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# Harmonising and integrating existing exposure factors systems world-wide

## Feasibility study report

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Abstract

Exposure factors systems (e.g. handbooks, guidance documents, on-line databases) help categorising and summarising exposure factors (or determinants) which are commonly used in exposure assessments and risk analysis. The objective of this report is to analyse, based on pre-selected criteria, the exposure factor systems which have been developed worldwide in order to illustrate their commonalities and differences (in terms of design, capabilities, data sources, availability and usage, upgrading planning, domains of application, quality criteria and validation procedures, etc.) with the ultimate aim to identify the potential for their harmonisation, interoperability and integration.

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## Objective

Exposure assessment is an integral part of human health risk assessment. This latter is an important tool for characterising the nature and magnitude of health risk to individuals or populations from chemicals and other environmental stressors. To perform an exposure assessment, it is necessary to consider and apply various human exposure factor data such as: anthropometric data (e.g., body weight, skin surface area, life expectancy); behavioural data (e.g., non-dietary ingestion rates, activity/time use patterns, consumer product use); physiological needs based data (e.g., water/food consumption rates, inhalation rates) and other data (e.g., building characteristics, ventilation rates); etc. These data are not chemical specific exposure factors and they are generally drawn from the scientific literature, governmental statistics, international organisations and agencies (WHO, FAO, UNECE) and industrial associations.

Exposure factors systems (e.g. handbooks, guidance documents, on-line databases) help categorising and summarising exposure factors (or determinants) which are commonly used in exposure assessments and risk analysis but not exclusively. The advancement of the exposure assessment field especially during the last two decades, implied the need for more comprehensive data on exposure factors. Progressively many of the exposure factors systems tend not just to provide single values but distributional data to support the need to characterise variability and to evaluate exposure among and across life stages and population sectors.

Several exposure factors systems have been developed worldwide in various formats using different exposure factors' categorisations and content updating mechanisms.

The objective of this report is to analyse, based on pre-selected criteria, the exposure factor systems which have been developed worldwide in order to illustrate their commonalities and differences (in terms of design, capabilities, data sources, availability and usage, upgrading planning, domains of application, quality criteria and validation procedures, etc.) with the ultimate aim to identify the potential for their harmonisation, interoperability and integration. Potential harmonisation, interoperability and integration of existing exposure factor systems world-wide, while respecting the inherent variability in exposure factors across countries (due to specificities in terms of anthropometrical and socio-cultural characteristics), will reinforce the process of achieving consensus about, pooling together and presenting -where feasible and appropriate- exposure factors values based on validated data. This would greatly facilitate exposure assessors in employing good quality and consensus driven exposure factors data in their exposure assessments.

## Introduction

Exposure factors are defined as factors related to human behaviour and characteristics that help determine an individual's and/or target population exposure to an agent. Some examples of exposure factors are: anthropometric data, housing conditions, consumption of food and beverages, human activity patterns in different microenvironments, product use. Exposure/risk assessors use exposure factors values (single or distributional data) as part of the input data needed by exposure models which are employed for assessing human exposure to various environmental stressors.

Several exposure factors systems (handbooks, guidance documents, on-line databases) have been implemented world-wide in order to compile, categorise and standardise numerous exposure factors needed in exposure and risk assessment related activities (listed below):

- **European exposure factors systems**
  1. The European exposure factors database: EU ExpoFacts
  2. Other EU national based exposure factors resources
  
- **Non-European exposure factors systems**
  3. US EPA Exposure Factors Handbook
  4. 2013 Canadian Exposure Factors Handbook
  5. Australian Exposure Factor Guide
  6. Exposure Factors Handbook of Chinese Population
  7. Japanese Exposure Factors Handbook
  8. Korean Exposure Factors Handbook

Background information on the exposure factor systems considered in the analysis is provided in Chapter 1.

In this report European and non-European exposure factors systems are analysed across their commonalities and differences with the objective to identify the potential for harmonisation, interoperability and integration.

To better fit the purpose of this report, the cross-analysis of the aforementioned exposure factors systems was based on 20 pre-selected criteria which were adopted from both, the WHO-IPCS harmonisation project on uncertainty and data quality in exposure assessment (IPCS, 2008) and the criteria for measuring and comparing information systems proposed by Palmius (Palmius J., 2007). The criteria have been grouped into the following five categories.

1. Exposure factors project management
  - a. Project owner and manager
  - b. Last update date
  - c. Updating planning/programme
2. Exposure factors design and architecture
  - a. Format
  - b. Searchability

3. Exposure factors data content
  - a. Exposure factors data classification
  - b. Exposure factors data presentation
  - c. Data source type
  - d. Primary source
  - e. Sample size
  - f. Statistical measures
4. Exposure factors data quality
  - a. Quality management
  - b. Transparency
  - c. Integrity
  - d. Accuracy
  - e. Variability
  - f. Uncertainty
5. Exposure factors data values type and usage
  - a. Recommended values
  - b. Guidance on data usage
  - c. Specific regulatory purpose(s)

In Chapter 2 the exposure factor systems are compared along each of the aforementioned criteria mostly by means of tabulated data. In Chapter 3 the results of the comparison of the eight exposure factor systems are discussed and in Chapter 4 are reported the main conclusions drawn and recommendations made out of the present work.

## **1. Background information on exposure factors systems worldwide**

### **1.1. The European exposure factors database: EU ExpoFacts**

The EU ExpoFacts database is mainly addressed to European exposure assessors and risk managers involved in public health and environmental issues, particularly in the areas of indoor air quality, dietary exposures and safety of consumer products and articles. Data are mostly on food intake, time-activity patterns, physiology, housing and demographic factors.

The ExpoFacts project was originally funded by the Long Range Initiative of the European Chemical Industry Council (CEFIC-LRI) (contract No NMALRI-C1.5KTL-0207 and LRI-C1.5.1-KTLE-0512) and contracted to National Public Health Institute of Finland - KTL (currently National Institute for Health and Welfare – THL, Finland). The first development was undertaken in the period from 2002 to 2006 (Vuori et al., 2006). Given the EU perspective of this database, at the end of this first stage of development, ExpoFacts database was handed over to the European Commission's Joint Research Centre (Ispra site), and became available on-line on 15<sup>th</sup> January 2007 via the European Commission's web server (EC, 2013).

The ExpoFacts database systematically gathers and makes available exposure factors data which are relevant to exposure and risk assessment of chemicals performed in the context of several EU legislations on environment and public health (e.g., REACH, Biocides Products Regulation - BPR, General products Safety Directive - GPSD, Plant Protection Products Regulation - PPPR, Cosmetics Products Regulation - CPR, dietary and food contact). It contains information on 19 categories of exposure factors and population data (see Table 3 in section '2.3. Exposure factors data content') covering all EU Member States plus Iceland, Norway and Switzerland (31 countries in total) with extensive links and references to the original data sources. ExpoFacts serves as a common gateway to gather and disseminate European based exposure factors data which have been scattered across various data source types (e.g. databases and information systems of national institutes, and international organisations such as WHO and UNECE, scientific articles in peer-reviewed journals, reports from national studies, etc.). The EU ExpoFacts related data have been compiled into an online database from over 120 data sources, from which it is possible to query, sort and retrieve the required information in a comprehensive and freely accessible way.

The EU ExpoFacts database is available on-line at: <http://expofacts.jrc.ec.europa.eu>

### **1.2. Other exposure factors systems in EU Member States**

In Europe, besides the EU ExpoFacts database there are also other exposure factors resources which have been developed in some EU countries (i.e., Germany, United Kingdom, the Netherlands and the Nordic countries) which are briefly outlined below:



- **The German exposure factors database (RefXP)**

The German Federal Environment Agency provides extensive current data facilitating population-based exposure modelling and assessment. These reference data describe inter alia:

- food and drinking water consumption
- time-location and activity patterns
- soil and dust ingestion
- residential characteristics
- anthropometrics

of the general German population typically stratified by gender and age.

A major update and expansion of these data was achieved in 2006 by the research project ***Evaluation of standards and models for probabilistic exposure assessment - Xprob***. This project was carried out within the framework of the German Environment and Health Action Programme (APUG). Xprob reviewed and assessed available data on various factors influencing human exposure to environmental and other stressors, with the aim of consistently compiling data supporting distribution-based (probabilistic) exposure estimation.

Based on the German “Standards for Exposure Estimation” published in 1995 by the German Environmental Health Council (AUH) scientists reviewed more than 50 sources of literature and survey files. They identified various additional datasets useful for exposure modelling and assessment purposes from Federal agencies and offices, from the German Federal States, and from scientific institutions and universities.

The Xprob scientists consolidated and organised these data by developing the ***German Exposure Factors Database - RefXP***. The RefXP database contains the recommended reference values and statistical distributions for the German population. RefXP provides data descriptions in English and is available on the Internet for free download. The national health related environmental monitoring program, consisting of the German Environmental Survey (GerES) and the Environmental Specimen Bank (ESB), is a key source for increasing and updating the data information of RefXP.

RefXP was funded by the Federal Environment Ministry (BUA) and endorsed by the German Working Group on Environment-related Health Protection (LAUG).

More information is available at:

<http://www.umweltbundesamt.de/en/topics/health/assessing-environmentally-related-health-risks/health-related-exposure-assessment/database-for-health-related-exposure-assessment>

- **Exposure Factors Sourcebook for European Populations (with focus on UK Data)** (ECETOC, 2001): this document updates and builds upon other compendia of exposure factors data - the AIHC Exposure Factors Sourcebook (AIHC, 1994) and the US EPA Expo-

sure Factors Handbook (US EPA, 1997). Whereas the EFS and EFH have focused on US data, this document focuses on representative exposure factor data for UK and/or Europe based populations. The exposure factors selected for inclusion are more relevant for contaminated land sites but are also applicable to exposure assessment and risk-based decision making in general. The data presented are structured as follows:

- *Physiological Parameters*: i.e., adult body weight, child body weight, total skin surface area, surface area of specific body parts, life expectancy
- *Time-Activity Patterns*: i.e., weekly work hours, daily hours at home/away, time indoors/outdoors, daily school hours, school time indoors/outdoors, outdoor recreation, shower duration
- n, employer tenure, residential tenure, school tenure
- *Receptor Contact Rates*: i.e., soil ingestion rates, soil adherence to skin, inhalation - short-term rate, inhalation - long-term rate, food consumption rates, home grown vegetable and fruit consumption rate, fish and shellfish consumption rate, meat and beef consumption rate, drinking water consumption rate, breast milk consumption rate.

More information is available at:

[http://www.ecetoc.org/index.php?mact=MCSOap.cntnt01.details.0&cntnt01by\\_category=5&cntnt01template=display\\_list\\_v2&cntnt01order\\_by=Reference%20Desc&cntnt01display\\_template=display\\_details\\_v2&cntnt01document\\_id=297&cntnt01returnid=89](http://www.ecetoc.org/index.php?mact=MCSOap.cntnt01.details.0&cntnt01by_category=5&cntnt01template=display_list_v2&cntnt01order_by=Reference%20Desc&cntnt01display_template=display_details_v2&cntnt01document_id=297&cntnt01returnid=89)

- **Dutch Fact sheets** (RIVM, 2006-2007): the Dutch National Institute for Public Health and the Environment (RIVM) developed the computer tool named ConsExpo which is a set of coherent, general models that enables the estimation and assessment of exposure to substances from consumer products that are used indoor and their uptake by humans. ConsExpo is used for the assessment of industrial chemicals within the EU regulations for chemicals (REACH - Registration Evaluation Authorisation and restriction of chemicals Regulation (CE) No 1907/ 2006)) and biocides (Biocidal Products Regulation (EU) No 528/2012). To enhance transparency and standardisation in assessing exposures for a number of product categories, default parameter values have been compiled in so-called fact sheets. The fact sheets are 'living documents' providing information that is important for the consistent estimation and assessment of the exposure to, and the uptake of, substances from consumer products while using ConsExpo. In these fact sheets, information about exposure to chemical substances is bundled into certain product or exposure categories and default parameters are given. The product categories are chosen so that products generating similar expected exposures can be combined. The following factsheets have been developed:
  - General fact sheet
  - Children's toys fact sheet

- Cleaning products fact sheet
- Cosmetics fact sheet
- Disinfectant products fact sheet
- Do-It-Yourself products fact sheet
- Paint products fact sheet
- Pest control products fact sheet

The Dutch factsheets can be accessed at:

<http://www.rivm.nl/en/Search/Library?kwoject=rivmp:77937&contenttype=report>

- **Existing Default Values and Recommendations for Exposure Assessment** (Nordic Exposure Group, 2011): The project was funded by the Nordic Council of Ministries ([www.norden.org](http://www.norden.org)) through the Nordic Chemicals Group. The project was launched and coordinated by the Nordic Exposure Group (experts in environmental and health risk assessment of chemicals from Denmark, Finland, Sweden, Norway and Iceland), which also act as a project steering group. The report presents an overview and provides guidance and recommendations for the use of exposure factors to be used by the Nordic authorities during the process of assessing the exposure to both adults and children as well as of risk assessment in relation to REACH, Biocides and Plant Protection Products Regulations. The exposure values were collected from relevant European sources (ECHA guidance documents, ConsExpo, EUSES, Biocide TNsG, ECETOC, EU ExpoFacts) as well as from WHO and US-EPA. The following non-chemical exposure factors are addressed:

- body weight
- body surface area
- inhalation rate
- soil and dust ingestion
- drinking water
- food intake
- non-dietary ingestion factors
- lifetime expectancy
- activity factors and
- consumer products

The existing default values and recommendations for exposure assessment in the Nordic countries can be accessed at the following link:

<http://www.norden.org/en/publications/publikationer/2012-505/>

- **ECHA Guidance on Regulation (EU) No 528/2012 concerning the making available on the market and use of biocidal products (BPR)), Guidance for Human Health Risk Assessment, Volume III, Part B, Exposure Assessment (ECHA, 2013).**

This ECHA guidance document is available at:

[http://echa.europa.eu/documents/10162/15623299/biocides\\_guidance\\_human\\_health\\_ra\\_iii\\_pa\\_rtb\\_en.pdf](http://echa.europa.eu/documents/10162/15623299/biocides_guidance_human_health_ra_iii_pa_rtb_en.pdf)

- **ECHA Guidance for REACH Regulation (EC) 1907/2006 on information Requirements and Chemical Safety Assessment, PART D, Exposure Scenario Building (ECHA, 2012)**

This ECHA guidance document available at:

[http://echa.europa.eu/documents/10162/13632/information\\_requirements\\_part\\_d\\_en.pdf](http://echa.europa.eu/documents/10162/13632/information_requirements_part_d_en.pdf)

- **ECHA Guidance on information requirements and chemical safety assessment; chapter R.15: consumer exposure estimation (ECHA, 2012)**

This ECHA guidance document is available at:

[http://echa.europa.eu/documents/10162/13632/information\\_requirements\\_r15\\_en.pdf](http://echa.europa.eu/documents/10162/13632/information_requirements_r15_en.pdf)

The exposure data used under the Biocides and REACH regulations have not been selected for the comparison purposes of the present report because they are either a compendium of data from sources already considered in this report (i.e. Existing Default Values and Recommendations for Exposure Assessment - Nordic Exposure Group, Exposure Factors Sourcebook for European Populations – ECETOC, etc) or because they strictly related to the usage of a particular tool for exposure assessment (i.e. Dutch Fact sheets - RIVM) for the purpose of building product-related exposure scenarios.

### **1.3. US-EPA Exposure Factors Handbook**

The US EPA Exposure Factors Handbook was first published in 1989 and was updated in 1997 and 2011. The US EPA Exposure Factors Handbook is a product of the Exposure Factors Program established by the U.S. Environmental Protection Agency (U.S. EPA), Office of Research and Development (ORD) and the National Center for Environmental Assessments (NCEA). The US EPA Exposure Factors Handbook provides a summary of the available statistical data on various physiological and behavioural factors commonly used in assessing human exposure to environmental chemicals.

The 2011 edition of the US EPA Exposure Factors Handbook presents recommended values for the exposure factors as well as discusses the underlying data used in developing the recommendations.

The data presented in this handbook have been compiled from various sources, including government reports and information presented in the scientific literature. The data presented are the result of analyses by the individual study authors. However, in some cases, the U.S. EPA conducted additional analysis of published primary data to present results in a way that will be use-

ful to exposure assessors and/or in a manner that is consistent with the recommended age groups.

This Handbook addresses exposure assessors inside the Agency as well as outside, who need to obtain data on exposure factors to calculate human exposure to toxic chemicals. These exposure factors include:

- drinking water consumption
- soil ingestion
- inhalation rates
- dermal factors including skin area and soil adherence factors
- consumption of fruits and vegetables, fish, meats
- dairy products
- home-grown foods
- human milk intake
- human activity factors
- consumer product use, and
- building characteristics.

Recommended values are for the general population and also for various segments of the population who may have characteristics different from the general population. NCEA has strived to include full discussions of the issues that assessors should consider in deciding how to use these data and recommendations.

In 2013, EPA released EPA-Expo-Box, an online resource for exposure assessment information. EPA-Expo-Box includes links to resources that may be useful to exposure assessors, including databases, models, guidance documents and other resources organized by topic areas. One of the resources featured in the EPA-Expo-Box is EPA's Exposure Factors Handbook: 2011 Edition. Its tables can be browsed through the EPA-Expo-Box's Exposure Factor Tables Search function.

More information is available at: <http://www.epa.gov/ncea/efh/report.html>

#### **1.4. 2013 Canadian Exposure Factors Handbook**

Risk assessments conducted in Canada require current data on various factors (e.g. body weights, inhalation rates, and time-activity patterns, time spent indoors versus outdoors, etc.) that reflect the Canadian population. To provide this needed information in one place, the *Compendium of Canadian Human Exposure Factors for Risk Assessment* was published in 1997 (Richardson GM, 1997) and has been the most common source of risk assessments in Canada.

To better reflect current Canadian population characteristics, behaviours, and activities the 1997 Compendium of Canadian Human Exposure Factors for Risk Assessment was replaced in 2013 by the Canadian Exposure Factors Handbook (Richardson GM and Stantec Consulting Ltd. (2013)). The Handbook includes data accessed from the following recent Statistics Canada surveys:

- The 2000 to 2010 Canadian Community Health Surveys,
- The 2005 and 2010 General Social Surveys and
- The 2007 Canadian Health Measures Survey.

The Canadian Exposure Factors Handbook is available at:

<http://www.usask.ca/toxicology/docs/cef>

### **1.5. Australian Exposure Factor Guide**

The Australian exposure factor guide was prepared as a companion to the 2012 update of the enHealth guidance document 'Environmental Health Risk Assessment: Guidelines for assessing human health risks from environmental hazards'. This latter document provides a national approach to environmental health risk assessment as well as a general environmental health risk assessment methodology, applicable to the range of environmental health hazards (i.e. chemical, physical, biological).

The recommended exposure factor values in this guide are envisaged to be used primarily for screening (i.e. Tier 1) risk assessments. More detailed risk assessments should use circumstance and scenario specific data where possible.

The Australian exposure factor guide is intended to provide risk assessors with sets of tabulated data on human factors that may be used as inputs to the exposure assessment component of an environmental health risk assessment (enHealth, 2012).

The guide includes factors such as:

- Body weight and height
- Total and exposed skin surface area
- Drinking water and food intake
- Soil and incidental water ingestion (while swimming)
- Inhalation rate
- Activity patterns (time spent indoors/outdoors, frequency of hand to mouth, ...)
- Inhalation and oral exposure parameters

The publication of both documents has been funded by the enHealth Council through a contract with the Australian Centre for Human Health Risk Assessment (ACHHRA) at Monash University. The two documents are available at:

<http://www.health.gov.au/internet/main/publishing.nsf/Content/health-publth-publicat-environ.htm>

## 1.6. Exposure Factors Handbook of Chinese Population (Adults) (CEFH-A)<sup>1</sup>

The Exposure Factors Handbook of Chinese Population (Adults) (CEFH-A) is the first exposure factors handbook in China developed by the Chinese Research Academy of Environmental Sciences. By filling existing exposure factors data gaps it will improve the accuracy of exposure and risk assessments for the Chinese population.

The development process of the CEFH-A (2011-2012) involved a two-steps design. On the first step, the Environmental Exposure Related Human Activity Patterns Survey of Chinese Population (Adults) was carried out in order to fill in the major data gaps especially time activity patterns data, drinking water intake data, etc. At the same time, data from other sources (e.g., the US NHANES program, national statistics, individual research projects, etc.) were collected. On step two, after critical evaluation of the data sources, recommended values for the exposure factors considered were devised and the handbook was developed.

Information about the Exposure Factors Handbook of Chinese Population has not been published yet in English. The English version of the entire handbook is expected by the end of 2014.

## 1.7. Japanese Exposure Factors Handbook

The Japanese Exposure Factors Handbook was developed in 2005-2006 by the National Institute of Advanced Industrial Science and Technology (AIST) (Gamo M. and Futatsumata M., 2006). Previously conservative default factors, arbitrary factors set by assessors, or factors cited from handbooks developed in other countries were often used in exposure/risk assessments performed in Japan. For that reason an exposure factors handbook compiling Japanese data have been required for conducting realistic exposure assessment in Japan.

The Japanese exposure factors handbook includes the following categories of exposure factors:

- Food consumption rates
- Intake of other items (e.g. cigarette, milk, soil, etc)
- Food self-sufficiency rate
- Time-activity patterns
- Human body related factors (e.g. body weight, body surface area, breathing rate, etc)
- Others

More information about the Japanese exposure factors handbook is available at:

- Summary page of Japanese exposure factors data (in English):  
[http://unit.aist.go.jp/riss/crm/exposurefactors/english\\_summary.html](http://unit.aist.go.jp/riss/crm/exposurefactors/english_summary.html)
- Japanese exposure factors handbook (in Japanese):  
<http://unit.aist.go.jp/riss/crm/exposurefactors/>

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<sup>1</sup> Information about the Exposure Factors Handbook of Chinese Population (Adults) was only retrieved via a summary information in English, as the English version of the entire handbook is not expected before the end of 2014. Once this latter document will be available the corresponding info of the present report will be updated accordingly.

## **1.8. Korean exposure factors handbook**

In Korea in 2000 it was identified the need to develop a reliable set of exposure factors to represent the entire population of Korea in order to ensure reliable risk assessment and establish at national level all relevant to the environment criteria.

The Korean Exposure Factors Handbook (Jae-Yeon J. et al., 2014a; 2014b; 2014c; 2014d), was initiated as a pilot study conducted as part of the "Human Exposure Assessment for Total Risk Assessment of Environmental Contaminants" in 2001. It was the Korean nation's first study that noted the need for recommended values of exposure factors and explored the potential for their development.

Since then, a good number of national statistics were established and the Core Environmental Technology Development Project for the Next Generation was launched to support basic environmental research. "Development and Application of Korean Exposure Factors" was one of the studies that benefited from its support.

The Korean Exposure Factors Handbook was finally developed based on the results of the three-year research project called "Development of the Korean Exposure Factors Handbook" which was conducted under the sponsorship of the Korean Ministry of Environment, between December 2004 and November 2007. In this research project the researchers reviewed the domestic data that could be used in the development of exposure factors, confirmed gaps in knowledge, and prioritised the development of the Korean Exposure Factors Handbook in various phases. According to the availability of data, data were processed or a survey was conducted to retrieve data. The study thus produced recommended values for 24 exposure factors grouped by general exposure factors, food ingestion factors, and activity factors by setting up a database of exposure factors and carrying out statistical analysis. This study has significantly contributed to reducing the potential uncertainty of the risk and exposure assessment derived by the application of foreign data or research findings lacking representativeness or grounds by developing a set of exposure factors reflecting the characteristics of the Korean people.

The Korean exposure factors handbook includes the following categories of exposure factors:

- Life expectancy
- Body weight
- Body surface area
- Population mobility
- Occupational mobility
- Food ingestion factors
- Time spent on routine activities, in certain locations and in vehicles
- Inhalation rate
- Drinking water intake
- Soil ingestion
- Washing, showering, bathing and swimming



A web-based information system was established to increase public accessibility and utilization. The web-based information system consists of a research introduction, user's manual, general, food ingestion, and activity factors, and exposure assessment. It also features a download menu to help users easily downloading parts of or the entire content of the handbook.

More information about the Korean exposure factors handbook is available at:

<http://www.kefh.or.kr/new/main/main.php> (official web site in Korean)

<http://www.ncbi.nlm.nih.gov/pmc/articles/PMC3930803/>

## 2. Comparison criteria

As already anticipated in the introductory chapter, the cross-analysis of the exposure factors systems considered in this report was based on a number of criteria which have been grouped into the following five categories:

1. Exposure factors project management
2. Exposure factors design and architecture
3. Exposure factors data content
4. Exposure factors data quality
5. Exposure factors data usage

In the following sections eight of the exposure factors systems considered were analysed in this report and can be identified by the following abbreviations:

- **EU:** The European exposure factors database: EU ExpoFacts
- **DE:** The German exposure factors database (RefXP)
- **US:** US EPA Exposure Factors Handbook
- **CAN:** 2013 Canadian Exposure Factors Handbook
- **AUS:** Australian Exposure Factor Guide
- **CHN:** Exposure Factors Handbook of Chinese Population
- **JPN:** Japanese Exposure Factors Handbook
- **KOR:** Korean Exposure Factors Handbook

It should be underlined that the analysis of the Exposure Factors Handbook of Chinese Population, the Japanese Exposure Factors Handbook and the Korean Exposure Factors Handbook was not based on the direct access to the corresponding information systems as info is not available in English. However, information about these exposure factor systems was retrieved as follows:

- *Exposure Factors Handbook of Chinese Population:* A document containing the recommended values extracted from the handbook was provided by Dr. Xiaoli Duan. The English version of the entire handbook is expected by the end of 2014.
- *Japanese Exposure Factors Handbook:* as the handbook is written in Japanese and only relevant information for this report was taken from a summary page in English which is available at:  
[http://unit.aist.go.jp/riss/crm/exposurefactors/english\\_summary.html](http://unit.aist.go.jp/riss/crm/exposurefactors/english_summary.html)
- *Korean exposure factors handbook:* the Korean exposure factors handbook is only available in Korean (<http://www.kefh.or.kr/new/main/main.php>). However info in English was retrieved via the following four articles which were published in April 2014 in the Journal of Preventive Medicine and Public Health:
  - Jae-Yeon Jang, Soo-Nam Jo, So-Yeon Kim, Hyung-Nam Myung (2014). Overview of the Development of the Korean Exposure Factors Handbook. Journal of Preventive Medicine and Public Health 2014;47:1-6

- Jae-Yeon Jang, So-Yeon Kim, Sun-Ja Kim, Kyung-Eun Lee, Hae-Kwan Cheong, Eun-Hye Kim, Kyung-Ho Choi, Young-Hee Kim (2014). General Factors of the Korean Exposure Factors Handbook. *Journal of Preventive Medicine and Public Health* 2014;47:7-17
- Jae-Yeon Jang Soo-Nam Jo, Sun-Ja Kim, Hyung-Nam Myung, Cho-Il Kim (2014). Food Ingestion Factors of the Korean Exposure Factors Handbook. *Journal of Preventive Medicine and Public Health* 2014;47:18-26
- Jae-Yeon Jang, Soo-Nam Jo, So-Yeon Kim, Kyung-Eun Lee, Kyung-Ho Choi, Young-Hee Kim (2014). Activity Factors of the Korean Exposure Factors Handbook. *Journal of Preventive Medicine and Public Health* 2014;47:27-35

## 2.1. Exposure factors project management

Table 1 summarises the ownership and management of the exposure factors systems along with some information concerning the last update date and plans for future upgrades.

**Table 1.** Existing exposure factors systems worldwide: ownership and management

|                                     | EU   | DE   | USA  | CAN   | AUS  | CHN   | JPN  | KOR  |
|-------------------------------------|--|--|--|---|--|---|--|--|
| <b>Project owner</b>                | EU Commission, DG JRC  | Federal Environment Agency - UBA   | U.S. Environmental Protection Agency (U.S. EPA)  | G. Mark Richardson and Stantec Consulting Ltd.  | Environmental Health Standing Committee (enHealth) | Ministry of Environmental Protection (MEP) of People's Republic of China                                  | National Institute of Advanced Industrial Science and Technology (AIST)            | J.Y. Jang and Ministry of Environment  |
| <b>Project manager</b>              |  |  |  |   | Toxikos Pty Ltd                                    |   |  |  |
| <b>Last update date</b>             | 2012   | 2011   | 2011   | 2013  | 2012   | 2012  | 2007   | 2007   |
| <b>Updating planning /programme</b> | The JRC is continuously monitoring and collecting EU related data as they become available in the published literature and/or by the EU Member States. | In 2012 an expert opinion was prepared about possible and necessary updates with regard to the graphical users interface (GUI) of the German exposure factors' database. | The plan is to update individual chapters of the US EPA Exposure Factors Handbook as new data become available that may warrant a change in recommendations. | There is no specific schedule or plan to update the Canadian Exposure Factors Handbook. | Not available                                      | A plan for updating the Exposure Factors Handbook of Chinese Population has not come into the agenda yet. | Currently there are no plans for upgrading the Japanese Exposure Factors Handbook. | Currently there are no plans for upgrading the Korean Exposure Factors Handbook. |

|  | EU | DE | USA  | CAN | AUS | CHN | JPN | KOR |
|--|----|----|--|-----|-----|-----|-----|-----|
|  |    |    | These updated chapters will be posted on line. |     |     |     |     |     |

## 2.2. Exposure factors design and architecture

Table 2 contains information on the format and searchability capabilities and functionalities of the exposure factors systems.

**Table 2.** Existing exposure factors systems worldwide: format and searchability capabilities and functionalities

|               | EU   | DE  | US  | CAN  | AUS  | CHN                                       | JPN  | KOR   |
|---------------|--|---|---|--|--|---|--|---|
| <b>Format</b> | Online free access at: <a href="http://expofac.ts.jrc.ec.europa.eu">http://expofac.ts.jrc.ec.europa.eu</a> | Desktop software downloadable at: <a href="http://www.apug.de/risiken/forschungsprojekte/xprob/RefXP_20110604_ReadVersion.zip">http://www.apug.de/risiken/forschungsprojekte/xprob/RefXP_20110604_ReadVersion.zip</a> | Freely available in PDF format at: <a href="http://www.epa.gov/ncea/efh/report.html">http://www.epa.gov/ncea/efh/report.html</a><br><br>Tables from the handbook can be identified from the US EPA-Expo-Box's Exposure Factor Tables Search at: <a href="http://cfpub.epa.gov/ncea/risk/expobox/efh">http://cfpub.epa.gov/ncea/risk/expobox/efh</a> | Freely available in PDF format at: <a href="http://www.usask.ca/toxicology/docs/cef">http://www.usask.ca/toxicology/docs/cef</a> | Freely available in PDF and DOC format at: <a href="http://www.health.gov.au/internet/main/publishing.nsf/Content/health-publth-publicat-environ.htm">http://www.health.gov.au/internet/main/publishing.nsf/Content/health-publth-publicat-environ.htm</a> | Available only as PDF document in Chinese | English Page (summary): <a href="https://unit.aist.go.jp/riss/crm/exposurefactors/english_summary.html">https://unit.aist.go.jp/riss/crm/exposurefactors/english_summary.html</a><br><br>Japanese website: <a href="http://unit.aist.go.jp/riss/crm/exposurefactors/">http://unit.aist.go.jp/riss/crm/exposurefactors/</a> | Available online in Korean: <a href="http://www.kefh.or.kr/new/main/main.php">http://www.kefh.or.kr/new/main/main.php</a> |

|                      | EU   | DE   | US   | CAN | AUS | CHN | JPN | KOR |
|----------------------|--|--|--|-----|-----|-----|-----|-----|
|                      |  |  | <a href="#">TableSearch.cfm</a>  |     |     |     |     |     |
| <b>Searchability</b> | Two searching functionalities are available:<br><br>– Free text search<br><br>– Guided search through four successive steps:<br><br>i. Country<br>ii. Category<br>iii. Table<br>iv. Year | Users can retrieve the information through a stepwise procedure:<br><br>i. Headlines<br>ii. Topics<br>iii. Parameter | The list of exposure factors tables can be refined by checking pre-set key words (e.g. Applicable Exposure Route, Activity Type, Spatial-Temporal Characteristics, etc.) within the US EPA-Expo-Box. | -   | -   | -   | -   | -   |

### 2.3. Exposure factors data content

Table 3 presents the exposure factors topics for each of the analysed systems. The structure of the tables reflects the content of Table 2 of Phillips and Moya (2014) which was expanded to include topics (highlighted in grey in Table 3 of the present report) relevant to exposure assessment practices about the following three exposure factors systems:

- The German exposure factors database (RefXP)
- 2013 Canadian Exposure Factors Handbook
- Exposure Factors Handbook of Chinese Population

**Table 3.** Existing exposure factors systems worldwide: types of data considered (expanded version of Table 2 by Phillips and Moya (2014))

| EXPOSURE FACTORS DATA TYPES                             | EXPOSURE FACTORS SYSTEMS |                  |    |     |     |     |     |     |
|---|--------------------------|------------------|----|-----|-----|-----|-----|-----|
|   | EU                       | DE               | US | CAN | AUS | CHN | JPN | KOR |
| <b>Water ingestion</b>                                  | X                        | <i>tap water</i> | X  | -   | X   | X   | X   | X   |
| <b>Non-dietary ingestion</b>                            | X                        | -                | X  | -   | X   | -   | -   | -   |
| <b>Soil/dust ingestion</b>                              | -                        | X                | X  | X   | X   | -   | X   | X   |
| <b>Oral bioavailability</b>                             | -                        | -                | -  | -   | X   | -   | -   | -   |
| <b>Inhalation rates</b>                                 |                          |                  |    |     |     |     |     |     |
| Activity-specific                                       | -                        | X                | X  | -   | X   | -   | -   | -   |
| Daily   | -                        | X                | X  | X   | X   | X   | X   | X   |
| <b>Ventilation rates</b>                                | X                        | -                | X  | -   | X   | X   | -   | -   |
| <b>Dermal</b>   |                          |                  |    |     |     |     |     |     |
| Surface area  | X                        | X                | X  | X   | X   | X   | X   | X   |
| Adherence of solids to skin                             | -                        | -                | X  | -   | X   | -   | -   | -   |
| Dermal bioavailability                                  | -                        | -                | -  | -   | X   | -   | -   | -   |
| <b>Body weight</b>                                      | X                        | X                | X  | X   | X   | X   | X   | X   |
| <b>Body height</b>                                      | X                        | X                | X  | -   | X   | -   | -   | -   |
| <b>Body mass index (BMI)</b>                            | -                        | X                | X  | -   | X   | -   | -   | -   |
| <b>Body fat</b>   | -                        | X                | -  | -   | -   | -   | -   | -   |
| <b>Energy expenditure</b>                               | X                        | -                | -  | -   | -   | -   | -   | -   |
| <b>Organ weights and tissue volumes</b>                 | -                        | -                | -  | -   | X   | -   | -   | -   |
| <b>Food intake</b>                                      | X                        | X                | X  | -   | X   | X   | X   | X   |
| <b>Dietary supplements and non-prescribed medicines</b> | X                        | -                | -  | -   | -   | -   | -   | -   |
| <b>Human milk</b>                                       |                          |                  |    |     |     |     |     |     |
| Human milk and lipid intake, lipid content              | X                        | -                | X  | -   | X   | -   | X   | -   |
| Incidence, frequency, and duration of feeding           | X                        | -                | X  | -   | X   | -   | -   | -   |

| EXPOSURE FACTORS DATA TYPES                | EXPOSURE FACTORS SYSTEMS |    |    |     |     |     |                |     |
|--|--------------------------|----|----|-----|-----|-----|----------------|-----|
|  | EU                       | DE | US | CAN | AUS | CHN | JPN            | KOR |
| <b>Time use</b>                            |                          |    |    |     |     |     |                |     |
| Time spent indoor                          | X                        | X  | X  | X   | X   | X   | <i>at home</i> | X   |
| Time spent outdoor                         | X                        | X  | X  | X   | X   | X   | X              | X   |
| Time-activity patterns                     | X                        | X  | X  | X   | X   | X   | X              | X   |
| Smoking                                    | -                        | -  | X  | -   | -   | -   | X              | -   |
| <b>Consumer product use</b>                | X                        | -  | X  | -   | -   | -   | -              | -   |
| <b>Life expectancy</b>                     | X                        | -  | X  | X   | X   | X   | X              | X   |
| <b>Residential characteristics</b>         | X                        | X  | X  | -   | X   | X   | X              | -   |
| <b>Commercial building characteristics</b> | X                        | -  | X  | -   | -   | -   | -              | -   |
| <b>Population data</b>                     | X                        | -  | -  | -   | -   | -   | -              | -   |

Note: 'X': data are available; '-': data are not available

Table 4 describes how exposure factors data are classified and presented in each of the exposure factors systems considered. It provides also information on the type of data sources, the sample size and the statistical measures used in each system.

**Table 4.** Existing exposure factors systems worldwide: data classification, presentation, source type, sample size and statistical measures

|   | EU  | DE  | US   | CAN  | AUS  | CHN | JPN   | KOR   |
|---|---|---|--|--|--|-----|---|---|
| <b>Exposure factors data classification</b> | Exposure factors are divided into eight categories:<br><ul style="list-style-type: none"> <li>– Physiology</li> <li>– Housing</li> <li>– Dietary ingestion</li> <li>– Non-dietary ingestion</li> <li>– Countries</li> </ul> | Exposure factors are divided into seven categories:<br><ul style="list-style-type: none"> <li>– Anthropometric</li> <li>– Time budget</li> <li>– Food con-</li> </ul> | Exposure factors are classified and reported under the following seventeen chapters:<br><ul style="list-style-type: none"> <li>– Ingestion of Water and</li> </ul> | Exposure factors are divided into six categories and corresponding chapters in the handbook:<br><ul style="list-style-type: none"> <li>– Life duration</li> <li>– Body weight</li> <li>– Inhalation</li> </ul> | Exposure factors are classified under the following six chapters:<br><ul style="list-style-type: none"> <li>– Anatomical and physiological parameters</li> </ul> | -   | Exposure factors are divided into seven categories:<br><ul style="list-style-type: none"> <li>– Food Consumption Rate</li> <li>– Intake of Other Items</li> <li>– Food Self-</li> </ul> | 24 exposure factors grouped into the following three categories:<br><ul style="list-style-type: none"> <li>– General Factors</li> <li>– Activity Factors</li> </ul> |



|  | EU   | DE   | US   | CAN   | AUS  | CHN | JPN   | KOR  |
|--|--|--|--|---|--|-----|---|--|
|  | <ul style="list-style-type: none"> <li>- Population</li> <li>- Time activity</li> <li>- Consumer Products</li> </ul> | <ul style="list-style-type: none"> <li>sumption</li> <li>- Soil intake</li> <li>- Inhalation</li> <li>- Dermal contact</li> <li>- Residence characteristics</li> </ul> | <ul style="list-style-type: none"> <li>Other Selected Liquids</li> <li>- Non-Dietary Ingestion Factors</li> <li>- Soil and Dust Ingestion</li> <li>- Inhalation Rates</li> <li>- Dermal Exposure Factors</li> <li>- Body Weight Studies</li> <li>- Intake of Fruits and Vegetables</li> <li>- Intake of Fish and Shellfish</li> <li>- Intake of Meats, Dairy Products, and Fats</li> <li>- Intake of Grain Products</li> <li>- Intake of Home-Produced Foods</li> <li>- Total Food Intake</li> <li>- Human Milk Intake</li> <li>- Activity Fac-</li> </ul> | <ul style="list-style-type: none"> <li>rates</li> <li>- Skin surface area</li> <li>- Time-activity</li> <li>- Soil ingestion rates</li> </ul> | <ul style="list-style-type: none"> <li>- Estimating intake from dermal exposure</li> <li>- Estimating intake from ingestion</li> <li>- Estimating intake via inhalation</li> <li>- Activity patterns</li> <li>- Residence and population mobility</li> </ul> |     | <ul style="list-style-type: none"> <li>sufficiency Ratio</li> <li>- Non-dietary ingestion</li> <li>- Time Activity</li> <li>- Human Body</li> <li>- Others</li> </ul> | <ul style="list-style-type: none"> <li>- Food Ingestion Factors</li> </ul> |

|   | EU  | DE  | US   | CAN   | AUS  | CHN  | JPN  | KOR   |
|---|---|---|--|---|--|--|--|---|
|   |   |   | tors<br>– Consumer Products<br>– Lifetime<br>– Building Characteristics  |   |  |  |  |   |
| <b>Exposure factors data presentation</b> | <p>Data are presented in tables. Some of them are country-specific (e.g. physical activity in Finland) and others have very narrow specificity (e.g. respiratory rate in the first 3 years of life, Italy).</p> <p>Data are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Country</li> <li>– Gender</li> <li>– Age group</li> </ul> <p>Age groups are not consistent across the whole database.</p> <p>Other parameters specific to each exposure</p> | <p>Data are <del>are</del> presented in tables and characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group</li> </ul> <p>Age groups are not consistent across the whole database.</p> | <p>Data are presented in tables and are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group</li> </ul> <p>Age groups are quite consistent across the handbook.</p> | <p>Data are presented in tables in which often a comparison between different sources is included.</p> <p>Data are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group</li> </ul> <p>The following age groups are well described:</p> <ul style="list-style-type: none"> <li>– Infant</li> <li>– Toddler</li> <li>– Child</li> <li>– Teen</li> <li>– Adult</li> </ul> | <p>Within each section Australian data are first provided; this may or may not be supplemented with overseas data to highlight the fact that not all overseas data reflect sectors of the current Australian population.</p> <p>Data are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group</li> </ul> <p>Age groups are quite consistent</p> | <p>Data are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group</li> <li>– Urban/Rural</li> </ul> <p>Recommended values are presented in a single table.</p> | <p>The English summary is a webpage which presents data in tables across the following categories:</p> <ul style="list-style-type: none"> <li>- Food consumption rate</li> <li>- Intake of other items</li> <li>- Food self-sufficiency ratio</li> <li>- Time-activity</li> <li>- Human body</li> <li>- Others</li> </ul> <p>Data are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Last update date</li> </ul> <p>Some data are</p> | <p>Data of each exposure factor, presented in the four articles, is grouped in a table. Values are characterised by the following parameters:</p> <ul style="list-style-type: none"> <li>– Gender</li> <li>– Age group (for the majority of the tables)</li> </ul> <p>For some data it is also available the geographical location (i.e. metropolitan city, small or medium-sized city, rural area)</p> |

|   | EU  | DE  | US  | CAN   | AUS  | CHN  | JPN  | KOR   |
|---|---|---|---|---|--|--|--|---|
|   | factor may be available (e.g. geographic location)  |   |   |   | across the guide.  |  | infant/children specific but the age groups are not specified.   |   |
| <b>Exposure factors data sources type</b>                 | <ul style="list-style-type: none"> <li>– Surveys</li> <li>– Study/Project Reports</li> <li>– Literature</li> <li>– International organisations databanks (e.g. WHO, UNECE)</li> </ul> | <ul style="list-style-type: none"> <li>– Survey files</li> <li>– Literature</li> </ul>  | <ul style="list-style-type: none"> <li>– National Surveys (e.g. US NHANES)</li> <li>– Scientific literature</li> <li>– Other US EPA agencies</li> </ul> | <ul style="list-style-type: none"> <li>– Statistics Canada surveys</li> <li>– Literature</li> </ul> | <ul style="list-style-type: none"> <li>– Australian Surveys</li> <li>– Australian Studies</li> <li>– International organisations data (e.g. International Commission on Radiological Protection)</li> <li>– Scientific literature</li> <li>– Other exposure factor systems (e.g. US EPA, EC, WHO)</li> </ul> | <ul style="list-style-type: none"> <li>– National Surveys</li> </ul>               | <ul style="list-style-type: none"> <li>– Scientific literature</li> <li>– Reports</li> <li>– Statistics</li> </ul> | <ul style="list-style-type: none"> <li>– National statistics</li> </ul>                     |
| <b>Exposure factors data primary source</b>               | NO  | NO  | NO  | NO  | NO   | YES  | NO   | YES   |
| <b>Exposure factors data sample size</b>                  | The sample size is not always reported.   | The sample size is reported.  | The sample size is reported.  | The sample size is reported.  | The sample size is rarely reported.  | -  | -  | The sample size is reported.  |
| <b>Exposure factors data related statistical measures</b> | <p>Always provided:</p> <ul style="list-style-type: none"> <li>– Average</li> </ul> <p>and often:</p> <ul style="list-style-type: none"> <li>– Median</li> </ul>                      | <p>Always provided:</p> <ul style="list-style-type: none"> <li>– Average</li> <li>– Variance</li> <li>– Standard deviation</li> </ul> | <p>Always provided:</p> <ul style="list-style-type: none"> <li>– Mean</li> <li>– Percentiles</li> </ul>   | <p>Always provided:</p> <ul style="list-style-type: none"> <li>– Average</li> </ul>                 | <p>Always provided:</p> <ul style="list-style-type: none"> <li>– Average</li> <li>– 95<sup>th</sup> Percentile</li> </ul>  | Only recommended values are provided (without indicating any statistical measures) | Only representative values are provided (without indicating any statistical measures)                              | The handbook presents statistical distribution values including means along with statistics |

|  | EU  | DE   | US   | CAN | AUS | CHN | JPN | KOR   |
|--|---|--|--|-----|-----|-----|-----|---|
|  | <ul style="list-style-type: none"> <li>– Percentiles</li> <li>– Min</li> <li>– Max</li> </ul> | <ul style="list-style-type: none"> <li>– Skewness</li> <li>– Min</li> <li>– Max</li> <li>– Median</li> <li>– Geometric mean</li> <li>– Geometric standard deviation</li> </ul> <p>For most exposure factors, RefXP provides descriptive statistics such as percentiles of the empirical distribution and fitted statistical distributions for the German population.</p> | <p>and often:</p> <ul style="list-style-type: none"> <li>– Standard error</li> <li>– Standard deviation</li> </ul> |     |     |     |     | by gender, age, and residential area for the exposure factors considered. |

## 2.4. Exposure factors data quality

Criteria for evaluating the data quality of exposure factor systems are commonly developed and used to select studies and data for inclusion in the systems. This allows for a more consistent characterisation of the strengths and limitations of the underlying data used to derive recommended values.

Table 5 compares the eight exposure factors systems on the basis of the following data quality criteria: *quality management, transparency, integrity, accuracy, variability and uncertainty*.

**Table 5.** Comparison of existing exposure factors worldwide based on data quality criteria.

|                           | EU   | DE   | US   | CAN                                      | AUS  | CHN  | JPN                                      | KOR  |
|---------------------------|--|--|--|--|--|--|--|--|
| <b>Quality management</b> | <p>The JRC assisted by a working group of European experts performs the following tasks:</p> <p>Evaluate the inclusion of new exposure factors and new associated data; validate the data to be fed into the EU ExpoFacts database; and provide advice on improving the functionalities (e.g. search function) and</p> | <p>When the database program was implemented, two steps of internal and external quality control have been organised.</p> <p>An external reviewer checked the code, compiled it independently and did a functional check.</p> <p>All XProb project members did the statistical analysis of the data independently.</p> | <p>The U.S. EPA's Science Policy Council recommends the use of five General Assessment Factors (GAFs) for evaluating the quality and relevance of scientific and technical information used in support of Agency actions. The handbook adopted those GAFs for evaluating the data to be included in the handbook.</p> <p>The five GAFs</p> | <p>No information could be retrieved</p> | <p>International peer review on the draft document was provided by Professor Steve Hrudey, University of Alberta, and ChemRisk LLC, San Francisco (Ellen Donovan and Hugh Scobie).</p> | <p>Consultation received from an advisory committee of international experts</p> <p>During the field survey on the human activity patterns quality assurance and control measures were undertaken (e.g. use of parallel questionnaires).</p> | <p>No information could be retrieved</p> | <p>An internal quality system was in place for the national data sources used.</p> |

|  | EU   | DE   | US   | CAN | AUS | CHN | JPN | KOR |
|--|--|--|--|-----|-----|-----|-----|-----|
|  | the users interface of the EU ExpoFacts db | <p>Before and after integrating the reference values into the database a second formal quality check was performed.</p> <p>All reference values used in the case studies got an extra control.</p> <p>Concerning the methods and the results an expert meeting has been organised at national level.</p> | <p>include:</p> <ul style="list-style-type: none"> <li>- soundness</li> <li>- applicability and utility</li> <li>- clarity and completeness</li> <li>- uncertainty and variability</li> <li>- evaluation and review</li> </ul> <p>These GAFs were adapted and expanded to include specific considerations deemed to be important during evaluation of exposure factors data and were used to judge the quality of the underlying data used to derive recommendations. In addition, confidence ratings were assigned to each recommendation to provide the user with an</p> |     |     |     |     |     |

|   | EU   | DE  | US   | CAN  | AUS  | CHN                                      | JPN                                      | KOR  |
|---|--|---|--|--|--|--|--|--|
|   |  |   | added perspective on the quality of the data.  |  |  |  |  |  |
| <b>Transparency</b><br><br><i>The clarity and completeness with which all key data, methods and processes, as well as the underlying assumptions and limitations, are documented and available</i><br><br><i>(WHO IPCS, 2008)</i> | <p>Source(s) for each exposure factor data is provided.</p> <p>Source retrieved related information (study date, sample size, study methods, and selection of the sample population) is provided in the EU Expofacts database documentation.</p> | <p>Source(s) for each exposure factor data is provided.</p>   | <p>Source(s) for each exposure factor data is provided.</p> <p>Detailed rationale about the selection and any limitations of the data is provided.</p> | <p>Source(s) for each exposure factor data is provided.</p> <p>Rationale about the selection of values is available.</p> | <p>Source(s) for each exposure factor data is provided.</p> <p>Rationale about the selection of values is available.</p> | <p>No information could be retrieved</p> | <p>No information could be retrieved</p> | <p>Source(s) for each exposure factor data is provided.</p> <p>The body of the handbook includes an overview, calculation of selected values, comparisons with cases from other countries, reliability, and limitations for each category of exposure factors.</p> |
| <b>Integrity</b><br><br><i>The degree to which the data collected and reported are what they purport to be</i><br><br><i>(WHO IPCS, 2008)</i>   | <p>Data are imported from the primary sources into the exposure factor system without any alteration.</p>  | <p>The German project is a re-analysis of the results of a vast, national exposure and health-related survey to generate a database with dis-</p> | <p>With very few exceptions, the data presented are the analyses of the primary sources.</p>   | <p>Data are reported from the primary sources into the exposure factor handbook without any alteration.</p>              | <p>Data are reported from the primary sources into the exposure factor handbook without any alteration.</p>              | -  | -  | <p>Some domestic data were processed before to be used as exposure factors data through:</p> <ul style="list-style-type: none"> <li>- statistical re-analysis</li> <li>- full-scale</li> </ul>   |

|  | EU  | DE  | US  | CAN  | AUS  | CHN   | JPN   | KOR   |
|--|---|---|---|--|--|---|---|---|
|  |   | tributonal data for probabilistic exposure analysis.  |   |  |  |   |   | reorganization<br>– recategorization<br>– reanalysis of raw data  |
| <p><b>Accuracy</b></p> <p><i>The degree to which measured, calculated or modelled values correspond to the true values of what they are intended to represent</i></p> <p><i>(WHO IPCS, 2008)</i></p> | Accuracy of the EU Expofacts data directly reflects the accuracy of the data in the primary source(s) | The accuracy requirements for the German exposure factor data follows the requirements of the German “Standards for Exposure Estimation” (published in 1995 by the German Environmental Health Council (AUH). | Since the studies included in the US EPA handbook are varying in terms of their objectives, design, scope, presentation of results, etc., the level of detail, statistics, terminology and accuracy may vary between studies and between factors. | The data and statistics presented in the 2013 Canadian Exposure Factors Handbook are based on surveys at national level.<br><br>As stated, the goal is to provide an accessible, up-to-date resource ensuring that human health risk assessments are relevant, accurate, and as free of uncertainty as possible. | The information in the Australian Exposure factors guidance should be checked by end users for their suitability. Explicit accuracy requirements could not be retrieved. | Data of the Environmental Exposure Related Human Activity Patterns Survey of Chinese Population (Adults) are characterised by the following indicators :<br><br>– representativeness<br>– validity<br>– accuracy<br>– reliability | Representative values were derived from the most relevant data sources according to the following criteria:<br><br>– new data<br>– large sample size<br>– nationwide survey<br>– randomized sampling strategy<br><br>Explicit accuracy requirements could not be retrieved. | Reliability of the data were based, among others, on:<br>– connections with the population characteristics<br>– collection period<br>– size of the study<br>– representativeness of the subjects<br>– the research design<br>– reliability of measurement<br><br>Explicit accuracy requirements could not be retrieved. |
| <p><b>Variability</b></p> <p><i>Heterogeneity of values over</i></p>   | Variability is addressed by presenting data on the expo-  | Variability is addressed by presenting data on the expo-  | Variability is addressed by presenting exposure fac-  | Variability is addressed by presenting exposure fac-   | Variability is addressed by presenting exposure factor   | Exposure factor data variability is addressed by presenting data  | No information could be retrieved   | For the majority of the exposure factors variability is   |



|  | EU   | DE   | US  | CAN   | AUS  | CHN  | JPN                                      | KOR  |
|--|--|--|---|---|--|--|--|--|
| <p><i>time, space or different members of a population, including stochastic variability and controllable variability.</i></p> <p><i>(WHO IPCS, 2008)</i></p>  | <p>sure factors as percentiles for various age groups, years and countries/regions.</p>                            | <p>sure factors as probability distributions and ranges across various age groups.</p> | <p>tors data in one of the following ways:</p> <ul style="list-style-type: none"> <li>– as percentiles or ranges of values for various age groups or other populations</li> <li>– as a qualitative analysis.</li> </ul> | <p>tors data in one of the following ways:</p> <ul style="list-style-type: none"> <li>– as ranges of values for various age groups and various study years</li> <li>– as a qualitative analysis.</li> </ul> | <p>data on as percentiles or ranges of values, and/or as estimated values.</p>                           | <p>for various age groups and regions.</p> |  | <p>addressed by presenting data as percentiles across various age groups.</p>  |
| <p><b>Uncertainty</b></p> <p><i>Lack of or “imperfect knowledge concerning the present of future state of an organism, system, or (sub) population under consideration”</i></p> <p><i>(WHO IPCS, 2004)</i></p> | <p>Uncertainty of the EU ExpoFacts data directly reflects the uncertainty of the data in the primary source(s)</p> | <p>No information could be retrieved</p>   | <p>Uncertainty is addressed by applying confidence ratings to the recommendations provided for the various factors, along with detailed discussions of any limitations of the data presented.</p>                       | <p>Uncertainty is implicitly addressed in the discussions of the recommended data.</p>  | <p>For each exposure factor, a brief discussion about the uncertainty in the estimates is presented.</p> | <p>No information could be retrieved</p>   | <p>No information could be retrieved</p> | <p>Uncertainty is addressed by associating to the calculation of the exposure factors data values explanations about the data selected, methodologies, and principal statistics.</p> |

## 2.5 Exposure factors data values type, usage and regulatory context

Table 6 specifies whether the exposure factors systems provide recommended values or not and also the specific regulatory frameworks for which the systems have been developed and/or used within.

**Table 6.** Existing exposure factors systems worldwide: data values type and usage in relation to specific regulatory frameworks

|                               | EU | DE   | US  | CAN | AUS | CHN | JPN | KOR |
|-------------------------------|----|--|-----|-----|-----|-----|-----|-----|
| <b>Recommended values</b>     | NO | YES<br><br>The RefXP reference were labelled "recommended" by the Federal Committee for Environment and Health (Länderaus-schuß für um-weltbezoge-nen Gesundheits-schutz LAUG) | YES | YES | YES | YES | YES | YES |
| <b>Guidance on data usage</b> | NO | NO   | YES | YES | YES | NO  | NO  | NO  |

|                                       | EU   | DE  | US  | CAN   | AUS   | CHN  | JPN  | KOR   |
|---------------------------------------|--|---|---|---|---|--|--|---|
| <b>Specific regulatory purpose(s)</b> | <p>EU ExpoFacts was developed with the purpose of collecting exposure factors data which can be widely used in various exposure assessments in the EU member states.</p> | <p>RefXP although it is not part of a directive, it has the status of a normative standard in Germany.</p> <p>The usage of the RefXP values is recommended for all projects and processes in Germany supporting environmental and health risks assessments.</p> | <p>The US EPA Exposure Factors Handbook was developed with the purpose of promoting consistency in US EPA's exposure assessment activities.</p> | <p>The 2013 Canadian exposure factors handbook was prepared and published to provide general assistance to Canadian risk assessors.</p> | <p>The Australian exposure factor guide (2012) aims to provide risk assessors with sets of tabulated data on human factors that can be used in the exposure and health risk assessments in Australia.</p> | <p>The Exposure Factors Handbook of Chinese Population was developed addressing the 12th Five-Year Plan on Environmental Health Work to improve the accuracy of exposure and risk assessments for the Chinese population</p> | <p>The Japanese exposure factors handbook was developed to provide a sound foundation for the exposure/risk assessments conducted in Japan in general.</p> | <p>Since the Korean exposure factors handbook is a national index for demonstrating the physiological, food ingestion, and behavioural characteristics of the Korean people, it can serve various purposes in addition to environmental risk assessment.</p> <p>Currently the Korean Ministry of Environment is preparing a law on exposure assessment for chemicals.</p> |

### **3. Comparison results of existing exposure factor systems worldwide**

Before discussing the outcome of the comparison of existing exposure factor systems worldwide, it should be underlined that information for the Chinese and Japanese exposure factors systems was retrieved only via the English summary information which was available at the time this report was prepared. Therefore, it was not possible to conduct a comprehensive evaluation of these two systems. Similarly, it was not possible to have access to the full set of data of the Korean Exposure Factors Handbook. However for this latter, the four articles published by Jae-Yeon Jang et al. in the Journal of Preventive Medicine and Public Health (2014, number 47, pages 1-35), provided enough information for the comparison purposes of this report.

#### Project Management of the exposure factors systems

Gathering and releasing exposure factors data is not effortless but time consuming. In several cases it is also difficult for the different organisations involved in the management of the exposure factors systems to make a rigorous and long-term planning for updating their data. Although collecting exposure factors data is a demanding task, it is however necessary to provide country-specific and quality assured data to be used as input values for exposure/risk assessments. In the past, Korea, Japan and China have been commonly using data from the US-Exposure Factors Handbook which contains relevant information relying on US specific data. However, these latter data should be used carefully in other countries due to their physiological and cultural specificities which may be influential for the exposure factors values.

In the Australian Exposure Factor Guide it is explicitly stated that in case Australian information is not available, overseas data (e.g. US EPA data) may be used in the exposure/risk assessments but upon a proper justification. At the same time the primary focus of the EU ExpoFacts is on collecting and presenting the most updated and representative data at national level in the EU Member States. Due to the high level of variability of the exposure factor data across the EU countries, it is almost impossible or meaningless to provide average values of these data at European level.

#### Design and architecture of exposure factors systems

The format of the exposure factors systems is a key aspect to be considered as it induces in the users patterns of use. The majority of the analysed systems are available on the internet as documents in PDF format. The German exposure factors database is a desktop software that is freely downloadable and has to be installed on a personal computer in order to be consulted. The US-Exposure Factors Handbook was initially in PDF format (the full handbook in one single file or one file for each chapter). In 2013, US EPA released its US EPA-Expo-Box, an online resource for exposure assessment information in which relevant tables and sections of the US EPA Exposure Factors Handbook can be accessed and browsed. The EU ExpoFacts database is a full web-based system freely accessible through internet which allows an easy access to its data through web based tables which are updated in a transparent manner for the end users.

### Exposure Factors data classification, presentation, sample size and source type

Exposure factors data classification and presentation are quite homogeneous across all analysed systems. Even if the nomenclature used may differ, a potential harmonisation of the exposure factors data categories can be a quite straightforward task.

The exposure factors data are commonly presented grouped by males and females, for various age groups and in the case of Chinese and Korean data grouped by urban and rural. Moreover, the sample size is always available. In this context, age group is a critical issue since there is not a consolidated common classification scheme for the existing exposure factors systems and sometimes even within the same system (e.g. in the case of EU ExpoFacts the classification can be country specific).

Only in China and Korea new data were collected from scratch (i.e. via national surveys) with the explicit aim of compiling exposure factor systems accustomed for specificities of these two countries. In other countries two types of sources have been considered: already available data gathered in the frame of national surveys and/or individual exposure factors studies accessible in scientific literature. Furthermore, some data of the US EPA Exposure Factors Handbook were collected by another federal agency and then analyzed by the US EPA (e.g. food consumption data analyses were conducted by US EPA from data collected by the U.S. Department of Agriculture).

In addition to the above considerations, the sources of some of the EU ExpoFacts tables (e.g. life expectancy, total dwellings) were retrieved from databanks of international organisations such as WHO and UNECE or studies and projects relying on third-parties surveys. One example are the food consumption data provided to EU ExpoFacts by the FACET project. The FACET project was developed in response to a call by the European Commission to produce a risk management tool consisting of a database containing information on the levels of food additives, food flavourings and food contact materials and corresponding food consumption data. It contains data collected by seven national surveys (i.e. Finland, France, Hungary, Ireland, Italy, Portugal, United Kingdom) via the respective national statistical bodies. In all existing exposure factors systems their data sources is presented in a transparent manner.

### Exposure factors data quality and statistical measures

The compilations of the 2013 Canadian Exposure Factors Handbook and the Japanese Exposure Factors Handbook have been carried without relying on a specific data quality management system. For the other exposure factors systems, each of the organisations in charge followed specific internal quality procedures. In China, an advisory committee with international experts was established, while in Germany a two-step internal and external quality control process has been implemented. In Australia their draft exposure factors document was undergone an international peer review.

The US EPA exposure factor handbook adopted the five General Assessment Factors (GAFs) recommended by the U.S. EPA's Science Policy Council which are part of the Agency's procedural guidance for ensuring and maximizing the quality of information, regardless of the source of in-

formation. These five quality indicators are: (1) soundness; (2) applicability and utility; (3) clarity and completeness; (4) uncertainty and variability; and (5) evaluation and review.

In Korea an internal quality system was in place for the national data sources used.

Regarding the EU ExpoFacts database, a working group composed of European experts was established by the JRC in order to discuss and propose the potential inclusion of new exposure factors and associated data, validate the data before feeding them into the EU ExpoFacts database and provide advice on improving the database's functionalities (e.g. search function) and users interface.

In order to handle inter-individual variability, the exposure factor systems analysed in this report rely on different statistical measures (e.g., mean, standard deviation, median, percentiles). However, the statistical measures are not used uniformly across the systems but even within the same system. This discrepancy is mainly due to the type of data sources used and the way the original source data were manipulated to compile the exposure factor data sets.

The German RefXP always provides data probability distributions and ranges across various age groups. On the opposite side, as data in EU ExpoFacts are not processed but presented as originally occur in their sources, the usage of statistical measures is very heterogeneous and source-dependent. In addition to that, EU ExpoFacts has the peculiarity to present data of many countries and some tables are country-specific (e.g. average energy expenditure in Belgium). In some cases this can cause some difficulty when trying to compare data between countries as not always all the countries are considered in the same table and countries' information on exposure factors can be inconsistent with: (i) the set of age groups, (ii) covered years (i.e. trend), and (iii) statistical measures used (e.g. probability distributions, mean values, range of values). On the contrary, data of the 2013 Canadian Exposure Factors Handbook are taken from three Statistics Canada surveys which apparently have been produced by using similar protocols and for that reason the presented data are mainly expressed as arithmetic mean body weight with  $\pm$  standard deviation.

A feasible solution for reducing uncertainty and help using the exposure factor data in a consistent way is by providing clear information about the data source(s), confidence ratings, methodology used and data limitations. All the exposure factor systems considered in this report indicate their data sources and uncertainty is addressed at different level of details.

#### Exposure factors data value type, usage and regulatory context

Even if only the Exposure Factors Handbook of Chinese Population has been developed to respond to a specific regulatory propose (i.e. 12<sup>th</sup> Five-Year Plan on Environmental Health Work), it is clear that the objective of all other exposure factor systems is primarily to provide exposure/risk assessors with robust and reliable sets of data on human exposure factors to use in the exposure/risks assessments which are performed in the different countries.

In Germany, RefXP has the status of a normative standard and the usage of its collection of reference values is recommended for all projects and processes that are conducted to support an exposure/risk assessment based decision making process in Germany.

EU ExpoFacts is the only system which does not propose any recommended values. The other seven systems which were analysed in this report propose recommended values for each exposure factor category. In some cases recommended values are provided as single numbers (e.g. Japan, China) in others (e.g. German RefXP) as distributed values by means of different statistical measures.

#### **4. Conclusions and recommendations**

Harmonisation of exposure factors values to use in exposure assessments has been recommended by the Nordic Exposure Group Project in 2011. In the context of this latter group, by harmonisation is meant to come up with recommended values for each exposure factor out of a data quality management process which will produce validated data.

The outcome of the present work supports the need of harmonising and integrating existing exposure factor systems world-wide, where appropriate and feasible, as it was already conceived and expressed by the Nordic Exposure Group Project. The outcome of the analysis in this report recommends to extend the scope of harmonisation and integration so to enable the possibility of cross-referencing and comparing exposure factor data collected by various countries along different jurisdictions and for application to various legislative frameworks and sectorial policies (e.g. chemicals, consumer products, food, biocides).

This endeavour should be faced via an international dialogue seeking consensus about the future development synergistically of new and/or updating existing exposure factor systems including: (a) the development of a standardised methodology and protocols for exposure factors data collection, processing/analysis and presentation; (b) the development of a common methodology for characterising variability and uncertainty of exposure factors systems across specific exposure scenarios and target population groups considered.

Such a harmonisation, interoperable and integrated framework while respecting the inherent variability in exposure factors across countries (due to specificities in terms of anthropometrical and socio-cultural characteristics) will reinforce the process of achieving consensus about, pooling together and presenting -where feasible and appropriate- exposure factors values based on validated data. It will also provide criteria for: (a) exposure factors data handling, processing and analysis without affecting the data integrity and (b) data presentation to avoid inconsistencies in data categorisation (e.g. by age groups) and use of statistical parameters for characterising the data variability.

With regard to age groups classification, an interesting attempt in the direction of making data comparable is available in the 2013 Canadian Exposure Factors Handbook. To ensure that the latest data are readily available to all jurisdictions, revised exposure factors derived from the

latest Statistics Canada and other data are presented retaining the original age groups as defined in the previous version of the handbook (1997). Another solution is suggested by Phillips and Moya (2013): *"normalizing exposure factors by body weight will further enhance comparability across populations"*.

In conclusion, to achieve harmonisation, interoperability and integration of existing exposure factors systems world-wide, it is recommended to undertake the following steps under the coordination of JRC-IHCP/I.1:

1. Establishment of a joint advisory board of experts (from existing exposure factor systems world-wide, potential data providers and users such as WHO, OECD, EUROSTAT, EFSA, ECHA and exposure and risk assessors) co-chaired by JRC-IHCP/I.1, US EPA and the Chinese Research Academy of Environmental Sciences to: (a) discuss and reach consensus on the development of a standardised methodology consisting of common statistical descriptors and criteria and protocols for exposure factor data collection, processing/analysis, quality evaluation and reporting. The ultimate objective will be to facilitate and enhance exposure factors systems' interoperability and consistency in terms of data accessibility, presentation and use (including proper characterisation of uncertainty related to the data usage) in various legislative frameworks and sectorial policies at international scale; (b) provide guidance for appropriate selection and use of exposure factors data in connection to specific exposure scenarios and population of interest and (c) identify and explore emerging needs of exposure assessors and consider options and recommend priorities for future developments and updates of existing exposure factors systems world-wide in a consistent and synergistic way. This forward-looking approach should consider the inclusion of factors extending from external dose to internal dose and target tissues, including biomarkers and factors needed for pharmacokinetic modelling to allow for dose reconstruction from human biomonitoring data (as recently stated in Phillips and Moya, 2014).
2. Implementation of a web-based overarching information portal for exposure factors (a *database of databases*) which will facilitate accessing and navigating in existing exposure factor systems world-wide through a "one stop access point". The portal should be designed and implemented having a three-fold objective: (a) to facilitate the indexing and retrieval of information from existing exposure factors systems world-wide using certain parameters (e.g. exposure factor data category); (b) to enable end-users performing a more knowledgeable evaluation and usage of the exposure factors data via a series of provided comparison utilities and guidelines; (c) to serve as a reference gateway for disseminating the on-going work and main deliverables of the aforementioned joint advisory board of experts (e.g. recommendations, guidance documents, standardised methodologies), thus increasing their visibility and stimulating their implementation on global scale.



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## LIST OF ACRONYMS

|                  |  |
|------------------|--|
| <b>ACHHRA</b>    | Australian Centre for Human Health Risk Assessment                       |
| <b>AIHC</b>      | American Industrial Health Council                                       |
| <b>AIST</b>      | Advanced Industrial Science and Technology                               |
| <b>APUG</b>      | German Environment and Health Action Programme                           |
| <b>AUH</b>       | German Environmental Health Council                                      |
| <b>BPR</b>       | Biocidal Products Regulation (EU) No 528/2012                            |
| <b>CEFH-A</b>    | Exposure Factors Handbook of Chinese Population (Adults)                 |
| <b>CEFIC-LRI</b> | Long-range Research Initiative of the European Chemical Industry Council |
| <b>CPR</b>       | Cosmetics Products Regulation (EC) No 1223/2009                          |
| <b>ECETOC</b>    | European Centre for Ecotoxicology and Toxicology of Chemicals            |
| <b>ESB</b>       | Environmental Specimen Bank  |
| <b>EUSES</b>     | European Union System for the Evaluation of Substances                   |
| <b>FAO</b>       | Food and Agriculture Organization  |
| <b>GAFs</b>      | General Assessment Factors   |
| <b>GPSD</b>      | General Products Safety Directive (2001/95/EC)                           |
| <b>GerES</b>     | German Environmental Survey  |
| <b>JRC</b>       | European Commission's Joint Research Centre                              |
| <b>LAUG</b>      | German Working Group on Environment-related Health Protection            |
| <b>NCEA</b>      | US National Center for Environmental Assessments                         |
| <b>NHANES</b>    | US National Health and Nutrition Examination Survey                      |
| <b>ORD</b>       | US Office of Research and Development                                    |
| <b>PPPR</b>      | Plant Protection Products Regulation (EC) No 1107/2009                   |

|               |   |
|---------------|---|
| <b>REACH</b>  | Registration Evaluation Authorisation and restriction of chemicals Regulation (CE) No 1907/ 2006        |
| <b>RefXP</b>  | The German exposure factors database  |
| <b>RIVM</b>   | Dutch National Institute for Public Health and the Environment  |
| <b>THL</b>    | Finnish National Institute for Health and Welfare   |
| <b>UBA</b>    | German Federal Environmental Agency   |
| <b>UNECE</b>  | United Nations Economic Commission for Europe   |
| <b>US EPA</b> | United States Environmental Protection Agency   |
| <b>WHO</b>    | World Health Organization   |
| <b>Xprob</b>  | German research project on the evaluation of standards and models for probabilistic exposure assessment |

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