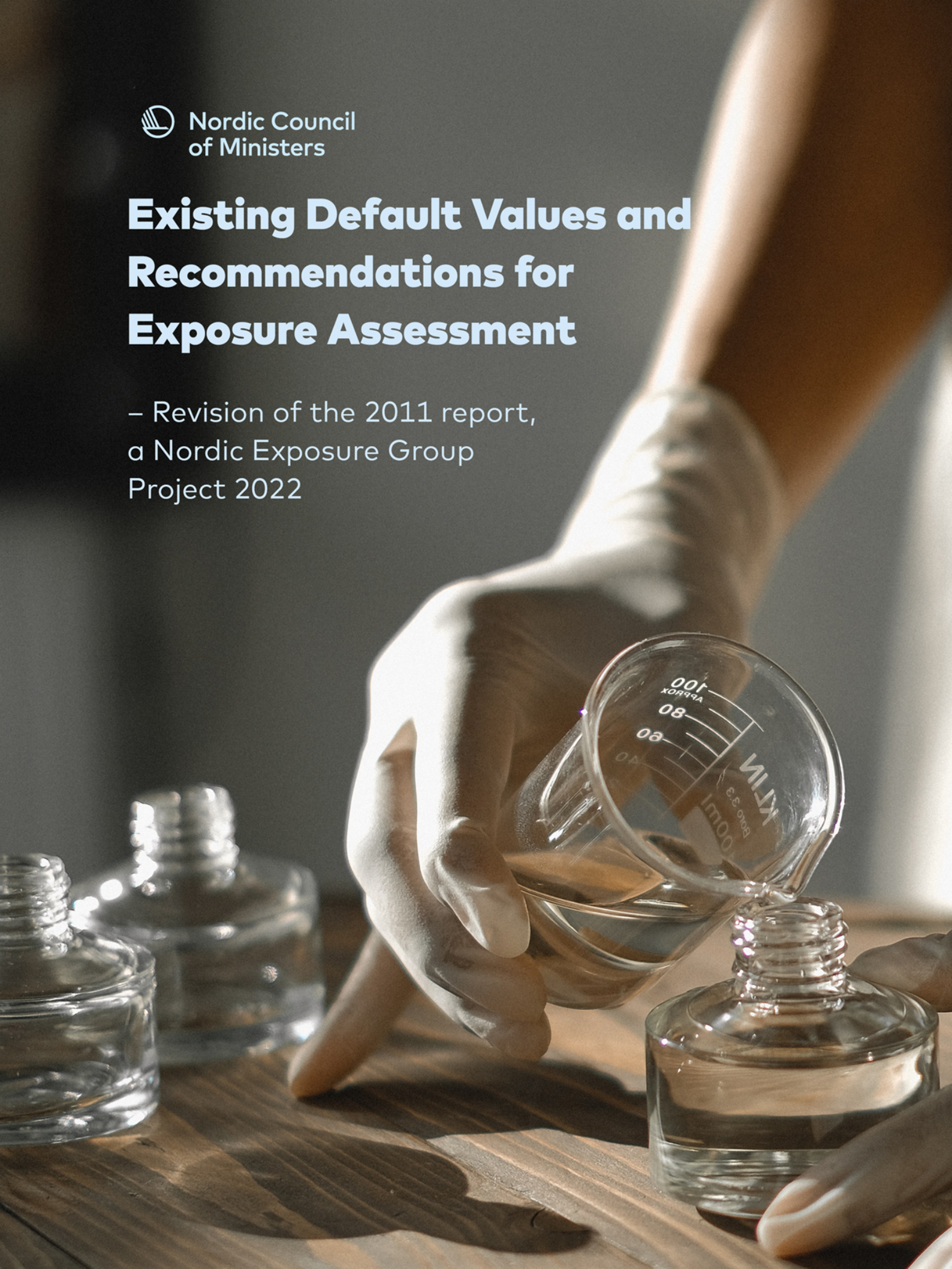




Nordic Council
of Ministers

Existing Default Values and Recommendations for Exposure Assessment

– Revision of the 2011 report,
a Nordic Exposure Group
Project 2022



Contents

Foreword	4
Abbreviations	5
Glossary	6
1. Introduction	8
1.1 Europe	11
1.2 The United States	15
1.3 WHO	17
2. Body weight	18
2.1. Europe	18
2.2. US-EPA	22
2.3. WHO	23
2.4 Conclusion and recommendations	24
3. Body surface areas	26
3.1. Europe	26
3.2. US-EPA	30
3.3. WHO	33
3.4. Conclusion and recommendations	33
4. Inhalation rates	34
4.1. Europe	34
4.2. US-EPA	40
4.3. WHO	43
4.4. Conclusion and recommendations	43
5. Drinking water	45
5.1. Europe	45
5.2. US-EPA	47
5.3. WHO	49
5.4. Conclusion and recommendations	50
6. Food intake	52
6.1. Europe	52
6.2. US-EPA	59
6.3. WHO	66
6.4. Conclusion and recommendations	67
7. Soil and dust ingestion and inhalation	69
7.1. Europe	70
7.2. US-EPA	71
7.3. WHO	72
7.4. Conclusion and recommendations	72

8. Non-dietary ingestion factors	74
8.1. Europe	74
8.2. US-EPA	74
8.3. WHO	76
8.4. Conclusion and recommendations	76
9. Lifetime expectancy	77
9.1. Europe	77
9.2. US-EPA	77
9.3. WHO	78
9.4. Conclusion and recommendations	78
10. Activity Factors	80
10.1 Europe	80
10.2 US-EPA	81
10.3 WHO	85
10.4. Conclusion and recommendations	85
11. Consumer products	86
11.1. Europe	86
11.2. US-EPA	101
11.3. WHO	102
11.4. Conclusion and recommendations	102
12. Summary, conclusions and recommendations	103
Body weight	105
References	110
About this publication	116

This publication is also available online in a web-accessible version
at <https://pub.norden.org/temanord2023-508>.

Foreword

As provided by NEXPO:

The project was funded by the Nordic Council of Ministries through the Nordic Chemicals Group. The project was launched and coordinated by the Nordic Exposure Group (NEXPO), which also acted as a project steering group. The draft report was made by revising the original report from 2011 by consultants from the Research Group for Chemical Risk Assessment and GMO at the National Food Institute, Technical University of Denmark. The draft was commented on by the members of the NEXPO, i.e., project steering group:

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Abbreviations

AIHC	American Industrial Health Council
CHAD	Consolidated Human Activity Database
D-EPA	The Danish Environmental Protection Agency
DIY	Do-it-yourself
ECETOC	European Centre for Ecotoxicology and Toxicology of Chemicals
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EUSES	European Union System for the Evaluation of Substances
ExpoFacts	European Exposure Factors database
GAF	General Assessment Factor
ICRP	The International Commission on Radiological Protection
IPCS	International Programme on Chemical Safety
METS	Metabolic equivalents
NHANES	The National Health and Nutrition Examination Survey
OECD	Organisation for Economic Co-operation and Development
REACH	Registration, evaluation, authorisation and restriction of chemicals
RIVM	The National Institute for Public Health and Environment, Netherlands
SCOOP	Scientific Co-operation on Questions relating to Food
TNsG	The Technical Notes for Guidance
US-EPA	The United States Environmental Protection Agency
WHO	World Health Organization

Glossary

Applied dose	Amount of a substance at the absorption barrier (skin, lung, gastrointestinal tract) available for absorption
Cloud volume	The volume of a cloud of particles to which a person is exposed during spraying of a product
Coefficient of variation	Ratio of the standard deviation to the mean
Confidence rating	A qualitative rating of low, medium, or high to each recommended value in the US-EPA EFH.
ConsExpo	Computer software model for consumer exposure assessment
Contact rate	Rate at which a product is applied to the skin, in weight per time unit
Contact rate aerosol spray cans	The dermal contact rate during spraying of a product from an aerosol spray can
Contact rate trigger sprays	The dermal contact rate during spraying of a product from a trigger spray
Default value	Standard value
Default parameter value	Standard value for a specific parameter
Delivered dose	The amount of a substance transported to an individual organ, tissue or fluid of interest (the target)
Density	Measure of how much mass is contained in a given unit volume (density = mass/volume)
Dermal exposure	Direct exposure of / contact with the skin
Effective (biologically) dose	Amount of a substance that actually reaches cells, sites or membranes
General Fact Sheet	Fact sheet containing the general information in relation to ConsExpo
Geophagy	Eating of soil
Hazard assessment	Effect assessment, i.e., assessment of possible adverse effects of a substance
Inhalation cut-off diameter	Measure for the diameter of spray droplets that can be inhaled and reach the lower areas of the lungs (alveoli, bronchioles, bronchia)
Inhalation exposure	Direct exposure of / contact with the respiratory tract
Internal dose	Amount of a substance that has been absorbed and is available for interaction with the biologically target organs and tissues
Key study	In the US-EPA EFH, the most useful studies for deriving exposure factors
Lognormal distribution	Probability distribution of a random variable whose logarithm is normally distributed
Mass generation rate	Mean mass generation rate during the entire duration of spraying calculated from the sprayed amount and the total duration of spraying
Molecular Weight Matrix	Parameter used to calculate the relative vapour pressure of a component
Mouthing times	Duration of an object kept in the mouth

Oral exposure	Direct exposure of / contact with the gastro-intestinal tract
Per capita	Per person
Physiologic information	Information on physiological parameters
Pica	Deliberate ingestion of larger amounts of non-nutritive substances
Planimeter	Measuring instrument used to determine the area of an arbitrary two-dimensional shape
Postpartum	Period just after delivery
Potential dose	Amount of a substance contained in material ingested, inhaled or in material applied to the skin
Product amount	Amount of a product used in a specific use scenario
Recreational marine intake	Consumption of marine fish catch as part of a sporting or recreational activity and not for the purpose of providing a primary source of food
Relevant study	In the US-EPA EFH, studies that are applicable or pertinent, but not necessarily the most important to derive exposure factors
Spray duration	Duration of spraying
Total duration	Entire duration of an activity
Use duration	Duration related to the use of a product

1. Introduction

The International Programme on Chemical Safety (IPCS) has defined exposure as the "contact of an organism with a chemical or physical agent, quantified as the amount of chemical available at the exchange boundaries of the organism and available for absorption." (WHO/IPCS, 2001). This means contact with the visible exterior of a person such as the skin, and openings such as the mouth, nostrils, and lesions.

The process of a chemical entering the body can be described in two steps: Contact (exposure) followed by entry (crossing the boundary, i.e., absorption). The process begins with a chemical being released from a source into the environment. Once in the environment, the chemical can be transformed and transported through the environment via air, water, soil, dust, and food. Individuals become in contact with the chemical in the environment through inhalation, ingestion, or skin/eye contact. Individuals may also come in contact with chemicals in consumer products as well as during work. The individual's activity patterns as well as the concentration of the chemical will determine the magnitude, frequency, and duration of the exposure. The exposure becomes an absorbed dose when the chemical crosses an absorption barrier (entry into the body). When the chemical or its metabolites interact with a target tissue, it becomes a target tissue dose, which may lead to an adverse health outcome, the biologically effective dose. Figure 1 illustrates the relationship between exposure and different types of dose.

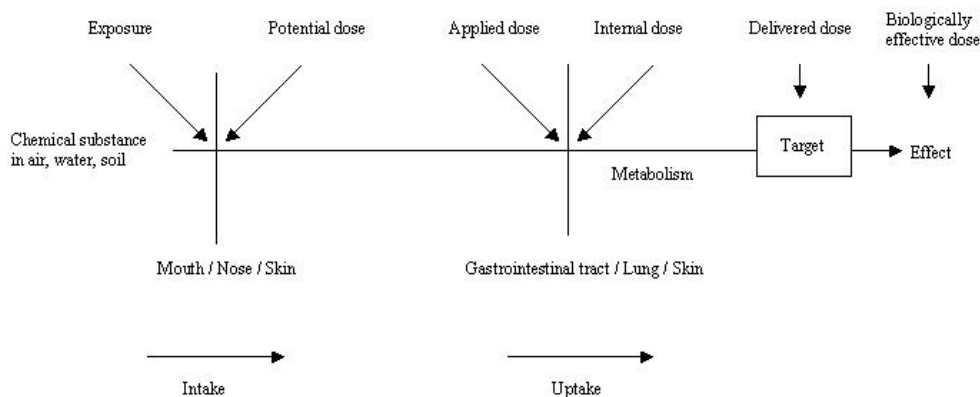


Figure 1. Correlation between exposure concentration and internal dose. Modified from US-EPA (1997)

The applied dose is the amount of a substance at the absorption barrier (skin, lung, gastrointestinal tract) available for absorption. Usually it is very difficult to measure the applied dose directly at the absorption barrier. An approximation of the applied dose can be made using the potential dose, which is the amount of the substance ingested, inhaled or in material applied to the skin. The applied dose, or the amount that reaches the exchange boundaries of the skin, lung or gastrointestinal tract, may often be less than the potential dose if the substance is only partly bioavailable. The amount of a substance that has been absorbed and is available for interaction with the biologically target organs and tissues is called the internal dose. The amount transported to an individual organ, tissue or fluid of interest (the target) is termed the delivered dose (or target tissue dose); the delivered dose may be only a part of the total internal dose. The biologically effective dose, or the amount that actually reaches cells, sites or membranes where adverse effects occur, may only be a part of the delivered dose. Doses are often presented as dose rates, or the amount of a chemical dose (applied or internal) per unit time (e.g., mg/day), or per-unit-body-weight-basis (e.g., mg/kg body weight per day). (WHO/IPCS, 1999).

The aim of an exposure assessment is to determine the nature and extent of contact with chemical substances experienced or anticipated under different conditions. An exposure assessment is the quantitative or qualitative evaluation of the amount of a substance that humans come into contact with and includes consideration of the intensity, frequency and duration of contact, the route of exposure (e.g., dermal, oral or respiratory), rates (chemical intake or uptake rates), the resulting amount that actually crosses the boundary (a dose), and the amount absorbed (internal dose). Depending on the purpose of an exposure assessment, the numerical output may be an estimate of the intensity, rate, duration and frequency of contact exposure or dose (the resulting amount that actually crosses the boundary). (WHO/IPCS, 1999).

Exposure data can be either measured or calculated. Measured exposure data are preferred, if they are valid. Often measured exposure data are not available, or they are not considered valid, and therefore model-generated data must be used. An exposure model is "*a conceptual or mathematical representation of the exposure process*" (WHO/IPCS, 2004); i.e., a tool to calculate an estimate (a figure) to use in the risk characterisation, e.g., where the outcome of the hazard assessment is compared with an exposure estimate. The output of an exposure model can be an exposure concentration; in practice, however, exposure often includes estimates of intake (e.g., amount of chemical inhaled or ingested) and the amount of a chemical that is absorbed into the body (e.g., amount of chemical that penetrates the skin or the lining of the lung) (WHO/IPCS, 2005). Exposure models can be developed to estimate exposures and doses of individuals, defined population groups, or entire populations. Exposure may be estimated as a continuous variable or integrated over time ranging from minutes to a lifetime. The modelled outputs may include mean or median values, distribution parameters (standard deviations, quartiles, ranges), or entire distributions. Consequently, exposure models vary widely in complexity, approach, inputs, and outputs (WHO/IPCS, 2005).

In order to perform an exposure assessment, it is necessary to apply various "non-chemical-specific" exposure related parameters such as e.g., body weight, body surface area, activity factors, ventilation rates, ingestion of water/food etc. These parameters are called non-chemical-specific exposure factors and are generally drawn from the scientific literature or governmental statistics.

The approach to exposure assessment is not as internationally harmonised as

hazard assessment. Although broad consistency in the overall approaches used by different bodies and countries in conducting exposure assessment exists, there is variation in the types of approaches and tools used, including the use of exposure factors.

The purpose of this report is to give an updated overview of non-chemical-specific exposure factors to be used by the authorities during the process of assessing exposure to both adults and children as well as of risk assessment in relation to REACH, and to contribute towards a further harmonisation of such exposure factors to be used in exposure assessments. Thus, the process of exposure assessment in itself is not further addressed in this report.

The following non-chemical-specific exposure factors are addressed in this report:

- Body weight
- Body surface areas
- Inhalation rates
- Ingestion of drinking water
- Intake of food
- Ingestion of soil and dust
- Non-dietary ingestion factors
- Lifetime expectancy
- Activity factors
- Consumer products

In the following, guidance and recommendations provided by various EU bodies, with the main focus on the information gathered in the *REACH Guidance on Information Requirements and Chemical Safety Assessment*¹ published by the European Chemicals Agency (ECHA) will be addressed first as this report is directed primarily towards the exposure factors to be used in exposure assessments in the context of the EU chemicals regulation 'REACH'. Then the US guidance and recommendations will be addressed as the most recent version of the US-EPA *Exposure Factor Handbook* currently with most chapters published in 2011 with updates of a number of chapters in 2017–2019 provides the most comprehensive overview, considerations, evaluations and recommendations in the area of non-chemical-specific exposure factors. Finally, guidance and recommendations provided by the WHO will be addressed as this report also is meant to contribute towards a further harmonisation of exposure factors to be used in exposure assessments.

Below, the main EU, US and WHO sources of non-chemical-specific exposure factors will be addressed. The OECD has not published any guidance or recommendations on the use of non-chemical-specific exposure factors.

The OECD Working Party on Exposure Assessment (WPEA) Children's Health subgroup will develop a children exposure factor web-based database in 2023 (Personnel communication).

1. <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

1.1 Europe

1.1.1 ECHA

The European Chemicals Agency (ECHA) under REACH has published a "*Guidance on Information Requirements and Chemical Safety Assessment*"² that describes the information requirements under REACH with regard to substance properties, exposure, use and risk management measures, and the chemical safety assessment. The 'Path Finder' to the REACH *Guidance on Information Requirements and Chemical Safety Assessment* is available here³. The REACH *Guidance on Information Requirements and Chemical Safety Assessment* includes a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes, as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH, and are updated on a regular basis.

Part D of the REACH *Guidance on Information Requirements and Chemical Safety Assessment* is dedicated to exposure assessment and details how to develop exposure scenarios and related exposure estimations. Part D also provides links to more in-depth guidance on exposure assessment. This includes: Occupational exposure assessment (Chapter R.14), exposure assessment related to consumers including releases from articles (Chapter R.15) and exposure assessment related to the environment including releases from waste life stage (Chapter R.16). Recommendations on exposure factors are generally limited although Chapter R.15 provides some information regarding default values for exposure factors to be used for consumer exposure assessment, such as amount of product used per application and exposure time. These recommendations are generally obtained from the RIVM (The National Institute for Public Health and the Environment, Netherlands) Fact Sheets for specific consumer products, in order to build consistency with ConsExpo, a computer tool for consumer exposure assessment (see Section 1.1.2). Chapter R.16 provides some information regarding default values to be used for exposure factors related to the environment, such as human intake rates of crops, meat and fish, dairy products and drinking water; these default values are used in EUSES, the computer tool used for exposure assessment related to the environment (see Section 1.1.3).

Chapter R.8 "*Characterisation of dose [concentration]-response for human health*" (ECHA, 2012), Table R.8–18, of the REACH *Guidance on Information Requirements and Chemical Safety Assessment* also provides some information regarding default values for exposure factors to be used for exposure assessments of consumers and man exposed indirectly via the environment as well as for exposure assessments of workers. It should be noted that the recommendations in Table R.8–18 are stated as "*taken from Gold et al., 1984 and ICRP, 1975*"; however, it is not clear whether the recommendations are taken from one of these references or both. The reference 'ICRP, 1975' is to the International Commission on Radiological Protection (ICRP) Publication No. 23 "*Report of the Task Group on Reference Man*", which was adopted in October 1974 and published in April 1975. It should be noted that other bodies, e.g., WHO (WHO/IPCS, 1994 and 1999) refer to this ICRP report as 'ICRP, 1974'.

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2. <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>
 3. <https://echa.europa.eu/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment>

A few of the Committee for Risk Assessment (RAC) opinions on '*an Annex XV dossier proposing restrictions on*' various chemical substances also provide some information regarding default values for exposure factors to be used for exposure assessments of consumers.

1.1.2 ConsExpo

The National Institute for Public Health and the Environment, Netherlands (RIVM) is a Dutch research institute that is an independent agency of the Dutch Ministry of Health, Welfare and Sport. In order to mathematically predict human exposure to consumer products, RIVM has developed the software model ConsExpo. ConsExpo, which can be downloaded from the internet⁴ is a set of coherent, general models that enables the estimation and assessment of the exposure to substances from consumer products and their uptake by humans. Data about the application of products and data from mathematical models are used to build up the program. The program is based on relatively simple exposure and uptake models. The starting point for these models is the route of exposure, i.e., the inhalation, dermal or oral route. The most appropriate exposure scenario and uptake model is chosen for each route. The parameters needed for the exposure scenario and the uptake models are then filled in. It is possible that exposure and uptake occur simultaneously via different routes. In addition to data about the exposure and uptake, general scenario data is also needed, such as the frequency and body weight of the exposed person. Using the data mentioned above, ConsExpo calculates the exposure and uptake. For this purpose Fact Sheets have been developed.

The Fact Sheets⁵ give information that is important for the consistent estimation and assessment of the exposure to, and the uptake of, chemical substances from consumer products, such as paints, do-it-yourself products, cosmetics and cleaning products. In the Fact Sheets, information about exposure to chemical substances is bundled into certain product or exposure categories. These categories are chosen so that products with similar exposures can be combined. On the one hand, each Fact Sheet gives general background information, while on the other hand, it quantifies exposure parameters which, together with an exposure scenario, or a combination of the various exposure scenarios, produces a quantitative estimate of the exposure.

In the *General Fact Sheet* (RIVM, 2014) general information is presented that is needed for consumer exposure assessment in addition to the more specific information provided in the specific Fact Sheets on the different product groups. Information includes: Room size and ventilation (Section 3), anthropometric parameters such as body weight, total body surface and surface of body parts, and inhalation rates (Section 4) and activity patterns (Section 5). Also general information on the specific Fact Sheets is given (Section 1.3).

In addition to the *General Fact Sheet* (RIVM, 2014), specific Fact Sheets are available for children's toys (RIVM, 2002), cleaning products (RIVM, 2006c, 2018), cosmetics (RIVM, 2006b), disinfectants (RIVM, 2006d), "do-it-yourself products" (RIVM, 2007a), paints products (RIVM, 2007b) pest control products (RIVM, 2006e), and air fresheners (RIVM, 2021).

In the *Exposure to chemicals via house dust* (RIVM, 2008), the potential of house

4. <https://www.rivm.nl/en/consexpo#tcm:13-42793>

5. <https://www.rivm.nl/en/consexpo#tcm:13-42793>

dust being a health risk is investigated and in this connection, exposure to dust via ingestion and inhalation have been examined.

The consumer exposure estimation should normally address the intended uses of the products that contain the substances under investigation. However, since consumers may not accurately follow instructions for use of products, an estimation of other reasonably anticipated uses should be made (ECHA, 2008).

In the Fact Sheets provided by the RIVM, the basis for the calculation and/or estimation of the default parameter values is a realistic worst-case scenario and considers consumers who frequently use a certain product under relatively less favourable circumstances. For example, when using a cosmetic product, basic assumptions are: relatively frequent use, application of a relatively large amount in a small room with a low ventilation rate, and a relatively long stay in that room. The parameter values in the Fact Sheets are aimed at (Dutch) consumers. They are chosen such that a relatively high exposure is calculated, in the order of magnitude of a 99th percentile of the population exposure distribution; in other words, the high-end user is aimed for. To achieve this goal, the 75th or the 25th percentile is calculated (or estimated) for each parameter. The 75th percentile is normally used for proportional parameters, except in the case of reverse

proportional parameters, for which the 25th percentile is used, e.g., for body weight. For a significant number of parameters, there are actually too few data to calculate the 75th or 25th percentile. In such cases, an estimate is made which corresponds to the 75th or 25th percentile (RIVM, 2014).

1.1.3 EUSES

The European Union System for the Evaluation of Substances (EUSES⁶) is the European reference tool for companies, authorities and researchers to prepare their environmental exposure assessments under the Biocidal Products Regulation and the REACH Regulation. EUSES was updated in 2019 particularly with regard to the environmental exposure and risk assessment for biocides.

Indirect exposure of humans via the environment may occur by consumption of food (fish, crops, meat and milk) and drinking water, inhalation of ambient air, and ingestion of soil. For substance having been on the European market for years, measured levels in various environmental compartments may be available; however, for newly introduced substances on the market, usually no relevant measured data are available and concentrations of a substance in the environment then have to be estimated.

EUSES estimates concentrations in food and the total daily intake of a substance based on predicted environmental concentrations for (surface) water, groundwater, soil, sediment and ambient air. The indirect exposure is assessed on three spatial scales: 1) At the 'personal scale', individual consumers or workers are considered, exposed directly to individual substances and preparations, and to substances embedded in a solid matrix; 2) the local scale considers the protection goals in the vicinity of one large point source of the substance; and 3) the regional scale assesses the risks to protection targets due to all releases in a larger region. A fourth spatial scale, the continental scale (defined as the sum of all EU Member States), is added

6. <https://echa.europa.eu/en/support/dossier-submission-tools/euses>

to serve as background for the regional system. The concentrations at the continental and global scales are not used for risk characterisation in terms of REACH.

EUSES can specifically be used in the initial, or screening, and intermediate, or refined, stages of assessment. On the basis of this screening, it can be decided if more data need to be generated and if a more refined (i.e., intermediate) assessment is necessary. EUSES can also be applied for intermediate or refined assessments by allowing the replacement of default values, estimated parameter values, or intermediate results by more accurately estimated values or by measured data. EUSES is not specifically designed for site-specific assessments, but adjustment of parameters may allow for insight into specific local or regional situations.

1.1.4 TNsG

According to the Biocidal Products Directive, a risk assessment of biocidal products is required before these can be placed on the European Market. The estimation of human exposure is fundamental for the risk assessment and requires quantification of the levels of exposure for both users of the biocidal product and others who may be exposed following its use. As there is still a paucity of exposure data on biocides, various approaches are used to estimate human exposure to them. From 1998 onwards the European Union funded a series of projects to both fill this knowledge gap and establish a harmonised approach for assessing human exposure to biocides. The outcome of these projects was the publication of the *Technical Notes for Guidance on Human Exposure to Biocidal Products* (TNsG) (TNsG, 2007). The Guidance covers all product types and presents worked examples for each of them. This TNsG consists of a written part, as well as a computerised database (BEAT) of exposure data (largely for occupational settings), and the consumer exposure model ConsExpo. The worked examples are indicated in the written part and are described in detail in the database.

1.1.5 ExpoFacts

The European Exposure Factors (ExpoFacts⁷) Sourcebook is a collection of statistics and references and is primarily aimed at being a tool for environmental exposure analysis and risk assessment, but it can also serve as a data source for administration, NGO's and anyone interested in European statistics.

The ExpoFacts Sourcebook contains data from 31 European countries. In addition to the population time use patterns and exposure route information, e.g., dietary statistics, the database contains socio-demographic and physiologic information to enable database use as a tool for population-wide exposure modelling and risk assessment.

As the ExpoFacts database has compiled the existing data, but created no new data, this database has not been used as a primary source for exposure factors in this report.

7. https://joint-research-centre.ec.europa.eu/expofacts-european-exposure-factors-sourcebook_en

1.1.6 ECETOC Sourcebook

ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) has published a report with European exposure factors titled *"Exposure Factors Sourcebook for European Populations, with Focus on UK Data"* (ECETOC, 2001). This document was the first broader compilation of European exposure factors and contained methodological information. The ECETOC sourcebook updated and built upon other collections of exposure factor data, including the 1994 *American Industrial Health Council's Exposure Factors Sourcebook* (AIHC) and the US-EPA *Exposure Factors Handbook* (US-EPA, 1997); the AIHC no longer exists.

The information in the ECETOC sourcebook includes physiological parameters (body weight, body surface areas, life expectancy), time-activity patterns (work hours, indoor/outdoor time, etc.), and receptor contact rates (soil ingestion rates, food consumption rates, etc.).

The ECETOC sourcebook has not been updated since the publication in 2001. Therefore, the information from the sourcebook is in this updated report only reflected in the text, but generally not addressed in the Conclusions and Recommendations Sections.

1.1.7 Other sources

In addition to the above-mentioned sources of exposure factors, there are a number of other sources. These sources will not be described here but will appear in the following chapters when appropriate.

1.2 The United States

The US-EPA Exposure Factors Handbook has been prepared to provide information and recommendations on various factors used in assessing exposure to both adults and children. The handbook provides non-chemical-specific data on a number of physiological and behavioural exposure factors such as e.g., body weight, dermal factors, lifetime, activity factors, inhalation rates, ingestion of water, food items, soil/dust and consumer products.

The Exposure Factors Handbook was first published in 1989, updated in 1997 (US-EPA, 1997), and then in 2011 (US-EPA, 2011). Recognising that exposures among infants, toddlers, adolescents, and teenagers can vary significantly, the US-EPA published the Child-Specific Exposure Factors Handbook in 2002 and an update version in 2008. The 2011 version of the Exposure Factors Handbook incorporates data from the 2008 version of the Child-Specific Exposure Factors Handbook and thus, supersedes the Child-Specific Exposure Factors Handbook published in 2008. Since October 2017, US-EPA has begun to release chapter updates individually in order to allow risk assessors to get the latest information as new data becomes available. To make it easier to find these chapter updates, the chapter date column has been added to Table 1 located at the US-EPA Exposure Factors Handbook website⁸.

8. <https://www.epa.gov/expobox/about-exposure-factors-handbook>

For children, the US-EPA standardized childhood age groups presented in the *Guidance for Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (US-EPA, 2005) are recommended for use in exposure assessments: Birth to <1 month, 1 to <3 months, 3 to <6 months, 6 to <12 months, 1 to <2 years, 2 to <3 years, 3 to <6 years, 6 to <11 years, 11 to <16 years, 16 to <21 years.

Adult data (i.e., for individuals >21 years old), on the other hand, are presented using the age groups defined by the authors of the individual studies.

The US-EPA Consolidated Human Activity Database (CHAD) (US-EPA, 2022) contains data on human behaviour from 22 separate exposure and time-use studies. The data include demographic information, including age, sex, employment, and education level, which allows researchers to examine specific groups within the general population and how their unique behaviour patterns influence their exposures to chemicals.

The data presented in the Exposure Factors Handbook have been compiled from various sources, including government reports and information presented in peer-reviewed scientific literature. The studies presented in the Exposure Factors Handbook were chosen because they were considered by the US-EPA as being useful and appropriate for recommending exposure factors.

When evaluating the scientific and technical information, the US-EPA has applied five so-called 'general assessment factors' (GAFs):

1. Soundness (adequacy of the study approach used and minimal or defined bias in the study design),
2. Applicability and utility (focus on the exposure factor of interest, representativeness of the population, currency of the information, and adequacy of the data collection period),
3. Clarity and completeness (accessibility, reproducibility, and quality assurance),
4. Variability and uncertainty (variability in the population and uncertainty in the results),
5. Evaluation and review (level of peer review and number and agreement of studies).

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.

The studies included in the Exposure Factors Handbook were designated as 'key studies' or 'relevant studies'. Key studies were generally defined as the most useful for deriving recommendations for exposure factors. The recommended values for most exposure factors in the Exposure Factors Handbook are based on the results of such key studies.

The US-EPA has assigned a confidence rating of low, medium, or high to each recommended value in each chapter (US-EPA, 2011). It has been underscored that this qualitative rating was not intended to represent uncertainty analyses but rather to represent the US-EPA's judgment on the quality of the underlying data used to derive the recommendations. The judgment was made using the GAFs. It is noted that there is a continuum from low to high and that judgment was used to assign a rating to each factor. The recommendations given in the Exposure Factors

Handbook are accompanied by a discussion of the rationale for their rating.

In the providing of recommendations for the various exposure factors, the US-EPA has made an attempt to present percentile values that are consistent with the exposure estimators defined in *Guidelines for Exposure Assessment* (US-EPA, 1992), i.e., mean and upper percentile (US-EPA, 2011). It is noted that this was, however, not always possible, because the available data were limited for some exposure factors, or the authors of the study did not provide such information. In the Exposure Factors Handbook (US-EPA, 2011), the term "upper percentile" is intended to represent values in the upper tail, i.e., between 90th and 99.9th percentile of the distribution of values for a particular exposure factor.

Finally, it is underscored that the recommendations provided in the Exposure Factors Handbook (US-EPA, 2011) should be interpreted as suggestions that exposure/risk assessors can consider and modify as needed based on their own evaluation of a given risk-assessment situation.

1.3 WHO

The WHO/IPCS has undertaken a project to harmonize approaches to the assessment of risk from exposure to chemicals through increased understanding. The project focuses on specific issues and attempts to achieve agreement on basic principles. Among the project's focus areas are exposure assessment and terminology for exposure assessment and risk assessment. The status for the activities of the harmonization project is published in a newsletter (WHO/IPCS, 2010).

Under this project, an *IPCS Harmonization Project Document on the Principles of Characterizing and Applying Human Exposure* (WHO/IPCS, 2005) and an *IPCS Harmonization Project Document on Characterizing and Communicating Uncertainty in Exposure Assessment* (WHO/IPCS, 2008) have been published. None of these documents contain specific recommendations on default values for human exposure factors.

The WHO recommendations on exposure factors included in this report stem mainly from data published by the International Commission on Radiological Protection (ICRP, 1974). These recommendations are to be found in reports which are produced in cooperation with the IPCS, namely the Environmental Health Criteria 170 and 210 (WHO/IPCS, 1994 and 1999 respectively). The reference 'ICRP, 1974' is to the ICRP Publication No. 23 "*Report of the Task Group on Reference Man*", which was adopted in October 1974 and published in April 1975.

The WHO/IPCS Environmental Health Criteria 214 (WHO/IPCS, 2000) addresses human exposure assessment in general and a section on exposure factors are included; however, no recommendations on specific values are provided in this document.

2. Body weight

The average daily dose is a dose that is typically normalized to the average body weight of the exposed population. If exposure occurs only during childhood years, the average child body weight during the exposure period should be used to estimate risk. Conversely, if adult exposures are being evaluated, an adult body weight value should be used. (US-EPA, 2011).

2.1. Europe

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012), a body weight of 60 and 70 kg is recommended for the general population and workers, respectively (p. 10). However, according to Table R.8–18 (p. 65) a body weight of 70 kg is recommended for consumers and man exposed indirectly via the environment and a body weight of 70 kg (men and women) is recommended for workers.

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.15: *Consumer exposure estimation* (ECHA, 2008), it is stated that default body weights of 70 kg for adult males and 60 kg for adult females may in principle be used. For further analyses, particularly for estimations of children's exposure, it is stated that more detailed compilations of body weights (including distributions) are available for Germany (AUH, 1995), The Netherlands (Bremmer et al., 2006; please note that this reference is to the ConsExpo General Fact Sheet RIVM, 2006a), as well as for the US (e.g., US-EPA, 1997), but no further recommendations are provided. In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default body weights are provided. Instead, there are references to the RIVM Fact Sheets, the JRC ExpoFacts site and the US-EPA *Exposure Factor Handbook*.

In the *RAC Opinion on an Annex XV dossier proposing restrictions on lead and lead compounds in jewellery* (RAC, 2011) and in the *RAC Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use* (RAC, 2013), a child body weight of 10 kg has been applied for the exposure estimations. There is no reference to the body weight and the age of the child has not been specified.

In the *RAC and Committee for Socio-economic Analysis (SEAC) Opinion on an Annex XV dossier proposing restrictions on Polycyclic-aromatic hydrocarbons (PAH)* (RAC, 2019), a body weight of 15.7 kg for a four-year-old child was estimated based on the 25th percentile of the body weight distributions among children aged between 3 and 6. The reference to the estimation is 'RIVM, 2014'; however, the RIVM (2014) reference could not be located in the opinion.

In the *RAC Opinion on an Annex XV dossier proposing restrictions on bisphenol A* (RAC, 2015a), a body weight of 70 kg was applied for the exposure estimations (Table 10 p. 35, Table 11 p. 38, Annex 3 p. 68). At all three places, there is a reference

to 'EFSA (2011) default assumption for adults'; however, the EFSA (2011) reference could not be located in the opinion.

In the RAC *Opinion on an Annex XV dossier proposing restrictions on methanol* (RAC, 2015b), a body weight of 60 kg was applied for the exposure estimations. There is a reference to ECHA Guidance, but not to a specific ECHA Guidance.

RIVM has in their *General Fact Sheet* (RIVM, 2014), calculated default values on body weight for adults, and children of various age groups, presented in Section 4, *Anthropometric parameters*. The default values for body weight have been selected as the 25th percentiles for the Dutch population (RIVM, 2014). The values are listed in Table 2.1.

According to the Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data (EFSA, 2012), a body weight of 70 kg should be used as default for the European adult population (age: above 18 years). It is underlined that this default value in some cases will lead to less conservative risk assessments compared to using 60 kg. However, a body weight of 70 kg is considered a more realistic estimate of the average body weight of the European population. Regarding dietary exposure assessment for children, a body weight of 12 kg should be used as default for European toddlers (age: 1–3 years) and a body weight of 5 kg for European infants (age: 0–12 months). The EFSA Comprehensive Database, which was built from existing national information on food consumption at a detailed level also contains detailed information on body weight and the recommended default values for adults and children were based on all surveys in the EFSA Comprehensive Database (EFSA, 2011). Default values for other specific population subgroups, e.g., pregnant women have not been recommended. Instead, it is noted that the EFSA Comprehensive Database may be used to extract specific values.

In the Guidance on the assessment of exposure of operators, workers, residents and bystanders (EFSA, 2022), a default body weight value of 60 kg is proposed for adults including adolescents from 14 years and up and is considered to be protective for the non-dietary risk assessment of all adults, including females and teenagers from 14 to 18 years, exposed from professional use of plant protection products. For infants, children, and adolescents up to 14 years old a default body weight of 10 kg (toddlers 1–3 years) is proposed as representing a worst-case scenario for the risk assessment for children up to 14 years old exposed as residents and bystanders. The default values have been based on the opinion of the EFSA Panel on Plant

Protection Products and their Residue (EFSA, 2010a) and updated reflecting more recent data from US-EPA Exposure Factors Handbook (US-EPA, 2011). No default body weight has been proposed for children less than a year old as this age group is not expected to be exposed through entry into treated fields. Exposure of this age group may occur via hand-to-mouth transfer by playing on lawns; however, the intensity of contact in terms of overall exposure is considered to be significantly higher for children > 1 year of age and therefore, these children are assumed to be the 'worst-case'.

According to the Report from the Commission on Dietary Food Additive Intake in the European Union, Commission of the European Communities (2001), the default value for young children (under three years), which is 15 kg of body weight and the default value for adults, which is 60 kg, should be used when reporting monitored

data. This report is the outcome of the SCOOP Task 4.2 on "Methodologies for monitoring of food additive intakes".

The Danish Environmental Protection Agency (D-EPA) has in their *Guidance from the Environmental Protection Agency No. 5* (D-EPA, 2006) recommended a default value of 13 kg for children aged one to three years, and a default value of 70 kg for adults (D-EPA, 2006).

The National Food Institute, Technical University of Denmark (DTU-FOOD), collected data on body weight in the latest dietary survey of individuals aged 4–75 years old. Data were collected between 2011 and 2013 (DTU-FOOD, 2015). Mean weights for smaller children (4–9 years), children/adolescents (10–17 years) and adults (18–75 years) was 26.0 kg, 54.2 kg and 78.3 kg, respectively. In a more recent survey (KOSS, 2014–2015 data), mean weights for infants/toddlers aged < 8 months, 8–10 months, 10–12 months, 1–2 years and 2–3 years were 8.4 kg, 9.3 kg, 9.8 kg, 11.7 kg and 13.7 kg, respectively.

Table 2.1 presents a summary of default values on body weights recommended by different European bodies.

Table 2.1: Default values on body weight recommended by various European bodies

Body weight (kg)	
EFSA (non-dietary exposure)	
Toddlers (infants, children and adolescents (up to 14 years)	10
Adults and adolescents (14–18 years)	60
EFSA (general default)	
Infant (0–12 months)	5
Toddlers (1–3 years)	12
Adults (>18 years)	70
Commission of the European Communities (SCOOP data)	
0–<3 years	15
Adults	60
ECHA	
Adults	70 (both sexes combined), 70 (men) / 60 (women)
RIVM	
0–1 months	2.4
1–3 months	4.5
3–6 months	6.1
6–12 months	8.0
1–2 years	9.8

2–3 year	12.4
2–6 years	14.3
3–6 years	15.7
6–11 years	24.3
11–16 years	44.8
16–18 years	59.3
Men	77.2
Women	64.1
Adults	68.8
Men (for probabilistic calculations)	84.9
Women (for probabilistic calculations)	70.6
Adults (for probabilistic calculations)	77.4

Sources: EFSA (2022), EFSA (2012), Commission of the European Communities (2001), ECHA (2012, 2008) and RIVM (2014)

According to the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), the recommended mean body weight for English adults aged 16 and older is 73.2 kg. In Table 2.2, age and gender specific distributions of English adults are presented from data based on anthropometric measures.

Table 2.2: Recommended values for adult body weight - as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Age (years)	Men			Women		
	Mean (kg)	5 th (kg)	95 th (kg)	Mean (kg)	5 th (kg)	95 th (kg)
16–24	72.8	54.5	97.1	62.7	47.8	85.9
25–34	80.7	60.9	105.6	67.0	50.0	91.3
35–44	82.4	63.1	107.6	67.8	50.4	93.7
45–54	82.7	62.3	106.5	69.3	50.9	94.3
55–64	82.8	63.4	107.3	70.7	52.0	95.0
65–74	78.9	60.0	100.5	68.2	48.2	92.0
75+	74.1	56.6	94.1	63.4	44.4	83.3
≥16	80.0	60.1	104.2	67.3	49.3	91.7

Source: UK Office for National Statistics (1998); modified from ECETOC (2001)

Table 2.3 presents mean body weight for children aged 2–15 years in England from the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001). The data are derived from the 1995–1997 Health Surveys for

England. All data were measured during the survey and the recommended mean body weight is 33 kg. For children younger than 2 years, ECETOC refers to the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997).

Table 2.3: Recommended values for child body weight - as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Age (years)	Males			Females		
	Mean (kg)	5 th (kg)	95 th (kg)	Mean (kg)	5 th (kg)	95 th (kg)
2	14.2	11.6	17.5	13.7	11.2	16.7
3	16.4	13.4	20.2	16.0	12.8	20.2
4	18.4	15.0	22.5	18.3	14.7	23.4
5	20.4	16.3	25.5	20.4	16.2	25.5
6	22.9	18.0	29.1	22.8	17.7	30.2
7	25.8	20.5	33.7	25.9	19.8	37.9
8	29.1	22.7	39.4	28.8	21.7	41.0
9	32.0	24.0	43.9	32.7	24.2	45.7
10	35.6	26.7	51.8	37.1	27.8	52.9
11	40.2	29.3	55.2	42.4	28.9	62.3
12	44.8	31.0	63.1	47.5	34.4	66.0
13	50.8	35.0	71.6	51.8	38.9	70.6
14	56.4	39.0	79.7	56.7	41.3	80.3
15	62.9	47.1	85.6	58.4	43.6	79.2
2–15	32.9	14.3	64.6	32.8	13.8	62.6

Source: UK Office for National Statistics (1999), modified from ECETOC (2001)

2.2. US-EPA

In the *Exposure Factors Handbook* Chapter 8 (US-EPA, 2011), one 'key study', a US-EPA analysis of NHANES 1999–2006 data, is the basis for the recommended values for body weight, see Table 2.4. The data were collected through direct measurements during a physical examination. The mean body weight for all adults combined is 80 kg. The US-EPA has noted that this mean recommended value is different from the 70 kg commonly assumed in the US-EPA risk assessments. The US-EPA therefore encouraged assessors to use the values which most accurately reflect the exposed population. When using values other than 70 kg, however, the assessors should consider if the dose estimate will be used to estimate risk by combining it with a dose-response relationship which was derived assuming a body weight of 70 kg. If such an inconsistency exists, the assessor should adjust the dose-response relationship (EFSA, 2011).

The values presented in Table 2.4 are well validated as the general assessment

factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – high, 3. clarity and completeness – high, 4. variability and uncertainty – high, and 5. evaluation and review – medium; the overall rating was high. (US-EPA, 2011).

In addition to the key study, 11 “relevant studies” for the general population were identified and presented in the *Exposure Factors Handbook* (US-EPA, 2011); however, most of them are old and were therefore not considered as representative for the US population of today due to the steep increase in body weight.

Table 2.4: Recommended values for body weight* - as presented in the Exposure Factors Handbook

Age group	Mean (kg)	5 th Percentiles	95 th Percentiles
0–<1 month	4.8	3.6	6.2
1–<3 months	5.6	4.5	7.3
3–<6 months	7.4	5.7	9.1
6–<11 months	9.2	7.1	11.3
1–<2 years	11.4	8.9	14.0
2–<3 years	13.8	10.9	17.1
3–<6 years	18.6	13.5	26.2
6–<11 years	31.8	19.7	52.5
11–<16 years	56.8	34.0	88.8
16–<21 years	71.6	48.2	108.0
Adults	80.0	-	-

* Males and Females Combined.

Source: US-EPA analysis of NHANES, 1999–2006 data, modified from US-EPA (2011).

2.3. WHO

WHO standard values for body weight are those recommended by the ICRP (ICRP, 1974, cited in WHO/IPCS, 1994 and 1999). These values are presented in Table 2.5. It should be noted that WHO uses 60 kg for calculation of acceptable daily intakes and water quality guidelines.

Table 2.5: WHO's standard values for body weight

Sex	Body weight (kg)
Men (adults)	70
Women (adults)	58
Men and women combined	64 ^a

a) WHO uses 60 kg for calculation of acceptable daily intakes and water quality guidelines.

Source: Modified from WHO/IPCS (1994, 1999)

2.4 Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) are the most comprehensive. The European data are more limited as are the WHO data.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended values in Table R.8–18 (p. 65) are stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommendations are taken from one of these references or both.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 (ECHA, 2008), no references for the recommended values are provided. In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default body weights are provided.

In the few RAC opinions on Annex XV dossier restriction proposals, either no reference for the applied body weights are provided or the references could not be located in the opinions.

The RIVM *General Fact Sheet* (RIVM, 2014) recommended values have been selected as the 25th percentiles for the Dutch population.

The EFSA *Default Guidance Document* (EFSA, 2012) recommended values are based on all surveys in the *EFSA Comprehensive Database*.

The EFSA *Guidance Document for Plant Protection Products* (EFSA, 2022) recommended values are based on the previous version (EFSA, 2010a) and updated reflecting more recent data from the US-EPA *Exposure Factors Handbook* (US-EPA, 2011).

The DTU-FOOD (DTU-FOOD, 2015; KOSS, 2014–2015 data) mean body weights are based on surveys for the Danish population.

The US-EPA recommended values for body weights presented in Table 2.4 are well validated and valid as the US-EPA overall confidence rating was high (US-EPA, 2011).

WHO standard values for body weight are those recommended by the ICRP (ICRP, 1974).

It should be noted that the references 'ICRP, 1974', 'ICRP, 1975' and 'ICRP, 1992' are to the same ICRP report (ICRP Report No. 23).

The RIVM default values are based on more recent data than the NHANES data

used by EU-EPA. However, the RIVM default values represent data from the 25th percentile and not the mean values. For adults, the currently most used default body weight for men and women combined is 70 kg. This value is somewhat lower than the mean body weight for both sexes in Denmark (78.3 kg) and in The Netherlands (mean body weight of 77.4 kg) and also in the US where the average adult body weight is 80 kg. However, the RIVM default adult body weight based on the 25th percentile is 68.8 kg and thus, fairly close to the currently most used default value of 70 kg for men and women combined.

In conclusion, the EFSA *Default Guidance Document* (EFSA, 2012) recommended values of 5 kg for European infants (age: 0–12 months), of 12 kg for European toddlers (age: 1–3 years) and of 70 kg for European adults (age: above 18 years) are considered as being the most valid values for body weight as of today for the European population as they are based on all surveys in the EFSA Comprehensive Database. These values are therefore recommended as default exposure factors for assessments of the European population in the context of REACH. For other specific population subgroups, e.g., men, women, pregnant women, specific child age groups, the EFSA Comprehensive Database may be used to extract specific default values.

The recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides, cosmetics, toys etc.

3. Body surface areas

Dermal exposure can occur during a variety of activities in different environmental media and microenvironments (US-EPA, 2011), including:

- Water (e.g., bathing, washing, swimming);
- Soil (e.g., outdoor recreation, gardening, construction);
- Sediment (e.g., wading, fishing);
- Liquids (e.g., use of commercial products);
- Vapours/fumes/gases (e.g., use of commercial products);
- Other solids or residues (e.g., soil/dust or chemical residues on carpets, floors, counter tops, outdoor surfaces, or clothing).

Dermal exposure can also occur via contact with articles and materials.

Surface area of the skin can be determined using measurement or estimation techniques. Coating, triangulation, and surface integration are direct measurement techniques that have been used to measure total body surface area and the surface area of specific body parts. The coating method consists of coating either the whole body or specific body regions with a substance of known density and thickness. Triangulation consists of marking the area of the body into geometric figures, then calculating the figure areas from their linear dimensions. Surface integration is performed by using a planimeter and adding the areas. (US-EPA, 2011).

3.1. Europe

The recommendations provided in the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.15: *Consumer exposure estimation* (ECHA, 2008) on body surface areas, taken from the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997), are presented in Table 3.1. In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default body surface areas are provided. Instead, there are references to the RIVM Fact Sheets, the JRC ExpoFacts site and the US-EPA *Exposure Factor Handbook*.

In the RAC *Opinion on an Annex XV dossier proposing restrictions on bisphenol A* (RAC, 2015a), the surface in contact with the till receipt was assumed to be 12 cm², i.e., the cumulated surface area of the pads of the ten fingertips. There is no reference to this surface area.

Table 3.1: ECHA's recommended standard values for body surface areas – as presented in the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15

Body Part	Men (mean, cm ²)	Women (mean, cm ²)
Head (face)	1,180	1,028
Trunk	5,690	4,957
Upper extremities	3,190	2,779
Arms	2,280	1,984
Upper arms	1,430	1,244
Forearms	1,140	992
Hands (fronts and backs)	840	731
Lower extremities	6,360	5,533
Legs	5,060	4,402
Thighs	1,980	1,723
Lower legs	2,070	1,801
Feet	1,120	1,001
Total	19,400	16,900

Source: Exposure Factors Handbook, US-EPA (1997), modified from ECHA (2008)

RIVM has in their *General Fact Sheet* (RIVM, 2014) calculated default values for body surface areas for adults, and children of various age groups, presented in Section 4, *Anthropometric parameters*. The default values for body surface areas have been selected as the 25th percentiles for the Dutch population (RIVM, 2014). The default values for adults are listed in Table 3.2 and for children in Table 3.3.

Table 3.2: Deterministic default values of the surface area and surface areas of different parts of the body based on 25th percentiles – as presented by RIVM

Surface Area	Men		Women		Adults ^a	
	m ²	Percent	m ²	Percent	m ²	Percent ^b
Head	0.13	6.8	0.12	6.7	0.12	6.75
Trunk	0.75	38.3	0.60	34.4	0.66	36.35
Arms	0.30	15	0.24	13.7	0.26	14.35
Hands	0.10	5.2	0.08	4.9	0.09	5.05
Legs	0.65	32.8	0.56	32.1	0.59	32.45
Feet	0.13	6.7	0.12	6.8	0.12	6.75
Total	1.97		1.73		1.82	

a) Men and women combined

b) For percentage of adults, the average of men and women is assumed

Source: Modified from RIVM (2014)

Table 3.3: Deterministic default values of the body surface area of children of different ages based on 25th percentiles – as presented by RIVM

Age	Head ^a	Trunk	Arms ^b	Hands	Legs	Feet
Percent of total surface area (%)						
Children						
0–1 m ^c	18.2	35.7	13.7	5.3	20.6	6.5
1–3 m	18.2	35.7	13.7	5.3	20.3	6.5
3–6 m	18.2	35.7	13.7	5.3	20.3	6.5
6–12 m	18.2	35.7	13.7	5.3	20.3	6.5
1–2 yrs.	16.5	35.5	13.0	5.7	23.1	6.3
2–3 yrs.	12.3	37.2	14.4	4.7	25.3	6.3
2–6 yrs.	12.3	37.2	14.4	4.7	25.3	6.3
3–6 yrs.	12.0	37.3	14.2	4.8	25.5	6.3
6–11 yrs.	10.2	36.9	14.0	4.9	27.5	6.7
11–16 yrs.	7.4	36.9	14.1	4.6	30.1	6.8
16–18 yrs.	6.2	38.6	14.7	4.5	29.9	6.4

Age	Total	Head ^a	Trunk	Arms ^b	Hands	Legs	Feet
Surface area (m ²)							
Children							
0–1 m ^c	0.20	0.036	0.071	0.027	0.011	0.040	0.013
1–3 m	0.28	0.051	0.100	0.038	0.015	0.058	0.018
3–6 m	0.34	0.062	0.121	0.047	0.018	0.070	0.022
6–12 m	0.41	0.075	0.146	0.056	0.022	0.084	0.027
1–2 yrs.	0.47	0.078	0.167	0.061	0.027	0.109	0.030
2–3 yrs.	0.57	0.070	0.212	0.082	0.027	0.144	0.036
2–6 yrs.	0.63	0.077	0.234	0.090	0.029	0.159	0.039
3–6 yrs.	0.69	0.082	0.257	0.098	0.033	0.176	0.044
6–11 yrs.	0.93	0.094	0.343	0.130	0.046	0.256	0.062
11–16 yrs.	1.40	0.105	0.517	0.198	0.064	0.421	0.095
16–18 yrs.	1.68	0.104	0.648	0.246	0.075	0.501	0.108

a) Incl. neck

b) Excl. hands

c) Month / months

Source: Modified from RIVM (2014)

In the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA, 2022), default surface areas for body parts are reported and presented in Table 3.4. The default values are from a document published by ECHA (ECHA, 2017).

Table 3.4: Default values for surface area of various parts of the body irrespective of gender

	Infant ^a	Toddler ^b	Child ^c	Adult ^d
Body part surface areas (cm ²)				
Hands (palms and backs of both hands)	196.8	230.4	427.8	820
Arms (both)	Upper = 352.6 Lower = 229.6 Total = 582.2	Upper = 412.8 Lower = 268.8 Total = 681.6	Upper = 772.8 Lower = 496.8 Total = 1269.6	Upper = 1141.2 Lower = 1128.8 Total = 2270
Head	344.4	403.2	531.3	1,110
Trunk (bosom, neck, shoulders, abdomen, back, genitals and buttocks)	1689.2	1977.6	3624.8	5940
Legs (both legs and thighs)	1041.4	1219.2	2741.6	5330
Feet (both)	246	288	604.9	1130
Total body surface area	4100	4800	9200	16600

a) based on female 6–< 12 months old

b) based on female 1–< 2 years old

c) based on female 6–< 12 years old

d) based on female 30–< 40 years old.

Source: EFSA (2022)

According to the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), skin surface area can be calculated using the US-EPA bivariate equation for populations in which both body weight and height are known:

US-EPA bivariate equation:

$SA = a H^b W^c$, where

SA= Surface Area (m²)

H = Height (cm)

W= Weight (kg)

a, b and c are constants (a = 0.0239, b = 0.417 and c = 0.517)

Source: US-EPA (1989), based on data from Murray & Burmaster (1992)

Alternatively, when only body weight data are available, skin surface area can be calculated using either the equation of Costeff or Burmaster:

Costeff Equation:

$SA = (4W + 7)/(W+90)$, where

SA = Surface Area (m²)

W = Weight (kg)

Source: Costeff (1966) in US-EPA (1997), based upon 220 observations of children

Burmasters Equation:

$SA = a * BW^c$ or $\ln SA = \ln a + c \ln BW$, where

SA = Skin Surface Area

BW = Body Weight, and:

$\ln a = -2.2781$, $c = 0.6821$ for all 401 people

$\ln a = -2.2752$, $c = 0.6868$ for males

$\ln a = -2.2678$, $c = 0.6754$ for females

Source: Burmaster (1998), based upon 401 observations of adults and children

According to ECETOC (ECETOC, 2001), the equation of Burmaster may give a better estimate of central values than that of Costeff, but overestimates skin surface area at upper values. Based upon mean English adult body weight and the equation of Burmaster, total skin surface area is estimated as 2.07 m² for males and 1.76 m² for females, with an average of 1.92 m² (ECETOC, 2001). Furthermore, ECETOC refers to the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997) for the use of body surface area standard values, see Table 3.1.

3.2. US-EPA

In the *Exposure Factors Handbook* Chapter 7 (US-EPA, 2011), three 'key studies' and five 'relevant studies' were identified. The recommendations for total body surface area are based on the most recent key study, which is a US-EPA analysis of weight and height 1999–2006 data from the National Health and Nutrition Examination Survey (NHANES) for children under age 21 years and are presented for the standard age groupings recommended by US-EPA (US-EPA, 2005) for male and female children combined. For adults 21 years and over, the recommendations for total body surface area are based on a US-EPA analysis of NHANES 2005–2006 data. Recommended values for total body surface area are presented in Table 3.5. The recommendations for the percentage of total body surface area represented by individual body parts are presented in Table 3.6.

The values presented in Table 3.5 and 3.6 are well validated as the general

assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – medium, 2. applicability and utility – medium, 3. clarity and completeness – medium, 4. variability and uncertainty – medium, and 5. evaluation and review – medium; the overall rating was medium for 'total surface area' and low for 'surface area of individual body parts' (US-EPA, 2011).

Table 3.5: Recommended values for total body surface area for children (genders combined) and adults by gender – as presented in the Exposure Factors Handbook

Age (group)	Mean (m ²)	95 th Percentile (m ²)
Children		
0–1 month	0.29	0.34
1–<3 months	0.33	0.38
3–<6 months	0.38	0.44
6–<12 months	0.45	0.51
1–<2 years	0.53	0.61
2–<3 years	0.61	0.70
3–<6 years	0.76	0.95
6–<11 years	1.08	1.48
11–<16 years	1.59	2.06
16–<21 years	1.84	2.33
Adult Men		
21–<30 years	2.05	2.52
30–<40 years	2.10	2.50
40–<50 years	2.15	2.56
50–<60 years	2.11	2.55
60–<70 years	2.08	2.46
70–<80 years	2.05	2.45
≥80 years	1.92	2.22
Adult Women		
21–<30 years	1.81	2.25
30–<40 years	1.85	2.31
40–<50 years	1.88	2.36
50–<60 years	1.89	2.38
60–<70 years	1.88	2.34
70–<80 years	1.77	2.13
≥80 years	1.69	1.98

Source: US-EPA analysis of NHANES 1999–2006 data, modified from US-EPA (2011)

Table 3.6: Recommended values of surface area of body parts for children (genders combined) and adults by gender - as presented in the Exposure Factors Handbook

Age	Head		Trunk		Arms		Hands		Legs		Feet	
Mean Percent of Total Surface Area (%) ^a												
Children												
0–1 m ^b	18.2		35.7		13.7		5.3		20.6		6.5	
1–<3 m	18.2		35.7		13.7		5.3		20.6		6.5	
3–<6 m	18.2		35.7		13.7		5.3		20.6		6.5	
6–<12 m	18.2		35.7		13.7		5.3		20.6		6.5	
1–<2 y ^c	16.5		35.5		13.0		5.7		23.1		6.3	
2–<3 y	8.4		41.0		14.4		4.7		25.3		6.3	
3–<6 y	8.0		41.2		14.0		4.9		25.7		6.4	
6–<11 y	6.1		39.6		14.0		4.7		28.8		6.8	
11–<16 y	4.6		39.6		14.3		4.5		30.4		6.6	
16–<21 y	4.1		41.2		14.6		4.5		29.5		6.1	
Adult Men												
≥21 y	6.6		40.1		15.2		5.2		33.1		6.7	
Adult Women												
≥21 y	6.2		35.4		12.8		4.8		32.3		6.6	

Age	Head		Trunk		Arms		Hands		Legs		Feet	
	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th
Surface Area (m ²) ^a												
Children												
0–1 m ^b	0.053	0.062	0.104	0.121	0.040	0.047	0.015	0.018	0.060	0.070	0.019	0.022
1–<3 m	0.060	0.069	0.118	0.136	0.045	0.052	0.017	0.020	0.068	0.078	0.021	0.025
3–<6 m	0.069	0.080	0.136	0.157	0.052	0.060	0.020	0.023	0.078	0.091	0.025	0.029
6–<12 m	0.082	0.093	0.161	0.182	0.062	0.070	0.024	0.027	0.093	0.105	0.029	0.033
1–<2 y ^c	0.087	0.101	0.188	0.217	0.069	0.079	0.030	0.035	0.122	0.141	0.033	0.038
2–<3 y	0.051	0.059	0.250	0.287	0.088	0.101	0.028	0.033	0.154	0.177	0.038	0.044
3–<6 y	0.061	0.076	0.313	0.391	0.106	0.133	0.037	0.046	0.195	0.244	0.049	0.061
6–<11 y	0.066	0.090	0.428	0.586	0.151	0.207	0.051	0.070	0.311	0.426	0.073	0.100
11–<16 y	0.073	0.095	0.630	0.816	0.227	0.295	0.072	0.093	0.483	0.626	0.105	0.136
16–<21 y	0.075	0.096	0.759	0.960	0.269	0.340	0.083	0.105	0.543	0.687	0.112	0.142
Adult Men												
≥21 y	0.136	0.154	0.827	1.100	0.314	0.399	0.107	0.131	0.682	0.847	0.137	0.161
Adult Women												
≥21 y	0.114	0.121	0.654	0.850	0.237	0.266	0.089	0.106	0.598	0.764	0.122	0.146

a) Please consult Table 7.2 in the Exposure Factors Handbook, chapter 7 for more detailed description of the categorization of body parts (US-EPA, 2011)

b) Month / months

c) Year / years Note: Surface area values reported in m² can be converted to cm² by multiplying by 10,000 cm²/m².

Mean Percent of Total Surface Area: Birth to < 2 years old – US-EPA (1985), 2 years old to < 21 years old – Boniol et al. (2008) (average of data for males and females, ≥ 21 years old – US-EPA analysis of NHANES 2005–2006 data and US-EPA (1985).

Mean Surface Area by Body Part: Birth to < 2 years old – US-EPA analysis of NHANES 1999–2006 data and US-EPA (1985), 2 years old to < 21 years old – US-EPA analysis of NHANES 1999–2006 data and Boniol et al. (2008), ≥ 21 years old – US-EPA analysis of NHANES 2005–2006 data and US-EPA (1985).

Source: Modified from US-EPA (2011)

3.3. WHO

No recommendations on body surface area are provided by WHO.

3.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) as well as the European data are comprehensive. No recommendations have been provided by the WHO.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 (ECHA, 2008), the recommended values presented in Table 3.1 are taken from the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997). In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default body surface areas are provided.

In the RAC Opinion on an Annex XV dossier proposing restrictions on bisphenol A, there is no reference for the surface area of finger pads.

The RIVM *General Fact Sheet* (RIVM, 2014) recommended values have been selected as the 25th percentiles for the Dutch population.

The EFSA *Guidance Document for Plant Protection Products* (EFSA, 2022) recommended values are from a document published by ECHA (ECHA, 2017).

The US-EPA recommended values for body surfaces presented in Table 3.5 and 3.6 are well validated as the US-EPA overall confidence rating was medium for 'total surface area' and low for 'surface area of individual body parts' (US-EPA, 2011).

No recommendations on body surface area are provided by WHO.

The RIVM default values for adults and children are based on more recent data than the NHANES data used by US-EPA. In relation to the data used by US-EPA for their recommended default values, RIVM (2014) stated: "*Using these two studies [US-EPA, 1985; Boniol et al., 2008] results in discrepancies between the absolute skin surface area of the heads of children and young adults, e.g. an unrealistic drop in the mean skin surface area of children in the age group 1 to <2 years old (from US-EPA 1997) and 2 to <3 years old (adapted from Boniol et al. 2008)*", which is obvious from the mean percentages of total surface area (%) listed in Table 3.6. RIVM (2014) noted that the data from Boniol et al. (2008) were preferred by the US-EPA because they are based on a large measurement dataset and updated methodology. The US-EPA default values represent data for the mean and 95th percentile whereas the RIVM default values represent data from the 25th percentile.

In conclusion, the RIVM recommended default values presented in Table 3.2 and 3.3 are considered as being the most valid values for body surface areas as of today for the European population and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

The recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides, cosmetics, toys etc.

4. Inhalation rates

Outdoor (ambient) and indoor air are potential sources of exposure to toxic substances. Adults and children can be exposed to contaminated air during a variety of activities in different environments. They may be exposed to contaminants in ambient air, and may also inhale chemicals from the indoor use of various sources (e.g., stoves, heaters, fireplaces, and consumer products) as well as from those that infiltrate from ambient air (US-EPA, 2011).

Due to their size, physiology, and activity level, the inhalation rates of children differ from those of adults. Infants and children have a higher resting metabolic rate and oxygen consumption rate per unit of body weight than adults, because of their rapid growth and relatively larger lung surface area per unit of body weight. Thus, while greater amounts of air and pollutants are inhaled by adults than children over similar time periods on an absolute basis, the volume of air passing through the lungs of a resting infant is up to twice that of a resting adult on a body weight basis. (US-EPA, 2011).

4.1. Europe

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012), an inhalation volume of 20 m³/day is recommended for exposure assessments of consumers and man exposed indirectly via the environment, and of 10 m³/8 hours light work for exposure assessments of workers (Table R.8–18). Furthermore, there are a number of default physiological parameters under the allometric scaling principle (Table R.8–2).

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.15: *Consumer exposure estimation* (ECHA, 2008), there are several recommended default values for respiratory volumes under various conditions. In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default respiratory volumes are provided. Instead, there are references to the RIVM Fact Sheets, the JRC ExpoFacts site and the US-EPA *Exposure Factor Handbook*.

The default values provided in the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012) Table R.8–2 and in the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.15: *Consumer exposure estimation* (ECHA, 2008) Tables R.15–14 to R.15–16 on respiratory volumes are presented in Table 4.1.

Table 4.1: ECHA's recommended standard values for respiratory volume – as presented in the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 and R.15

Body Weight ^{a, b}	70 kg
Respiratory volume ^b	0.2 liter/minute/kg bw
For relevant duration ^b	
6 hour exposure	5 m ³ /person
8 hour exposure	6.7 m ³ /person
24 hour exposure	20 m ³ /person
Respiratory volume light activity for worker ^{a, b}	
8 hour exposure	10 m ³ /person
Respiratory volume related to activity level ^c	
Men: 20–30 years; women: 20–33 years	
Resting	
Men	6.5–10.8 m ³ /day
Women	6.5–8.6 m ³ /day
Pregnant women	14 m ³ /day
Light activity	
Men	29–42 m ³ /day
Women	23–27 m ³ /day
Medium activity	
Men	62 m ³ /day
Women	36 m ³ /day
Heavy activity	
Men	160 m ³ /day
Women	130 m ³ /day
Respiratory volume for short-term exposure ^c	
Resting	
Children	
<1 year	1.4 m ³ /day
1–3 years	2.9 m ³ /day
4–6 years	5.8 m ³ /day
7–9 years	8.6 m ³ /day
10–14 years	12 m ³ /day
Adolescents	
15–19 years	13 m ³ /day
Adults	

20–75 years	13 m ³ /day
Light activity	
Children	
<1 year	2.9 m ³ /day
1–3 years	5.8 m ³ /day
4–6 years	12 m ³ /day
7–9 years	12 m ³ /day
10–14 years	23 m ³ /day
Adolescents	
15–19 years	26 m ³ /day
Adults	
20–75 years	26 m ³ /day
Medium activity	
Children	
<1 year	5.8 m ³ /day
1–3 years	12 m ³ /day
4–6 years	23 m ³ /day
7–9 years	35 m ³ /day
10–14 years	46 m ³ /day
Adolescents	
15–19 years	51 m ³ /day
Adults	
20–75 years	51 m ³ /day
Heavy activity	
Children	
<1 year	10 m ³ /day
1–3 years	20 m ³ /day
4–6 years	40 m ³ /day
7–9 years	61 m ³ /day
10–14 years	81 m ³ /day
Adolescents	
15–19 years	91 m ³ /day
Adults	
20–75 years	91 m ³ /day
Respiratory volume for a whole day exposure ^c	
Children	

<1 year	3 m ³ /day
1–3 years	7 m ³ /day
4–6 years	11 m ³ /day
7–9 years	14 m ³ /day
10–14 years	18 m ³ /day
Adolescents	
15–19 years	20 m ³ /day
Adults	
20–75 years	18 m ³ /day

Sources:

a) ECHA (2012), taken from Gold et al., (1984) and ICRP, (1975) – cited in ECHA, (2012)

b) ECHA (2012), no reference(s) provided for the default physiological parameters in Table R.8-2

c) ECHA (2008), taken from AUH, (1995) – cited in ECHA, (2008b)

RIVM has in their *General Fact Sheet* (RIVM, 2014) not provided default values for inhalation rates. Instead it is noted that when the default values for body weight are used, then ConsExpo calculations result in values for inhalation rate.

In the Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment of plant protection products (EFSA, 2022), the recommendations regarding inhalation rates are based upon data from the 2011 version of the US-EPA *Exposure Factors Handbook* (US-EPA, 2011). For operators and workers, the exposure by inhalation is estimated for a whole working day and therefore, an average inhalation rate of 1.25 m³/hour is used (with a reference to a document published by ECHA in 2017) and the daily exposure calculated by multiplying the inhalation rate/hour by the working hours per day. For resident exposure to vapours (longer term exposure), the daily inhalation rates recommended are presented in Table 4.2.

Table 4.2: Daily inhalation rates, for longer term exposures – as presented in EFSA (2022)

Age group (based on EFSA, 2012)	Inhalation rate		
	Mean daily inhalation rate (US-EPA, 2011)	Mean daily inhalation rate, adjusted for group body weight	Comment
<1 year			Selected worst-case scenario across the available ages up to 14-year-old children
1–<3 years	1–<2 years: 8.0 m ³ /day	1–<2 years: 0.8 m ³ /day/kg bw	
3–10 years	Not needed as toddler’s exposures are expected to be greater		
10–14 years			
14–18 years	16.0 m ³ /day ^a	0.27 m ³ /day/kg bw ^b	Selected worst-case scenario across the adult ages
Adults			

a) 31–< 41, 41–< 51 years

b) Adults (including adolescents ≥ 14 years old)

Source: US-EPA (2011), modified from EFSA (2022)

For bystanders, inhalation exposure could occur predominantly over a shorter period (i.e., typically less than 30 minutes in duration) and during which activity could be markedly more intense than the daily average (EFSA, 2022). Therefore, higher values are recommended for such situations, see Table 4.3. As for daily inhalation rate, the hourly inhalation rate of children aged 1 year to less than 3 years of 0.228 m³/hour per kg bw was selected to be the worst-case scenario across the available scenarios up to 14-year-old children and to be protective for other age groups.

Table 4.3: Hourly inhalation rates, for acute exposures – as presented in EFSA (2022)

Age group (based on EFSA, 2012)		Inhalation rate	
		High intensity short-term inhalation rate (US-EPA, 2011)	Hourly inhalation rate, adjusted for group body weight
<1 year			
1–<3 years		0.038 m ³ /minute ^a	0.228 m ³ /hour per kg bw ^b
3–10 years		Not needed as toddler's exposures are expected to be greater	
10–14 years			
14–18 years		0.053 m ³ /minute ^c	0.053 m ³ /hour per kg bw ^d
Adults			
Comment			
Worst-case scenario across the available scenarios up to 14-year-old children			
Selected worst-case scenario across the adult ages			

a) 1–<2 years

b) 1–<3 years

c) 51–61 years

d) Adults (including adolescents ≥ 14 years old)

Source: US-EPA (2011), modified from EFSA (2022)

In the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), the recommended long-term and short-term inhalation rates are taken from the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997). ECETOC has noted that these values are based upon US data, but are probably representative of Europeans as well, see Table 4.4 and 4.5.

Table 4.4: Values for long-term inhalation rates recommended by ECETOC – as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Population	Gender	Mean m ³ /day
Infants:		
< 1 year	-	4.5
Children:		
1–2 years	-	6.8
3–5 years	-	8.3
6–8 years	-	10.0
9–11 years	Female	13.0

9–11 years	Male	14.0
12–14 years	Female	12.0
12–14 years	Male	15.0
15–18 years	Female	12.0
15–18 years	Male	17.0
Adults:		
19–65 years	Female	11.3
19–65 years	Male	15.2

Source: US-EPA (1997), modified from ECETOC (2001)

Table 4.5: Values for short-term inhalation rates recommended by ECETOC - as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Population	Activity Level	Mean m ³ /hour
Adults:		
	Rest	0.4
	Sedentary	0.5
	Light	1.0
	Moderate	1.6
	Heavy	3.2
Children:		
	Rest	0.3
	Sedentary	0.4
	Light	1.0
	Moderate	1.2
	Heavy	1.9
Outdoor Workers:		
	Slow	1.1
	Moderate	1.5
	Heavy	2.5
	Hourly Average	1.3 (upper percentile of 3.3)

Source: US-EPA (1997), modified from ECETOC (2001)

The Danish Environmental Protection Agency (D-EPA) has in their *Guidance from the Environmental Protection Agency No. 5* (D-EPA, 2006) based their recommended inhalation rate upon data in the 1997 version of the US-EPA *Exposure Factors Handbook* (US-EPA, 1997). A default value 0.5 m³ air/kg body weight for children aged one to five is recommended (D-EPA, 2006).

4.2. US-EPA

In the *Exposure Factors Handbook* Chapter 6 (US-EPA, 2011), four 'key studies' and 14 'relevant studies' were identified. The recommended inhalation rates for adults and children are based on four key studies (2006-2009). The US-EPA has noted that these key studies represent an improvement upon those previously used for recommended inhalation rates in previous versions of the *Exposure Factors Handbook*, because they have used a large data set that is representative of the US as a whole and consider the correlation between body weight and inhalation rate (US-EPA, 2011). It was also noted that the selection of inhalation rates to be used for exposure assessments depends on the age of the exposed population and the specific activity levels of this population during various exposure scenarios (US-EPA, 2011).

The recommended long-term inhalation rates for adults and children (including infants) for use in various exposure scenarios are presented in Table 4.6. The values are averages of the inhalation rate data from the key studies for which data were available for the selected age groups. The US-EPA has defined long-term inhalation as "repeated exposure for more than 30 days, up to approximately 10% of the life span in humans (more than 30 days)" (US-EPA, 2011). The US-EPA has noted that all of the 95th percentile values represent unusually high inhalation rates for long-term exposures, even for the upper end of the distribution, but that they were included in the *Exposure Factors Handbook* to provide exposure assessors a sense of the possible range of inhalation rates for adults and children. Therefore, the US-EPA advises that these values should be used with caution when estimating long-term exposures.

Table 4.6: Recommended long-term exposure values for inhalation⁹ – as presented in the Exposure Factors Handbook

Inhalation rate – long-term exposure (more than 30 days)		
	Mean m ³ /day	95 th Percentile m ³ /day
Infants:		
Birth to 1 month	3.6	7.1
1–<3 months	3.5	5.8
3–<6 months	4.1	6.1
6–<12 months	5.4	8.0
Birth to <1 year	5.4	9.2
Children:		
1–<2 years	8.0	12.8
2–<3 years	8.9	13.7
3–<6 years	10.1	13.8
6–<11 years	12.0	16.6
11–<16 years	15.2	21.9
16–<21 years	16.3	24.6
Adults (>21 years):		
21–<31 years	15.7	21.3
31–<41 years	16.0	21.4
41–<51 years	16.0	21.2
51–<61 years	15.7	21.3
61–<71 years	14.2	18.1
71–<81 years	12.9	16.6
≥81 years	12.2	15.7

Source: Modified from US-EPA (2011)

Recommended short-term inhalation rates are presented in Table 4.7 for men and women combined, for adults and children for whom activity patterns are known. These values represent averages of the activity level data from one key study from which short-term inhalation rate data were available. The US-EPA has defined short-term exposure as "*repeated exposure for more than 24 hours, up to 30 days*" (US-EPA, 2011).

Each activity pattern was assigned a 'metabolic equivalents of work' (METs) value, i.e., an energy expenditure metric used by exercise physiologists and clinical nutritionists to represent activity levels. METs are based on statistical sampling of the distribution assigned by CHAD (the US-EPA's Consolidated Human Activity

9. Inhalation rate for males and females combined

Database) to each activity code. The inhalation rate for each activity within the 24-hour simulated activity pattern for each individual was estimated as a function of VO₂ (oxygen consumption rate), body weight, age, and gender. Following this, the average inhalation rate was calculated for each individual for the entire 24-hour period, as well as for four separate classes of activities based on METS value (US-EPA, 2011):

- Sedentary/passive, METS less than or equal to 1.5;
- Light intensity, METS greater than 1.5 and less than or equal to 3.0;
- Moderate intensity, METS greater than 3.0 and less than or equal to 6.0;
- High intensity, METS greater than 6.0.

Table 4.7: Recommended short-term exposure (less than 30 days) values for inhalation rates¹⁰ – as presented in the Exposure Factors Handbook

Age (years)	Sleep or nap		Sedentary/passive		Light intensity		Moderate intensity		High intensity	
	Mean m ³ /min	95 th m ³ /min	Mean m ³ /min	95 th m ³ /min	Mean m ³ /min	95 th m ³ /min	Mean m ³ /min	95 th m ³ /min	Mean m ³ /min	95 th m ³ /min
0–<1	3.0E-03	4.6E-03	3.1E-03	4.7E-03	7.6E-03	1.1E-02	1.4E-02	2.2E-02	2.6E-02	4.1E-02
1	4.5E-03	6.4E-03	4.7E-03	6.5E-03	1.2E-02	1.6E-02	2.1E-02	2.9E-02	3.8E-02	5.2E-02
2	4.6E-03	6.4E-03	4.8E-03	6.5E-03	1.2E-02	1.6E-02	2.1E-02	2.9E-02	3.9E-02	5.3E-02
3–<6	4.3E-03	5.8E-03	4.5E-03	5.8E-03	1.1E-02	1.4E-02	2.1E-02	2.7E-02	3.7E-02	4.8E-02
6–<11	4.5E-03	6.3E-03	4.8E-03	6.4E-03	1.1E-02	1.5E-02	2.2E-02	2.9E-02	4.2E-02	5.9E-02
11–<16	5.0E-03	7.4E-03	5.4E-03	7.5E-03	1.3E-02	1.7E-02	2.5E-02	3.4E-02	4.9E-02	7.0E-02
16–<21	4.9E-03	7.1E-03	5.3E-03	7.2E-03	1.2E-02	1.6E-02	2.6E-02	3.7E-02	4.9E-02	7.3E-02
21–<31	4.3E-03	6.5E-03	4.2E-03	6.5E-03	1.2E-02	1.6E-02	2.6E-02	3.8E-02	5.0E-02	7.6E-02
31–<41	4.6E-03	6.6E-03	4.3E-03	6.6E-03	1.2E-02	1.6E-02	2.7E-02	3.7E-02	4.9E-02	7.2E-02
41–<51	5.0E-03	7.1E-03	4.8E-03	7.0E-03	1.3E-02	1.6E-02	2.8E-02	3.9E-02	5.2E-02	7.6E-02
51–<61	5.2E-03	7.5E-03	5.0E-03	7.3E-03	1.3E-02	1.7E-02	2.9E-02	4.0E-02	5.3E-02	7.8E-02
61–<71	5.2E-03	7.2E-03	4.9E-03	7.3E-03	1.2E-02	1.6E-02	2.6E-02	3.4E-02	4.7E-02	6.6E-02
71–<81	5.3E-03	7.2E-03	5.0E-03	7.2E-03	1.2E-02	1.5E-02	2.5E-02	3.2E-02	4.7E-02	6.5E-02
≥81	5.2E-03	7.0E-03	4.9E-03	7.0E-03	1.2E-02	1.6E-02	2.5E-02	3.1E-02	4.8E-02	6.8E-02

Source: Modified from US-EPA (2011)

The US-EPA recommended values for inhalation rates presented in Table 4.6 and 4.7 for long-term and short-term exposure, respectively, are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – medium,

10. An individual's ventilation rate for the given activity category equals the weighted average of the individual's activity-specific ventilation rates for activities falling within the category, estimated using a multiple linear regression model, with weights corresponding to the number of minutes spent performing the activity. Numbers in these two columns represent averages, calculated across individuals in the specified age category, of these weighted averages. These are weighted averages, with the weights corresponding to the 4-year sampling weights assigned within NHANES 1999–2002.

2. applicability and utility – high, 3. clarity and completeness – medium, 4. variability and uncertainty – medium, and 5. evaluation and review – high; the overall rating was medium. (US-EPA, 2011).

4.3. WHO

WHO standard values for respiratory volumes (average figures) are those recommended by the ICRP (ICRP, 1974, cited in WHO/IPCS, 1994 and 1999). These values are presented in Table 4.8.

Table 4.8: WHO's standard values for respiratory volumes

Condition	Respiratory volume (average)
Long-term exposure (8 hours resting, 16 hours light/non-occupational activity):	
Child (10 years)	15 m ³ /day
Adult man	23 m ³ /day
Adult woman	21 m ³ /day
Men and women combined	22 m ³ /day
Short-term exposure:	
Resting	
Child (10 years)	2300 litres/8 hour
Adult man	3600 litres/8 hour
Adult woman	2900 litres/8 hour
Light/non-occupational activity	
Child (10 years)	6240 litres/8 hour
Adult man	9600 litres/8 hour
Adult woman	9100 litres/8 hour

Source: Modified from WHO/IPCS (1994 and 1999)

4.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) are the most comprehensive. The European data are limited as are the WHO data.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended values in Table R.8–18 are stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommended values are taken from one of these references or both. There are no references provided for the default physiological parameters presented in Table R.8–2.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 (ECHA, 2008), the recommended values presented in Table 4.1 are taken from a German document (AUH, 1995, cited in ECHA, 2008). In the updated version of Chapter R.15 (ECHA, 2016a), no recommendations for default respiratory volumes are provided.

The RIVM *General Fact Sheet* (RIVM, 2014) did not provide default values for inhalation rates.

The EFSA *Guidance Document for Plant Protection Products* (EFSA, 2022) recommended values are based upon data from the 2011 version of the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) and with reference to a document published by ECHA (ECHA, 2017).

The US-EPA recommended values for inhalation rates presented in Table 4.6 and 4.7 for long-term and short-term exposure, respectively, are well validated and valid as the US-EPA overall confidence rating was medium (US-EPA, 2011).

The WHO's standard values (Table 4.8) are based on recommendations from the ICRP (ICRP, 1974).

It should be noted that the references 'ICRP, 1974' and 'ICRP, 1975' are to the same ICRP report (ICRP Report No. 23).

Activity levels might be different among US individuals compared to Europeans. Despite this, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommended values are considered as being the most valid values for inhalation rates as of today as these recommendations are based on four key studies published in the period from 2006–2009. In contrast, the European data are predominantly based on older references (ICRP, 1975; AUH 1995; US-EPA, 1997) or no references have been provided for the recommended values (e.g., REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8, Table R.8–2). One European body, namely EFSA (EFSA, 2022) has based their recommended values on the most recent version of the *Exposure Factors Handbook* (US-EPA, 2011).

In conclusion, the US-EPA recommended values presented in Table 4.6 and 4.7 are considered as being the most valid values for inhalation rates as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

The recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides, cosmetics, toys etc.

5. Drinking water

Drinking water is a potential source of human exposure to chemical substances, naturally occurring or contaminants. Contamination of drinking water may occur by, for example, percolation of chemicals through the soil to ground water that is used as a source of drinking water; runoff or discharge to surface water that is used as a source of drinking water, intentional or unintentional addition of substances to treat water (e.g., chlorination), and leaching of materials from plumbing systems (e.g., lead). The exposure is usually expressed as an average amount of drinking water consumed per unit time (e.g., litre/day).

For the estimation of the magnitude of the potential dose of chemicals from drinking water, information on the quantity of water consumed per unit time is required. The intake of drinking water depends on age, level of physical activity (working, running, walking or resting), and the ambient temperature.

For the purposes of exposure assessments involving site-specific contaminated drinking water, ingestion rates based on the community supply are most appropriate. Given the assumption that bottled water, and purchased foods and beverages that contain water are widely distributed and less likely to contain source-specific water, the use of total water ingestion rates may overestimate the potential exposure to toxic substances present only in local water supplies (US-EPA, 2011).

5.1. Europe

In the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012) the standard value for daily water intake is 2.0 litres (Table R.8-18).

In the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.16 (ECHA, 2016b) the standard value for daily water intake is 2.0 litres (Table R.16-17).

According to the Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data (EFSA, 2012), a 2 litre default value for chronic daily total liquid intake (i.e. milk, tap water, other beverages) is recommended for European adults, including the elderly. There is no recommendation for children's total liquid intake, but the reader is referred to the opinion on dietary reference values for water of the EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA), where adequate intake levels are provided according to their age (EFSA, 2010b). A default value for acute daily total liquid intake is not proposed because acute risk assessment should be based on actual consumption data for particular beverages. It is noted that the EFSA Comprehensive Database, which was built from existing national information on food consumption at a detailed level also contains data from different EU Member States on daily total liquid intake, but due to different methodologies used to collect and report total liquid intake data in the various studies, these data sets cannot be

aggregated in order to determine a default value for total liquid intake for European adults.

In the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001) an average value of 1.1 litre/day for adults and 0.5 litre/day for 1–11-year-olds is recommended based upon a 1980 survey of Great Britain (Hopkin and Ellis, 1980, as cited in the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997)), see Table 5.1. This survey, included in the 2009 version of the *Exposure Factors Handbook* (US-EPA, 2009) as a “relevant study” was based on questionnaires and diaries indicating the type and quantity of beverages consumed over a one-week period. In the survey, drinking water is estimated as total tap water ingestion, which includes tap water consumed directly and in prepared items such as tea, coffee and other drinks, excludes water ingestion from bottled beverages. Because bottled items are likely to originate from different water sources (US-EPA, 1997), total tap water ingestion is therefore, according to ECETOC a better estimation of intake from the greatest single water source. (ECETOC, 2001).

Table 5.1: Summary of total tap water intake for men and women - as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Age group (years)	Mean intake (litre/day)		10 and 90 Percentiles (litre/day)	
	Men	Women	Men	Women
1–4	0.477	0.464	0.17 – 0.85	0.15 – 0.89
5–11	0.550	0.533	0.22 – 0.90	0.22 – 0.93
12–17	0.805	0.725	0.29 – 1.35	0.31 – 1.16
18–30	1.006	0.991	0.45 – 1.62	0.50 – 1.55
31–54	1.201	1.091	0.64 – 1.88	0.62 – 1.68
55+	1.133	1.027	0.62 – 1.72	0.54 – 1.57

Source: US-EPA (1997) citation of Hopkin and Ellis (1980), modified from ECETOC (2001)

The Danish Environmental Protection Agency (D-EPA) has in their *Guidance from the Environmental Protection Agency No. 5* (D-EPA, 2006) based their recommended intake of tap water upon data in the *Exposure Factors Handbook* (US-EPA, 1997). For new-borns, the mean intake is 35 ml/kg body weight/day, while the 95th percentile is 127 ml/kg body weight/day. For children aged one to ten years, the mean intake is set to 31 ml/kg body weight/day and the 95th percentile is 79.4 ml/kg body weight/day (D-EPA, 2006). It was considered most applicable to use the values for children (one to ten years) due to possible differences in breastfeeding patterns in Denmark and the US. These differences across countries may be important for the intake of tap water for new-borns (D-EPA, 2006).

The National Food Institute, Technical University of Denmark (DTU-FOOD) collected data on the intake of drinking water in the latest dietary survey of individuals aged 4–75 years old. Data was collected between 2011 and 2013 (DTU-FOOD, 2015). Mean daily drinking water intakes for smaller children (4–9 years), children/adolescents

(10–17 years) and adults (18–75 years) were 592 g, 752 g and 953 g, respectively. Daily drinking water intakes for the 95th percentile (same age groups) were 1138 g, 1637 g and 2226 g, respectively. In a more recent survey (KOSS, 2014–2015 data), mean daily drinking water intakes for infants/toddlers aged < 8 month, 8–10 month, 10–12 month, 1–2 years and 2–3 years were 175 g, 270 g, 284 g, 378 g and 368 g, respectively. Daily drinking water intakes for the 95th percentile (same age groups) were 455 g, 591 g, 609 g, 691 g and 664 g, respectively.

5.2. US-EPA

In the *Exposure Factors Handbook* Chapter 3 (US-EPA, 2019) consumption of beverages is divided into "per capita" and "consumers only". Per capita intake rates for drinking water are *"generated by averaging consumer-only intakes over the entire population (including those individuals that reported no intake)"*, while *"Consumer-only intake represents the quantity of water consumed only by individuals that reported consuming water during the survey period"*.

Historically, the US-EPA has assumed a drinking water ingestion rate of 2 litres per day for adults and 1 litre per day for infants and children less than 10 years of age (US-EPA, 2000). This rate includes water consumed in the form of juices and other beverages containing tap water.

The US-EPA analysis of National Health and Nutrition Examination Survey (NHANES) data for 2005–2010 was selected as the key study for drinking water ingestion for the general population and for pregnant and lactating women as NHANES 2005–2010 contains the most up-to-date information on water intake rate estimates (US-EPA, 2019). The recommended values for intake of drinking water are presented in Table 5.2. Ingestion rates are for combined direct and indirect water from community water supply. Direct ingestion is defined as direct consumption of water as a beverage and indirect ingestion includes water added during food or beverage preparation, but not water present in purchased foods. Estimates are based on the average of two days of water consumption reported for each NHANES respondent. If the respondent reported zero consumption on one of the two days and non-zero consumption on the other day, his/her average consumption would be the average of zero and non-zero consumption.

The recommended values presented in Table 5.2 are well validated as the general assessment factors (GAFs, described in Section 2.1) were used to judge the quality of the underlying data used to derive the recommendations. For adults, children and infants the US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – medium to high, 2. applicability and utility – high, 3. clarity and completeness – high, 4. variability and uncertainty – high, and 5. evaluation and review – medium; the overall rating was medium to high, but low for footnote 'a' in Table 5.2 (US-EPA, 2019).

For pregnant and lactating women, the US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – low, 2. applicability and utility – low-medium, 3. clarity and completeness – medium, 4. variability and uncertainty – low, and 5. evaluation and review – medium; the overall rating was low (US-EPA, 2019).

Table 5.2: Recommended values for intake of drinking water - as presented in the Exposure Factors Handbook¹¹

Age group	Mean (ml/day)	Mean (ml/kg bw ^a /day)	95 th Percentile (ml/day)	95 th Percentile (ml/kg bw ^a /day)
Per Capita				
Children and adolescent				
Birth–<1 month	184	42	851 ^b	200 ^b
1–<3 month	145	25	905 ^b	164 ^b
3–<6 month	187	27	981 ^b	141 ^b
6–<12 month	269	30	988	112
Birth–<1 year	220	29	974	137
1–<2 years	146	13	565	51
2–<3 years	205	15	778	58
3–<6 years	208	11	741	42
6–<11 years	294	10	1071	34
11–<16 years	315	6	1395	26
16–<21 years	436	6	1900	28
Adults				
21–<30 years	781	10	2848	39
30–<40 years	902	11	2967	38
40–<50 years	880	11	2964	38
50–<60 years	956	12	2976	37
60–<70 years	941	12	2972	35
70–<80 years	772	10	2273	31
≥ 80 years	784	11	2122	30
21–< 50 years	858	11	2938	38
≥ 50 years	902	11	2827	35
All ages	711	11	2641	37
Pregnant women	731	9.8	2859	37.3
Lactating women	1075	16.5	3061 a	47.0
Childbearing age	683	9.8	2634	38.2
Consumers Only				
Children and adolescent				
Birth–<1 month	581	133	938 ^b	224 ^b
1–<3 month	785	136	1224 ^b	267 ^b
3–<6 month	649	93	1125 ^b	158 ^b

11. Ingestion rates for combined direct and indirect water from community water supply.

6–<12 month	554	62	1104 ^b	133 ^b
Birth–<1 year	595	79	1106 ^b	174 ^b
1–<2 years	245	22	658	57
2–<3 years	332	24	901	67
3–<6 years	338	19	836	45
6–<11 years	455	15	1258	41
11–<16 years	562	10	1761	31
16–<21 years	722	10	2214	31
Adults				
21–<30 years	1183	16	3407	47
30–<40 years	1277	16	3278	44
40–<50 years	1356	17	3374	43
50–<60 years	1419	18	3388	42
60–<70 years	1394	17	3187	40
70–<80 years	1214	16	2614	37
≥ 80 years	1087	16	2250	33
21–< 50 years	1277	16	3353	44
≥ 50 years	1343	17	3081	40
All ages	1096	17	2972	44
Pregnant women	1158	15.5	2935 ^b	37.7
Lactating women	1495	22.9	3061 ^b	47.0
Childbearing age	1082	15.6	2956	44.6

a) Body weight.

b) Estimates are less statistically reliable (US-EPA, 2019).

Source: US-EPA analysis of 2005–2010 National Health and Nutrition Examination Survey (NHANES), modified from US-EPA (2019)

5.3. WHO

Table 5.3 presents WHO's standard values of daily fluid intake for different conditions based on recommendations from the ICRP (ICRP, 1974 – cited in WHO/IPCS, 1994 and 1999).

In developing drinking water guideline values for potentially hazardous chemicals, the WHO (WHO, 2008) assumes a daily per capita consumption of 2 litres of drinking water by a person weighing 60 kg. This standard value is considered to be on the safe side in most situations. But under certain circumstances, this assumption may underestimate the consumption of water per unit weight, and thus exposure, for those living in hot climates as well as for infants and children, who consume more fluid per unit weight than adults. Where it was judged that children were at a particularly high risk from exposure to certain chemicals, the drinking water guideline value was derived on the basis of a 10-kg child consuming 1 litre of drinking water

per day, or a 5-kg infant consuming 0.75 litre per day. The corresponding daily fluid intakes are higher than for adults on a body weight basis (WHO, 2008).

Table 5.3: WHO's Standard Values for Daily Fluid Intake

Condition	Daily fluid intake (ml/day) (milk, tap water, other beverages)
Normal conditions	
Adults	1000–2400, representative figure = 1900 ^a (excluding milk: 1400 ^b)
Adult men	1950
Adult women	1400
Child (10 years)	1400
High average temperature (32°C)	
Adults	2840–3410
Moderate activity	
Adults	3700

a) WHO uses a daily per capita drinking-water consumption of 2 litres in calculating water quality guidelines.

b) From Health and Welfare Canada (1992).

Source: Modified from WHO/IPCS (1994 and 1999)

5.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2019) are the most comprehensive. The European data are limited as are the WHO data.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended value for water intake in Table R.8–18 is stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommendation is taken from one of these references or both.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.16 (ECHA, 2016b) the recommended value for drinking water in Table R.16–17 is from EUSES.

The EFSA *Default Guidance Document* (EFSA, 2012) recommended value for daily total liquid intake (i.e. milk, tap water, other beverages) for adults is in accordance with total liquid intakes reported for adult males and adult females in an EFSA NDA Panel opinion (EFSA, 2010b) and the ICRP (1975) report.

The DTU-FOOD (DTU-FOOD, 2015; KOSS, 2014–2015 data) recommended values for drinking water intakes are based on surveys for the Danish population.

The US-EPA recommended values for intake of drinking water presented in Table 5.2 are well validated and valid as the US-EPA overall rating was medium to high for the

general population, except the overall rating of low for footnote 'a' values in Table 5.2. For pregnant and lactating women, the US-EPA overall rating was low (US-EPA, 2019).

The WHO's standard values of daily fluid intake (Table 5.3) are based on recommendations from the ICRP (ICRP, 1974).

It should be noted that the references 'ICRP, 1974' and 'ICRP, 1975' are to the same ICRP report (ICRP Report No. 23).

Drinking water intakes might be different among US individuals compared to Europeans. Considering the inherent variation in drinking water intakes also among the European population, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommended values are considered as being the most valid values for drinking water intakes as of today as these recommendations are based on the most recent analysis on NHANES 2005–2010 data by US-EPA (2019). In contrast, the European data are very limited and predominantly based on older references, except for the DTU-FOOD data. In addition, the US-EPA recommended values are for drinking water whereas other recommended values are for the total liquid intake.

In conclusion, the US-EPA recommended values presented in Table 5.2 are considered as being the most valid values for intake of drinking water as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH. Alternatively, data from national surveys could be recommended.

The recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides etc.

6. Food intake

Even though food supply in the Western world is generally considered to be safe, contamination of foods may occur as a result of environmental pollution of the air, water, or soil, or the intentional use of chemicals such as pesticides or other agrochemicals. Ingestion of contaminated foods is a potential pathway of exposure to such contaminants. To assess chemical exposure through this pathway, information on food ingestion rates is needed.

6.1. Europe

In the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012) the standard value for daily food intake is 1.4 kg per day (Table R.8–18).

In the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.16 (ECHA, 2016b) the standard value for daily intake of fish is 0.115 kg/day, for leaf crops (incl. fruit and cereals) 1.2 kg/day, for root crops 0.384 kg/day, for meat 0.301 kg/day and for dairy products 0.561 kg/day (Table R.16–17).

According to the Guidance on selected default values to be used by the EFSA Scientific Committee, Scientific Panels and Units in the absence of actual measured data (EFSA 2012), a single default value for daily total solid food intake for adults for harmonised use across the EFSA Panels was neither needed nor justifiable. Instead it was recommended that the *EFSA Comprehensive Database* is consulted to check the relevance of the default values that are used. The Database is a comprehensive collection of dietary data from European countries. Statistics on chronic and acute food consumption are available for the total population ("all subjects" and "all days") and for consumers only, and in grams per day (g/day) or grams per day per kilogram body weight (g/kg bw per day). The database is continually updated when EU member states forward new dietary surveys to EFSA. However, dietary surveys in the database do not necessarily represent the most recent national survey data available, e.g. for Danish data.

The recommended food consumption rates from the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001) are presented in Table 6.1.

Table 6.1: Recommendations on the average food consumption in the European Community and its member countries - as presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Food	EC	B	DK	F	D	GR	IRL	I	NL	P	SP	UK	Range Max.
Average food consumption (kg per capita per year)													
Meat ^a	94.0	105.0	108.9	109.9	104.9	76.4	87.3	87.5	88.8	68.4	95.0	77.3	109.9
Beef and veal	22.0	22.3	18.1	30.7	23.7	19.0	19.0	26.8	19.3	13.6	11.5	17.0	30.7
Pork	40.7	49.1	69.1	37.6	63.2	22.2	34.7	30.8	47.6	25.9	47.4	24.8	69.1
Other	21.7	19.3	13.3	25.2	12.6	29.5	26.7	20.9	18.5	21.9	27.4	25.0	29.5
Fish	10.1	10.2	41.8	7.5	7.4	7.2	12.6	10.1	9.8	24.7	20.3	3.5	41.8
Milk + yoghurt	82.4	67.8	74.2	65.8	65.8	66.9	173.6	69.7	79.3	52.1	102.6	122.3	173.6
Butter	4.9	8.6	6.9	8.6	8.5	1.0	5.5	2.4	3.9	0.9	0.6	4.2	8.6
Cheese	14.5	12.6	12.8	22.4	17.4	22.1	5.4	17.6	15.0	5.2	5.5	8.0	22.4
Fruit + vegetables	205.6	173.8	149.8	194.0	196.4	248.3	148.3	277.5	242.5	165.4	252.6	131.6	277.5
Cereals	116.5	98.7	93.1	101.8	99.6	145.2	144.7	160.0	74.5	125.4	97.7	119.6	160.0
Potatoes	83.3	97.6	62.9	73.6	69.6	86.4	140.2	38.0	87.0	111.5	107.0	106.7	140.2
Average food consumption (g per kg body weight per Day^b)													
Meat ^a	4.4	5.0	5.1	5.2	5.0	3.6	4.1	4.1	4.2	3.2	4.5	3.7	5.2
Beef and veal	1.0	1.1	0.9	1.5	1.1	0.9	0.9	1.3	0.9	0.6	0.5	0.8	1.5
Pork	1.9	2.3	3.3	1.8	3.0	1.0	1.6	1.5	2.2	1.2	2.2	1.2	3.3
Other	1.0	0.9	0.6	1.2	0.6	1.4	1.3	1.0	0.9	1.0	1.3	1.2	1.4
Fish	0.5	0.5	2.0	0.4	0.3	0.3	0.6	0.5	0.5	1.2	1.0	0.2	2.0
Milk + yoghurt	3.9	3.2	3.5	3.1	3.1	3.2	8.2	3.3	3.7	2.5	4.8	5.8	8.2
Butter	0.2	0.4	0.3	0.4	0.4	0.0	0.3	0.1	0.2	0.0	0.0	0.2	0.4
Cheese	0.7	0.6	0.6	1.1	0.8	1.0	0.3	0.8	0.7	0.2	0.3	0.4	1.1
Fruit + vegetables	9.7	8.2	7.1	9.2	9.3	11.7	7.0	13.1	11.5	7.8	11.9	6.2	13.1
Cereals	5.5	4.7	4.4	4.8	4.7	6.9	6.8	7.6	3.5	5.9	4.6	5.6	7.6
Potatoes	3.9	4.6	3.0	3.5	3.3	4.1	6.6	1.8	4.1	5.3	5.1	5.0	6.6

a) Total does not reflect the sum of the subgroups.

b) Averages over lifetime assuming average bodyweight of 58 kg (Table 1 values divided by 58 kg and 365 days/year).

Source: ECETOC (1994) citation of Euromonitor (1992), European Marketing Data and Statistics, modified from ECETOC (2001)

According to the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), the recommendations for breast milk intake are the same as presented in the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997). No UK studies were cited in US-EPA (1997), but breast milk consumption values for Swedish infants were similar to those of US infants. The data from US-EPA (1997) are presented in Table 6.2.

Table 6.2: Standard Breast Milk Intake Rates - as Presented in the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data*

Age	Mean (ml/day)	Upper percentile (mean + 2 SD)
1–6 months	742	1033
12 months	688	980

Source: US-EPA (1997), modified from ECETOC (2001)

The National Food Institute, Technical University of Denmark (DTU-FOOD) has investigated the dietary habits of the Danish population in a document called *Dietary habits in Denmark 2011–2013 – Main Results* (DTU-FOOD, 2015) (*Danskernes Kostvaner 2011–2013 – Hovedresultater*). In this survey, dietary data from 3946 individuals aged 4–75 years have been collected through a seven day diary between 2011 and 2013. Table 6.3 and 6.4 present main results from the Danish survey.

Table 6.3: Dietary Habits in Denmark 2011–2013 – Per Capita

Group (years)	Mean	50 th percentiles	95 th percentiles	97.5 th percentiles
Dairy products exclusive cheese (g/day)				
All children 4–9	428	402	848	1003
All children 10–17	407	358	840	1015
All adults 18–75	304	255	748	899
Total (all)	331	278	792	923
Cheese and cheese products (g/day)				
All children 4–9	20.5	16.8	49.0	62.2
All children 10–17	24.8	20.3	59.2	75.7
All adults 18–75	44.1	37.1	104.9	127.0
Total (all)	39.1	31.6	96.3	120.2
Cereals including bread (g/day)				
All children 4–9	216	210	315	348
All children 10–17	219	205	365	408

All adults 18–75	218	208	368	412
Total (all)	218	208	364	408
Vegetables exclusive potatoes (g/day)				
All children 4–9	157	136	357	433
All children 10–17	144	128	280	346
All adults 18–75	199	177	407	477
Total (all)	187	166	391	452
Potatoes and potato products (g/day)				
All children 4–9	40.2	31.7	117.9	136.2
All children 10–17	73.7	61.6	189.2	227.1
All adults 18–75	90.8	70.5	254.1	314.5
Total (all)	83.2	63.3	237.3	293.1
Fruits and fruit products exclusive juice (g/day)				
All children 4–9	188	163	407	468
All children 10–17	141	108	379	434
All adults 18–75	190	160	469	555
Total (all)	183	153	450	542
Juice (g/day)				
All children 4–9	58.6	25.4	228.2	304.3
All children 10–17	75.2	50.7	253.5	304.3
All adults 18–75	56.5	12.7	228.2	289.2
Total (all)	59.1	25.4	228.2	304.3
Meat and meat products (g/day)				
All children 4–9	87	81	165	174
All children 10–17	120	106	253	308
All adults 18–75	134	118	288	342
Total (all)	127	112	276	328
Poultry (g/day)				
All children 4–9	16.5	9.0	53.3	64.9
All children 10–17	26.6	18.4	82.6	98.7
All adults 18–75	26.5	17.3	83.8	108.5
Total (all)	25.4	16.3	81.4	103.1
Fish and fish products (g/day)				
All children 4–9	16.4	10.0	53.9	67.3
All children 10–17	14.9	8.3	51.6	69.1
All adults 18–75	36.8	28.1	107.0	128.7
Total (all)	31.8	22.1	99.7	121.4
Ice cream (g/day)				

All children 4–9	8.5	7.1	28.6	35.7
All children 10–17	9.0	0.0	35.7	42.9
All adults 18–75	7.2	0.0	29.7	41.1
Total (all)	7.6	0.0	29.7	41.1
Eggs and egg products (g/day)				
All children 4–9	17.8	14.7	44.5	48.1
All children 10–17	17.2	12.8	46.9	61.9
All adults 18–75	24.4	20.3	60.8	73.0
Total (all)	22.7	18.5	58.0	69.4
Beverages exclusive milk and juice (g/day)				
All children 4–9	758	708	1.359	1.511
All children 10–17	1.120	1.045	2.146	2.438
All adults 18–75	2.184	2.098	3.642	3.980
Total (all)	1.894	1.831	3.526	3.857
Fats (g/day)				
All children 4–9	37.3	35.3	64.1	73.1
All children 10–17	35.9	32.1	72.0	82.7
All adults 18–75	40.8	36.3	83.6	98.3
Total (all)	39.8	35.4	80.3	94.1
Sugar, honey and candy (g/day)				
All children 4–9	34.7	31.2	74.1	84.6
All children 10–17	38.1	33.5	84.8	102.3
All adults 18–75	36.8	29.1	93.9	114.9
Total (all)	36.7	30.1	89.6	108.7
Energy (MJ/day)				
All children 4–9	8.1	7.9	11.0	12.1
All children 10–17	8.8	8.4	13.6	15.3
All adults 18–75	9.8	9.4	15.2	16.5
Total (all)	9.5	9.0	14.9	16.2

Source: Modified from Dietary habits in Denmark 2011–2013 – Main Results. National Food Institute, Technical University of Denmark (DTU-FOOD, 2015)

Table 6.4: Dietary Habits in Denmark 2011–2013 – Consumers Only

Group (years)	Mean	50 th percentiles	95 th percentiles	97.5 th percentiles
Dairy products exclusive cheese (g/day)				
All children 4–9	428	402	848	1003
All children 10–17	407	358	840	1015
All adults 18–75	304	255	748	899

Total (all)	331	278	792	923
Cheese and cheese products (g/day)				
All children 4–9	20.7	16.8	49.2	62.2
All children 10–17	25.0	20.4	59.2	75.7
All adults 18–75	44.4	37.3	105.2	127.4
Total (all)	39.4	31.8	96.4	120.7
Cereals including bread (g/day)				
All children 4–9	216	210	315	348
All children 10–17	219	205	365	408
All adults 18–75	218	208	368	412
Total (all)	218	208	364	408
Vegetables exclusive potatoes (g/day)				
All children 4–9	157	136	357	433
All children 10–17	144	128	280	346
All adults 18–75	199	177	407	477
Total (all)	187	166	391	452
Potatoes and potato products (g/day)				
All children 4–9	43.6	35.1	122.3	145.0
All children 10–17	76.8	64.3	189.3	227.1
All adults 18–75	94.6	73.6	258.0	316.4
Total (all)	87.0	66.8	240.5	295.9
Fruits and fruit products exclusive juice (g/day)				
All children 4–9	188	163	407	468
All children 10–17	141	109	379	434
All adults 18–75	191	162	469	557
Total (all)	184	154	451	544
Juice (g/day)				
All children 4–9	90	63	284	355
All children 10–17	110	76	279	355
All adults 18–75	107	76	279	380
Total (all)	106	76	279	355
Meat and meat products (g/day)				
All children 4–9	87	81	165	174
All children 10–17	120	106	253	308
All adults 18–75	135	119	288	342
Total (all)	128	112	276	328
Poultry (g/day)				
All children 4–9	19.8	13.6	56.9	65.7
All children 10–17	29.4	24.0	84.5	99.0

All adults 18–75	30.7	24.2	90.0	113.0
Total (all)	29.4	22.6	85.3	108.5
Fish and fish products (g/day)				
All children 4–9	20.4	14.4	63.0	71.7
All children 10–17	18.7	13.5	56.9	70.6
All adults 18–75	40.3	31.2	110.7	134.5
Total (all)	35.8	26.9	104.0	125.1
Ice cream (g/day)				
All children 4–9	15.0	14.3	34.6	42.9
All children 10–17	18.7	14.3	42.9	57.1
All adults 18–75	17.6	14.3	43.9	57.1
Total (all)	17.4	14.3	42.9	53.6
Eggs and egg products (g/day)				
All children 4–9	17.9	14.8	44.5	48.1
All children 10–17	17.3	12.9	46.9	61.9
All adults 18–75	24.5	20.4	60.9	73.0
Total (all)	22.9	18.7	58.2	69.4
Beverages exclusive milk and juice (g/day)				
All children 4–9	758	708	1359	1511
All children 10–17	1.120	1.045	2146	2438
All adults 18–75	2.184	2.098	3642	3980
Total (all)	1.894	1.831	3526	3857
Fats (g/day)				
All children 4–9	37.3	35.3	64.1	73.1
All children 10–17	35.9	32.1	72.0	82.7
All adults 18–75	40.8	36.3	83.6	98.3
Total (all)	39.8	35.4	80.3	94.1
Sugar, honey and candy (g/day)				
All children 4–9	34.8	31.2	74.5	84.6
All children 10–17	38.6	33.6	84.8	102.3
All adults 18–75	37.3	29.5	94.5	115.7
Total (all)	37.2	30.5	90.1	109.4

Source: Modified from Dietary habits in Denmark 2011–2013 – Main Results. National Food Institute, Technical University of Denmark, (DTU-FOOD, 2015)

6.2. US-EPA

In the *Exposure Factors Handbook*, recommendations on intake of food are divided into different food categories:

- Fruits and vegetables
- Fish
- Meats, dairy products and fats
- Grains
- Total food intake
- Human breast milk and lipids

In general, the US-EPA analysis of data based on food and water intake data obtained from the National Health and Nutrition Examination Survey (NHANES) 2003–2006 was used for the recommended values for food and water intakes for the general population (US-EPA, 2011). Since 2017, US-EPA has released Chapter updates individually and for some of the food categories updated versions are available, i.e., for fruits and vegetables (US-EPA, 2018a), meats, dairy products and fats (US-EPA, 2018b), and grains ((US-EPA, 2018c).

6.2.1. Fruits and vegetables

In the *Exposure Factors Handbook* Chapter 9 (US-EPA, 2018a), the recommended intake values for fruits and vegetables were based on the US-EPA analysis of 2005–2010 NHANES data. Table 6.5 presents a summary of the recommended values for per capita and consumer-only intakes of fruits and vegetables, on an as-consumed basis. Total fruits intakes refer to the sum of all fruits consumed in a day including canned, dried, frozen, and fresh fruits. Likewise, total vegetables intakes refer to the sum of all vegetables consumed in a day including canned, dried, frozen, and fresh vegetables. The fruit and vegetable intakes cover the edible portion, uncooked weight. Vegetables data include potatoes.

The US-EPA recommended values presented in Table 6.5 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high for total fruits and vegetables, low for some individual fruits and vegetables with small sample size, 2. applicability and utility – medium, 3. clarity and completeness – high, 4. variability and uncertainty – medium to high for averages, low for long-term upper percentiles, low for individual fruits and vegetables, and 5. evaluation and review – medium; the overall rating was medium to high for confidence in the averages, low for some individual fruits and vegetables with small sample size, low for confidence in the long-term upper percentiles (US-EPA, 2018a).

Table 6.5: Recommended values for 2-day average intake of fruits and vegetables, as consumed - as presented in the *Exposure Factors Handbook*

Age	Total fruits (g/kg body weight per day)				Total Vegetables (g/kg body weight per day)			
	Per Capita		Consumers Only		Per Capita		Consumers Only	
	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th
3-<6 m	4.4	19.2	8.8	26.9	3.2	11.2	4.9	12.7
6-<12 m	9.4	26.5	10.3	28.9	7.6	19.2	7.9	19.5
0-<1 y	5.8	23.0	9.9	27.2	4.7	16.9	6.7	18.7
1-<2 y	9.3	23.9	9.8	24.0	6.7	16.3	6.7	16.3
2-<3 y	7.5	20.0	7.7	20.5	6.0	14.0	6.0	14.0
3-<6 y	5.6	16.2	5.8	16.4	5.3	13.3	5.3	13.3
6-<11 y	3.0	9.9	3.2	10.0	3.8	9.9	3.8	9.9
11-<16 y	1.3	4.8	1.6	5.2	2.4	6.3	2.4	6.3
16-<21 y	0.9	3.5	1.1	4.0	2.3	5.3	2.3	6.3
21-<50 y	1.1	4.1	1.3	4.3	2.5	6.1	2.5	6.1
≥50 y	1.4	4.3	1.6	4.5	2.6	6.0	2.6	6.0

Source: US-EPA analysis of 2005-2010 NHANES data, modified from US-EPA (2018a)

6.2.2. Fish

In the *Exposure Factors Handbook* Chapter 10 (US-EPA, 2011), the recommended intake values for fish were based on the US-EPA analysis of 2003–2006 NHANES data. General population data on finfish, shellfish and the combined intake of finfish and shellfish are presented in Table 6.6. Recreational population combined intakes of finfish and shellfish are presented in Table 6.7. Data in the tables represent uncooked fish weight.

The US-EPA recommended values presented in Table 6.6 and Table 6.7 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations.

For the values presented in Table 6.6, the US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – high, 3. clarity and completeness – high, 4. variability and uncertainty – medium to high for averages, low for long-term upper percentiles, and 5. evaluation and review – medium; the overall rating was medium to high for mean, medium for long-term upper percentiles (US-EPA, 2011).

For the values presented in Table 6.7, the US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – medium, 2. applicability and utility – low to medium, 3. clarity and completeness – medium, 4. variability and uncertainty – low, and 5. evaluation and review – medium; the overall rating was low to medium for adults, low for children (US-EPA, 2011).

Table 6.6: Recommended values for general population fish intake – as presented in the Exposure Factors Handbook

Age	Finfish (g/kg body weight per day)				Shellfish (g/kg body weight per day)			
	Per Capita		Consumers Only		Per Capita		Consumers Only	
	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th
0–<1 y	0.03	0.0	1.3	2.9	0.0	0.0	0.42	2.3
1–<2 y	0.22	1.2	1.6	4.9	0.04	0.0	0.94	3.5
2–<3 y	0.22	1.2	1.6	4.9	0.04	0.0	0.94	3.5
3–<6 y	0.19	1.4	1.3	3.6	0.05	0.0	1.0	2.9
6–<11 y	0.16	1.1	1.1	2.9	0.05	0.2	0.72	2.0
11–<16 y	0.10	0.7	0.66	1.7	0.03	0.0	0.61	1.9
16–<21 y	0.10	0.7	0.66	1.7	0.03	0.0	0.61	1.9
21–<50 y	0.15	1.0	0.65	2.1	0.08	0.5	0.63	2.2
≥50 y	0.20	1.2	0.68	2.0	0.06	0.3	0.53	1.8
21–<50 y	1.1	4.1	1.3	4.3	2.5	6.1	2.5	6.1
≥50 y	1.4	4.3	1.6	4.5	2.6	6.0	2.6	6.0
Females ^a	0.14	0.9	0.62	1.8	0.05	0.4	0.41	1.2

Age	Finfish and shellfish (g/kg body weight per day)			
	Per Capita		Consumers Only	
	Mean	95 th	Mean	95 th
0–<1 y	0.04	0.00	1.2	2.9
1–<2 y	0.26	1.2	1.5	5.9
2–<3 y	0.26	1.2	1.5	5.9
3–<6 y	0.24	1.6	1.3	3.6
6–<11 y	0.21	1.4	0.99	2.7
11–<16 y	0.13	1.0	0.69	1.8
16–<21 y	0.13	1.0	0.69	1.8
21–<50 y	0.23	1.3	0.76	2.5
≥50 y	0.25	1.4	0.71	2.1
Females ^a	0.19	1.2	0.68	1.9

a) 13 to 49 years old.

Source: US-EPA analysis of 2003–2006 NHANES data, modified from US-EPA (2011)

Table 6.7: Recommended values for recreational marine fish intake – as presented in the Exposure Factors Handbook

Age	Recreational marine fish intake (g/person per day) - intake for recreational fishing population only					
	Marine fish – Atlantic		Marine fish - Gulf		Marine fish - Pacific	
	Mean	95 th	Mean	95 th	Mean	95 th
3–<6 y	2.5	8.8	3.2	13	0.9	3.3
6–<11 y	2.5	8.6	3.3	12	0.9	3.2
11–<16 y	3.4	13	4.4	18	1.2	4.8
16–<18 y	2.8	6.6	3.5	9.5	1.0	2.5
>18 y	5.6	18	7.2	26	2.0	6.8

Source: modified from US-EPA (2011)

6.2.3. Meats, dairy products and fats

In the *Exposure Factors Handbook* Chapter 11 (US-EPA, 2018b), the recommended intake values for meats, dairy products and fats were based on the US-EPA analysis of 2005–2010 NHANES data. Table 6.8 presents a summary of the recommended values for per capita and consumer-only intakes of meats, dairy products and fats, on an as-consumed basis. The intake data relate to the uncooked weight of the edible portion.

The US-EPA recommended values presented in Table 6.8 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – high for meats and dairy products, medium for fats, 3. clarity and completeness – high, 4. variability and uncertainty – medium to high for averages, low for long-term upper percentiles, low for individual foods, and 5. evaluation and review – medium; the overall rating was medium to high for confidence in the averages, low for confidence in the long-term upper percentiles (US-EPA, 2018b).

Table 6.8: Recommended values for intake of meats, dairy products and fats, as consumed - as presented in the Exposure Factors Handbook

Age	Total meats (g/kg body weight per day)				Total dairy products (g/kg body weight - day)			
	Per Capita		Consumers Only		Per Capita		Consumers Only	
	Mean	95 th	Mean	95 th	Mean	95 th	Mean	95 th
3–<6 m	0.2	1.6	1.6	5.3	5.1	16.1	6.5	17.8
6–<12 m	2.4	8.1	3.1	9.3	16.1	78.7	17.0	83.2
0–<1 y	1.3	5.7	3.0	8.9	10.9	57.1	13.1	64.2
1–<2 y	3.9	9.5	4.1	9.6	48.8	100.5	48.8	100.5
2–<3 y	4.2	9.5	4.3	9.6	36.1	78.3	36.1	78.3
3–<6 y	4.0	9.0	4.0	9.0	22.6	51.1	22.6	51.1

6–<11 y	3.0	6.6	3.0	6.7	13.8	31.8	13.8	31.8
11–<16 y	2.1	4.9	2.2	4.9	6.8	18.2	6.8	18.2
16–<21 y	2.0	4.6	2.0	4.6	4.0	13.0	4.0	13.0
21–<50 y	1.8	4.1	1.8	4.1	3.2	9.6	3.2	9.6
≥50 y	1.4	3.2	1.5	3.2	3.2	9.6	3.2	9.6
≥80 y	1.2	2.8	1.2	2.8	4.0	10.2	4.0	10.2
Age	Total fats (g/kg body weight per day)							
	Per Capita				Consumers Only			
	Mean		95 th		Mean		95 th	
0–<1 m	5.2		16		7.8		16	
1–<3 m	4.5		12		6.0		12	
3–<6 m	4.1		8.2		4.4		8.3	
6–<12 m	3.7		7.0		3.7		7.0	
1–<2 y	4.0		7.1		4.0		7.1	
2–<3 y	3.6		6.4		3.6		6.4	
3–<6 y	3.4		5.8		3.4		5.8	
6–<11 y	2.6		4.2		2.6		4.2	
11–<16 y	1.6		3.0		1.6		3.0	
16–<21 y	1.3		2.7		1.3		2.7	
21–<31 y	1.2		2.3		1.2		2.3	
31–<41 y	1.1		2.1		1.1		2.1	
41–<51 y	1.0		1.9		1.0		1.9	
51–<61 y	0.9		1.7		0.9		1.7	
61–<71 y	0.9		1.7		0.9		1.7	
71–<81 y	0.8		1.5		0.8		1.5	
≥81 y	0.9		1.5		0.9		1.5	

Source: US-EPA analysis of 2005-2010 NHANES data, modified from US-EPA (2018b)

6.2.4. Grains

In the *Exposure Factors Handbook* Chapter 12 (US-EPA, 2018c), the recommended intake values for grains were based on the US-EPA analysis of 2005-2010 NHANES data. Table 6.9 presents a summary of the recommended values for per capita and consumer-only intakes of grains, on an as-consumed basis. The intake data relate to the uncooked weight of the edible portion.

The US-EPA recommended values presented in Table 6.9 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – high, 3. clarity and completeness – high, 4. variability and uncertainty – medium to high for averages, low for long-term upper percentiles, low

for individual foods, and 5. evaluation and review – medium; the overall rating was medium to high for confidence in the averages, low for confidence in the long-term upper percentiles (US-EPA, 2018c).

Table 6.9: Recommended values for intake of grains, as consumed - as presented in the Exposure Factors Handbook

Age	Grains (g/kg body weight per day)			
	Per Capita		Consumers Only	
	Mean	95 th	Mean	95 th
3–<6 m	1.9	6.5	2.7	7.7
6–<12 m	4.3	9.5	4.4	9.6
0–1 y	2.8	8.2	3.9	8.7
1–<2 y	6.4	12.7	6.4	12.7
2–<3 y	6.4	11.7	6.4	11.7
3–<6 y	6.0	10.5	6.0	10.5
6–<11 y	4.6	8.7	4.6	8.7
11–<16 y	2.7	5.7	2.7	5.7
16–<21 y	2.3	5.0	2.3	5.0
21–<50 y	2.1	4.6	2.1	4.6
≥50 y	1.7	3.6	1.7	3.6
≥80 y	1.6	3.0	1.6	3.0

Source: US-EPA analysis of 2005-2010 NHANES data, modified from US-EPA (2018c)

6.2.5. Total food intake

In the *Exposure Factors Handbook* Chapter 14 (US-EPA, 2011), the recommended intake values for total food for the general population were based on the US-EPA analysis of 2003–2006 NHANES data. Table 6.10 presents a summary of the recommended values for total food, defined as intake of the sum of all foods, beverages, and water ingested, per capita. The intake data relate to the uncooked weight of the edible portion.

The US-EPA recommended values presented in Table 6.10 are well validated as the general assessment factors (GAFs, described in Section 1.1) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – medium, 3. clarity and completeness – medium, 4. variability and uncertainty – medium, and 5. evaluation and review – medium; the overall rating was medium (US-EPA, 2011).

Table 6.10: Recommended values for Per Capita total food intake, as consumed - as presented in the Exposure Factors Handbook

Age	Grains (g/kg body weight per day)	
	Mean	95 th
0–<1 y	91	208
1–<3 y	113	185
3–<6 y	79	137
6–<11 y ^a	47	92
11–<16 y ^b	28	56
16–<21 y ^b	28	56
21–<50 y	29	63
≥50 y	29	59

Total food intake was defined as intake of the sum of all foods, beverages, and water ingested.

a) Based on data for ages 6 to <13 years.

b) Based on data for ages 13 to <20 years.

Source: US-EPA analysis of 2003–2006 NHANES data, modified from US-EPA (2011)

6.2.6. Human breast milk and lipids

According to the *Exposure Factors Handbook* Chapter 15 (US-EPA, 2011), among infants born in 2004, 73.8% were breastfed postpartum, 41.5% at 6 months, and 20.9% at 12 months.

Seven key studies were identified which gave rise to the recommended values for human milk and lipid intake as presented in Table 6.11. These key studies among nursing mothers in industrialized countries have shown that average intakes among infants ranged from approximately 500 to 800 ml/day, with the highest intake reported for infants 3 to below 6 months old. It should be noted that the decrease in human milk intake with age is likely a result of complementary foods being introduced as the child grows and not necessarily a decrease in total energy intake. Recommendations were converted to ml/day using a density of human milk of 1.03 g/ml rounded up to two significant figures (US-EPA. 2011).

The US-EPA recommended values presented in Table 6.11 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – medium, 2. applicability and utility – medium, 3. clarity and completeness – medium, 4. variability and uncertainty – low, and 5. evaluation and review – high; the overall rating was medium (US-EPA, 2011).

Table 6.11: Recommended values for human breast milk and lipid intake rates for exclusively breastfed infants - as presented in the Exposure Factors Handbook

Age	Human milk intake			
	ml/day		ml/kg body weight per day	
	Mean	95 th , ^a	Mean	95 th , ^a
0–<1 m	510	950	150	220
1–<3 m	690	980	140	190
3–<6 m	770	1000	110	150
6–<12 m	620	1000	83	130

Age	Lipid intake ^b			
	ml/day		ml/kg body weight per day	
	Mean	95 th , ^a	Mean	95 th , ^a
0–<1 m	20	38	6.0	8.7
1–<3 m	27	40	5.0	8.0
3–<6 m	30	42	4.2	6.1
6–<12 m	25	42	3.3	5.2

a) Upper percentile is reported as mean plus 2 standard deviations.

b) The recommended value for lipid content of human milk is 4.0%.

Source: Neville et al. (1988), Pao et al. (1980), Butte et al. (1984), Dewey and Lönnerdal (1983), Butte et al. (2000), Dewey et al. (1991b), Arcus-Arth et al. (2005), all cited in US-EPA (2011). Modified from US-EPA (2011)

6.3. WHO

The WHO standard values for food intake are those recommended by the ICRP (ICRP, 1974, cited in WHO/IPCS, 1994 and 1999). These values are presented in Table 6.12.

Table 6.12: WHO's standard values on dietary intake

Food	Daily intake in g per day ^a
Cereals	323 (flour and milled rice)
Starchy Roots	225 (sweet potatoes, cassava and other)
Sugar	72 (includes raw sugar, excludes syrups and honey)
Pulses and nuts	33 (includes cocoa beans)
Vegetables and fruits	325 (fresh equivalent)
Meat	125 (includes offal, poultry and game in terms of carcass weight, excluding slaughter fats)
Eggs	19 (fresh equivalent)
Fish	23 (landed weight)
Milk	360 (excludes butter; includes milk products as fresh milk equivalent)
Fats and oils	31 (pure fat content)

a) Based on average of estimates for seven geographical regions.

Source: Modified from WHO/IPCS (1994)

6.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011), along with the updated chapters (US-EPA, 2018a,b,c) as well as the European data are comprehensive. The WHO data are limited.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended value for food intake in Table R.8–18 is stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommendation is taken from one of these references or both.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.16 (ECHA, 2016b) the recommended values for intakes of different food categories in Table R.16–17 are from EUSES.

The EFSA *Default Guidance Document* (EFSA, 2012) did not recommend a single default value for daily total solid food intake for adults for harmonised use across the EFSA Panels as it was considered neither needed nor justifiable. Instead it was recommended to check the *EFSA Comprehensive Database* for default values to be used.

The DTU-FOOD (DTU-FOOD, 2015) recommended values for food intakes in Table 6.3 and 6.4 are based on surveys for the Danish population collected in 2011–2013. These most recent Danish data are, however, not included in the *EFSA Comprehensive Database*, which therefore only include the data collected in 2003–2008 (DTU-FOOD, 2010).

The US-EPA recommended values for food intakes presented in Tables 6.5 to 6.11 are well validated and valid as the US-EPA overall ratings in general were medium to high (US-EPA, 2011, 2018a,b,c).

The WHO standard values on dietary intake presented in Table 6.12 are those recommended by the ICRP (ICRP, 1974).

It should be noted that the references ‘ICRP, 1974’ and ‘ICRP, 1975’ are to the same ICRP report (ICRP Report No. 23).

The US-EPA recommendations are considered as being highly valid values for food consumption rates as these recommendations are based on comprehensive analyses of fairly recent data. They are the best dietary data available for the US population. Americans, however, can have quite different dietary habits compared to Europeans and dietary habits can also differ markedly within European countries. Thus, national dietary data should preferably be used for the population/populations that are to be assessed. For this purpose, the *EFSA Comprehensive European Food Consumption Database* offers a valuable set of data although national agencies may possess more recent dietary data as is, e.g. the case for the Danish data on food consumption.

According to ECETOC (ECETOC, 2001), breast milk consumption values for Swedish infants were similar to those of US infants. Thus, the US-EPA recommendations for human breast milk and lipid intake rates (US-EPA, 2011) are considered as being representative for European infants as well.

In conclusion, the data compiled in the *EFSA Comprehensive European Food Consumption Database* are considered as being the most valid values for food

consumption rates as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH. Alternatively, data from national surveys could be recommended.

For breast milk intake, the US-EPA recommendations presented in Table 6.11 are considered as being the most valid values as of today and are therefore recommended as default exposure factors for assessments of European infants in the context of REACH.

The recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides etc.

7. Soil and dust ingestion and inhalation

The ingestion of soil is a potential source of human exposure to chemical substances. The exposure is usually expressed as an average amount of soil ingested per unit time (e.g., mg/day).

The potential for exposure to contaminants via soil is greater for small children because they are naturally curious and often examine new objects by putting them into their mouth; this mouthing behaviour is considered to be a normal phase of childhood development. In addition to ingestion of soil through the mouthing of objects or hands, true eating of soil (geophagy) is also a source of oral exposure to chemicals for children. Furthermore, children tend to play on the ground and on the floor, which also may lead to an increased exposure to chemicals in soil and dust particles when compared to adults. Soil ingestion among children may be uneven as most children only ingest relatively small amounts, while a few children may consume larger amounts. Deliberate ingestion of larger amounts of soil is termed "pica" (pica, which is the Latin word for the magpie, refers to "*the persistent eating of non-nutritive substances*"). Adults may also ingest soil and dust particles that adhere to food, cigarettes, or their hands thereby being exposed to contaminants in soil and dust particles.

There are several methodologies presented in the literature related to soil and dust ingestion (US-EPA, 2017). Two methodologies combine biomarker measurements with measurements of the biomarker substance's presence in environmental media. One of the biomarker methodologies, the "tracer element" methodology measures quantities of specific elements present in faeces, urine, food and medications, yard soil, house dust, and sometimes also in community soil and dust. This information is then combined by using assumptions about the elements' behaviour in the gastrointestinal tract in order to provide estimates of the amounts of soil and dust ingested. The other biomarker methodology, the "bio-kinetic model comparison" methodology compares results from a bio-kinetic model of lead exposure and uptake that predicts blood lead levels, with biomarker measurements of lead in blood. Lead isotope ratios have also been used as a biomarker with measurements of different lead isotopes in blood and/or urine, food, water, and house dust and compares the ratio of different lead isotopes to infer sources of lead exposure that may include dust or other environmental exposures. A third methodology, the "activity pattern" methodology combines information from activity patterns, e.g. hand-to-mouth and object-to-mouth behaviours with data on time spent at different locations to estimate soil and dust ingestion. The behavioural information can be obtained using videography techniques or from surveys obtained from about children's activities, behaviours, and locations. A fourth methodology applies assumptions regarding ingested quantities of soil and dust based on a general knowledge of human behaviour.

7.1. Europe

In the RAC and SEAC *Opinion on an Annex XV dossier proposing restrictions on Polycyclic-aromatic hydrocarbons (PAH)* (RAC, 2019), a soil uptake of 0.09 g is given for children aged 2–10 years with a reference to a new US-EPA (2017a) soil study. The US-EPA (2017a) reference is to the updated US-EPA *Exposure Factors Handbook* Chapter on soil and dust. The orally ingested amounts used for exposure estimations of rubber granules were 90 mg/event for children (<11 years) and 50 mg/event for children (11 years and up) and for adults when assuming playing on playgrounds and playing sports as an outfield player.

In the *Exposure to chemicals via house dust* (RIVM, 2008), values for ingestion and inhalation of house dust are provided. Table 7.1 presents the default values, which have been based on several studies.

Table 7.1: Default values for house dust ingestion and inhalation

	Ingestion of house dust (mg/day)	Inhalation of house dust (mg/day)	Total intake of house dust (mg/day)
Adult	50	0.8	50
Child	100	2.0	100

Source: RIVM (2008)

In the REACH *Guidance on information requirements and chemical safety assessment* Chapter R.15: *Consumer exposure estimation* (ECHA, 2016a), a conservative estimate of 100 mg/day has been proposed for house dust intake for children with a reference to RIVM (2008).

The Danish Environmental Protection Agency (D-EPA) has in their *Guidance from the Environmental Protection Agency No. 5* (D-EPA, 2006) recommended values for intakes of soil as presented in Table 7.2. The recommendations are based on the 1997 version of the *Exposure Factors Handbook* (US-EPA, 1997).

Table 7.2: Recommended default values for intake of soil

Route of exposure	Default value
Oral, maximum single intake	10 g
Oral, mean daily intake	0.1 g/day
Oral, 95 th percentile	0.2 g/day
Dermal contact, mean daily	1 g/day
Dermal contact, maximum	10 g/day

Source: D-EPA (2006)

In the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), median soil ingestion rates have been estimated as 40 mg/day and 1 mg/day for children and adults, respectively. The data were based upon US studies (Calabrese et al., 1997; Stanek et al., 1997), but represented the best available information according to ECETOC (2001). Upper limits for soil ingestion of 200 mg/day for children and 300 mg/day for adults were considered to be supported by the available data. ECETOC has noted that the higher upper limit for adults is related to data variability and indicates the uncertainty in current estimates. It was also noted that the recommended values were based upon studies performed in the summer or autumn and that soil ingestion during winter is likely lower.

7.2. US-EPA

In the *Exposure Factors Handbook* (US-EPA, 2017), 14 'key studies' were identified. The key studies were used to recommend values for soil and dust ingestion for adults and children. Only two key studies provided data for adults. The US-EPA noted that many of the key studies pre-dated the recommendations on age groups in the US-EPA's *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (US-EPA, 2005), and were performed on groups of children of varying ages. Therefore, central tendency and upper percentile recommendations could only be developed for some combined age categories.

Table 7.3 presents the central tendency and upper percentile recommendations for daily ingestion of soil, dust, or soil + dust, in mg/day and rounded to one significant figure. The soil ingestion recommendations represent ingestion of a combination of soil and outdoor settled dust, without distinguishing between these two sources. The dust ingestion recommendations include solely indoor settled dust. The soil + dust recommendations were derived from the soil + dust values assuming 45% soil and 55% dust.

Table 7.3 also presents the soil-pica and geophagy recommendations for daily ingestion of soil, in mg/day. No data were available on which to base recommendations for dust or soil + dust for adults or children. The US-EPA has noted that, due to the current state of research on soil and dust ingestion, the upper percentile recommendations are called "soil-pica" (the recurrent ingestion of unusually high amounts of soil, i.e., on the order of 1000-5000 mg/day or more) or "geophagy" (the intentional ingestion of earths, usually associated with cultural practises) recommendations that are likely to represent high soil ingestion episodes or behaviours at an unknown point on the high end of the distribution of soil ingestion.

Table 7.3: Recommendation for soil and dust ingestion

Age	Soil ^a				Dust ^b		Soil and dust ^c	
	Central Tendency mg/day	Upper percentile mg/day	Soil-Pica mg/day	Geophagy mg/day	Central Tendency mg/day	Upper percentile mg/day	Central Tendency mg/day	Upper percentile mg/day
< 6 months	20	50	-	-	20	60	40	100
6–<12 months	30	90	-	-	40	100	70	200
1–<2 years	40	90	1,000	50,000	50	100	90	200
2–<6 years	30	90	1,000	50,000	30	100	60	200
1–<6 years	40	90	1,000	50,000	40	100	80	200
6–<12 years	30	90	1,000	50,000	30	100	60	200
12 years through adult	10	50	-	50,000	20	60	30	100

-) No recommendation.

a) Includes soil and outdoor settled dust.

b) Includes indoor settled dust only.

c) Total soil and dust ingestion rate assuming 45% soil and 55% dust .

Source: Modified from US-EPA (2017)

The US-EPA recommended values for intake of soil and presented in Table 7.3 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – low, 2. applicability and utility – low, 3. clarity and completeness – medium, 4. variability and uncertainty – low, and 5. evaluation and review – medium; the overall rating was low. (US-EPA, 2017).

7.3. WHO

WHO (WHO, 1994) has specified the daily amount of soil ingested as 20 mg/day. This is a median value from the national Department of Health of the Government of Canada (Health and Welfare Canada, 1992). It has not been specified whether this standard value is valid for adults or for children.

7.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2017) are the most comprehensive and most recent. The European data are limited as are the WHO data.

In the RAC and SEAC opinion on an Annex XV dossier proposing restrictions on Polycyclic-aromatic hydrocarbons (PAH), the soil uptake is taken from the updated US-EPA *Exposure Factors Handbook* Chapter on soil and dust.

In the *Exposure to chemicals via house dust* (RIVM, 2008), the recommended values presented in Table 7.1 are based on Dutch data.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 (ECHA, 2016a), the recommended value for house dust intake is taken from RIVM (2008).

The US-EPA recommended values for intake of soil and dust presented in Table 7.3 are well validated as the general assessment factors were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA overall rating was low (US-EPA, 2017).

The WHO standard value on soil ingestion is a median value from the national Department of Health of the Government of Canada (Health and Welfare Canada, 1992). It has not been specified whether this standard value is valid for adults and/or for children.

Data on soil and dust ingestion rates are generally limited and variable, and region specific differences in child play and hygienic patterns will likely affect typical soil and dust ingestion rates. Thus, there might be differences between the US and European population regarding soil and dust intake. Despite this, the US-EPA recommendations are considered as being representative for the European population as well. Furthermore, the US-EPA recommendations are considered as being the most valid values for soil and dust ingestion rates as of today despite the overall rating as low, as these recommendations are based on additional more recent key studies than the European recommendations and updated in 2017 (US-EPA, 2017). Furthermore, the US-EPA recommendations are considering both soil and dust ingestion separately for various age groups whereas the RIVM / REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 only consider house dust ingestion for children of unspecified age.

In conclusion, the US-EPA recommended values presented in Table 7.3 are considered as being the most valid values for soil and dust ingestion rates as of today and are therefore recommended as default exposure factors for assessments of soil and/or dust ingestion for the European population in the context of REACH.

8. Non-dietary ingestion factors

Adults and children have the potential for exposure to toxic substances through non-dietary ingestion pathways other than soil and dust ingestion, e.g., ingesting pesticide residues that have been transferred from treated surfaces to the hands or objects that are mouthed. Adult's mouth objects such as cigarettes, pens/pencils, or their hands. Young children mouth objects, surfaces or their fingers as they explore their environment. Mouthing behaviour includes all activities in which objects, including fingers, are touched by the mouth or put into the mouth except for eating and drinking, and includes licking, sucking, chewing, and biting (US-EPA, 2011).

8.1. Europe

In the *RAC Opinion on an Annex XV dossier proposing restrictions on lead and lead compounds in jewellery* (RAC, 2011), a child mouths a jewel for one hour with a surface of 10 cm² and a weight of 10 g. In the *RAC Opinion on an Annex XV dossier proposing restrictions on lead and its compounds in articles intended for consumer use* (RAC, 2013), a child mouths an article (or part thereof) with a surface area of 10 cm² and a weight of 10 g for 60 minutes. There is no references to the mouthing time, surface area of the jewel/article or to the weight of the jewel/article.

In the *Children's Toys Fact Sheet* (RIVM, 2002), default values of hand-to-mouth contact and direct ingestion are presented. As these values are based on various sorts of toys, they are described in the section on Consumer Products (Section 11.2.6).

In the *Preparation of a Guidance Document on Pesticide Exposure; Assessment for Workers, Operators, Bystanders and Residents* (EFSA, 2022), the default value for hand-to-mouth activity for children is set to 9.5 events per hour with a surface area of 20 cm² of the mouthed hands with a reference to a US-EPA document regarding standard operating procedures for residential exposure assessments (US-EPA, 2001).

8.2. US-EPA

In the *Exposure Factors Handbook* (US-EPA, 2011) key studies for mouthing frequency and for mouthing duration were used to develop recommended values, respectively, among children. Only one relevant study was located that provided data on mouthing frequency or duration for adults.

Table 8.1 presents the recommended mouthing frequencies, expressed in units of contacts per hour, between either an object or surface and the mouth (object-to-mouth), or between any part of the hand (including fingers and thumbs) and the mouth (hand-to-mouth) and the duration of object-to-mouth contacts.

The recommended hand-to-mouth frequencies are based on data from Xue et al. (2007, cited in US-EPA, 2011), which provided data for the age groups in US-EPA's *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (US-EPA, 2005) and categorized the

data according to indoor and outdoor contacts. The recommendations for object-to-mouth contact frequencies are based on data from Xue et al. (2010, cited in US-EPA, 2011). Recommendations for duration of object-to-mouth contacts are based on data from three key studies (Juberg et al., 2001; Greene, 2002; Beamer et al., 2008 – all cited in US-EPA, 2011). These recommendations pre-dated the US-EPA's *Guidance on Selecting Age Groups for Monitoring and Assessing Childhood Exposures to Environmental Contaminants* (US-EPA, 2005). In cases for which age groups of children in the key studies did not correspond exactly to US-EPA's recommended age groups, the closest age group was used.

Table 8.1: Recommendations on mouthing frequency and duration among children

Age	Object to mouth					
	Indoor frequency		Outdoor frequency		Duration	
	Mean contacts/hr	95 th Percentile contacts/hr	Mean contacts/hr	95 th Percentile contacts/hr	Mean contacts/hr	95 th Percentile contacts/hr
0–1 months	-	-	-	-	-	-
1–<3 months	-	-	-	-	-	-
3–<6 months	11	32	-	-	11	26
6–<12 months	20	38	-	-	9	19
1–<2 years	14	34	8.8	21	7	22
2–<3 years	9.9	24	8.1	40	10	11
3–<6 years	10	39	8.3	30	-	-
6–<11 years	1.1	3.2	1.9	9.1	-	-
11–<16 years	-	-	-	-	-	-
16–<21 years	-	-	-	-	-	-

Age	Hand-to-mouth			
	Indoor frequency		Outdoor frequency	
	Mean contacts/hr	95 th Percentile contacts/hr	Mean contacts/hr	95 th Percentile contacts/hr
0–1 months	-	-	-	-
1–<3 months	-	-	-	-
3–<6 months	28	65	-	-
6–<12 months	19	52	15	47
1–<2 years	20	63	14	42
2–<3 years	13	37	5	20
3–<6 years	15	54	9	36
6–<11 years	7	21	3	12
11–<16 years	-	-	-	-
16–<21 years	-	-	-	-

Sources: 'Object-to-mouth' frequencies: Xue et al. (2010), 'Hand-to-mouth' frequencies: Xue et al. (2007), 'Mouthing duration': Juberg et al. (2001); Greene et al. (2002) and Beamer et al. (2008), modified from US-EPA (2011).

Note: All references are cited in US-EPA (2011)

The US-EPA recommended values for non-dietary ingestion factors presented in Table 8.1 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – low, 2. applicability and utility – low, 3. clarity and completeness – low, 4. variability and uncertainty – low, and 5. evaluation and review – medium; the overall rating was low for both frequency and duration of hand-to-mouth and object-to-mouth. (US-EPA, 2011).

8.3. WHO

No recommendations on non-dietary ingestion factors are provided by the WHO.

8.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) are the most comprehensive. The European data are limited to single values for specific assessment purposes. No recommendations have been provided by the WHO.

In the two RAC opinions on lead in jewels or in articles, there is no references to the mouthing time, surface area of the jewel/article or to the weight of the jewel/article.

The EFSA *Guidance Document for Plant Protection Products* (EFSA, 2022) recommended values are taken from a US-EPA document regarding standard operating procedures for residential exposure assessments (US-EPA, 2001).

The US-EPA recommended values for non-dietary ingestion factors presented in Table 8.1 are well validated as the general assessment factors were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA overall rating was low for both frequency and duration of hand-to-mouth and object-to-mouth (US-EPA, 2011).

There might be some differences between US and European children regarding hand-to-mouth and hand-to-object frequency and duration. Despite this, the US-EPA recommended values are considered as being representative for European children as well. Furthermore, the US-EPA recommendations are considered as being the most valid values for non-dietary ingestion factors as of today despite the overall rating as low, as these recommendations are based on relatively recent key studies published in the period 2001–2008.

In conclusion, the US-EPA recommended values presented in Table 8.1 are considered as being the most valid values for non-dietary ingestion factors as of today and are therefore recommended as default exposure factors for assessments of European children in the context of REACH. No studies have been located on mouthing frequency or duration for adults and therefore, no default exposure factors can be recommended.

9. Lifetime expectancy

The length of an individual's life is an important factor to consider when evaluating cancer risk because the dose estimate is averaged over an individual's lifetime. Since the average lifetime expectancy is found in the denominator of the dose equation, a shorter lifetime expectancy would result in a higher potential risk estimate, and conversely, a longer lifetime expectancy would produce a lower potential risk estimate (US-EPA, 2011).

9.1. Europe

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012), the recommended lifespan is 75 years for exposure assessments of consumers and man exposed indirectly via the environment (Table R.8–18).

According to the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001), the average life expectancy of a UK child born in 1998 is 78 years.

9.2. US-EPA

According to the *Exposure Factors Handbook* (US-EPA, 2011), current data suggest that 78 year is an appropriate value to reflect the average life expectancy of the general population and is therefore the recommended value for men and women together. It is noted, however, that if gender is a factor considered in the assessment, the recommended average life expectancy value for females is higher than for males, i.e. 75 years for males and 80 years for females, based on life expectancy data from 2007 (Xu et al., 2010 – cited in US-EPA, 2011). Table 9.1 presents recommended values for life expectancy at birth.

The US-EPA recommended values for lifetime expectancy are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness – high, 2. applicability and utility – high, 3. clarity and completeness – high, 4. variability and uncertainty – medium, and 5. evaluation and review – high. The overall rating was high.

Table 9.1: Recommended values for expectation of life at birth: 2007

Population	Life expectancy (years)
Men	75
Women	80
Total	78

Source: Xu et al. (2010); modified from US-EPA (2011)

9.3. WHO

WHO has estimated worldwide life expectancy at birth for the year 2008 (WHO, 2010). Table 9.2 presents life expectancy at birth for all European countries combined and global.

Table 9.2: Life expectancy at birth for the European countries and global

Population	Life Expectancy (years)
European Region	
Men	71
Women	79
Men and women	75
Global	
Men	66
Women	70
Men and women	68

Source: WHO (2010)

9.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) as well as the European and WHO data are limited.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended value in Table R.8–18 is stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommendations are taken from one of these references or both.

The US-EPA recommended values for lifetime expectancy are well validated and valid as the US-EPA overall rating was high.

The WHO recommended values in Table 9.2 are from statistics published in 2010. There is a very recent draft statistics published in 2022; however, information in this

draft document cannot be quoted without the permission from WHO and is therefore, not taken into account here.

Lifetime expectancy is very different for various countries and parts of the World. The data published by the WHO in 2010 for the European Region are considered as being the most representative for European lifetime expectancy as of today.

In conclusion, the WHO recommended values for the European Region presented in Table 9.2 are considered as being the most valid values for lifetime expectancy as of today for the European population and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

10. Activity Factors

Individual or group activities are important determinants of potential exposure, because toxic chemicals introduced into the environment may not cause harm to an individual until an activity is performed that subjects the individual to contact with those contaminants. An activity or time spent in a given activity will vary among individuals on the basis of, for example, culture, ethnicity, hobbies, location, gender, age, socioeconomic characteristics, and personal preferences (US-EPA, 2011).

10.1 Europe

In the *REACH Guidance on information requirements and chemical safety assessment* Chapter R.8 (ECHA, 2012), the recommended length of a workday is set to 8 hours, working days per week are 5, working weeks per year are 48 weeks, and work life is 40 years (Table R8–18).

The *General Fact Sheet* (RIVM, 2014) presents time activity patterns based on surveys in the Netherlands. Time is distinguished into three main categories:

- Mandatory time: going to school, working hours, housekeeping and caring
- Personal time: sleeping and eating
- Leisure time

Mandatory time covers 25% of the weekly hours. Adult women spend more time on housekeeping than men, 25 hours versus 12.4 hours per week. In addition, women spend twice as much time at cooking and cleaning than men. Personal time covers 46% of the weekly hours. Adult men and women (>12 years) spend an average of 8.5 hours per day sleeping with women tending to sleep almost two hours per week more than men. Approximately 6 hours per week are spent on physical care, such as personal hygiene, cosmetics and getting dressed. Leisure covers 28% of the weekly hours with 40% spend using different media, such as reading, watching television or using the computer. Parents with a child below the age of 4 years have the least leisure time, while persons above the age of 40 years have the most time for leisure (RIVM, 2014).

Table 10.1. presents recommended values for activity factors for UK adults and children according to the *Exposure Factors Sourcebook for European Populations, with Focus on UK Data* (ECETOC, 2001).

Table 10.1: Standard values for activity factors for UK adults and children

Activity scenario	Mean/Median time spent
Work hours per week	38 ^a hours/day
Indoors (adults)	22 hours/day
Outdoors (adults)	2 hours/day
School day for children	7 ^b hours/day (for 190 day per year)
Indoors	5 hours/day
Outdoors	2 hours/day
Time spent at home	
For full-time workers	15 hours/day (14 indoors, 1 outdoors)
For individuals not employed outside of the home	20.5 hours/day (18.5 indoors, 2 outdoors)
Time spent away	
For full-time workers	9 hours/day
For individuals not employed outside of the home	3.5 hours/day
Outdoor recreation (for adults)	0.3 hours/day (for 365 days per year)
Employment tenure^c	8 years
Residential tenure	9 years
School tenure	7 years primary school
	5 years secondary school

a) Based upon the assumption of 6 weeks for combined vacation and leave, an estimate of ~230 workdays/year (46 weeks at 5 days/week) is obtained.

b) For secondary school children involved in extracurricular activities, a value of 8 hours/day may be more representative.

c) Time spent working for current employer.

Source: Modified from ECETOC (2001)

10.2 US-EPA

In the *Exposure Factors Handbook* (US-EPA, 2011), recommended standard values for activity factors are based on different key studies and values for various scenarios are presented in Table 10.2.

The values presented in Table 10.2 are well validated as the general assessment factors (GAFs, described in Section 1.2) were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA has assigned the following confidence ratings for the five GAFs: 1. Soundness –high, 2. applicability and utility – medium, 3. clarity and completeness – medium, 4. variability and uncertainty – medium, and 5. evaluation and review – medium. The overall rating was medium for the mean and low for the upper percentile (US-EPA, 2011).

Table 10.2: Recommended values for activity patterns

Age group	Mean	95 th Percentile	Reference
Time indoors (total) in minutes per day			
0–1 month	1,440	-	US-EPA analysis of source data from Wiley et al. (1991) for age groups from birth to < 12 months.
1–<3 months	1,432	-	
3–<6 months	1,414	-	
6–<12 months	1,301	-	
1–<2 years	1,353	-	US-EPA re-analysis of source data from US-EPA (1996) for age groups from 1 to < 21 years.
2–<3 years	1,316	-	
3–<6 years	1,278	-	
6–<11 years	1,244	-	
11–<16 years	1,260	-	
16–<21 years	1,248	-	
18–<65 years	1,159	-	
≥65 years	1,142	-	
Time outdoors (total) in minutes per day			
0–1 month	0	-	US-EPA analysis of source data from Wiley et al. (1991) for age groups from birth to < 12 months.
1–<3 months	8	-	
3–<6 months	26	-	
6–<12 months	139	-	
1–<2 years	36	-	US-EPA re-analysis of source data from US-EPA (1996) for age groups from 1 to < 21 years.
2–<3 years	76	-	
3–<6 years	107	-	
6–<11 years	132	-	
11–<16 years	100	-	
16–<21 years	102	-	
18–<65 years	281	-	
≥65 years	298	-	
Time indoors (at residence) in minutes per day			
0–<1 year	1,108	1,440	Children, Birth to <21 years: US-EPA re-analysis of source data from US-EPA (1996).
1–<2 years	1,065	1,440	
2–<3 years	979	1,296	
3–<6 years	957	1,355	
6–<11 years	893	1,275	
11–<16 years	889	1,315	

16–<21 years	833	1,288	
18–<65 years	948	1,428	Adults, ≥ 18 years (US-EPA, 1996).
≥65 years	1,175	1,440	
Showering in minutes per day			
0–<1 year	15	-	
1–<2 years	20	-	
2–<3 years	22	44	US-EPA re-analysis of source data from US-EPA (1996).
3–<6 years	17	34	
6–<11 years	18	41	
11–<16 years	18	40	
16–<21 years	20	45	
Bathing in minutes per day			
0–<1 year	19	30	
1–<2 years	23	32	
2–<3 years	23	45	US-EPA re-analysis of source data from US-EPA (1996).
3–<6 years	24	60	
6–<11 years	24	46	
11–<16 years	25	43	
16–<21 years	33	60	
Bathing and showering in minutes per day			
18–<65 years	17	-	US-EPA (1996).
≥65 years	17	-	
Swimming in minutes per month			
0–<1 year	96	-	Children, Birth to < 21 years: US EPA re-analysis of source data from US EPA (1996).
1–<2 years	105	-	
2–<3 years	116	181	
3–<6 years	137	181	
6–<11 years	151	181	
11–<16 years	139	181	
16–<21 years	145	181	
18–<65 years	45 ^a	181	Adults, ≥18 years (US EPA, 1996).
≥65 years	40 ^a	181	
Playing on sand/gravel in minutes per day			
0–<1 year	18	-	Children, Birth to < 21 years: US EPA re-analysis of source data from US EPA (1996).
1–<2 years	43	121	
2–<3 years	53	121	

3–<6 years	60	121	
6–<11 years	67	121	
11–<16 years	67	121	
16–<21 years	83	-	
18–<65 years	0 ^a	121	Adults, ≥18 years (US EPA, 1996).
≥65 years	0 ^a	-	
Playing on grass in minutes per day			
0–<1 year	52	-	Children, Birth to < 21 years: US EPA re-analysis of source data from US EPA (1996).
1–<2 years	68	121	
2–<3 years	62	121	
3–<6 years	79	121	
6–<11 years	73	121	
11–<16 years	75	121	
16–<21 years	60	-	
18–<65 years	60 ^a	121	Adults, ≥18 years (US EPA, 1996).
≥65 years	121 ^a	-	
Playing on dirt in minutes per day			
0–<1 year	33	-	Children, Birth to < 21 years: US EPA re-analysis of source data from US EPA (1996).
1–<2 years	56	121	
2–<3 years	47	121	
3–<6 years	63	121	
6–<11 years	63	121	
11–<16 years	49	121	
16–<21 years	30	-	
18–<65 years	0 ^a	121	Adults, ≥18 years (US EPA, 1996).
≥65 years	0 ^a	-	

- Percentiles were not calculated for sample sizes less than 10 or in cases where the mean was calculated by summing the means from multiple locations or activities.

a) Median value, mean not available in US-EPA (1996).

Note: All activities are reported in units of minutes/day, except swimming, which is reported in units of minutes/month. There are 1,440 minutes in a day. Time indoors and outdoors may not add up to 1,440 minutes due to activities that could not be classified as either indoors or outdoors.

Source: Modified from US-EPA (2011)

10.3 WHO

No recommendations on activity factors are provided by WHO.

10.4. Conclusion and recommendations

The data presented in the US-EPA *Exposure Factors Handbook* (US-EPA, 2011) are the most comprehensive. The European data are limited. No recommendations have been provided by the WHO.

In the REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8 (ECHA, 2012), the recommended values in Table R.8–18 are stated as “taken from Gold et al., 1984 and ICRP, 1975”; however, it is not clear whether the recommendations are taken from one of these references or both.

The RIVM *General Fact Sheet* (RIVM, 2014) include three main categories (mandatory time, personal time and leisure time) for the Dutch population.

The US-EPA recommended values are well validated as the general assessment factors were used to judge the quality of the underlying data used to derive the recommendations. The US-EPA overall rating was medium for the mean and low for upper percentile.

Activity levels might be different among US individuals compared to Europeans. Despite this, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommendations are considered as being the most valid values for activity factors. It should be noted that the recommended values in the 2011 version of the *Exposure Factors Handbook* (US-EPA, 2011) are based on two key studies published in 1991 and 1996.

In conclusion, the US-EPA recommended values presented in Table 10.2 are considered as being the most valid values for activity factors for Europeans as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

No default values for working activities are recommended by the US-EPA as the working environment is not the responsibility of US-EPA. For working activities, the recommended values presented in Table 10.1 are recommended as default exposure factors for assessments of European workers in the context of REACH.

11. Consumer products

Consumer products may contain toxic or potentially toxic chemical substances to which people can be exposed during use of such consumer products. For example, household cleaners can contain ammonia, alcohols, acids, and/or organic solvents. Potential routes of exposure to consumer products or chemical substances released from consumer products during use include inhalation and dermal contact as well as ingestion. Individuals, including children, can be passively exposed to chemical substances in the consumer products. Since people spend a large amount of time indoors, the use of household products in the indoor environment can be an important source of exposure (US-EPA, 2011).

In order to estimate consumer product exposure, three exposure routes are to be considered: inhalation, dermal and oral routes, each exposure calculated separately (RIVM, 2006a):

- *Inhalation:*
 - It is assumed that all substances are released as a gas, vapour or airborne particulate into a standard room. This may be due to direct release or to evaporation from a liquid or a solid matrix
- *Dermal*, two options:
 - The substance is contained in a preparation. This option is applicable when, for example, hands are put into a solution containing the substance under evaluation, or splashes occur (painting).
 - Substance migrating from an article; applicable, for example, when residual dyes in clothing are in contact with skin and migrate from the clothing.
- *Oral*, two options:
 - Substance in a product unintentionally swallowed during normal use.
 - Substance migrating from an article; applicable for example when a substance migrates from a pen, cutlery or textile.

11.1. Europe

As mentioned in section 1.1.2, RIVM has provided Fact Sheets with default values for several consumer products, which are used for calculation of exposure by using the ConsExpo software model¹². The default values in the fact sheets have been collected for consumers (private or non-professional users). The fact sheets, therefore, only describe consumer products, which are available to the consumer for private use (RIVM, 2014).

The default parameter values in the fact sheets are aimed at (Dutch) consumers. The basis for the default values is a realistic worst-case scenario that considers consumers who frequently use a specific consumer product under relatively less favourable conditions. They are chosen such that a relatively high exposure is calculated, in the order of magnitude of a 99th percentile of the population exposure distribution. To achieve this goal, the 75th or the 25th percentile is calculated for each

12. <https://www.rivm.nl/en/consexpo#tcm:13-42793>

parameter. The 75th percentile is normally used for proportional parameters, except in the case of reverse proportional parameters, for which the 25th percentile is used, e.g. for body weight. For a significant number of parameters, there are actually too few data to calculate the 75th or 25th percentile. In such cases, an estimate is made which corresponds to the 75th or 25th percentile (RIVM, 2014).

11.1.1. Cosmetics

The *Cosmetics Fact Sheet* (RIVM, 2006b) covers the use of cosmetics by consumers for 35 product categories including shampoo, make-up, lipstick, deodorant and toothpaste. Default models and values for all 35 product categories have been determined to assess exposure and intake of compounds in cosmetics (RIVM, 2006b).

Exposure assessments for sprays can be very complicated and several parameters have to be taken into account such as e.g. the room size where the spraying process takes place, the size of the droplets and the composition of the substance. Especially the size of the droplets is important. During spraying the user can inhale droplets of the product. Sprays produce an aerosol cloud of very small to small droplets. The speed with which the droplets fall depends on the size of the droplet; smaller droplets stay in the air longer and smaller droplets are more prone to be inhaled. In the *Cosmetics Fact Sheet* (RIVM, 2006b), different terminologies are used in order to describe the exposure for spraying towards a person:

- *Cloud volume*: During the actual spraying of a cosmetic product towards a person, the person is exposed to an aerosol cloud with fine particles. In the ConsExpo 4.0 spray model, the volume of the cloud after 1 second is assumed to further increase linearly in time until spraying stops or the cloud volume equals the volume of the room. It is assumed that during the use of the spray (the actual spraying) the breathing zone of the exposed person is located inside this volume. After spraying, the sprayed material is assumed to be homogeneously dispersed over the entire room. The default value for cloud volume is set at 1/16 m³ or 0.0625 m³. This cloud volume matches a cone measuring 1 m (length) and 0.5 m (diameter); in addition, it matches a sphere with a diameter of 0.5 m.
- *Airborne fraction*: The airborne fraction is the fraction of non-volatile material that becomes airborne in the form of droplets. The airborne fraction depends on the way it is used, i.e. spraying on a surface (paint, wood preservative) or spraying in the air (spraying against flies), and on the droplet size distribution that has been specified. Several airborne fractions have been investigated and based on these measures, the default values for air space sprays and surface sprays have been set. The airborne fraction for air space sprays has been set to 1. The airborne fraction for surface sprays with a median of the initial particle distribution < 50 µm has been set to 1 and for surface sprays with a median of the initial particle distribution ≥ 50 µm to 0.2.
- *Initial particle distribution*: As mentioned earlier, the droplet size is an important parameter when estimating the exposure. Smaller drops fall at a lower speed and stay in the air for longer. The large droplets will quickly disappear from the air after being formed. As an indication the falling time for droplets with a diameter of 100 µm from a height of 3 meters is calculated to 11 seconds and for droplets with a diameter of 10 µm it is calculated at 17 minutes.

- **Inhalation cut-off diameter:** The inhalation cut-off diameter is the measure for the diameter of the spray droplets that can be inhaled and reach the lower areas of the lungs, i.e. the alveoli, bronchioles and bronchia. Droplets that are above this diameter will deposit in the upper respiratory tract and will be cleared from the airways via the gastro-intestinal tract, leading to oral exposure. The inhalation cut-off diameter is an approximation and is around 10-15 µm. According to RIVM, the default value is set at 15 µm.
- **Density:** Many non-volatile substances in cosmetics are made of large organic compounds with densities usually between 1.0 and 1.5 g/cm³. For a complex mixture of compounds, the density is set at 1.8 g/cm³. The density of salts generally varies between 1.5 and 3.0 g/cm³ (RIVM, 2006b).

In Table 11.1 a summary of general default values for cosmetic sprays is presented and in Table 11.2, default values for the density of solvents and non-volatile compounds are presented (RIVM, 2006b).

Table 11.1: General default values for cosmetic sprays

Inhalation, spray model: spraying towards exposed person	Default value
Cloud volume	
Spray cans	0.0625 m ³
Pump sprays	0.0625 m ³
Airborn fraction	
Airspace sprays / surface sprays with median of the initial particle distribution < 50 µm	1
Surface sprays with median of the initial particle distribution ≥ 50 µm	0.2
Inhalation cut-off diameter	15 µm
Source: Modified from the Cosmetics Fact Sheet, RIVM (2006b)	

Table 11.2: Default values for density

Type	Main ingredient	Density [g/cm ³]
Solvents	Volatile organic solvents	0.7
	Water	1
Non-volatile compounds	Large organic compounds	1.5
	Salts	3.0
	Complex mixture of compounds, especially organic compounds	1.8

Source: Modified from the Cosmetics Fact Sheet, RIVM (2006b)

In the *Cosmetics Fact Sheet* (RIVM, 2006b) default values on the use of various cosmetic products are provided. The majority of the products are assumed only to be used by women with a body weight of 61 kg. The 'normal' use of cosmetics by children, such as the use of baby salves, baby powder, sunscreen lotions and toothpaste, for example, is included in the *Cosmetics Fact Sheet* (RIVM, 2006b). Whereas cosmetic products used as children's toys are included in the *Children's Toys Fact Sheet* (RIVM, 2002). It is assumed that the room temperature is 20 °C, that the room height is 2.5 m and that the uptake fraction (inhalation and oral) is 1.

As all default values for the various cosmetic products are input parameters to ConsExpo and thus, included in the model as well as in the *Cosmetics Fact Sheet* (RIVM, 2006b), the default values are not reproduced in this report.

11.1.2. Cleaning products

In the *Cleaning Product Fact Sheet* RIVM (2006c) cleaning products are classified into 36 product categories, which are drawn up according to the type of product. As in the *Cosmetics Fact Sheet* (RIVM, 2006b) various default exposure models are chosen and filled in with default parameter values. These models are thoroughly described in the Fact Sheets, but will only shortly be mentioned here, when necessary. The *Technical Notes for Guidance on Human Exposure to Biocidal Products* (TNsG) has provided most of the data used in this fact sheet (TNsG, 2007).

Most cleaning products are ready for use. However, some of the cleaning products require preparation before they can be used; so-called mixing and loading has to be applied first. During the mixing and loading process additional exposure may occur.

The parameters during the spraying process are mentioned in the previous section, however, there are some differences when spraying with cosmetics and cleaning products. Cosmetics sprays are used directly towards the consumer whereas cleaning products are used to clean different surfaces away from the consumer. Here, only the parameters that differ from the spraying process for cosmetics are mentioned:

- *Spray duration and exposure duration*: The duration of spraying and rinsing/cleaning is directly related to the size of the cleaned area. The default values for spraying and for cleaning are set at 14.3 sec/m² and 110 sec/m², respectively, based on a pilot study (RIVM, 2006c).
- *Mass generation rate*: The default value for mass generation rate is set at 0.78 g/sec and it is used for the following trigger sprays: all-purpose spray, bathroom spray, glass spray and oven spray. This default value is based on different studies (RIVM, 2006c).
- *Initial particle distribution*: This parameter is described under "cosmetics", however, default values for initial particle distribution for cleaning sprays are given. For aerosol spray cans, the default is a lognormal distribution with median 25 µm, coefficient of variation 0.4. For trigger sprays, the default is a lognormal distribution with median 100 µm, coefficient of variation 0.6 (RIVM, 2006c).
- *Airborne fraction*: The default values for airborne fraction are identical for

cosmetic sprays and cleaning sprays.

- *Density*: See under "cosmetics".
- *Inhalation cut-off diameter*: See under "cosmetics".

In Table 11.3, an overview is given for the default values of aerosol spray cans and trigger sprays that are used repeatedly in the *Cleaning Product Fact Sheet* (RIVM, 2006c).

Table 11.3: Overview of default values of aerosol cans and trigger sprays

Aerosol spray can	Default value
Inhalation, spray model	
Mass generation rate	1.5 g/sec
Airborne fraction	1
Density non-volatile	1.8 g/cm ³
Initial particle distribution; median (CV)	25 µm (0.4)
Inhalation cut-off diameter	15 µm
Dermal, constant rate	
Contact rate	100 mg/min
Trigger sprays	
Inhalation, spray model	
Mass generation rate	0.78 g/sec
Airborne fraction	0.2
Density non-volatile	1.8 g/cm ³
Initial particle distribution; median (CV)	100 µm (0.6)
Inhalation cut-off diameter	15 µm
Dermal, constant rate	
Contact rate	46 mg/min

Source: Modified from the Cleaning Product Fact Sheet, RIVM (2006c)

In the *Cleaning Product Fact Sheet* (RIVM, 2006c), dermal exposure of the user during application is calculated based on the 'constant rate' model from ConsExpo. The *Technical Notes for Guidance on Human Exposure to Biocidal Products* (TNsG, 2007) has provided the data for this model. For the 'constant rate' model the parameter 'contact rate' is required. The contact rate is the rate at which the product is applied to the skin, in weight per time unit. The 'constant rate' model is used for all spray applications. The following parameters are used in the 'constant rate' model:

- *Contact rate aerosol spray cans:* The dermal exposure on hands and forearms ranges from 1.7 to 156 mg/min with a 75th percentile of 64.7 mg/min. The dermal contact rate for legs, feet and face ranges from 17 to 45.2 mg/min with a 75th percentile of 35.7 mg/min. Using these data, the default value for contact rate aerosol spray cans is set at 100 mg/minute (RIVM, 2006c).
- *Contact rate trigger sprays:* The dermal exposure on hands and forearms ranges from 3 to 68.2 mg/min with a 75th percentile of 36.1 mg/min. The dermal contact rate for legs, feet and face ranges from 1.9 to 12.4 mg/min with a 75th percentile of 9.7 mg/min. Using these data, the default value for contact rate for trigger sprays is set at 46 mg/minute.

In Table 11.4, an overview is given for generic default values that are used repeatedly in the *Cleaning Product Fact Sheet* (RIVM, 2006c).

Table 11.4: Default values used repeatedly in the Fact Sheet

	Default value
Ventilation rates (inhalation model – spraying and evaporation)	
Bathroom/toilet	2.0 h ⁻¹
Kitchen	2.5 h ⁻¹
Living room	0.5 h ⁻¹
Garage	1.5 h ⁻¹
Non-specified room	0.6 h ⁻¹
Room temperature (inhalation model)	20 °C
Room volumes (inhalation model – spraying and evaporation)	
Bathroom	10 m ³
Toilet	2.5 m ³
Kitchen	15 m ³
Living room	58 m ³
Garage	34 m ³
Non-specified room	20 m ³
Standard room height (inhalation model – spraying and evaporation)	2.5 m
Uptake fraction (inhalation, dermal and oral uptake)	1 (potential dose)
Inhalation rate (inhalation)	24.1 l/min (light exercise)

Source: The Cleaning Product Fact Sheet, RIVM (2006c)

An updated version of the *Cleaning Product Fact Sheet*, RIVM (2018) is available and provides more detailed information than the 2006 version (RIVM, 2006c), according to RIVM (2018). The structure of the updated version is completely different from that in the 2006 version, as well as is the terminology of default values. According to RIVM (2018) "*all changes to exposure scenarios, selected ConsExpo models and default parameter values in comparison with the previous version, published in 2006, are shown in a single data table, so that they can easily be identified.*"

As all default values for the various cleaning products are input parameters to ConsExpo and thus, included in the model as well as in the *Cleaning Product Fact Sheet* (RIVM, 2018), the default values are not reproduced in this report.

11.1.3. Do-it-yourself products

In the *Do-it-yourself Products Fact Sheet* (RIVM, 2007a), do-it-yourself (DIY) products are classified into 26 categories, which are characterized according to the type of use and exposure. DIY tasks are carried out mainly during leisure time. According to data from Statistics Netherlands (2005), approximately 25% of the Dutch population (age over 14 years) spends one to four hours per week on DIY tasks. Furthermore, Statistics Netherlands specifies that 6% of that population spends over five hours per week on DIY tasks during their leisure time (RIVM, 2007a).

Like in the two previous described Fact Sheets, default models and default parameter values are proposed for each product category. The default values provided in the *Do-it-yourself Products Fact Sheet* (RIVM, 2007a) are mainly based on an observational study by RIVM by Magré from 2005 (Magré, 2005). However, the observations in this study were quite low. Therefore, the information gathered in the study can be used as preliminary data which can be considered indicative for consumer use of DIY products.

The exposure models are also thoroughly described in this Fact Sheet and will only shortly be mentioned under each product. The more complicated model 'spraying' is already described in the two previous sections. A few general default values will be described here:

- *Non-specified room:* Unless it is obvious or specified where the task will be performed, a 'non-specified room' will be considered. The non-specified room has a volume of 20 m³ with a ventilation rate of 0.6 h⁻¹. The temperature is usually that of the room, which is set at 20 °C and the standard room height is 2.5 m (RIVM, 2007a).
- *The user:* Users of DIY products are both men and women, (although men use these items more often. The average size of body parts for adults is used here from General Fact Sheet (RIVM, 2006a). The body weight of the adult user is set at 65 kg as a default. It is most likely that individuals will be dermally exposed to their hands while working with DIY products, where both intentionally or accidental contact may occur. The surface area for both hands is set at 860 cm² by default, whereas sometimes only one hand or one palm will be taken as exposure area. These surface areas relate to the total surface area by factor 0.5 or 0.25, respectively. Fingertips are quite often used to smooth

joints made from sealants. Their surface area is set at 1 cm² per fingertip (RIVM, 2007a).

- **Molecular Weight Matrix:** DIY products are in most cases mixtures of compounds; in the case of a mixture the evaporation is not only determined by the compound of interest, but also by the other constituents. The molecular weight of the matrix (or: mol. weight matrix) is the weighted average of the matrix, which contains the chemical of interest. The mol. weight matrix parameter is used to correct for the evaporation rate since it describes the average mol. weight of the rest of the total product (the product minus the compound of interest). This parameter can be left blank when the product purity is 100%. The exact composition is not known in most cases. When the composition is unknown the mol. weight matrix will be set at 3000 g/mol as a worst case value when nothing else is stated. Roughly, inserting this value in the evaporation model will result in an estimation of a product in its pure form (RIVM, 2007a).

As all default values for the various DIY products are input parameters to ConsExpo and thus, included in the model as well as in the *Do-it-yourself Products Fact Sheet* (RIVM, 2007a), the default values are not reproduced in this report.

11.1.4. Paint products

In the *Paint Products Fact Sheet* (RIVM, 2007b), paint products are classified into product categories, which are drawn up according to the type of product and the application method, i.e. 'Brush and roller painting' and 'Spray painting'.

According to the *Paint Products Fact Sheet* (RIVM, 2007b), there is a relationship between the type of paint, use duration and product amount. Spray cans with paint are usually applied during a short time. Latex wall paint is usually applied for large surfaces in larger quantities and the application duration will be relatively long. The quantity of paint used per unit of time when painting a chair or a window frame will be much smaller than when painting a lathed wall or varnish a floor. If paint is sprayed, aerosol particles are formed which can be inhaled, which may lead to inhalation exposure to non-volatile compounds present in the paint (RIVM, 2007b).

Several models and parameters have already been discussed in the previous sections. It is assumed that the body weight is 65 kg (default values for adults (RIVM, 2006a) and the room temperature is 20 °C.

As all default values for the various paint product categories are input parameters to ConsExpo and thus, included in the model as well as in the *Paint Products Fact Sheet* (RIVM, 2007b), the default values are not reproduced in this report.

11.1.5. Disinfectant products

Disinfectant products are used to control or to prevent growth of micro-organisms i.e. bacteria, viruses, and fungi. There is a great diversity in use and application types for the products. There are liquids, granulates, powders, tablets, gasses. Some of these products can be used without any preparation, while others have to be

processed (mixed and loaded) before use, for example by diluting or cutting up (RIVM, 2006d).

In the *Disinfectant Products Fact Sheet* (RIVM, 2006d), the 'disinfectant products' are divided into the following product categories: algae, green deposit removers, swimming pool disinfectants, disinfectants for animal accommodations or animal transport vehicles (RIVM, 2006d).

As all default values for the various disinfectant product categories are input parameters to ConsExpo and thus, included in the model as well as in the *Disinfectant Products Fact Sheet* (RIVM, 2006d), the default values are not reproduced in this report.

11.1.6. Children's toys

In the *Children's Toys Fact Sheet* (RIVM, 2002), default values on different toys are classified according to the ways in which children can be exposed instead of by product type.

Default values on mouthing times for children are calculated based on an extensive study by Groot et al. (cited in RIVM, 2002). Results from the study are multiplied by a factor of 1.5 to include the night-time because only daily duration was considered in the study. For mouthing times on a pacifier, only average times are known and no standard deviations. The calculated default values on mouthing times for children are presented in Table 11.5.

With regard to the age category, RIVM has in each case chosen the age category for which the highest exposure is expected. In practice, it means that the youngest children who played with a certain type of toy were chosen for the defaults. The youngest children are the lightest and have the highest uptake per kg of body weight for the same exposure (RIVM, 2002). Moreover, when applying default values, it is not possible to work with time periods, but instead, a point in time must be chosen. For example, a body weight to a child of 3 to 6 months cannot be attributed; you must choose a point in time (4.5 months) (RIVM, 2002).

Table 11.5: Default values on mouthing times for children

Period ^a (months)	Age ^a (months)	Default mouthing times (min/day)			
		Pacifier	Toys for mouthing ^b	Other toys ^c	Non toys ^d
3–6	4.5	285	11	27	8
6–12	7.5	82	21	63	23
12–18	13.5	52	0	9	26
18–36	18	62	0	3	6

a) When applying default values, it is not possible to work with time periods. For example, you cannot attribute a body weight to a child of 3 to 6 months; you must choose a point in time (4.5 months).

b) Toys meant for mouthing: all kinds of teething rings, some rattles.

c) Other toys: cloth books, plastic books, cuddly toy.

d) Non toys: a piece of cloth, a piece of paper, a book for adults, flatware.

Reference: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

If a child puts an object in its mouth, pieces of the object can break away, and these can be swallowed. When toys are mouthed, pieces can also break off and be swallowed, such as paint from the metal toy car, for example. Apart from putting objects in the mouth, substances can be taken in by hand-mouth contact.

In order to estimate default values on direct ingestion, the following parameters must be taken into account: the composition of the ingested product, the density of the product, the dilution of the product before it is ingested and the amount of product taken in. However, due to a lack of measurements data on the amount ingested, only estimates on a few specific toys are made: modelling clay, paint from a toy car, and a ball pen. When calculating default values on mouth-hand contact the composition of the product ingested and the ingestion rate (in volume-units per unit time) is the only parameters that has to be estimated (RIVM, 2002). Table 11.6 presents default values on direct ingestion of children's toys and Table 11.7 presents default values on hand-mouth contact.

Table 11.6: Default values on direct ingestion of children's toys

	Default value	Comments
Modelling clay^a		
Contact		
Frequency	52/year	Estimation
Total duration	60 minutes	Estimation
Use duration	60 minutes	Estimation
Oral		
Product volume	0.5 cm ³	Estimation
Density	2 g/cm ³	Estimation
Absorbed fraction	1	Potential dose
Paint from a toy car^b		
Contact		
Frequency	150/year	Estimation, 3x/week
Total duration	3 minutes	See Table 3.2.1. "other toys"
Use duration	3 minutes	See Table 3.2.1. "other toys"
Oral		
Product volume	0.05 cm ³	Estimation
Density	2 g/cm ³	Estimation
Absorbed fraction	1	Potential dose
Ball pen^c		
Contact		
Frequency	365/year	Estimation

Total duration	30 minutes	Estimation
Use duration	30 minutes	Estimation
Oral		
Product volume	0.2 cm ³	Estimation
Density	1.5 g/cm ³	Estimation
Absorbed fraction	1	Potential dose

a) For a 4.5 years old child weighting 16.3 kg – see section 3.2. and Table 3.2.1.

b) For an 18 months old child weighting 9.85 kg - see section 3.2. and Table 3.2.1.

c) For a 6.5 years old child weighting 20.6 kg - see section 3.2. and Table 3.2.1.

Source: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

Table 11.7: Default values on hand-mouth contact

	Default value	Comments
Piece of chalk^a		
Contact		
Frequency	100/year	Estimate; 2 times per week
Total duration	45 minutes	Estimate
Use duration	45 minutes	Estimate
Oral		
Ingestion rate	6 mg/minute	The estimate of the ingestion rate for the piece of chalk is based on soil, i.e. on the default of 300 mg per day (thus an ingestion of 300 mg in 50 minutes). The daily intake is calculated to be 45/50 x 300 = 270 mg. This amount is ingested in 45 minutes; the ingestion rate is therefore 6 mg/min.
Absorbed fraction	1	Potential dose
Finger paint^b		
Contact		
Frequency	100/year	Estimate; 2 times per week
Total duration	45 minutes	Estimate
Use duration	45 minutes	Estimate
Oral		
Ingestion rate	30 mg/minute	Based on the differences between soil and mud, the default value for products which stick to the skin is first estimated at an amount 5 times as large (as soil/chalk), i.e. the ingestion rate for finger paint is estimated at 30 mg/min.
Absorbed fraction	1	Potential dose
Face paint^a		

Contact		
Frequency	12/year	Estimate
Total duration	480 minutes	Estimate
Use duration	480 minutes	Estimate
Oral		
Ingestion rate	0.44 mg/minute	For the indirect contact with face paint, it should be noted that it concerns a substance that sticks to the skin and, in addition to dermal exposure, is taken in orally via the hands. It is assumed that the face paint is removed at the end of the day (default: after 8 hours; 480 min.). The total amount of face paint on the skin is 1.4 g (see: § 5.4.2). We estimate that 15% of this is ingested per day, which means an ingestion rate of $210/480 = 0.44$ mg/min.
Absorbed fraction	1	Potential dose

a) For a 4.5 years old child weighting 16.3 kg – see section 3.2. and Table 3.2.1.

b) For an 18 months old child weighting 9.85 kg - see section 3.2. and Table 3.2.1.

Source: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

With regard to inhalation, the *Children's Toys Fact Sheet* (RIVM, 2002) refers to the more or less volatile organic compounds that evaporate from the toy. The inhalation exposure to fine particles is described with the "cloud volume" model in section 11.2. This model is developed to estimate exposure to aerosols, but exposure to particles falls within the assumptions of the model. The user of the product that produces particles is assumed, worst case, to have his "nose in the cloud". Default values on inhalation from children's toys are presented in Table 11.8.

Table 11.8: Default values on inhalation from children's toys

	Default value	Comments
Dust from chalk^a		
Contact		
Frequency	100/year	See Table 12.2.2.3.
Total duration	45 minutes	
Use duration	45 minutes	
Inhalation		
Emission rate formulation	11 mg/minute	It is assumed that 10 gram of chalk is used. It is estimated that 5% of the used chalk is released as dust in the air, resulting in 500 mg. If this is released over 45 minutes, the average emission rate becomes 11 mg/minute.
Density	2 g/cm ³	Estimation

Airborne fraction	0.05	The airborne fraction defines how much of the potential release of particles is actually released into air. No data is available for the particle size distribution of chalk dust. It is assumed that the smallest 10% of the dust particles have an average size of 25 µm, and that 5% has an average size of 10 µm. The default for the airborne fraction is set to 0.05, the default for the particle size to 10 µm and the default for the respirable fraction to 1.7%. These defaults imply that less than 0.1% ($0.05 \times 0.017 = 0.00085$) of the chalk dust is available for inhalatory exposure.
Droplet size	10 µm	
Release height	100 cm	Estimation
Radius aerosol cloud	20 cm ³	Estimation
Room volume	20 m ³	
Target area	8 m ²	Surface room
Absorbed fraction	1	Potential dose
Inhalation rate	9.2 litre/minute	
Respirable fraction	1.7%	See airborne fraction and droplet size
Dust from blusher^a		
Contact		
Frequency	12/year	Estimation
Total duration	480 minutes	8 hours; estimation
Use duration	5 minutes	Estimation
Inhalation		
Emission rate formulation	12 mg/minute	It is estimated that 300 mg of blusher is used in 5 minutes time. It is assumed that 20% of this amount is released into air, being 60 mg. The emission rate of dust is therefore 12 mg/minute.
Density formulation	1.8 g/cm ³	Estimation
Airborne fraction	0.05	See emission rate formulation
Droplet size	10 µm	See dust of chalk
Release height	100 cm	Estimation
Radius aerosol cloud	20 cm	Estimation
Room volume	20 m ³	
Target area	8 m ²	Surface room
Absorbed fraction	1	Potential dose
Inhalation rate	9.2 litre/minute	
Respirable fraction	1.7%	See dust of chalk

a) For a 4.5 years old child weighting 16.3 kg – see section 3.2. and Table 3.2.1.
Source: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

Children use cosmetics as a game to imitate the behaviour of adults and are therefore exposed to cosmetic products on the skin. The use of cosmetics during play will often take place during dressing up, at children's parties, for example. It will therefore usually occur incidentally and not periodically, as is usual with cosmetics. The sorts of cosmetics usually used are those with which a colour is applied i.e. lipsticks, nail polish, eye shadow and blusher. It is assumed that if cosmetics are used during play, these 4 products will be applied one after the other. According to RIVM, it is assumed that the amount that is applied is 3 times as large (unit per surface) as the amount of cosmetics that is usually used (RIVM, 2002). Default values for cosmetics used as children's toy, is presented in Table 11.9.

Table 11.9: Default values for cosmetics as children's toys – application on skin

	Default value	Comments
Lipstick^a		
Contact		
Frequency	12x/ year	Estimation
Use duration	3 minutes	Estimation
Total duration	240 minutes	4 hours; estimation
Oral		
Amount product	0.03 g	Estimation based on the use of cosmetics by adults – see Table 11.2.1.1.
Density	1.3 g/cm ³	Estimation
Absorbed fraction	1	Potential dose
Nail polish^a		
Contact		
Frequency	12x/ year	Estimation
Use duration	5 minutes	Estimation
Total duration	480 minutes	8 hours; estimation
Dermal		
Amount product	0.75 g total, 0.25 g on skin	1/3 on skin, 2/3 on nail, estimation
Density	0.9 g/cm ³	Estimation
Exposed area	10 cm ²	On skin, estimation
Blood volume	1 cm ³	
Skin blood flow	0.14 cm ³ /minute	
Eye shadow^a		
Contact		
Frequency	12x/ year	Estimation
Use duration	5 minutes	Estimation

Total duration	480 minutes	8 hours; estimation
Dermal		
Amount product	0.03 g	Estimation based on the use of cosmetics by adults – see Table 11.2.1.1.
Density	1.3 g/cm ³	Estimation
Exposed area	8 cm ²	Estimation
Blood volume	0.8 cm ³	
Skin blood flow	0.11 cm ³ /minute	
Blusher^a		
Contact		
Frequency	12x/ year	Estimation
Use duration	5 minutes	Estimation
Total duration	480 minutes	8 hours; estimation
Dermal		
Amount product	0.3 g total	3 mg/cm ²
Density	1.8 g/cm ³	Estimation
Exposed area	100 cm ²	Estimation
Blood volume	10 cm ³	
Skin blood flow	1.4 cm ³ /minute	

a) For a 4.5 years old child weighting 16.3 kg – see section 3.2. and Table 3.2.1.
Source: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

Children are exposed to intensive hand contact via playing with finger paint and modelling clay. In the *Children's Toys Fact Sheet* (RIVM, 2002), it assumed that the product is continuously present on the hands. Since there is intensive hand contact for a prolonged period of time, the total amount of clay is taken as the amount of product. The crucial difference is the age of the users: finger paint will be used by much younger children than for modelling clay. Table 11.10 presents default values on intensive hand contact during play.

Table 11.10: Default values on intensive hand contact during play

	Default value	Comments
Modelling clay^a		
Contact		
Frequency	52 x/ year	Estimation
Use duration	60 minutes	Estimation
Total duration	60 minutes	Estimation
Dermal		
Amount product	350 g	Estimation
Density	2 g/cm ³	Estimation
Exposed area	390 cm ²	Area hands
Blood volume	39 cm ³	
Skin blood flow	5.5 cm ³ /minute	
Finger paint^b		
Contact		
Frequency	100 x/ year	Estimation
Use duration	45 minutes	Estimation
Total duration	45 minutes	Estimation
Dermal		
Amount product	20 g	Estimation
Density	1.3 g/cm ³	Estimation
Exposed area	124 cm ²	½ area hands
Blood volume	12 cm ³	
Skin blood flow	1.7 cm ³ /minute	

a) For a 4.5 years old child weighting 16.3 kg – see section 3.2. and Table 3.2.1.

b) For an 18 months old child weighting 9.85 kg – see section 3.2. and Table 3.2.1.

Source: Modified from the Children's Toys Fact Sheet (RIVM, 2002)

11.2. US-EPA

In the *Exposure Factors Handbook* (US-EPA, 2011), information on the amount of product used, frequency of use, and duration of use for various consumer products typically found in consumer households, is provided. However, due to the large range and variation among consumer products and their exposure pathways, no recommendations on specific exposure values are given.

No data on consumer product from the US will be included in this report. This is because this report is directed primarily towards the exposure factors to be used in exposure assessments in EU in the context of REACH and therefore, the focus will be on the numerous and well validated European data.

11.3. WHO

No recommendations on consumer products are provided by WHO.

11.4. Conclusion and recommendations

RIVM has provided Fact Sheets with default values on several consumer products, which are used for calculation of exposure by using the ConsExpo software model. The default values in the Fact Sheets have been collected for consumers (private or non-professional users). These Fact Sheets, therefore, only describe consumer products, which are available to the consumer for private use. Moreover, it should be noted that realistic worst case scenarios are chosen to describe the exposure and the 75th percentile is always used. Therefore, circumstances are chosen in such a way that they will lead to relatively high exposures.

No data on consumer products from the US has been included in this report as the primary focus is on the exposure factors to be used in the context of REACH and the European data are very comprehensive.

No recommendations on consumer products are provided by WHO.

In conclusion, the recommendations as provided in the various RIVM Fact Sheets are considered as being valid values for consumer products and are therefore, recommended as the default exposure factors for assessments of the European population in the context of REACH.

12. Summary, conclusions and recommendations

The aim of an exposure assessment is to determine the nature and extent of contact with chemical substances experienced or anticipated under different conditions. An exposure assessment is the quantitative or qualitative evaluation of the amount of a substance that humans come into contact with and includes consideration of the intensity, frequency and duration of contact, the route of exposure (e.g., dermal, oral or respiratory), rates (chemical intake or uptake rates), the resulting amount that actually crosses the boundary (a dose), and the amount absorbed (internal dose).

In order to perform an exposure assessment, it is necessary to apply various “non-chemical-specific” exposure related parameters such as e.g., body weight, body surface area, activity factors, ventilation rates, ingestion of water/food etc. These parameters are called non-chemical-specific exposure factors and are generally drawn from the scientific literature or governmental statistics.

The approach to exposure assessment is not as internationally harmonised as hazard assessment. Although broad consistency in the overall approaches used by different bodies and countries in conducting exposure assessment exists, there is variation in the types of approaches and tools used, including the use of exposure factors.

The purpose of this report is to give an updated overview of non-chemical-specific exposure factors to be used by the authorities during the process of assessing exposure to both adults and children as well as of risk assessment in relation to REACH, and to contribute towards a further harmonisation of such exposure factors to be used in exposure assessments. Thus, the process of exposure assessment in itself is not further addressed in this report.

Guidance and recommendations provided by various EU bodies, with the main focus on the information gathered in the REACH *Guidance on Information Requirements and Chemical Safety Assessment* published by the European Chemicals Agency (ECHA) have primarily been addressed as this report is directed primarily towards the exposure factors to be used in exposure assessments in the context of REACH. The US guidance and recommendations are also addressed as the most recent version of the US-EPA *Exposure Factor Handbook* currently with most chapters published in 2011 with updates of a number of chapters in 2017–2019 provides the most comprehensive overview, considerations, evaluations and recommendations in the area of non-chemical-specific exposure factors. Finally, guidance and recommendations provided by the WHO are addressed as this report also is meant to contribute towards a further harmonisation of exposure factors to be used in exposure assessments.

The following non-chemical-specific exposure factors are addressed in this report:

- Body weight
- Body surface areas
- Inhalation rates

- Ingestion of drinking water
- Intake of food
- Ingestion of soil and dust
- Non-dietary ingestion factors
- Lifetime expectancy
- Activity factors
- Consumer products

In general, the data presented in the US-EPA Exposure Factors Handbook are the most comprehensive, whereas the European data are more limited, as are the WHO data.

The US-EPA recommended values are very well validated. The US-EPA has assigned a confidence rating of low, medium, or high to each recommended value. The US-EPA has underscored that this qualitative rating was not intended to represent uncertainty analyses but to represent the US-EPA's judgment on the quality of the underlying data used to derive the recommendations. The judgment was made using five so-called "general assessment factors" (GAFs, described in Section 1.2). The US-EPA noted that there is a continuum from low to high, and that judgment was used to assign a rating to each factor. The recommended values presented in the US-EPA Exposure Factors Handbook are accompanied by a discussion of the rationale for their rating.

The US-EPA recommendations have formed the basis for the recommended values in this report for many of the human exposure factors. One reason is that the US-EPA recommended values generally are based on the most comprehensive and well validated data, whereas the European data are more scarce and limited. Furthermore, the US-EPA recommended values are considered as being the most valid values for most of the human exposure factors as these values in general are based on analyses of more recent data than the European data, which in general are based on older references (published more than 10 years ago). In addition, the US-EPA recommended values in general are considered as being representative for Europeans as well for many of the human exposure factors despite that Americans might be different to Europeans in some ways. Finally, harmonisation of default values for exposure factors to be used in exposure assessments would be desirable, i.e., the ideal situation. As this report is also meant to contribute towards a further harmonisation of human exposure factors to be used in exposure assessments, the most comprehensive and well validated data have been selected as the basis for the recommended values for each exposure factor in this report regardless whether the data are European or American. As an alternative to implement the US-EPA recommended values for non-chemical-specific exposure factors to be used in the context of REACH instead of the currently used European exposure factors when these are considered as being obsolete, the data forming the basis for the recommended values by various European bodies, e.g., ECHA, EFSA, RIVM (ConsExpo) should be updated, evaluated and validated and the recommended values should be revised accordingly.

In the following sections, the recommended values for the non-chemical-specific exposure factors addressed in this report are presented. Although the focus of this report is to recommend values for non-chemical-specific exposure factors to be used

in the context of REACH, the recommended values can also be used in the context of other chemical regulations such as those for e.g., biocides, pesticides, cosmetics, toys etc.

Body weight

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive. The European data are more limited as are the WHO data.

The RIVM default values (Table 2.1) are based on more recent data than the NHANES data used by EU-EPA. However, the RIVM default values represent data from the 25th percentile and not the mean values. For adults, the currently most used default body weight for men and women combined is 70 kg. This value is somewhat lower than the mean body weight for both sexes in Denmark (78.3 kg) and in The Netherlands (mean body weight of 77.4 kg) and also in the US where the average adult body weight is 80 kg. However, the RIVM default adult body weight based on the 25th percentile is 68.8 kg and thus, fairly close to the currently most used default value of 70 kg for men and women combined.

The EFSA *Default Guidance Document* recommended values (Table 2.1) are based on all surveys in the *EFSA Comprehensive Database*. A body weight of 70 kg should be used as default for the European adult population (age: above 18 years). It is underlined that this default value in some cases will lead to less conservative risk assessments compared to using 60 kg. However, a body weight of 70 kg is considered a more realistic estimate of the average body weight of the European population.

In conclusion, the EFSA *Default Guidance Document* recommended values of 5 kg for European infants (age: 0–12 months), of 12 kg for European toddlers (age: 1–3 years) and of 70 kg for European adults (age: above 18 years) are considered as being the most valid values for body weight as of today for the European population as they are based on all surveys in the EFSA Comprehensive Database. These values are therefore recommended as default exposure factors for assessments of the European population in the context of REACH. For other specific population subgroups, e.g. men, women, pregnant women, specific child age groups, the EFSA Comprehensive Database may be used to extract specific default values.

Body Surface Area

The data presented in the US-EPA *Exposure Factors Handbook* as well as the European data are comprehensive. No recommendations have been provided by the WHO.

The RIVM default values for adults and children are based on more recent data than the NHANES data used by US-EPA. In relation to the data used by US-EPA for their recommended default values, RIVM stated: "*Using these two studies results in discrepancies between the absolute skin surface area of the heads of children and young adults, e.g. an unrealistic drop in the mean skin surface area of children in the*

age group 1 to <2 years old (from US-EPA 1997) and 2 to <3 years old (adapted from Boniol et al. 2008)", which is obvious from the mean percentages of total surface area (%) listed in Table 3.6. The US-EPA default values represent data for the mean and 95th percentile whereas the RIVM default values represent data from the 25th percentile.

In conclusion, the RIVM recommended default values presented in Table 3.2 and 3.3 are considered as being the most valid values for body surface areas as of today for the European population and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

Inhalation rates

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive. The European data are limited as are the WHO data.

Activity levels might be different among US individuals compared to Europeans. Despite this, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommended values are considered as being the most valid values for inhalation rates as of today as these recommendations are based on four key studies published in the period from 2006–2009. In contrast, the European data are predominantly based on older references or no references have been provided for the recommended values (e.g., REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.8, Table R.8-2). One European body, namely EFSA has based their recommended values on the most recent version of the *Exposure Factors Handbook*.

In conclusion, the US-EPA recommended values presented in Table 4.6 and 4.7 are considered as being the most valid values for inhalation rates as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

Drinking water

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive. The European data are limited as are the WHO data.

Drinking water intakes might be different among US individuals compared to Europeans. Considering the inherent variation in drinking water intakes also among the European population, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommended values are considered as being the most valid values for drinking water intakes as of today as these recommendations are based on the most recent analysis on NHANES 2005–2010 data by US-EPA. In contrast, the European data are very limited and predominantly based on older references, except for the DTU-FOOD data. In addition, the US-EPA recommended values are for drinking water whereas other recommended values are for the total liquid intake.

In conclusion, the US-EPA recommended values presented in Table 5.2 are considered as being the most valid values for intake of drinking water as of today and are

therefore recommended as default exposure factors for assessments of the European population in the context of REACH. Alternatively, data from national surveys could be recommended.

Food Intake

The data presented in the US-EPA *Exposure Factors Handbook*, along with the updated chapters as well as the European data are comprehensive. The WHO data are limited.

The US-EPA recommendations are considered as being highly valid values for food consumption rates as these recommendations are based on comprehensive analyses of fairly recent data. They are the best dietary data available for the US population. Americans, however, can have quite different dietary habits compared to Europeans and dietary habits can also differ markedly within European countries. Thus, national dietary data should preferably be used for the population/populations that are to be assessed. For this purpose, the *EFSA Comprehensive European Food Consumption Database* offers a valuable set of data although national agencies may possess more recent dietary data as is, e.g. the case for the Danish data on food consumption.

According to ECETOC, breast milk consumption values for Swedish infants were similar to those of US infants. Thus, the US-EPA recommendations for human breast milk and lipid intake rates are considered as being representative for European infants as well.

In conclusion, the data compiled in the *EFSA Comprehensive European Food Consumption Database* are considered as being the most valid values for food consumption rates as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH. Alternatively, data from national surveys could be recommended.

For breast milk intake, the US-EPA recommendations presented in Table 6.11 are considered as being the most valid values as of today and are therefore recommended as default exposure factors for assessments of European infants in the context of REACH.

Soil and Dust Ingestion

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive and most recent. The European data are limited as are the WHO data.

Data on soil and dust ingestion rates are generally limited and variable, and region specific differences in child play and hygienic patterns will likely affect typical soil and dust ingestion rates. Thus, there might be differences between the US and European population regarding soil and dust intake. Despite this, the US-EPA recommendations are considered as being representative for the European population as well. Furthermore, the US-EPA recommendations are considered as

being the most valid values for soil and dust ingestion rates as of today despite the overall rating as low, as these recommendations are based on additional more recent key studies than the European recommendations and updated in 2017. Furthermore, the US-EPA recommendations are considering both soil and dust ingestion separately for various age groups whereas the RIVM / REACH *Guidance on Information Requirements and Chemical Safety Assessment* Chapter R.15 only consider house dust ingestion for children of unspecified age.

In conclusion, the US-EPA recommended values presented in Table 7.3 are considered as being the most valid values for soil and dust ingestion rates as of today and are therefore recommended as default exposure factors for assessments of soil and/or dust ingestion for the European population in the context of REACH.

Non-Dietary Ingestion Factors

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive. The European data are limited to single values for specific assessment purposes. No recommendations have been provided by the WHO.

There might be some differences between US and European children regarding hand-to-mouth and hand-to-object frequency and duration. Despite this, the US-EPA recommended values are considered as being representative for European children as well. Furthermore, the US-EPA recommendations are considered as being the most valid values for non-dietary ingestion factors as today despite the overall rating as low, as these recommendations are based on relatively recent key studies published in the period 2001–2008.

In conclusion, the US-EPA recommended values presented in Table 8.1 are considered as being the most valid values for non-dietary ingestion factors as of today and are therefore recommended as default exposure factors for assessments of European children in the context of REACH. No studies have been located on mouthing frequency or duration for adults and therefore, no default exposure factors can be recommended.

Lifetime Expectancy

The data presented in the US-EPA *Exposure Factors Handbook* as well as the European and WHO data are limited.

Lifetime expectancy is very different for various countries and parts of the World. The data published by the WHO in 2010 for the European Region are considered as being the most representative for European lifetime expectancy as of today.

In conclusion, the WHO recommended values for the European Region presented in Table 9.2 are considered as being the most valid values for lifetime expectancy as of today for the European population and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

Activity Factors

The data presented in the US-EPA *Exposure Factors Handbook* are the most comprehensive. The European data are limited. No recommendations have been provided by the WHO.

Activity levels might be different among US individuals compared to Europeans. Despite this, the US-EPA recommended values are considered as being representative for Europeans as well. Furthermore, the US-EPA recommendations are considered as being the most valid values for activity factors. It should be noted that the recommended values in the 2011 version of the US-EPA *Exposure Factors Handbook* are based on two key studies published in 1991 and 1996.

In conclusion, the US-EPA recommended values presented in Table 10.2 are considered as being the most valid values for activity factors for Europeans as of today and are therefore recommended as default exposure factors for assessments of the European population in the context of REACH.

No default values for working activities are recommended by the US-EPA as the working environment is not the responsibility of US-EPA. For working activities, the recommended values presented in Table 10.1 are recommended as default exposure factors for assessments of European workers in the context of REACH.

Consumer Products

RIVM has provided Fact Sheets with default values on several consumer products, which are used for calculation of exposure by using the ConsExpo software model. The default values in the Fact Sheets have been collected for consumers (private or non-professional users). These Fact Sheets, therefore, only describe consumer products, which are available to the consumer for private use. Moreover, it should be noted that realistic worst case scenarios are chosen to describe the exposure and the 75th percentile is always used. Therefore, circumstances are chosen in such a way that they will lead to relatively high exposures.

No data on consumer products from the US has been included in this report as the primary focus is on the exposure factors to be used in the context of REACH and the European data are very comprehensive.

In conclusion, the recommendations as provided in the various RIVM Fact Sheets are considered as being valid values for consumer products and are therefore, recommended as the default exposure factors for assessments of the European population in the context of REACH.

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