Design and Development of Comprehensive Exposure Scenarios to Chemicals

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Abstract

In the regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH), the supplier of a substance or a preparation is required to ensure that exposure to these substances throughout the entire life-cycle is below the threshold level beyond which adverse effects may occur. Although scenarios of exposure to chemicals throughout the life-cycle of chemicals are needed for risk management, there is no comprehensive database for the making of exposure scenarios. In this study, a prototype of comprehensive exposure scenarios throughout the life-cycle of chemicals was developed by extracting exposure scenarios from laws and regulations related to emission of or exposure to chemicals in Japan, risk assessment documents, and exposure assessment tools. Separate databases of emission sources and exposure scenarios after chemical releases were constructed in order to assemble a database of comprehensive scenarios of exposure of humans to chemicals. Further studies are needed to apply these databases in risk-based screening for human health.

Key words: Risk assessment/ Human health risk/ Exposure scenario

1. Introduction

The commitment to the management of chemicals throughout their life-cycle has been renewed as advanced in Agenda 21 at the World Summit on Sustainable Development (WSSD) in August and September 2002, in Johannesburg (United Nations, 2005). The aim of the commitment is that chemicals will be used and produced in ways that lead to the minimization of significant adverse effects on human health and the environment by the year 2020. The Strategic Approach to International Chemicals Management (SAICM) was issued in June 2006 as a policy framework to achieve the WSSD's goal, i.e., to promote chemical safety around the world (UNEP and WHO, 2006).

Following the WSSD's goal and establishment of the SAICM, laws and regulations associated with the management of chemicals throughout their life-cycle have been newly established and dramatically renewed in the European Union (EU) and Japan, respectively. The USA's laws on chemical management, i.e., the Toxic Substances Control Act (TSCA) are under discussion (Boucher, 2009). The regulation concerning the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) in the EU entered into force on June 2007. In the REACH, the supplier of a substance or a preparation is required to ensure that exposure to these substances throughout their life-cycle is below the threshold level beyond which adverse effects may occur, when substances are manufactured, placed on the market, and used (Bernauer et al., 2007). The Japanese law on chemical management (Act on the Evaluation of Chemical Substances and Regulation of Their Manufacture, etc.) was renewed in May 2009. The major points of the law revision are to include not only new chemicals but existing

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chemicals as target chemicals and to change hazard-based evaluation to risk-based evaluation (Ministry of Economy, Trade and Industry (METI), 2009).

The risk assessment required in these laws and regulations on the management of chemicals was composed of the classification and assessment of hazard, building of exposure scenarios, estimation of exposure levels, and risk characterization. Public hazard databases of chemicals such as the International Uniform Chemical Information Database (IUCLID) (European Chemicals Agency (ECHA), 2009) and the Chemical Risk Information Platform (CHRIP) (National Institute of Technology and Evaluation (NITE), 2008) were available to classify and assess the hazard of chemicals. The EU, the U.S. EPA, and Japan developed exposure assessment tools such as EUSES (European Chemicals Bureau (ECB), 2010), Simple Box, E-FAST, and MuSEM for estimating the concentration and amount of exposure to humans and the environment (Yoshida, 2000). Although the building of exposure scenarios throughout the life-cycle of chemicals is one of the core parts of risk assessment (Gade et al., 2008), there is no comprehensive database of exposure scenarios that is available as public information.

In this study, a prototype of comprehensive exposure scenarios throughout the life-cycle of chemicals was designed and developed by extracting exposure scenarios from laws and regulations related to emission of or exposure to chemicals in Japan, risk assessment documents such as the Toxicological Profile by ATSDR (Agency for Toxic Substances and Disease Registry) in the USA and the European Union Risk Assessment Report by the ECB (European Chemicals Bureau) in the EU, and exposure assessment tools such as EUSES, Simple Box, and MuSEM.

2. Methods

2.1 Design of the exposure scenario database

Separate databases of emission sources and exposure scenarios after chemical releases were constructed in order to assemble a database of comprehensive scenarios of exposure of humans to chemicals. The database of emission sources was composed of three classifications (i.e., production stage, process, and detailed process) of industrial processes that have potential to be an emission source of chemicals.

The database of exposure scenarios after chemical releases was constructed as follows. Briefly, exposure scenario components classified in terms of 1) emission medium, 2) exposure medium, 3) exposure population, 4) exposure route, and 5) exposure duration were extracted from risk assessment documents, exposure assessment tools, and so on. Raw exposure scenarios after chemical releases were automatically assembled in all combinations of the exposure scenario components. The database of exposure scenarios after chemical releases was constructed after eliminating impractical and negligible exposure scenarios.

2.2 Data sources of the exposure scenario

2.2.1 Data on emission sources

Available data on emission sources were described in the REACH Implementation Project (RIP). In these data sources, Sector Notebooks and Best Available Techniques Reference Documents (BREF) authorized by the U.S. EPA and the European Integrated Pollution Prevention and Control Bureau (EIPPCB), respectively, include detailed industrial process information and pollutant release data (U.S.EPA, 2007;

European Integrated Pollution Prevention and Control Bureau (EIPPCB), 2009). The contents of Sector Notebooks mostly overlap with those in BREF. However, Sector Notebooks, which involves unity among industrial categories, was selected as a prior data source in this study. A list of Sector Notebooks and BREF surveyed in this study is given in Table 1.

Table 1 List of Sector Notebooks and BREF Surveyed in This Study.

Industry		Industry	
Sector Notebooks		21	Organic Chemical Industry
1	Agricultural Chemical, Pesticide and Fertilizer Industry	22	Petroleum Refining Industry
2	Agricultural Crop Production Industry	23	Pharmaceutical Industry
3	Agricultural Livestock Production Industry	24	Plastic Resins and Man-made Fibers Industry
4	Aerospace Industry	25	Printing Industry
5	Air Transportation Industry	26	Pulp and Paper Industry
6	Dry Cleaning Industry	27	Rubber and Plastics Industry
7	Electronics and Computer Industry	28	Shipbuilding and Repair Industry
8	Fossil Fuel Electric Power Generation Industry	29	Stone, Clay, Glass and Concrete Industry
9	Ground Transportation Industry	30	Textiles Industry
10	Healthcare Industry	31	Transportation Equipment Cleaning Industry
11	Inorganic Chemical Industry	32	Water Transportation Industry
12	Iron and Steel Industry	33	Wood Furniture and Fixtures Industry
13	Lumber and Wood Products Industry	**BREF**	
14	Metal Casting Industry	34	Emissions from Storage of Bulk or Dangerous Materials
15	Metal Fabrication Industry	35	Food, Drink and Milk Processes
16	Metal Mining Industry	36	Large-volume Inorganic Chemicals - Solid & Others
17	Motor Vehicle Assembly Industry	37	Specialty Inorganic Chemicals
18	Nonferrous Metals Industry	38	Surface Treatments Using Solvents
19	Non-fuel, Non-metal Mining Industry	39	Waste Incineration
20	Oil and Gas Extraction Industry	40	Waste Treatments [Previously Waste Recovery/Disposal Activities]

2.2.2 Data on exposure scenarios after chemical releases

The laws and regulations related to emission of or exposure to chemicals in Japan such as the Labour Standards Law and Air Pollution Control Act have reflected chemical accidents and damage to humans and the environment in the past. Risk assessment documents such as the Toxicological Profile by ATSDR and the European Union Risk Assessment Report by the ECB have summarized existing and well-known information on exposure scenarios (Table 2). In addition, exposure assessment tools such as EUSES, Simple Box, and MuSEM have covered broad and detailed exposure routes. Therefore, we selected these data sources given above as data sources of exposure scenarios after chemical releases in this study.

Table 2 List of Risk Assessment Report Surveyed in This Study

Government and Organization		**Risk Assessment Report**
Australia	National Industrial Chemicals Notification and Assessment Scheme (NICNAS)	PEC (Priority Existing Chemicals) Assessment Reports
Canada	Environment Canada and Health Canada	CEPA- PSAP (Canadian Environmental Protection Act – Priority Substance Assessment Program) Assessment Reports
EU	European Chemicals Bureau (ECB)	Risk Assessment Report
Germany	Gesellschaft Deutscher Chemiker (GDCh)	BUA Reports
Japan	National Institute of Advanced Industrial Science and Technology (AIST)	AIST Risk Assessment Document
USA	Agency for Toxic Substances & Disease Registry (ATSDR)	Toxicological Profile
International Programme on Chemical Safety (IPCS)		Concise International Chemical Assessment Documents (CICADs) Environmental Health Criteria (EHC)
Organisation for Economic Co-operation and Development (OECD)		Screening Information Data Set (SIDS) Assessment Report
European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC)		Joint Assessment of Commodity Chemicals (JACC) Report

3. Results and discussion

3.1 Systematic extraction of emission sources

The emission processes for 40 industrial categories given in Table 1 were extracted and categorized in terms of 1) production stage, 2) process, and 3) detailed process. The emission processes for the textile industry are given in Table 3 as an example. The total number for the production stage and detailed process was 163 and approximately 1700, respectively.

In the case of building the database of exposure indirectly via the environment, the production stage would be appropriate because factors of emission to the environment have been set for each production stage in the Japanese Pollutant Release and Transfer Register (PRTR) (METI, 2004) and Emission Scenario Document (ESD) (Organisation for Economic Co-operation and Development (OECD), 2006). In contrast, the detailed process should be selected as an emission source for building the database of occupational exposure because the potential for occupational exposure differs widely according to each detailed process.

Table 3 Industrial Processes of Textile Industry

Category	Production Stage	Process	Detailed Process
Textile Industry	Yarn Formation	Fiber Preparation	Opening/Blending
Textile Industry	Yarn Formation	Fiber Preparation	Carding
Textile Industry	Yarn Formation	Fiber Preparation	Combing
Textile Industry	Yarn Formation	Fiber Preparation	Drawing
Textile Industry	Yarn Formation	Fiber Preparation	Drafting
Textile Industry	Yarn Formation	Spinning	Spinning
Textile Industry	Fabric Formation	Warping	Warping
Textile Industry	Fabric Formation	Slashing/Sizing	Slashing/Sizing
Textile Industry	Fabric Formation	Weaving	Shedding
Textile Industry	Fabric Formation	Weaving	Picking
Textile Industry	Fabric Formation	Weaving	Battening
Textile Industry	Fabric Formation	Weaving	Taking up and letting off
Textile Industry	Fabric Formation	Shuttleless Looms	Shuttleless Looms
Textile Industry	Fabric Formation	Knitting	Weft Knitting
Textile Industry	Fabric Formation	Knitting	Warp Knitting
Textile Industry	Fabric Formation	Tufting	Tufting
Textile Industry	Wet Processing	Fabric Preparation	Singeing
Textile Industry	Wet Processing	Fabric Preparation	Desizing
Textile Industry	Wet Processing	Fabric Preparation	Scouring
Textile Industry	Wet Processing	Fabric Preparation	Bleaching
Textile Industry	Wet Processing	Fabric Preparation	Mercerizing
Textile Industry	Wet Processing	Dyeing	Yarn Dyeing
Textile Industry	Wet Processing	Dyeing	Piece Dyeing
Textile Industry	Wet Processing	Printing	Rotary Screen Printing
Textile Industry	Wet Processing	Printing	Direct Printing
Textile Industry	Wet Processing	Printing	Discharge Printing
Textile Industry	Wet Processing	Printing	Resist Printing
Textile Industry	Wet Processing	Printing	Ink-jet Printing
Textile Industry	Wet Processing	Printing	Heat-transfer Printing
Textile Industry	Wet Processing	Finishing	Heat Setting
Textile Industry	Wet Processing	Finishing	Brushing and Napping
Textile Industry	Wet Processing	Finishing	Softening
Textile Industry	Wet Processing	Finishing	Optical Finishing
Textile Industry	Wet Processing	Finishing	Shearing
Textile Industry	Wet Processing	Finishing	Compacting
Textile Industry	Wet Processing	Finishing	Optical Finishes
Textile Industry	Wet Processing	Finishing	Absorbent and Soil-release Finishes
Textile Industry	Wet Processing	Finishing	Softener Sand Abrasion-resistant Finishes
Textile Industry	Wet Processing	Finishing	Physical Stabilization and Crease-resistant Finishes
Textile Industry	Fabrication	Cutting/Sewing	Cutting/Sewing

3.2 Categorization of exposure scenario components

The extraction and categorization of exposure scenario components should be separated into three groups in terms of 1) human exposure indirectly via the environment, 2) occupational exposure, and 3) consumer exposure, due to differences in exposure routes among the three groups. The exposure scenario components associated with human exposure indirectly via the environment, occupational exposure, and consumer exposure were extracted from the data sources given above, and those associated with human exposure indirectly via the environment are given in Table 4 as an example.

Table 4 Exposure Scenario Components on Exposure Indirectly via the Environment

Emission medium	Exposure medium	Exposure population	Exposure route	Exposure duration
Ambient air	Local air	Local population	Inhalation	Acute
River and lake waters	Regional air	Regional population	Dermal	Subacute and subchronic
Seawater	National air	General population	Ingestion	Chronic
Groundwater	Tapwater			
Soil	Groundwater			
	River and lake waters			
	Seawater			
	Soil			
	Seafood			
	Meat			
	Dairy products			
	Crop			
	Other foods			

Raw exposure scenarios after chemical releases were automatically assembled in all combinations of the exposure scenario components given in Table 4. In the case of exposure via the environment, 1755 raw exposure scenarios were built from the combination of 5, 13, 3, 3, and 3 components for emission medium, exposure medium, exposure population, exposure route, and exposure duration, respectively. The database of exposure scenarios after chemical releases was then constructed after eliminating impractical and negligible exposure scenarios.

The combinations of components as indicated below (scenarios 1) to 6)) were set as impractical exposure scenarios. In addition, scenarios 7) and 8) were removed because the respective scenarios can be described by using of general populations instead of local and regional populations in scenario 7), and using of local populations instead of regional and general populations in scenario 8):

1) Exposure medium: tapwater, groundwater, river and lake water, and seawater
   Exposure route: inhalation
2) Exposure medium: seafood, meat, dairy products, crops, and other foods
   Exposure route: inhalation
3) Exposure medium: local air
   Exposure population: regional and general populations
4) Exposure medium: regional air
   Exposure population: local and general populations
5) Exposure medium: national air
   Exposure population: local and regional populations
6) Exposure medium: local, regional, and national air
   Exposure route: ingestion
7) Exposure medium: tapwater, river and lake water, seawater, seafood, meat, dairy products, crops, and other foods
   Exposure population: local and regional populations
8) Exposure medium: groundwater and soil
   Exposure population: regional and general populations

The combinations of components as indicated below were set to be negligible exposure scenarios. The scenarios 9) and 12) were removed because dermal exposure is much smaller than other exposure route (International Programme on Chemical Safety (IPCS), 1996) (Nakanishi and Inoue, 2007). The scenarios 10), 11), 13), 14), and 15) were sequentially removed due to sufficient dilution and low frequency of exposure in the environment:

9) Exposure medium: regional and national air
   Exposure route: dermal
10) Emission medium: all media except river and lake water
   Exposure medium: river and lake water
   Exposure route: ingestion and dermal
11) Emission medium: all media except seawater
   Exposure medium: seawater
   Exposure route: ingestion and dermal
12) Exposure medium: seafood, meat, dairy products, crops, and other foods
   Exposure route: dermal
13) Emission medium: seawater
   Exposure medium: tapwater, groundwater, soil, meat, dairy products, crops, and other foods
14) Emission medium: groundwater
   Exposure medium: local, regional, and national air, river and lake water, seawater, and soil
15) Emission medium: all media except ambient air and soil
   Exposure medium: soil

Finally, the number of exposure scenarios after chemical releases was 183 for exposure via the environment after eliminating impractical and negligible exposure scenarios.

3.3 Approach to screening of exposure scenarios of very high concern

The databases of emission sources and exposure scenarios after chemical releases developed in this study were combined in Microsoft Office Access and Excel in order to establish a searchable database of exposure scenarios (ARCHE: Advanced and Retrieval Database for Chemical Exposure Scenario). Selecting a component in a drop-down box with each input data item, which were set to be 1) emission source, 2) emission medium, 3) exposure medium, 4) exposure population, 5) exposure route, and 6) exposure duration, will output relevant exposure scenarios in xls or csv format.

In addition to the searchable database of exposure scenarios, a screening method for extracting exposure scenarios of very high concern is needed for rapid and appropriate risk assessment because there is a number of exposure scenarios in our database described in this study. Detailed exposure routes such as those shown in Figure 1 are for correlating the exposure potentials of the scenarios in our database with the physicochemical parameters of chemicals. In the near future, we will develop a screening method for extracting exposure scenarios of very high concern from the ARCHE to make contributions to rapid and appropriate risk assessment.

4. Conclusions

In this study, separate databases of emission sources and exposure scenarios after chemical releases were constructed. This study indicated that the database of emission sources should be merged to the database of exposure scenarios after chemical releases, in order to assemble a database of comprehensive scenarios of exposure of humans to chemicals. Further studies are needed to apply these databases in risk-based screening for human health. Application of these databases involving the physicochemical parameters of chemicals to the extraction of exposure scenarios of very high concern will provide valuable information on rapid and appropriate risk assessment.

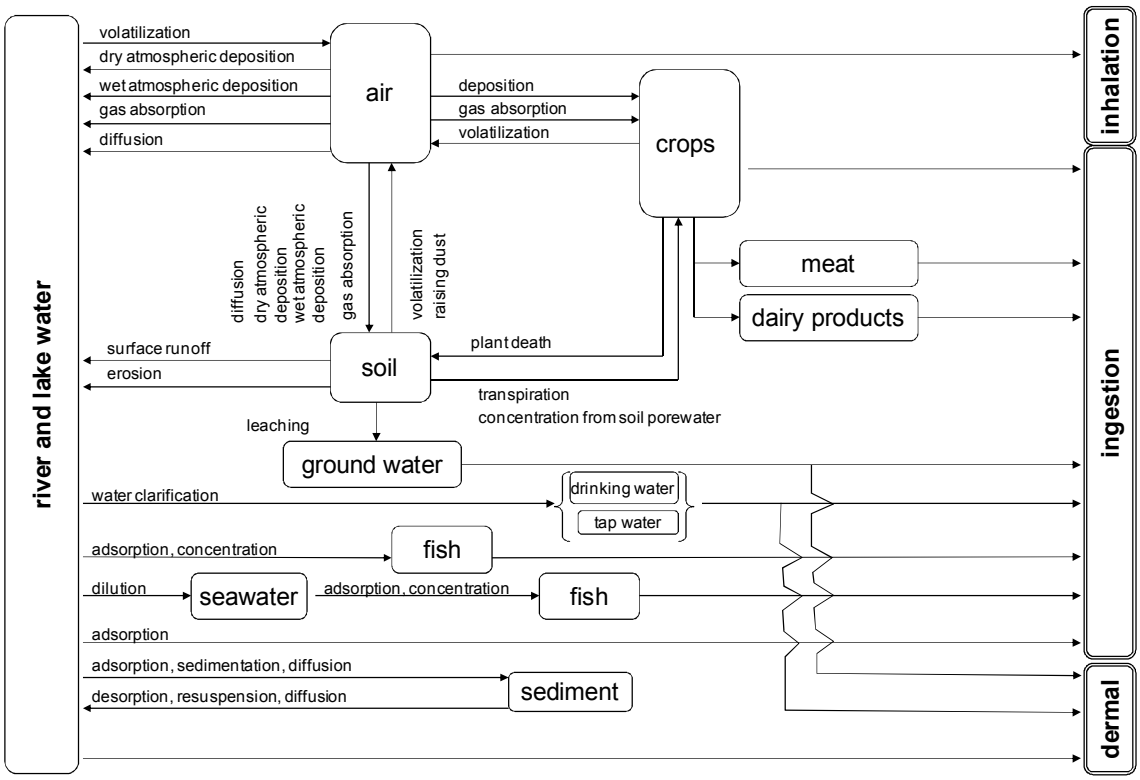

Figure 1 Detailed Exposure Routes for Screening Exposure Scenario of Very High Concern on Emission to River and Lake Water

5. Acknowledgements

Part of this study was supported by a The Kurita Water and Environment Foundation (KWEF) grant and Special Coordination Funds for Promoting Science and Technology, 783400001, Japan.

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