provides the European entry point for water related data as part of the Water Information System for Europe (WISE). It contains the input (reporting mechanisms) and output (visualisation of results) for compliance information under several water directives (WFD, Bathing water, UWWT directive, etc) as well as voluntary information as reported e.g. under the EEA regulation through the Eionet. The information compiled and maintained here is used in indicators, assessments and policy developments that are further accessible through the thematic links in WISE.

### Data centres under responsibility of EUROSTAT

- European data centre for waste**  
The central entry point for reporting of data under Community legislation on waste and providing information on waste and the associated environmental impacts.
- Environmental Data Centre on Natural Resources and Products**  
The Environmental Data Centre on Natural Resources and on Products is your gateway to information related to the environmental thematic areas of sustainable use of natural resources and products. This web-based system provides information for the following types: Metadata (contextual information), Data, Indicators, and Assessments.

### Data centres under responsibility of Joint Research Centre (JRC)

- European soil data centre (ESDAC)**  
The European Soil Data Centre acts as the primary data contact point for the European Commission's DG ENV in order to fulfill its soil information needs.
- European forest data centre (EFDAC)**  
The European Forest Data Center (EFDAC) is a focal point for policy relevant forest data and information by hosting and pointing to relevant forest products and by providing web-based tools for accessing and updating information located in EFDAC.

Source: European Environment Agency, Environmental Data Centre Website, [www.eea.europa.eu/data-and-maps/european-data-centres](http://www.eea.europa.eu/data-and-maps/european-data-centres).

Figure D.2: Data portal site of the Institute of Environment and Sustainability of the European Commission's Joint Research Centre

The screenshot shows the 'Data Portals' page of the Institute of Environment and Sustainability (IES) at the European Commission's Joint Research Centre. The page has a blue header with the IES logo and navigation links like 'Home', 'The Institute', 'Our Activities', 'Data Portals', 'Documentation', 'Job Opportunities', and 'Public Procurement'. A search bar is located at the top right. On the left, there is a sidebar with a list of data portals, including AFOLU DATA, CID Portal, Datasets for Atmospheric Modelling, Emissions Database for Global Atmospheric Research (EDGAR), European Drought Observatory, European Forest Data Center (EFDAC), European Forest Fire Information System (EFFIS), European Radiological Data Exchange Platform (EURDEP), European Soil Map Server, FLOODS Portal, Fraction of Absorbed Photosynthetically Active Radiation, Global Burnt Area 2000 Database, Global Land Cover 2000 Database, Image 2000 Database, Ispra Meteorological Station, Leaf Optical Properties Experiment 93 (LOPEX93), Multiscale European Soil Information System, Ocean Colour Data Portal, River and Catchments Database for Europe, Soil Erosion Risk Estimates, Soil Organic Carbon Content, The Environmental Marine Information System, The European Soil Portal, The INSPIRE Geoportal, and WMO World Data Centre for Aerosols. The main content area features three highlighted portals: 'The INSPIRE Geoportal', 'The CID Portal', and 'The European Soil Portal'. Each portal has a small thumbnail image and a brief description of its services and data sources.

Source: EC Joint Research Centre, Institute of Environment and Sustainability, Data portals, <http://ies.jrc.ec.europa.eu/index.php?page=data-portals>.

## ANNEX E: MONITORING PROGRAMMES IN CANADA

In Canada, monitoring occurs at the federal, provincial and municipal levels. The *Canadian Environmental Protection Act, 1999* provides the federal government with the authority to request information from industry to determine the commercial status of substances in Canada, to help set priorities, and to provide an updated knowledge base in support of subsequent risk assessment and risk management. Some of the types of information collected include substance identification, information on import and manufacturing activity, commercial and consumer use codes and North American Industry Classification System (NAICS) codes.

The following is an outline (not fully inclusive) of the monitoring programmes currently conducted in Canada.

### *Emissions monitoring programmes*

The **National Pollutant Release Inventory (NPRI)**<sup>65</sup> is Canada's legislated, publicly accessible inventory of pollutant releases (to air, water and land), disposals and transfers for recycling. The NPRI is managed by Environment Canada and currently tracks over 300 substances and groups of substances. The NPRI only collects information from industrial, commercial, institutional and other facilities that meet reporting requirements.

The NPRI is a key resource for identifying pollution prevention priorities, supporting the assessment and risk management of chemicals and air quality modelling, helping develop targeted regulations for reducing releases of toxic substances and air pollutants, encouraging actions to reduce the release of pollutants into the environment and improving public understanding.

The **National Emissions Reduction Plan** of the Chemistry Industry Association of Canada is an industry-led initiative that surveys member companies' emissions, off-site transfer activity and total quantities and waste material. This is an important initiative in that it records emissions of numerous chemicals not monitored on the NPRI. Survey information can be obtained from its website.<sup>66</sup>

### *Ambient air*

The **National Air Pollution Surveillance (NAPS)** database<sup>67</sup> is a joint programme by federal, provincial, territorial and regional governments to monitor and assess the quality of ambient air in Canada. NAPS gathers measurements from 152 stations in 55 major urban and rural locations across the country for sulphur dioxide, carbon monoxide, nitrogen dioxide, ozone, particulate matter (all components of smog), volatile organic compounds, and selected polycyclic aromatic hydrocarbons.

Air quality data collected by the NAPS network also help evaluate air pollution control strategies, identify urban air quality trends and forewarn of emerging air pollution episodes.

Additionally the provinces may also undertake air monitoring. Examples of provincial monitoring programmes are shown below:

- British Columbia: BC Air Quality Health Index (AQHI)<sup>68</sup>
- Ontario: Air Quality Index (AQI)<sup>69</sup>
- Alberta: Ambient Air Monitoring<sup>70</sup>
- Manitoba: Manitoba Air Quality<sup>71</sup>

Finally, although provincial governments in conjunction with Environment Canada monitor the air quality of various municipalities, the **Hamilton Air Monitoring Network (HAMN)**, as of 1 May 2003, maintains, operates and services the point source air quality monitoring network in the City of Hamilton, Ontario. Hamilton is unique in that it is home to various industrial sectors, including iron and steel companies, chemical producers, manufacturers and several recycling facilities. Air monitoring data in the Hamilton area can be obtained from the HAMN website.<sup>72</sup>

### *Indoor air*

The **Residential Indoor Air Quality Guidelines** and Guidance documents published by Health Canada<sup>73</sup> summarise the health risks posed by specific indoor pollutants, based on a review of the best scientific information available. They summarise the known health effects, detail the indoor sources and, where possible, provide a recommended exposure level below which health effects are unlikely to occur. The guidelines are recommendations only and are meant to serve as a scientific basis for activities to reduce the risk from indoor air pollutants.

Since 2004, Health Canada has conducted studies to measure indoor air pollutant levels in homes in different regions of the country to better understand the sources of pollutants and the levels present in Canadian homes. Studies have been conducted with regional partners in Windsor (as part of the Border Air Quality Study), Quebec City, Regina, Halifax and Edmonton. These studies are used by Health Canada to assess Canadians' exposure to indoor air pollutants, to measure the effect of outdoor air pollution on indoor air quality and to identify steps to improve residential indoor air quality. The **National Indoor Air Survey of CEPA/CMP Chemicals**, initiated by Health Canada in 2008, is generating national representative data on the levels of selected priority chemicals listed under the Canadian Environmental Protection Act, 1999, and the Chemicals Management Plan in Canadian residential indoor air. Indoor air samples are being collected and analysed in a randomly selected national sample of Canadian homes whose occupants are participating in the Canadian Health Measures Survey.

Additionally, other indoor air surveys are currently measuring particulate matter, air pollution in high-rise apartments and the effect of wood stoves on indoor air pollution.

### *Water*

The **Guidelines for Canadian Drinking Water Quality**<sup>74</sup> are published by Health Canada on behalf of the Federal-Provincial-Territorial Committee on Drinking Water. These guidelines are based on current, published scientific literature. Health-based guidelines are established on the basis of comprehensive review of the known health effects associated with each contaminant, exposure levels and the availability of treatment and analytical technologies. Aesthetic effects (e.g. taste, odour) are taken into account when these play a role in determining whether consumers will consider the water drinkable. Operational considerations are factored in when the presence of a substance may interfere with or impair a treatment process or technology or adversely affect drinking water infrastructure.

Municipal and provincial governments are mainly responsible for drinking water monitoring, and a few examples are shown below:

- Municipal drinking water monitoring programmes:
  - Toronto: Toronto Water<sup>75</sup>
  - Vancouver: City of Vancouver Water<sup>76</sup>
  - Calgary: City of Calgary Water Services<sup>77</sup>
- Provincial drinking water monitoring programmes:
  - Ontario: Drinking Water Surveillance Programme<sup>78</sup>
  - Alberta: Surface Water Quality Data<sup>79</sup>

A two-year study, **National Survey of Disinfection By-Products and Selected New and Emerging Contaminants in Canadian Drinking Water**, initiated by Health Canada in 2009, investigated the occurrence of new and regulated disinfection by-products and selected contaminants of emerging concern in Canadian drinking water. More than 100 water quality parameters/characteristics were analysed during the two year study in 65 water treatment facilities across the country and each water system was sampled twice in the same year (winter/summer) in order to assess temporal variations of some of the parameters.

### ***Soil/dust***

The Canadian Council of Ministers of the Environment's Soil Quality Guidelines Task Group is responsible for the development of Canadian Soil Quality Guidelines<sup>80</sup> for the protection of environmental and human health; guidance on other soil quality and contaminated site-related activities; and developing and maintaining the Canada-wide Standard for Petroleum Hydrocarbons in Soil and the requirements under it.

The **Canadian House Dust Study**<sup>81</sup> being undertaken by Health Canada is a population-based study looking at the levels of lead and other chemicals (metals, triclosan, parabens, bisphenol A, musks, pesticides and flame retardants) in the house dust of randomly selected urban Canadian homes, to establish an "urban baseline" that can be considered nationally representative.

### ***Biomonitoring***

The **Canadian Health Measures Survey**<sup>82</sup> is a nationally representative survey carried out by Statistics Canada, in collaboration with Health Canada and the Public Health Agency of Canada, to collect information from Canadians about their health. The survey includes a biomonitoring component, which collects blood and urine samples that are analysed to provide information on exposure to selected environmental chemicals. The first cycle collected information from 5 600 Canadians aged 6 to 79 years during the period 2007–2009.<sup>83</sup> The second cycle (2009–2011) includes children as young as 3 years of age. Sample collection for Cycle 3 (2012–2013) is currently underway. The **Maternal-Infant Research on Environmental Chemicals Study**,<sup>84</sup> led by Health Canada and Montreal's Ste. Justine Hospital, has recruited 2 000 pregnant women from 10 sites across Canada from 2008 to 2011. In addition to measuring the potential health effects of environmental chemicals on the mother and foetus, the study will generate national-level biomonitoring data from maternal blood and urine, cord blood, infant meconium, breast milk and maternal hair samples. Additionally, as part of this study, the effects of potentially endocrine disrupting and neurotoxic chemicals will be studied in 400 infants to determine if prenatal exposure to these chemicals affects post-natal growth, behaviour and sensory development. The **Pilot Study to Assess**

**the Feasibility of Measuring Chronic Exposure to Lead Among Canadians**, initiated by Health Canada in 2008, examined the body burden of lead in Canadians of all ages (including children) as well as the toxicokinetics of lead (how it is absorbed, metabolized, and disposed of) in blood, serum and bone. It will provide measures of both current and historical lead exposure and will demonstrate the feasibility of quantifying cumulative lead exposure in bone. The **P4 Study: Plastics and Personal-Care Product Use in Pregnancy study** initiated by Health Canada in 2008, recruited 80 pregnant women from the Ottawa, Ontario, area and collected multiple maternal urine samples, detailed consumer product/food packaging diaries, infant urine and meconium, and breast milk for detection of parent/metabolites of phthalates, bisphenol A, triclosan and triclocarban. Indoor and personal naphthalene measurements along with biomarkers of exposure to naphthalene were also made during pregnancy.

Additional studies are also under way to assess exposure of pregnant women to persistent organic pollutants.

The **Northern Contaminants Program** was established in 1991 in response to concerns about human exposure to elevated levels of contaminants in wildlife species that are important to the traditional diets of northern Aboriginal peoples. The Program's key objective is to work towards reducing and, where possible, eliminating contaminants in traditional/country foods, while providing information that assists individuals and communities in making informed decisions about their food use. Biomonitoring, health effects, and risk communication studies continue to be undertaken to characterise human exposures to and the health impacts of environmental chemicals for Aboriginal populations in the Canadian Arctic.

The **First Nations Biomonitoring Initiative** is a five-year (2008–2012) cross-Canada health survey designed to establish a baseline of First Nations' exposure levels to environmental chemicals. This initiative is a partnership between Health Canada and the Assembly of First Nations. The survey is exclusive to First Nations living on reserve (south of the 60th parallel) and serves to complement the Canadian Health Measures Survey. Components of the survey include a household questionnaire, direct physical measurements, and biospecimen collection (blood and urine).

**Canadian study of the impact of residential sources of lead on blood lead levels of young children** - This study, initiated by Health Canada in 2008, evaluated the importance of sources of lead exposure, such as drinking water in contact with lead service lines, dust and paint in Canadian children aged 1–5. Dust and tap water samples were taken in each residence and analysed for lead. Measurement of the content of lead in residential paint was also carried out. Relevant exposure information was collected by questionnaire. The blood lead level (BLL) of each child was determined and its relationship with residential sources of lead was estimated.

**Biomonitoring for environmental lead exposure in children from pre-1970s housing in St. John's, Newfoundland and Labrador** - This study, initiated by Health Canada in 2009, measured lead exposure (blood lead levels) in young children living in a range of housing ages in St. John's. Concurrent measurement of residential lead levels in the sample households will permit an evaluation of exposure sources.

**Biological monitoring of exposure to inorganic arsenic in a population in the Abitibi-Témiscamingue region using drinking water from private wells** – This study, initiated by Health Canada in 2008, conducted biological monitoring of exposure to arsenic in a population in the mining area of Abitibi-Témiscamingue, Quebec, where drinking water from private wells was used. Variations in internal doses of arsenic as a function of the various levels of contamination in the wells is being evaluated, as well as exploring whether there is a potential relationship between internal dose of arsenic and arsenic contamination levels in the wells with diabetes prevalence. Finally, the study is examining whether there is

a correlation between the internal dose of arsenic and the levels of thyroid hormones circulating in the blood.

**Biomonitoring of arsenic species in rural Nova Scotia communities** - This study, initiated by Health Canada in 2009, is developing and testing a group of biomarkers of exposure in rural Nova Scotia communities. These biomarkers will indicate both short- and long-term exposure to arsenic. The biomarkers are being related to well water concentrations of both total arsenic and arsenic species (which are known to vary in their toxicity). In addition, a novel and recently developed non-invasive method for analysing concentrations of total arsenic in skin and nails as a biomarker of long-term exposure is being tested.

**Assessment of long-term indoor residential pollution exposures among Canadian children** - This study, initiated by Health Canada in 2009, is providing estimates of exposure to contaminants in young children, through the analysis of data and information obtained as part of the Canadian Healthy Infant Longitudinal Development (CHILD) study. Biological samples (meconium, cord serum, and urine) and house dust are being analysed for levels of cotinine (tobacco smoke exposure biomarker) and a variety of phthalate metabolites.

**Dietary exposure of young children to emerging persistent organic pollutants and plasticizers** - This study, initiated by Health Canada in 2008, is producing child-specific dietary exposure estimates for a number of emerging persistent organic pollutants and plasticizers. Foods frequently consumed by infants and young children are being analysed for contaminants including perfluorinated compounds (PFCs), polybrominated diphenyl ethers (PBDEs), and bisphenol A. Dietary exposure of children to these chemicals is being calculated using the food concentration data obtained from this study and existing food intake data for young Canadians.

**Human exposure assessment of perfluorinated compounds in fish caught near possible major industrial sources, and effects of skin removal and cooking on exposure** - This study, initiated by Health Canada in 2009, is estimating dietary exposures to perfluorinated compounds (PFCs) for consumers of Ontario sport fish caught near possible major industrial sources. Fish are being collected near facilities such as adhesives and packaging manufacturing plants, near a former PFC spill site, as well as sewage treatment plants. The effects of food preparation, such as cooking and skin removal, on concentrations of PFCs in the fish are being examined so that better estimates of human dietary exposure can be obtained.

**Assessing biomarkers of exposure to manganese in children exposed through well water in New Brunswick** - This study, initiated by Health Canada in 2011, is examining children's exposure to manganese in New Brunswick, where there are naturally elevated levels of this metal in groundwater. The study is investigating the association between exposure to manganese from drinking water and the concentration of manganese in the hair and saliva of children.

The **Commission for Environmental Cooperation (CEC)** has conducted a trinational biomonitoring study, in collaboration with Health Canada researchers, to document exposure to environmental contaminants for women who are pregnant for the first time (primiparous) in Canada and Mexico, and women of childbearing age in the United States. The objectives of the study were to examine geographic differences in residue concentrations, as well as to develop comparable analytical chemistry research capacity across all three countries. The trinational report was published in October 2011.



## Notes

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<sup>65</sup> [www.ec.gc.ca/inrp-npri](http://www.ec.gc.ca/inrp-npri)

<sup>66</sup> [www.canadianchemistry.ca/EnvironmentBRSustainability/ReducingEmissionsBR](http://www.canadianchemistry.ca/EnvironmentBRSustainability/ReducingEmissionsBR)

<sup>67</sup> [www.ec.gc.ca/rnsps-naps](http://www.ec.gc.ca/rnsps-naps)

<sup>68</sup> [www.bcairquality.ca/readings/air-quality-health-index.html](http://www.bcairquality.ca/readings/air-quality-health-index.html)

<sup>69</sup> [www.airqualityontario.com/science/background.php](http://www.airqualityontario.com/science/background.php)

<sup>70</sup> <http://environment.alberta.ca/0949.html>

<sup>71</sup> <http://web20.gov.mb.ca/EnvistaWeb/Default.ltr.aspx>

<sup>72</sup> [www.hamnair.ca](http://www.hamnair.ca)

<sup>73</sup> [www.hc-sc.gc.ca/ewh-semt/air/in/res-in/index-eng.php](http://www.hc-sc.gc.ca/ewh-semt/air/in/res-in/index-eng.php)

<sup>74</sup> [www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2012-sum\\_guide-res\\_recom/index-eng.php](http://www.hc-sc.gc.ca/ewh-semt/pubs/water-eau/2012-sum_guide-res_recom/index-eng.php)

<sup>75</sup> [www.toronto.ca/water](http://www.toronto.ca/water)

<sup>76</sup> [http://app.vancouver.ca/EngWaterQuality\\_Net/Default.aspx](http://app.vancouver.ca/EngWaterQuality_Net/Default.aspx)

<sup>77</sup> [www.calgary.ca/UEP/Water/Pages/Water-Services.aspx](http://www.calgary.ca/UEP/Water/Pages/Water-Services.aspx)

<sup>78</sup> [www.ene.gov.on.ca/environment/en/monitoring\\_and\\_reporting/drinking\\_water\\_surveillance\\_program/index.htm](http://www.ene.gov.on.ca/environment/en/monitoring_and_reporting/drinking_water_surveillance_program/index.htm)

<sup>79</sup> <http://environment.alberta.ca/01288.html>

<sup>80</sup> [www.ccme.ca/ourwork/soil.html?category\\_id=44](http://www.ccme.ca/ourwork/soil.html?category_id=44)

<sup>81</sup> [www.hc-sc.gc.ca/ewh-semt/contaminants/dust-poussiere-eng.php](http://www.hc-sc.gc.ca/ewh-semt/contaminants/dust-poussiere-eng.php)

<sup>82</sup> [www.statcan.gc.ca/chms](http://www.statcan.gc.ca/chms)

<sup>83</sup> [www.health.gc.ca/biomonitoring](http://www.health.gc.ca/biomonitoring)

<sup>84</sup> [www.hc-sc.gc.ca/ewh-semt/contaminants/human-humaine/mirec-eng.php](http://www.hc-sc.gc.ca/ewh-semt/contaminants/human-humaine/mirec-eng.php)

## ANNEX F: MONITORING PROGRAMMES IN JAPAN

Japan conducts many monitoring programmes for chemicals in media such as air, water, soil, biota (living organisms) and waste, and humans. The Ministry of the Environment (MOE) is involved in the majority of these monitoring programmes. This annex contains some relevant examples from the monitoring programme for the general environment (“Chemicals in the Environment” survey), the air monitoring programme and the water monitoring programme.

### General environmental monitoring programme

MOE has been conducting successive investigations into the persistence of chemical substances in the general environment since 1974 and has published the results in *Chemicals in the Environment*. The latest results appear on the MOE website<sup>85</sup> in Japanese, and some summaries are compiled in English, in “Chemicals in the Environment (FY2005)” (Japanese MOE, 2005). This report outlines how target substances were selected, and the outputs of three types of survey which are described below, each with a different purpose:

- The “Initial Environmental Survey” is designed to monitor concentrations of chemical substances to know persistence of chemical substances in the environment, targeting the Designated Chemical Substances specified by the Law Concerning the Examination and Manufacture, etc. of Chemical Substances (known as Chemical Substances Control Law), candidate substances for the Pollutant Release and Transfer Register (PRTR) system, unintentionally formed substances, and substances required by social factors.
- The “Environmental Survey for Exposure Study” is designed to determine the amounts of chemical substances to which humans and wildlife are exposed, to conduct environmental risk assessment.
- The “Monitoring Investigation” is designed to monitor target substances included in the Stockholm Convention on Persistent Organic Pollutants, and other substances that are possible candidates as target substances of the convention - highly persistent substances for which environmental standards have not yet been established, but whose environmental status must be determined annually as required for Class 1 and 2 Specified Chemical Substances, and Designated Chemical Substances specified in the Chemical Substances Control Law.

Target chemicals are selected every year and for each survey; some of the target chemicals are also monitored continuously for multiple years. Until recently (the 2010 report for the 2009 survey), the cumulative number of surveyed chemicals was 1 208, and the target media included air, water, sediment, biota, air, food and others. This survey provides data for the exposure assessment of chemicals in Japan, through the interactive selection of target chemicals, environmental media, detection and selectivity set up, or other means of interaction. To avoid duplication, the results for chemical substances (*e.g.* dioxins) that have been monitored by other divisions of MOE are not included in the description above (see Table F.1).

There are many other environmental monitoring programmes carried out by MOE, and Table F.1 summarises some of the major surveys. Air and water monitoring programmes are described below:

**Table F.1: Environmental investigation by other divisions of the Ministry of the Environment in Japan (as of September 2005)**

Name of investigation	Media	Target chemical substances
Monitoring investigation of hazardous air pollutants	Air	Benzene, aldehydes, mercury and its compounds, benzo[ <i>a</i> ]pyrene, etc. (19 species)
Water quality monitoring	Surface water, ground water	Cadmium, total cyanogen, etc.
Environmental investigation of Agrochemicals	Soil, agricultural products, air, surface water	Pesticides
Monitoring of precautionary monitoring targets	Surface water, ground water	Chloroform, <i>trans</i> -1,2-dichloroethylene, etc.
Priority substances for the survey on method and monitoring	Water environment	Zinc, etc.
Investigation of Dioxins	Air, surface water, bottom sediment, soil, wildlife	PCDDs, PCDFs, coplanar PCBs PBDDs, PBDFs

Notes: PBDDs, polybrominated dibenzo-*p*-dioxins; PBDFs, polybrominated dibenzofurans; PCBs, polychlorinated biphenyls; PCDDs, polychlorinated dibenzo-*p*-dioxins; PCDFs, polychlorinated dibenzofurans

Source: Japan Ministry of the Environment (2005), *Chemicals in the Environment (Fiscal Year 2005)*, [www.env.go.jp/chemi/kurohon/en/index.html](http://www.env.go.jp/chemi/kurohon/en/index.html), accessed 17 January 2013.

### Air monitoring programme

The MOE conducts monitoring programmes for air pollutants, hazardous air pollutants, pollen, dioxins, acid precipitation and environmental radiation, among others. Air pollutant monitoring programmes are conducted at about 1 700 monitoring stations, most of which monitor continuously. Major pollutants include nitrogen oxide, particulates, sulphur oxide, photochemical oxidants, non-methane hydrocarbons, and carbon monoxide. Results are presented in a web-based geographic information system (GIS), as shown in Figure F.1 and Figure F.2.

Figure F.1: Presentation of GIS-based system for air pollutants and an example of monitoring stations and results (oxidant level in stations in Kanto region): Part 1

**そらまめ君** そらまめ君は、空をマメに監視します。

**環境省大気汚染物質広域監視システム**  
Atmospheric Environmental Regional Observation System : AEROS

全国の大気汚染状況について、24時間、情報提供しているサイトです。  
大気汚染測定結果(時間値)と光化学オキシダント(注意値・警報値)の最新の1週間分のデータを地図で見ることができます。

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**お知らせ**

- ・震災の影響により、一部の測定地点においてデータが表示されない場合がございます。
- ・PM2.5濃度データを追加しました。
- ・新たに機能追加を追加しました。  
(測定時報値の地域選択機能、濃度別測定局検索機能、国設局表示機能)

**測定時報値**  
見たい地域をクリックして下さい

北海道  
東北  
関東  
中部  
近畿  
中国・四国  
九州  
沖縄

光化学オキシダント注意値  
警報値を状況

北海道  
東北  
関東  
東海  
中部  
近畿  
中国・四国  
九州  
沖縄  
全国一覧

測定局一覧 測定局の検索 携帯サイト 工事情報 リンク  
測定局配置図 データ収集状況 説明を見る 問い合わせ先

※そらまめ君に掲載されているデータは、速報値であり、確定値ではありません。  
速報値は、データ検証の結果、後日修正されることがありますので、調査研究等でのデータ利用には確定値を入手されることをおすすめします。

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携帯のバーコードリーダーを左の画像に合わせると、下記URLにアクセスできます。  
<http://sora.taiki.go.jp>

**ご質問・ご意見**  
このサイトに関するご質問・ご意見は、環境省水・大気環境局大気環境課 [soramame@env.go.jp](mailto:soramame@env.go.jp)までお寄せ下さい。

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- ・本サイト上に掲載されている資料・データ等の著作権は、環境省、それぞれの地方公共団体及び国立環境研究所が保有します。

環境省 国立環境研究所 EICネット

Source: Japan Ministry of the Environment, Atmospheric Environmental Regional Observation System (AEROS) website, <http://soramame.taiki.go.jp/>, accessed 17 January, 2013.

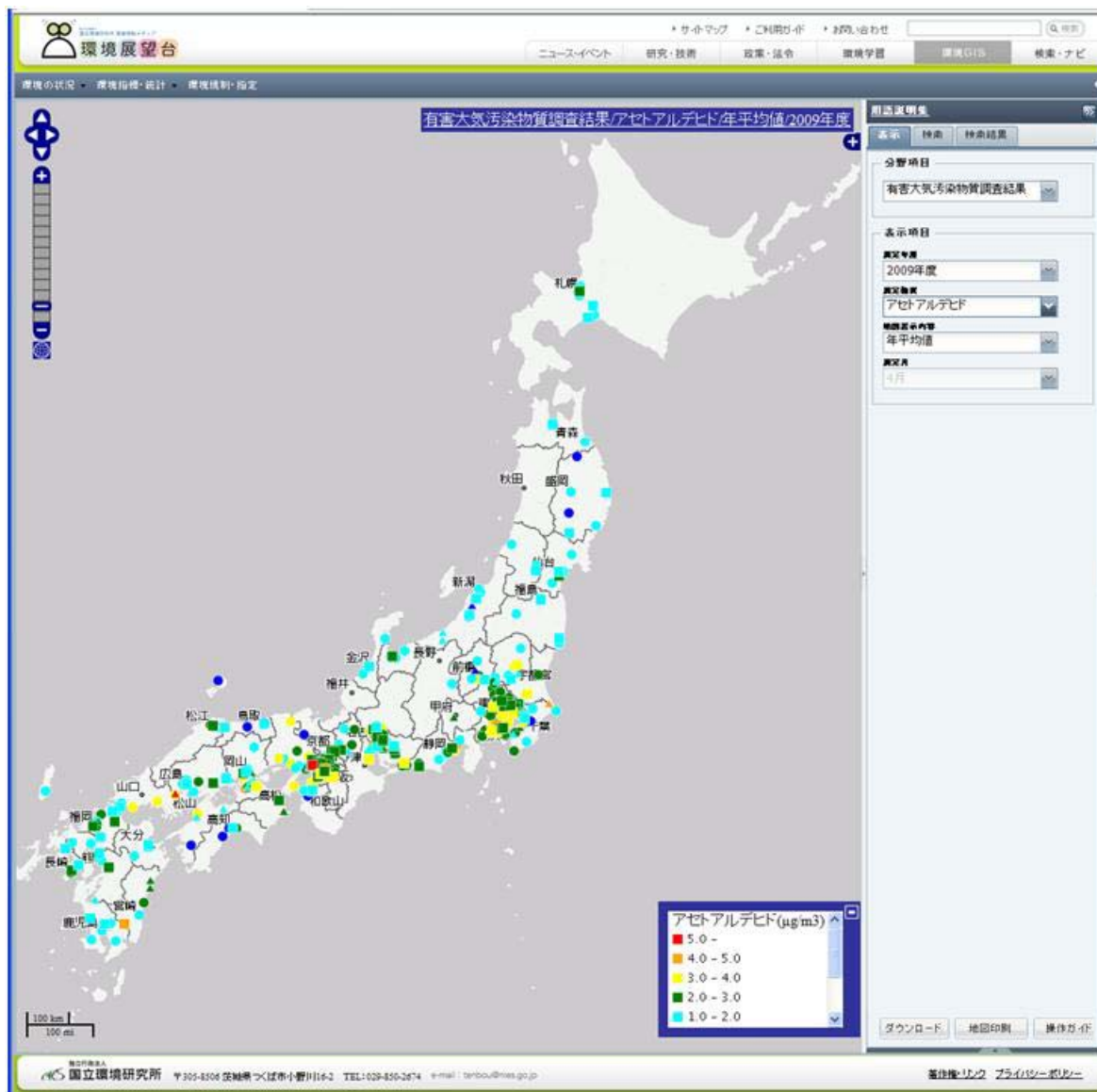
Figure F.2: Presentation of a GIS-based system for air pollutants and an example of monitoring stations and results (oxidant level in stations in Kanto region): Part 2



Source: Japan Ministry of the Environment, Atmospheric Environmental Regional Observation System (AEROS) website, <http://soramame.taiki.go.jp/>, accessed 17 January, 2013.

The hazardous air pollutants (HAPS) programme monitors 21 substances. These include benzene, trichloroethylene, tetrachloroethylene and dichloromethane, which have environmental quality standards; acrylonitrile, vinyl chloride monomer, chloroform, 1,2-dichloroethane, mercury and its compounds, nickel and its compounds, arsenic and its compounds and 1,3-butadiene, which have guideline values; and acetaldehyde, methyl chloride, chromium and its compounds, ethylene oxide, toluene, beryllium and its compounds, benzo(a)pyrene, formaldehyde and manganese and its compounds, which do not yet have guideline values. The number of monitoring stations ranges from 300 to 400, depending on the chemical. Monitoring results for hazardous air pollutants are also presented in the GIS-based system as shown in Figure F.3. Results of dioxin and acid precipitation monitoring are also presented in a similar GIS-based system.

Figure F.3: Monitoring results for acetaldehyde, 2009



Source: National Institute of Environmental Studies Japan, Environmental GIS webpage, <http://tenbou.nies.go.jp/gis/>, accessed 17 January, 2013

The results of the air monitoring programmes are used to check compliance with air quality standards or guideline values. Also, the results are used for exposure assessment for various purposes that need estimates of exposure to air contaminants. Method development and quality assurance or quality control procedures are an essential part of those monitoring programmes, operated co-operatively by local and national governments.

### Water quality monitoring

MOE conducts a water monitoring programme for several categories of target pollutants. Results can be viewed on its website<sup>86</sup> (in Japanese).

The Living Environment monitoring programme, to determine compliance with environmental quality standards, is performed at about 3 000 sampling locations measuring biochemical oxygen demand, chemical oxygen demand, total nitrogen and total phosphorus, among others.

The Human Health monitoring programme, to determine compliance with its environmental quality standards, is done at about 3 000–4 000 sampling locations. Target chemicals are cadmium, total cyanide, lead, chromium(VI), arsenic, total mercury, alkyl mercury, PCBs, dichloromethane, carbon tetrachloride, 1,2-dichloroethane, 1,1-dichloroethylene, *cis*-1,2-dichloroethylene, 1,1,1-trichloroethane, 1,1,2-trichloroethane, trichloroethylene, tetrachloroethylene, 1,3-dichloropropene, thiuram, simazine, thiobencarb, benzene, selenium, nitrate-nitrogen/nitrite-nitrogen, fluorine and boron.

The Monitoring of the Precautionary Monitoring Targets programme has been carried out at about 500–1 000 sampling locations, measuring chloroform, *trans*-1,2-dichloroethylene, 1,2-dichloropropene, *p*-dichlorobenzene, isoxathion, diazinon, fenitrothion, isoprothiolane, copper 8-quinolate, chlorothalonil, propylamide, EPN, dichlorvos, fenobucarb, iprobenfos, chlornitrofen, toluene, xylene, di(ethylhexyl) phthalate, nickel, molybdenum, antimony, vinyl chloride monomer, epichlorohydrin, manganese and uranium, from 1994 to 2009.

There are also extensive monitoring programmes for enclosed seawater, groundwater, soil and dioxins, which are not included here.

The results of water monitoring programmes are used to check compliance with environmental quality standards and other guideline levels. Like the air monitoring programmes, the results of water monitoring are used for various purposes that need estimates of exposure to chemicals from water, including for the protection of humans and ecosystems. Method development and quality assurance or quality control procedures are an essential part of these monitoring programmes, operated jointly by local and national governments.

### **The air monitoring programme design concept**

The design concept of the hazardous air pollutants monitoring programme in Japan is based on the systematic selection of target chemicals, sampling or analytical methods, and sampling locations. The following text from the Berlin workshop report (OECD, 2000) describes how a monitoring programme is designed, using two examples, one of which is hazardous air pollutants.<sup>87</sup>

Among the various kinds of environmental monitoring programmes for chemicals, mainly two different types exist in Japan. One, the “General Inspection Survey”, designed to provide early warning of chemical pollution, was introduced under the Chemical Substances Control Law (CSCL) in 1974.<sup>88</sup> The other one, “Monitoring of Hazardous Air Pollutants (HAPs)”, designed to provide both screening and quantitative level information on HAPs pollution, was introduced under the amended Air Pollution Control Law (APCL) in 1997. Environmental monitoring of chemicals is expanding following recent changes in chemical regulations based on exposure and risk assessment. The need for a systematic approach is being discussed, which could efficiently link various regulations, monitoring, databases, the Pollutant Release and Transfer Register (PRTR), and so on.

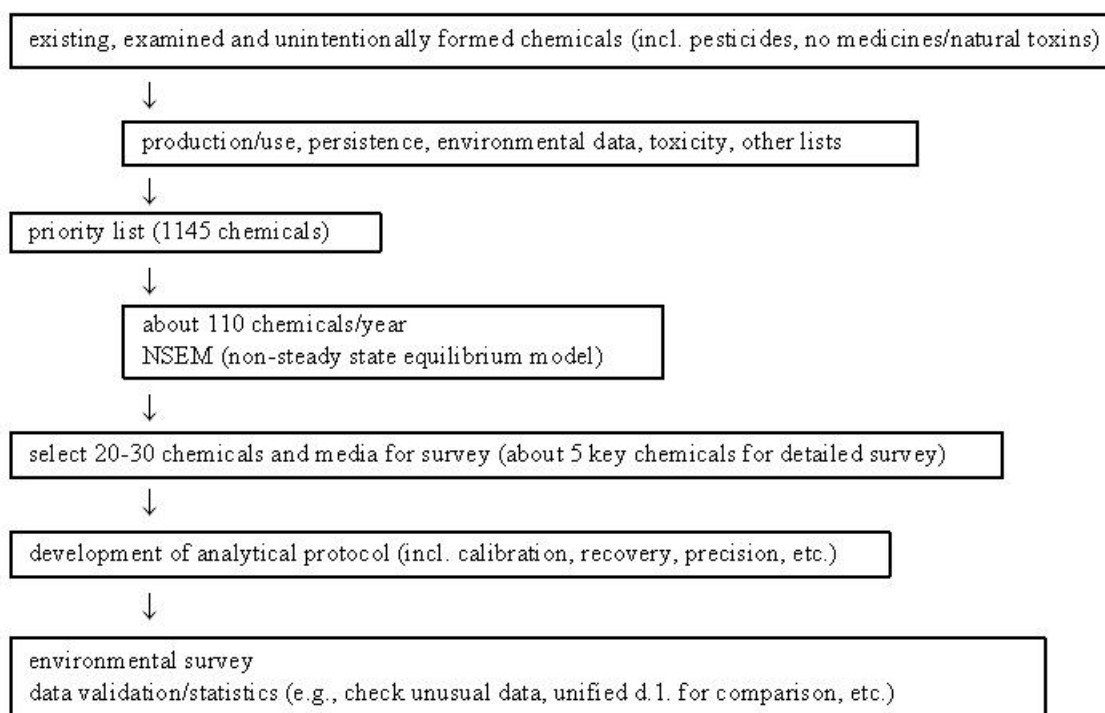
#### ***General inspection survey (environmental survey on existing and examined chemicals)***

The Chemical Substances Control Law was enacted in 1973 following serious problems caused by chemicals such as PCBs. It requires: 1) various evaluations of chemicals, and 2) classification of chemicals by persistence, bio-accumulation and toxicity, in order to create regulations for them. New

chemicals are to be tested by the manufacturer or importer, and existing chemicals are under investigation by the government. Bio-degradation and accumulation are tested by the Ministry of International Trade and Industry, toxicity is examined by the Ministry of Health and Welfare, and the Environment Agency (EA) is responsible for environmental persistence and monitoring.

The EA initiated environmental monitoring surveys for checking pollution levels, and to give early warning of chemical pollution in 1974. The monitoring consists of an environmental survey of existing and examined chemicals and the monitoring of classified chemicals such as PCBs, DDT, PCDDs, and so on. The survey is a screening system for chemicals in the environment, and is therefore carried out systematically, as shown in 4. A list of approximately 1 000 priority chemicals was selected based on production volume, use pattern, persistence, toxicity, and so on. Since the survey operates on a 10-year cycle (in its second phase at the time of writing: 1989 to 1998), about 110 chemicals are picked up every year from the list, and 20-30 chemicals are selected for the survey (of which about 5 are considered key chemicals) based on prediction by a non-steady state equilibrium model. Environmental media are also selected based on this prediction. Prior to the survey, detailed analytical protocols are developed for the selected compounds and media.

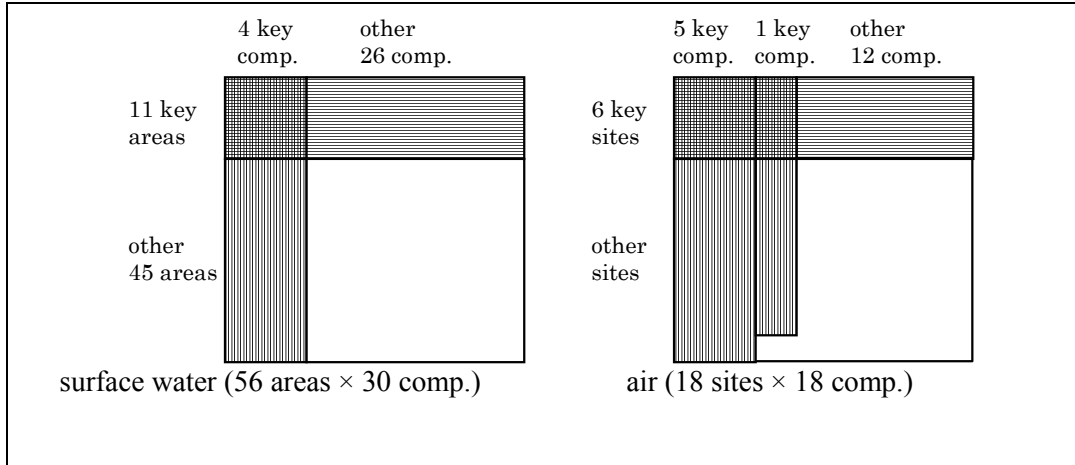
**Figure F.4: Outline of existing and examined chemicals environmental surveys**



\*unified d.l.=unified detection limit



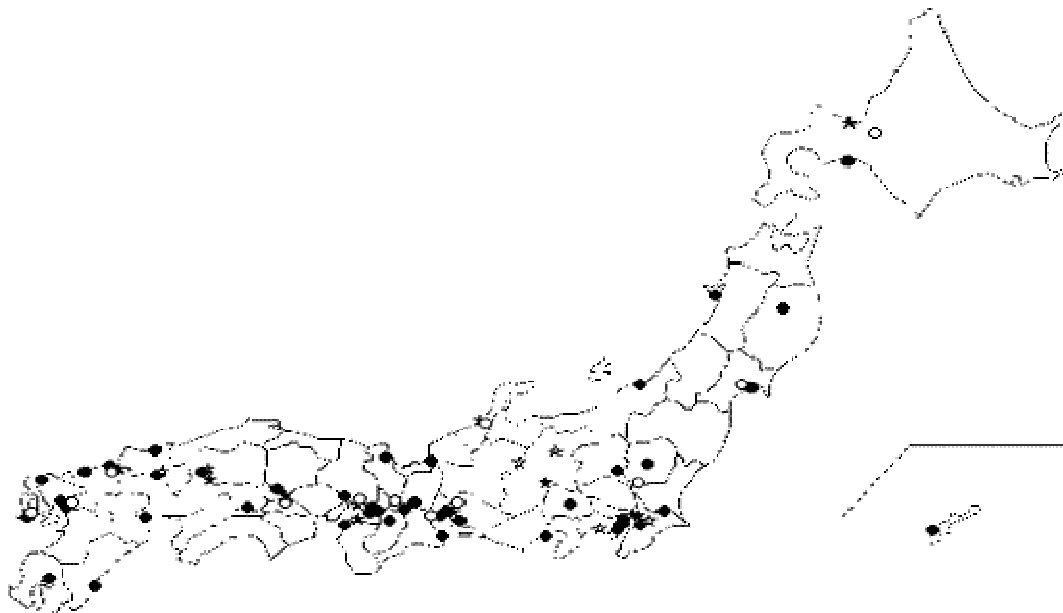
**Figure F.5: Outline of the surface water and air surveys (surveys of sediments and fish have a similar structure for efficient data collection)**



“comp.” means compartment.

In 1995, 3 surface water and sediment samples were collected in 56 areas, 3 fish samples were collected in 52 areas, and 3 consecutive 24-hour air samples were collected in 18 areas. For efficient data collection, a survey was carried out as shown in Figure F.5. For surface water samples, 4 key compounds were analysed for all samples, and all 30 compounds were analysed for 11 key area samples. Analysis of non-key compounds in non-key areas was carried out case by case. For air, 5 key compounds were analysed for all samples and 1 key compound was analysed for 16 area samples. All 18 compounds were analysed for 6 key area samples. The actual monitoring, including sampling, analysis and so on, were carried out by local research or testing institutions. The survey covers Japanese islands, as shown in Figure F.6. Sampling areas or sites were selected to reflect a variety of types and sizes of urban areas.

Figure F.6: Sampling areas/sites for environmental survey



☆,● sampling areas for water, sediments and fish consist of 11 key (☆), 14 industrial, 16 residential/commercial, 1 agricultural and 14 mixed areas

☆,○ sampling sites for air include 6 key areas (☆)

Source: Prepared from Japan Ministry of the Environment (2005), *Chemicals in the Environment (Fiscal Year 2005)*, [www.env.go.jp/chemi/kurohon/en/index.html](http://www.env.go.jp/chemi/kurohon/en/index.html), accessed 17 January 2013.

Table F.2 shows the numbers of detected and investigated chemicals in the survey from 1974 to 1995. Not all chemicals are measured in all media. Therefore, the numbers are different by media. Overall, 287 chemicals have been detected in the environment, while 752 chemicals were investigated. The results have triggered various responses, such as detailed studies, classification and regulation under CSCL, regulations by responsible authorities under other laws, and so on.

**Table F.2: Numbers of detected/investigated chemicals in environmental survey (1974–1995)**

	Detected(A)	Investigated(B)	A/B(%)
Water	135	731	18.5
Sediment	219	710	30.8
Fish	87	226	38.5
Air	104	174	59.8
Total	287	752	38.2

Source: Prepared from Japan Ministry of the Environment (2005), *Chemicals in the Environment (Fiscal Year 2005)*, [www.env.go.jp/chemi/kurohon/en/index.html](http://www.env.go.jp/chemi/kurohon/en/index.html).

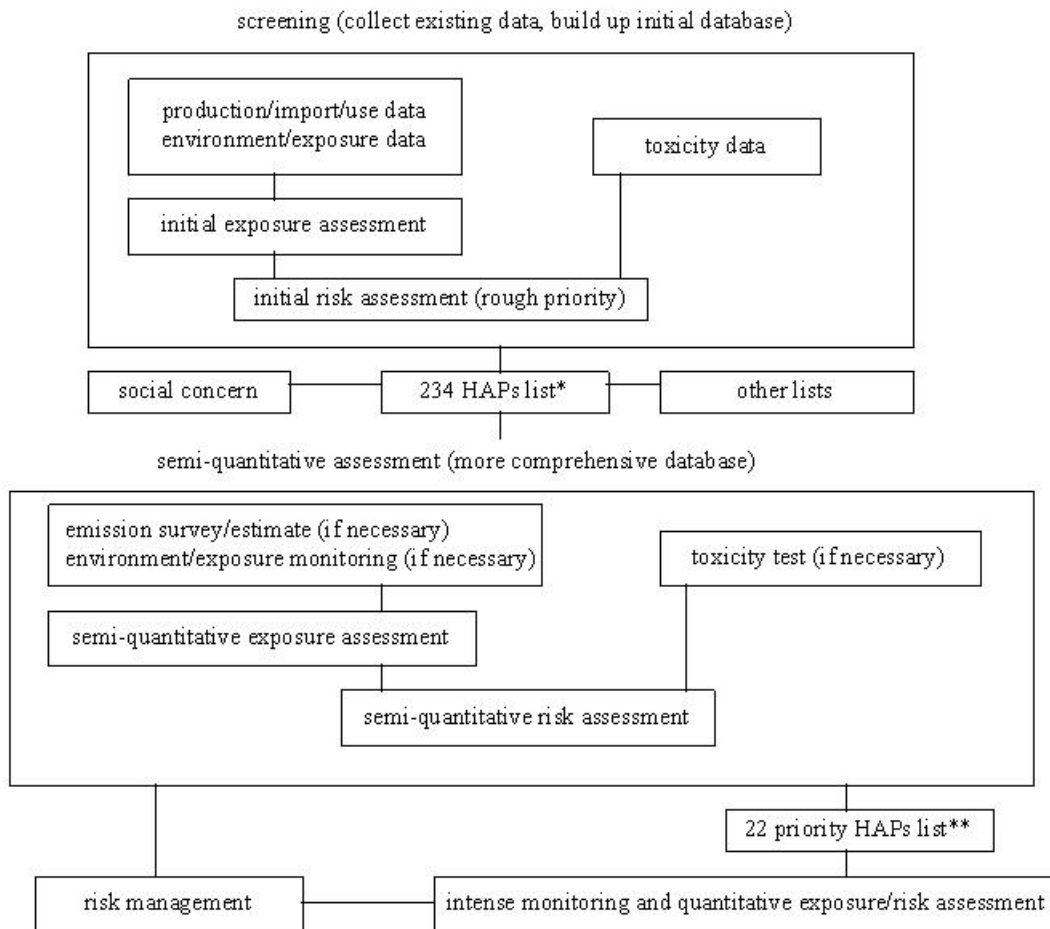
### ***Monitoring hazardous air pollutants (HAPs)***

In recent years the chronic effects of environmental chemicals, especially carcinogenicity, have been a cause of public concern, encouraging the government to establish new management systems for chemicals based on exposure and risk assessment. One systematic approach is the HAPs monitoring and management system under the amended Air Pollution Control Law (APCL), enforced in 1997. The system has been designed following a tiered structure of risk assessment and management, shown in Figure F.7.

Based on screening level investigations, 234 HAPs were listed, including various organics, inorganics, minerals, and so on. From the list, 22 priority HAPs were selected for considering air pollution control, based on semi-quantitative exposure or risk assessment from existing information, such as temporal monitoring data. Four of the 22 were judged to represent an unacceptable level of risk, and were designated “specified” HAPs (see Table F.3).

HAPs are mainly managed through industry voluntary emission reductions, and by regulations for specified HAPs based on environmental and emission standards.

**Figure F.7: Conceptual framework for monitoring hazardous air pollutants**



**Table F.3: Priority hazardous air pollutants (HAPs)**

Acrylonitrile	1,2-Dichloroethane	Trichloroethylene*	Formaldehyde
Acetaldehyde	Dichloromethane	Nickel and its compounds	Manganese and its compounds
Vinyl chloride	Mercury and its compounds	1,3-Butadiene	Chromium(VI)
Chloroform	Talc	Beryllium and its compounds	
Chloromethylmethylether	PCDDs and PCDFs*	Benzene*	
Ethylene oxide	Tetrachloroethylene*	Benzo(a)pyrene	

\*specified HAPs

Source: Japan Ministry of the Environment (2013), Prepared from Hazardous air pollutant list (in Japanese), <http://www.env.go.jp/air/kijun/index.html>, accessed 17 January, 2013

The HAPs monitoring programme has a two-tiered approach, as described above.

The greater part of the monitoring programme mainly focuses on quantitative exposure or risk assessment of the 22 priority HAPs. Local authorities – all 47 prefectures and 78 large cities – are responsible for the monitoring, which is carried out at about 10 sites in each prefecture; these include sites near to HAP sources, sites in the general environment, and roadside residential sites. One set of 24-hour data per month is used to estimate the yearly average. Every year, 12 data sets per site are collected at about 400 sites. The monitoring methods must satisfy certain performance specifications; for example, target determination limits must correspond to a  $10^{-6}$  risk level and  $\pm 30\%$  overall accuracy (analytical quality control normally uses these recommended methods, as provided in their manuals). The results are used for quantitative exposure or risk assessment, and to evaluate the effectiveness of voluntary emission reductions and legal regulations on the four specified HAPs. The results will also be used to judge whether or not regulation is needed of non-specified priority HAPs.

The 234 listed HAPs are monitored by the national government. A lack of environmental data made it difficult to list and select priority pollutants, to quantitatively evaluate their exposure and risk. The national government therefore selected about 10 sites in different types of environment, such as in a large city, a remote area, and so on. In 1997, 24-hour samples were collected at these sites in summer and winter, and about 30 volatile organic compounds and 5 polycyclic aromatic hydrocarbons were analysed by GC/MS (gas chromatography–mass spectrometry) and HPLC (high-performance liquid chromatography) respectively. The results are used for the semi-quantitative exposure and risk assessment of listed HAPs, in order to judge whether further management is necessary. However, as many HAPs as possible should be measured, so monitoring methods need to continue being developed.

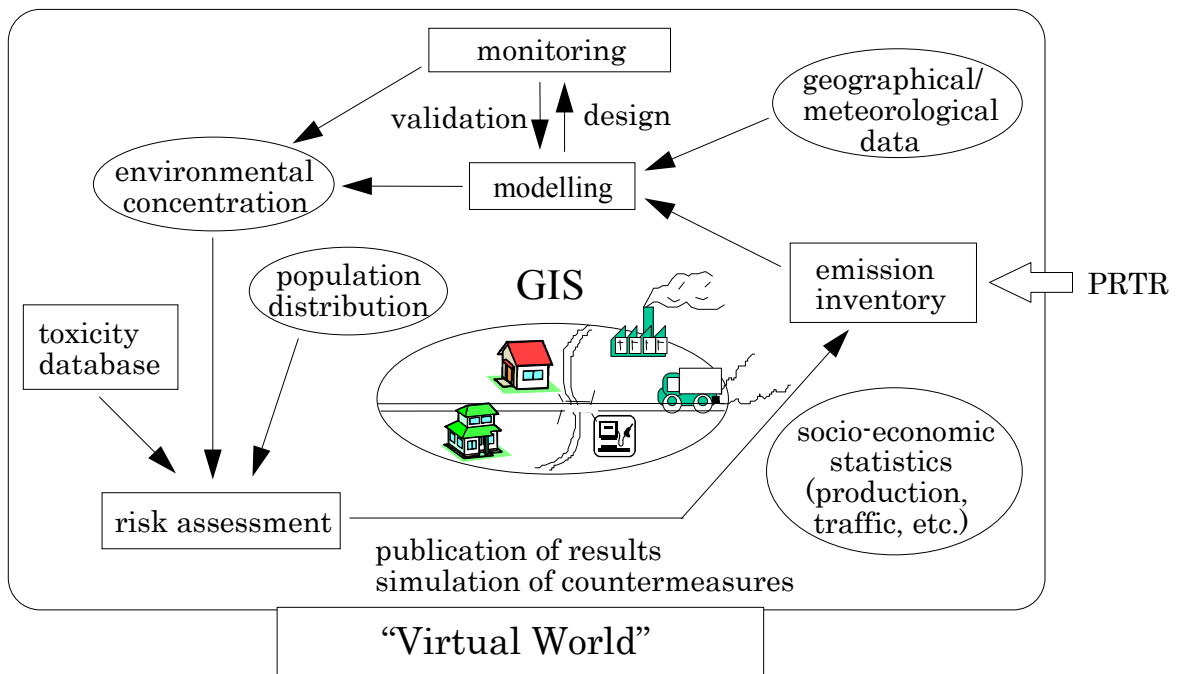
**Other activities relating to chemical monitoring and management**

A similar approach to HAPs monitoring and management is currently being considered for water pollution. Some chemicals found in water, mainly pesticides, are already subject to rigorous monitoring. About 300 hazardous water pollutants will be listed for the first time, and screening-level monitoring of these pollutants will be initiated in the near future.

Improvements in chemical monitoring and management reflect growing public awareness of environmental pollution by chemicals, and a more systematic approach is also under consideration. One possibility is the construction of a database of basic information on chemicals such as physico-chemical properties, toxicities, environmental concentrations and regulatory information. The database is expected to become both a means of outputting collected data, and a starting point for exposure and risk assessment and management.

Environmental models had not yet been used much to evaluate chemical pollution. A General Inspection Survey started in 1974, and is proceeding as planned. HAPs monitoring relates to regulations, so actual monitoring has an important role to play. However, good simulation models have also been developed over recent years, and it seems that both monitoring and models may provide a better understanding of environmental exposure, with the minimum of cost and requirements. Currently, the General Inspection Survey uses model prediction to select chemicals and environmental media. When the model was introduced, its results were validated by using existing survey results, as well as conventional parameter settings.

**Figure F.8 Conceptual framework for a further utilised model**



GIS: geographic information system; PRTR: Pollutant Release and Transfer Register

The further use of models is being researched. As shown in Figure F.8, the system consists of good emission information provided by the PRTR (Pollutant Release and Transfer Register), various models, and a GIS (geographic information system) with geographical and meteorological information. A chemical database is under construction including toxicity information, population statistics and so on.

This system is expected to be used for: 1) the prediction of environmental pollution by various chemicals; 2) exposure and risk evaluation and communication; and 3) simulation of management measures. Monitoring data will also be handled by the system for a better, easy-to-understand evaluation, as well as for comparison with model prediction and observed data.

### ***The use of monitoring data for exposure assessment***

Outputs from the “Chemicals in the Environment Survey” are mainly used for estimating exposure in screening-level risk assessments in Japan, using the guidelines shown in Annex A above. When a more detailed exposure estimate is needed, data collected in the existing and/or newly installed extensive monitoring programmes are summarised, as shown in Annex B. Monitoring programmes in Japan are therefore based, in terms of their detail and scale, on the needs of exposure assessment, which will use the monitoring programmes’ outputs. The tiered structure of the monitoring programme, shown above in Section “The air monitoring programme design concept”, is one of the most organised examples of a monitoring system in Japan.

### **Reference**

Japan Ministry of the Environment (2005), *Chemicals in the Environment (Fiscal Year 2005)*, [www.env.go.jp/chemi/kurohon/en/index.html](http://www.env.go.jp/chemi/kurohon/en/index.html), accessed 17 January 2013.

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<sup>85</sup> [www.env.go.jp/chemi/kurohon.html](http://www.env.go.jp/chemi/kurohon.html)

<sup>86</sup> [www.env.go.jp/water/suiiki/index.html](http://www.env.go.jp/water/suiiki/index.html)

<sup>87</sup> This originally appeared in OECD (2000), but has been slightly edited by the OECD Secretariat for use in this document. It was called “Two Examples of Japan’s Environmental Monitoring Programmes for Chemicals” and was written by Kiyoshi Tanabe, National Institute for Environmental Studies, Environment Agency, Japan

<sup>88</sup> *Chemicals in the Environment - Report on Environmental Survey and Wildlife Monitoring of Chemicals in Fiscal Year 1995*. Environmental Health and Safety Division, Environment Agency (former Ministry of the Environment), Japan (1997).