



EUROPEAN COMMISSION
DIRECTORATE GENERAL JRC
JOINT RESEARCH CENTRE
Institute for Health and Consumer Protection (IHCP)
Physical and Chemical Exposure Unit (PCE)

**Status Report
about the development of the**

“European Exposure Assessment Toolbox”

**at
EIS-ChemRisks**

**The
European Information System on
“Risks from chemicals released from consumer products/articles”**

on behalf of the
Directorate General
Health and Consumer Protection
(DG SANCO)

1.2 draft Version

Ispra, 12 November 2003

Foreword

Human exposure data to chemicals represent a major bottleneck in the risk assessment process. This has been recognised by the EU Council of Environmental Ministers by putting forward a request to the European Commission to undertake action for eliminating existing deficiencies in exposure data. To respond to this challenge, DG Health and Consumer Protection (DG SANCO) requested the JRC to develop and operate a European Information System on Chemical Risks from human exposure to chemicals released from consumer products/articles (EIS-ChemRisks) to systematically collect, store, and assess information.

For information please contact:

Dr. Demosthenes Papameletiou
Tel. ++39. 0332. 78 5282 (direct)
Tel. ++39. 0332. 78 9952 (secretariat)
demosthenes.papameletiou@jrc.it

Project Coordinator

- Toolbox
- Sectorial workshops
- EU Exposure Assessment Network

Dr. Pertti Hakkinen
pertti.hakkinen@jrc.it

- Exposure Factors, Data and Scenarios

Dr. Alexandre Zenié
alexandre.zenie@jrc.it

- Exposure Factors, Data, and Models

Dr. Dietrich Schwela
dieter.schwela@jrc.it

- Exposure and Health Data

Dr. Vittorio Reina
vittorio.reina@jrc.it

- Web System

European Commission, Joint Research Centre (JRC),
Institute for Health and Consumer Protection,
Physical and Chemical Exposure Unit
I-21020 Ispra (VA) Italy

Contents

1. Introduction

1.1. Rationale and objectives

2. The EIS-ChemRisks Toolbox

2.1. "EU-ExpoFactors" - EU-Reference System for Exposure Factors

2.2. "ExpoData" - Reference Exposure Data

2.3. "ExpoHealthData" - Reference Exposure-associated-Health-Data

2.4. "ExpoScenarios" - Reference Exposure Scenarios

3. Outlook: towards a globally aligned approach

Annex 1: Comparative study of major reference systems on exposure factors

Annex 2: Key Guidance Documents on Exposure Assessment

1 Introduction

EIS-ChemRisks is being designed as a European-wide expert and stakeholders “network of networks” to systematically exchange and assess information on risks from chemicals released from consumer products/articles. The JRC efforts are focusing on filling the exposure data gaps in a systematic and coherent manner. This work supports the rapid exchange (RAPEX) notifications system of the General Product Safety Directive (2001/95/EC) and may provide technical support to the relevant aspects of REACH (Registration, Evaluation and Authorisation of CHemicals), i.e., regarding downstream users.

The task of developing and operating EIS-ChemRisks is a very complex and demanding one, as heterogeneous users, and a multitude of sources are being targeted. The JRC is establishing a single Web-based gateway to all major European initiatives in the field of Human Exposure to Chemicals contained and released from products/articles. This gateway is being designed to act as an interactive EU-wide information source and a common communication tool for the user society to develop and continuously update reference data and tools on the themes listed below (see Box).

Thematic Structure of EIS-ChemRisks

- ◆ “EU Exposure Assessment Network”
- ◆ European inventory and harmonisation of exposure data sources and data sets in the EU
- ◆ European Exposure Assessment Toolbox (Exposure Scenarios, Data and Factors)
- ◆ Sectorial product/article-specific state-of-the-art exposure analysis workshops and reference systems (textiles, toys, etc.)
- ◆ State-of-the-art reviews on promising emerging approaches for improving exposure assessments such as toxicogenomics and low-dose/concentration biomarkers.
- ◆ European Annual Status Report “Risks from Human Exposure to Chemicals released from Consumer Products/Articles”

For more detailed information, please consult the Action Plan of EIS-ChemRisks at:

http://europa.eu.int/comm/consumers/cons_safe/news/eis_plan_052003_en.pdf

1.1 Rationale and Objectives for the development of the EIS-ChemRisks Exposure Assessment Toolbox

The purpose of the present document is to provide a brief overview about the current state of development of the “European Exposure Assessment Toolbox”.

The overall objective is to develop tools and reference data to enable harmonised exposure assessment procedures in the EU. These tools and reference data will

support the development of a structured stakeholder dialogue, initially in the frame of the **General Product Safety Directive (GPSD) (2001/95/EC)** (sectorial workshops of EIS-ChemRisks) and progressively in the frame of the forthcoming REACH (Registration, Evaluation, Authorisation of CHemicals).

The use of the EIS ChemRisks toolbox is intended to be, as much as possible, user-friendly. To this end, the JRC is currently

- developing prototype tools that are Web-based and designed to be on-line accessible.
- seeking bilateral collaborations with interested stakeholders to jointly develop and test the prototype concepts.
- developing guidance documents (in parallel to the concept development of the prototype tools).
- carrying out user requirements and feasibility studies for the large scale implementation of the prototype concepts.

2 The EIS-ChemRisks “Exposure Assessment Toolbox”

The EIS-ChemRisks toolbox offers the following four major reference systems to systematically support exposure assessors in the EU:

- **“EU-ExpoFactors”** EU-Reference System for Exposure Factors
- **“ExpoData”** Reference Exposure Data
- **“ExpoHealthData”** Reference Exposure-associated-Health-Data
- **“ExpoScenarios”** Reference Exposure Scenarios

The following working definitions are made for exposure factors and data:

“Exposure factors”: are defined in the same way as in the US EPA’s Exposure Factors Handbook and contain practically just the “non-chemical-specific” exposure related parameters such as physiological data i.e. body weight, skin surface area, etc. .

“Exposure Data”: are defined as chemical-specific exposure parameters and contain exposure concentrations, migration rates, and other technical/scientific parameters, such as leaching, skin permeability coefficients, etc. for the different exposure routes (inhalation, oral, dermal).

All the above EIS-ChemRisks Reference Systems use published and unpublished information to develop reference data by applying authoritative peer review and data validation procedures.

Central focus is placed in the specification of a standardised format for carrying out the exposure assessments by using reference data and for presenting the results. This is being approached by specifying an “exposure scenario template” as a key tool for several purposes:

- to allow stakeholders to develop and report their exposure assessments in a harmonised way
- to allow systematic information exchange and use of reference data
- to allow transparent and efficient review and validation procedures

The overall information flow is shown in Figure 1.

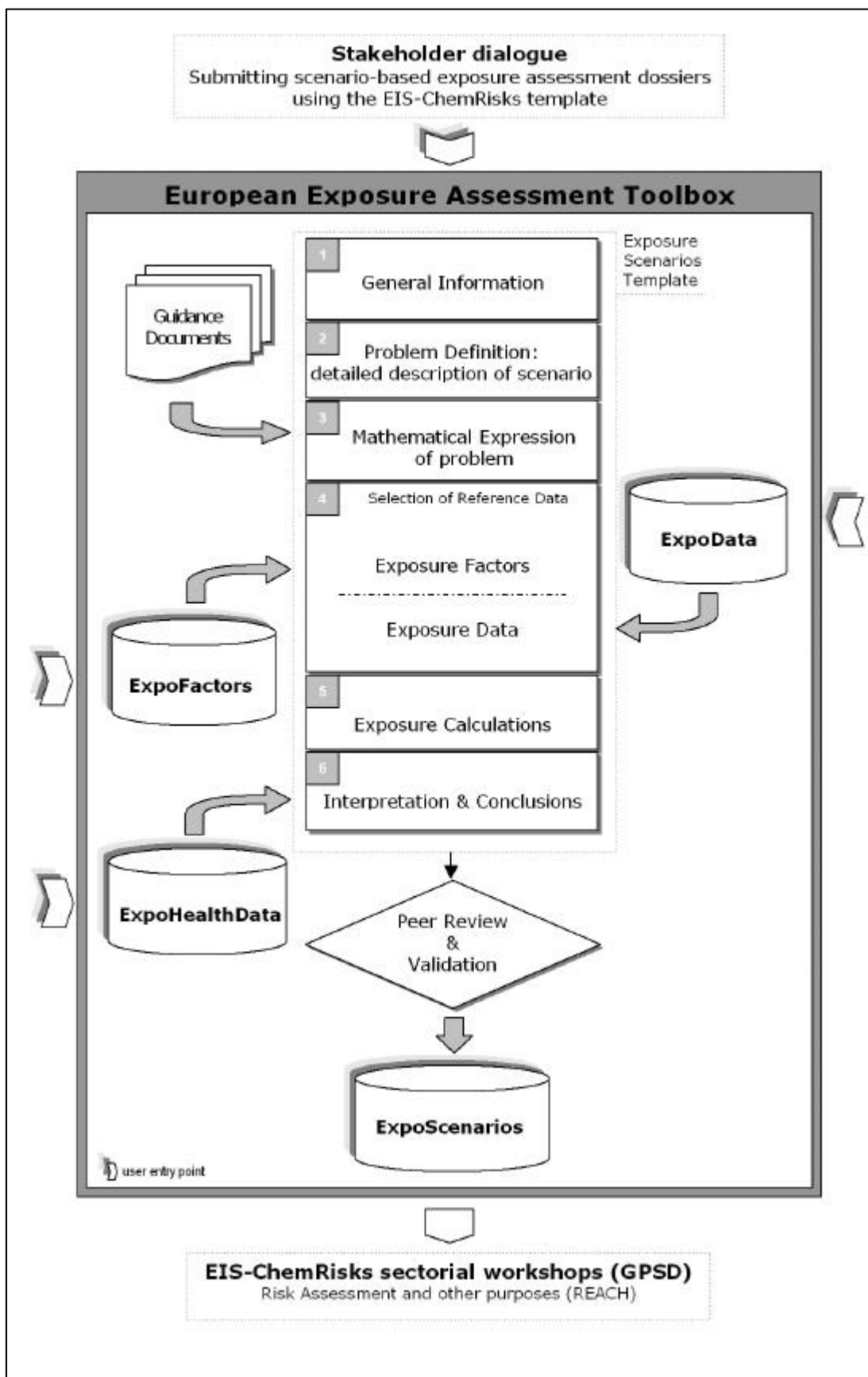


Figure 1 The European Exposure Assessment Toolbox at EIS-ChemRisks

2.1 “EU-ExpoFactors”: EU-Reference System for Exposure Factors

The “EU-ExpoFactors” system develops reference data that are specific for the EU. It is quite close in design and content to the US EPA’s Exposure Factors Handbook of information focussed on US assessment needs, and contains practically just the “**non-chemical-specific**” factors typically needed in exposure assessments. The non-chemical specific factors are aggregated into the following EIS-ChemRisks categories:

- **Anthropometric/Physiological Parameters**,
e.g., body weights and skin surface areas.
- **Population Data**,
e.g., population size of a member state, or data on length of time living in a residence before moving.
- **Lifestyle/Time-Activity Patterns**,
e.g., micro- and macro-activity factors such as time spent indoors and typical patterns of behaviour over the course of a day.
- **Residential/Living Environment Factors**
e.g., residence and room volumes.
- **Product Usage Patterns**
e.g., frequency and duration of product usage for a particular type of task, and the typical (or reasonably foreseeable) tasks associated with a type of product.

Currently the JRC is carrying out the following activities in this area:

- Comparative study of major reference systems on exposure factors across the world, most particularly the US EPA’s Exposure Factors Handbook, to distill the lessons learned during their development and operation, and future plans (Annex 1)
- Critical evaluation of the availability of data sources and data situation in the EU. This project will be carried in co-operation with the “EU Exposure Assessment Network”.
- Prototype development including
 - system design,
 - screening, selection, and definition of
 - types of exposure factors by
 - gender
 - age
 - nationality
 - ethnicity
 - geographic region
 - socio-economic factors
 - product
 - the types of tasks associated with a product
 - special focus groups, such as “children”
 - data formats

- procedures for
 - data collection,
 - data maintenance
 - data harmonisation across the EU,
 - data validation

Compared to the US EPA Exposure Factors Handbook, the EIS-ChemRisks activity is aiming to provide:

- a similar data structure and data formats on the traditional types of exposure factors (such as the representative anthropometric data for the EU population),
- similar rigorous data selection and validation procedures and quality standards,
- a harmonisation procedure for the different data formats from the different EU Member States,
- a stronger focus on
 - data distributions, to support probabilistic assessment where needed;
 - specific factors for various categories of consumer products;
 - the integration to other key reference systems (such as “ExpoData”, “ExpoHealthData” and “ExpoScenarios”) which will continuously provide new elements for updating data and system design;
 - on the continuous and Web-based updating of the data contents.

Regarding the project deployment in 2003/2004 the following milestones are foreseen:

- development of prototype concept,
- user requirements and feasibility study,
- pilot demonstration.

Regarding the critical evaluation of the data sources and data situation in the EU the project planning consists of the following two thematic work packages on

- General Exposure Factors
- Product-specific Exposure Factors.

2.1.1 General Exposure Factors

These belong to the following broad categories:

- Anthropometric/Physiological Parameters,
- Population Data,
- Lifestyle/Time-Activity Patterns,
- Residential/Living Environment Factors,

- Product Usage Patterns.

This work package is deployed in co-operation with the national focal points of the “EU Exposure Assessment Network”. A first systematic activity is being launched in November 2003, as a coordinated pilot data-inventory project in four Member States (Denmark, Germany, Sweden, The Netherlands). On the basis of the results, the rest of the EU will be covered by follow-up studies in 2004.

At EU level, a significant part of the information needed may be developed in co-operation with Eurostat and National Statistical bodies, which are being invited to participate in the project. In addition, JRC co-operates with ExpoFacts, a “Exposure Factors Sourcebook for Europe” project carried out by the Finnish National Public Health Institute under Cefic’s LRI funding as a Web-based resource compiled from extensive national and international data that is both published and unpublished¹.

2.1.2 Product-related Exposure Factors

These include for specified products and conditions (age, gender, population, region, socio-economic/professional factors, etc.) the following type of information:

- Frequency of use by task/event
- Exposure time during use by task/event
- Amount of product used/consumed per task/event
- Exposure time after end of use by task/event

The above type of information will be developed in co-operation with the product specific Expert Task Force Groups within EIS-ChemRisks. First projects are being deployed in the areas of textiles, toys and personal care products.

2.2 “ExpoData”: Reference Exposure Data

The “ExpoData” system develops generally applicable reference data on chemical-specific exposure parameters, such as concentrations of chemical substances in consumer products, chemical concentrations in media contacting the human, and volatilisation/migration/leaching rates, etc., describing the contacting patterns between the human body and the chemical substances in product-related exposure situations. It is broadly structured by the following default “exposure routes and parameters” according to the TGD², 2003.

¹ (<http://www.ktl.fi/expofacts/> and http://www.cefic-lri.org/Files/Publications/LRI_Projects_June2003.pdf)

² European Commission, Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC, 2003 (see Annex 2)

- Inhalation Route (“a substance that is released as a gas, vapour or airborne particulate into a room...”)
- Dermal Route #1 (substance in a medium)
- Dermal Route #2 (substance migrating from an article)
- Oral Route #1 (substance in a product is unintentionally swallowed during normal use...)
- Oral Route #2 (a substance migrating from an article...”)

The above default exposure routes and parameters represent a starting point for the development of “ExpoData”. Additional parameters, such as mass transfer coefficients, leaching, absorption factors etc, may be added during the course of the development work depending on the needs of the user society.

For each reference value, the various background data and interrogation options are available by using the following attributes:

- chemical
- product
- measurement/modelling methods (including standardisation status)
- measurement/modelling institutes (including accreditation status)
- measurement/modelling reports and publications
- exposure settings (typical exposure scenario boundary conditions)
- measurement/modelling conditions
- measurement/modelling method application details and R&D needs
- measurement/modelling measurement results
- validation reports

Currently the “ExpoData” system development is being carried out at the JRC. A relational database relating functionally of the above information attributes has been designed and is being tested “in-house”. The work consists of

- introducing into the system key reports on exposure data available at the JRC
- expanding the “in-house” software into a Web-accessible system
- to train external institutions and to develop bi-lateral collaborations for the testing of the system
- to improve system design and user friendliness

In early 2004 the system will be presented to the “EU Exposure Assessment Network” and on-line access will be given to all interested stakeholders. In addition, quality assurance and data validation procedures will be developed.

Systematic data validation into “Reference Data” will be carried out in the second half of 2004. The preparation of the data validation reports will be outsourced to specialised academic institutions, whereas the validation procedure will be supervised

and concluded by the Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE).

2.3 “ExpoHealthData”: Reference Exposure associated Health Data

A third reference system on “health data” will be added during 2004 into the toolbox. The overall objective is to develop a reference system of data that can be associated to exposure data and scenarios included in “ExpoData” and “ExpoScenarios”.

On this system, the JRC is currently

- undertaking an exploratory scoping study,
- developing product-specific “health effect reviews” in the frame of the sectorial workshops,
- launching (in 2004) a “low dose biomarkers” state of the art review and workshop.

The above mentioned scoping study includes the objective of studying the feasibility of developing “health observatories” on the basis of

- existing institutions, such as poison centres and hospital ambulatories,
- thematic expert networks such as paediatricians and dermatologists,
- biomonitoring data and activities.

For the time being, the information that can be made available on this issue is from isolated publications in the clinical literature. This is being systematically evaluated in the above mentioned “health effect reviews”. Progressively, as the “observatories” will be made operational, their output will be considered in the health effect reviews. These will be updated periodically and undergo peer review and validation.

2.4 “ExpoScenarios”: Reference Exposure Scenarios

Exposure scenarios have been typically defined as the set of facts, assumptions and inferences about how exposure takes place. As such they represent a framework for reporting the data and the calculations needed in an exposure assessment.

The importance of scenario building in exposure and risk assessment was recently highlighted by the TGD (Technical Guidance Document; see Annex 2). However, systematic guidance on how to build exposure scenarios for consumer products is still missing. As a consequence, exposure scenarios have been presented to date by the stakeholders in various non-uniform formats.

2.4.1 The introduction of a “standard” Exposure Scenario Template

In this light, the exposure scenario concept was chosen by EIS-ChemRisks to develop a “standard” template format for reporting the results and the background assumptions and data used in exposure assessments.

The harmonised use of the “EIS-ChemRisks Exposure Scenario Template” will be promoted and tested initially within the sectorial workshops. To make this possible, the EIS-ChemRisks is currently developing a detailed guidance procedure and documentation.

Stakeholders are invited to build or review their scenarios by using uniformly the “exposure scenario template” and the appropriate reference systems (“EU ExpoFactors”, “ExpoData”, “ExpoHealthData”) for selecting the background data needed in their exposure assessments.

The “standard exposure scenario template“ introduces the following working steps and information flow:

- Problem definition: detailed description of the scenario(s),
- Mathematical expression of the problem,
- Selection of reference exposure factors and data,
- Exposure calculations,
- Interpretation of the results.

2.4.2 Data requirements for scenario-based exposure assessment at EIS-ChemRisks

The scenarios and exposure assessments, which are developed by using the EIS-ChemRisks toolbox by particular stakeholders, are subject to review by all the stakeholders participating in the sectorial workshops, the “EU Exposure Assessment Network”, and the CSTEE.

The different pieces of information, that are prescribed by the “standard template”, can be submitted to EIS-ChemRisks separately and undergo stepwise peer review and validation procedures. Peer review, at a higher level, will be initiated only after concluding the preceding review procedure.

In general the section of problem definition must include information about

- product specifications, e.g., composition, labelling, and packaging,
- the reasonably foreseeable use and misuse patterns associated with the product
- the chemical substances considered,
- population and/or subpopulation groups, and geographic regions addressed,
- exposure routes and exposure parameters considered.

Providing data on all the above elements is essential. However, the level of detail that is required to adequately describe the above elements is left open to the judgment of the stakeholders submitting a scenario file using the template approach. Here, it is understood that the level of detail will be adjusted by the dynamics of the stakeholders dialogue and the peer review and validation procedures depending on

- the intended use of the scenario and
- on the rules underlying the corresponding risk assessment procedures.

The second step is to convert the problem definition into a mathematical expression. To this end, the available tools and algorithms described in various guidance documents indicated in Annex 2 are recommended for use by the scenario builders. The peer review and validation procedures will review the validity of converting the problem definition into the relevant mathematical expression. Comments for improvements may have impact on both, the scenario definition and/or the way of expressing it mathematically.

Once the mathematical expression exercise is completed, the next steps are dedicated to collecting the data needed to carry out the exposure calculations and to interpret the results. Here the use of reference data from “EU ExpoFactors”, “ExpoData” and “ExpoHealthData” is recommended. In the transient phase of the development of these systems, the information flow will be in the opposite direction, i.e., from the scenario section to the reference systems for several types of data and factors. However, it is conceivable that the above systems will become operational in a reasonable time from now.

2.4.3 Peer review/validation procedures

The review and validation procedures will focus on the quality control of the selection of data used in the exposure calculations. A discussion will be initiated whenever these data deviate from EIS-ChemRisks reference values. In all cases where EIS-ChemRisks data are missing, the data submitted within the scenario files will be processed in the corresponding reference system of the Toolbox and undergo the validation procedures pertaining to the system.

The overall results of the review procedures will be documented and included in a Web-based tool called “Reference Exposure Scenarios”. Based on the outcome of the stakeholder dialogue and the level of review/validation, rating categories will be assigned and will include the following levels:

- Exposure Scenario submitted to EIS-ChemRisks,
- Exposure Scenario reviewed by the thematically competent EIS-ChemRisks Task Force,
- Exposure Scenario reviewed by the “EU Exposure Assessment Network”,
- Reference Exposure Scenario validated by the CSTEE.

3 Outlook: towards a globally aligned approach

Several of the tools included in the toolbox described in this paper are the first of their kind in exposure assessment at a world scale, for example:

- “reference exposure data”,
- “reference health data associate to exposure events”,
- “standard exposure scenario template”.

The basic concepts were recently presented in a workshop to an international expert audience at the 2003 Annual Meeting of the International Society of Exposure Analysis (ISEA). According to the preliminary feedback obtained from international key representatives from Authorities and other stakeholders, the toolbox presented in this paper has the potential to become a globally applicable common approach.

Global co-operation to define and agree on a common working approach would greatly expand the opportunities for data exchange and interoperability of exposure assessment procedures. In addition, it would help maximize the efforts of the rather limited exposure assessment expertise currently available in the various governmental organizations, and in industry, academia, and elsewhere. In this light, it is conceivable that sharing efforts for further developing the EIS-ChemRisks Toolbox at a global scale would provide a critical mass needed to accelerate the deployment of the project. Therefore, key players from the USA, Canada, and Japan (and perhaps other countries as expertise and interest are identified), as well as key international organisations including WHO and OECD are invited to participate in the meetings of the “EU Exposure Assessment Network” and to contribute to the project development.

At present the Toolbox is being discussed systematically and tested with the following actors

- Authorities from Denmark, Germany, Sweden, and The Netherlands,
- The EIS-ChemRisks Task Force on “Textiles”,
- Key stakeholders from the thematic areas of “toys” and “personal care products”.

The first evaluation results will be presented in early 2004 in dedicated meetings of the “EU Exposure Assessment Network”, which will be announced during November 2003.

Annex 1

Comparative study of major reference systems on exposure factors

AIHC (American Industrial Health Council). (1995). Exposure Factors Sourcebook. Washington, DC. / Essentially equal to the content of Gephart, L.A., J.G. Tell, and L.R. Triemer. 1994. Exposure Factors Manual. J. Soil Contam. 3(1): 47-117.

Health Canada, (1995), Investigating Human Exposure to Contaminants in the Environment. A Handbook for Exposure Calculations, Parts 1, 2, and 3.
http://www.hc-sc.gc.ca/ehp/ehd/catalogue/bch_pubs/95ehd193/part1.pdf

U.S. EPA, (!997) Exposure Factors Handbook (1997; EPA/600/P-95/002Fa,b,c. Hardcopy, or 21 PDF files via the Web or as a CD-ROM; CD-ROM version has a 1999 publication year and is EPA/600/C-99/001)
<http://www.epa.gov/ncea/exposfac.htm>

U.S. EPA, (2002) Child-Specific Exposure Factors Handbook (2002; EPA-600-P-00-002B. 01. Interim Report).
<http://www.epa.gov/ncea/csefh2.htm>
(not yet considered in the comparative table below)

Arbeitsgruppe Risikoabschätzung und –bewertung in der Umwelthygiene (AGLMB): Standards Zur Expositionsabschätzung Bericht Des Ausschusses für Umwelthygiene. Arbeitsgemeinschaft der Leitenden Medizinalbeamtinnen und Beamten der Länder. Herausgeber: Behörde für Arbeit, Gesundheit und Soziales, Hamburg .(2000)
http://www.uke.uni-hamburg.de/zentren/experimentelle_medizin/biometrie/publikationen/berichte/auh/AUH.pdf,

RIVM Factsheet general (March 2000): Bremmer, H.J. and van Veen M.P. “Factsheet algemeen: Randvoorwaarden en betrouwbaarheid, ventilatie, kamergrootte, lichaamsoppervlak”, RIVM rapport 612810 009
<http://www.rivm.nl/bibliotheek/rapporten/612810009.html>

ECETOC (June 2001): Exposure Factors Sourcebook for European Populations (with focus on UK Data), Technical Report No. 79, Brussels
<http://www.ecetoc.org/entry.htm>

KTL- National Public Health Institute of Finland, Kuopio, ExpoFacts, Cefic-LRI European Exposure Factors Sourcebook,
<http://www.ktl.fi/expofacts/>

In the following Table the systems are compared in terms of their coverage for particular exposure factors.

Exposure Factors	AIHC 1994 USA	Health Canada 1995	US EPA 1997	AGLMB 2000 Germany	RIVM 2000 The Netherlands	ECETOC 2001 UK	ExpoFacts 2003 EU
Anthropometric / Physiological Parameters							
Body Weight	+	+	+	+	+	+	+
Body Height / Length	+	-	-	+	+	-	+
Total Skin / Body Surface Area	+	+	+	+	+	+	(+)
Surface Area of Specific Body Parts		+	+	+	+	+	
Life Expectancy / Lifetime	-	-	+	-	-	+	+
...							
Life style / Time-Activity Patterns							
Time at Work (Weekly Hours)	+	-	-	+	+	+	-
Time at Home (Daily Hours / Weekly)	+	-	-	+	+	+	-
Time Away from Home (Daily Hours / Weekly)	+	-	-	-	+	+	-
Time Spent inside Vehicle	-	-	+	+	+	-	-
Time Indoors	+	-	+	+	+	+	-
Time Outdoors	+	-	+	+	+	+	-
School Hours (Daily)	-	-	+	-	+	+	+
School Time Indoors	-	-	+	-	-	+	-
School Time Outdoors	-	-	+	-	-	+	-
Outdoor Recreation	-	-	+	-	+	+	-
Showering / Bathing Duration	+	-	+	-	-	+	-
Swimming Duration	-	-	+	-	-	-	-
Employment / Occupational / Working Tenure	+	-	+	-	-	+	+ / + / -
Residential Tenure / Time OR Population Mobility	+	-	+	-	-	+	+
School Tenure	-	-	+	-	-	+	-
Time Use Patterns	+	-	+	+	-	-	+

Contact Rates							
Residential / Living Environment Factors							
Residence Volume / Types	-	-	+	-	+	-	- / +
Residential Air Exchange Rates	-	-	+	-	+	-	-
Ventilation Rate	-	-	+	-	+	-	-
...							
Product Usage Patterns							
Frequency of use for household products/articles	-	-	+	-	-	-	-
Exposure time of use for household products/articles	-	-	+	-	-	-	-
Amount of product/article used for household products/articles	-	-	+	-	-	-	-
Time exposed after duration of use for household products/articles	-	-	+	-	-	-	-
...							
Respiratory Rates							
Respiratory / Breathing Rates	-	-	+	+	-	-	(+)
Short Term Inhalation Rates (Hourly)	+	-	+	-	-	+	(+)
Long Term Inhalation Rates (Daily)	-	+	+	+	-	+	(+)
...							
Soil/Particles/Dust Contact Factors							
Soil Ingestion Rates	+	+	+	+	-	+	-
House Dust Ingestion Rates	-	-	+	+	-	-	-
Particles Deposition Rates	-	-	+	+	-	-	+
Soil Adherence to Skin	-	+	+	+	-	+	(-)
...							
Relevant Dietary Intake Factors							
Food Consumption Rates / Total Dietary Intake	+	+	+	+	-	+	+
Fruits Consumption Rates	-	+	+	+	-	-	+
Vegetables Consumption Rates		+	+	+	-		
Home Grown Vegetable and Fruit Consumption Rates	+	-	+	-	-	+	-

Fish and Shellfish Consumption Rates	+	+	+	+	-	+	+
Meat and Beef Consumption Rates	+		+	+	-	+	+
Grain / Cereal Consumption Rates	-	+	+	+	-	-	+
Drinking Water Consumption Rates	+	+	+	+	-	+	(+)
Liquid / Beverage Consumption Rates	-	-	+	+	-	-	+
Breast Milk Consumption Rates	-	-	+	-	-	+	+
...							
Other Life Style Factors							
Smoking Consumption Rates	-	-	-	-	-	-	-
Non-prescription Drugs Consumption Rates	-	-	-	-	-	-	+
...							
Population Data							
Total Population	-	-	-	-	-	-	+
Total Immigration and Emigration (Yearly)	-	-	-	-	-	-	+
Income Status	-	-	-	-	-	-	+
Occupational Status	-	-	-	-	-	-	+
Education Status	-	-	-	-	-	-	+
Age Distribution (5 years age group)	-	-	-	-	-	-	+
Birth Rates	-	-	-	-	-	-	+
Death Rates	-	-	-	-	-	-	+

The “+” means considered, the “-” means not considered while the “(+)” means eventually considered within the ongoing project. The absence of value means uncertainty.

Annex 2

“Chemicals /Consumer Products”: Key Guidance Documents on Exposure Assessment

European Commission, Technical Guidance Document on Risk Assessment in Support of Commission Directive 93/67/EEC on Risk Assessment for new notified substances, Commission Regulation (EC) No 1488/94 on Risk Assessment for existing substances, and Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market. Part 1. (2003)

(<http://ecb.jrc.it/cgi-bin/reframer.pl?A=ECB&B=/tgd/doc/>)

[Section 2.3 (Consumer Exposure Assessment) and Appendix I (Consumer Exposure) are of primary relevance.]

European Commission, Scientific Committee on Toxicity, Ecotoxicity and the Environment (CSTEE) Final report on: Exposure Data in Risk Assessments of Organic Chemicals Expressed at the 25th CSTEE plenary meeting Brussels, 20 July 2001

http://europa.eu.int/comm/food/fs/sc/sct/out114_en.pdf

Arbeitsgruppe Risikoabschätzung und –bewertung in der Umwelthygiene AGLMB): Standards Zur Expositionsabschätzung Bericht Des Ausschusses für Umwelthygiene. Arbeitsgemeinschaft der Leitenden Medizinalbeamtinnen und Beamten der Länder. Herausgeber: Behörde für Arbeit, Gesundheit und Soziales, Hamburg, Germany (2000)

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[hamburg.de/zentren/experimentelle_medizin/biometrie/publikationen/berichte/auh/AUH.pdf](http://www.uke.uni-hamburg.de/zentren/experimentelle_medizin/biometrie/publikationen/berichte/auh/AUH.pdf)

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