



Project No. 018385  
INTARESE  
Integrated Assessment of Health Risks of Environmental Stressors in Europe

Integrated Project  
Thematic Priority

# Deliverable 26

## Chemicals Assessment protocol

Due date of deliverable: April 2007  
Actual submission date: April 2007

Start Date of Project: 1 November 2005

Duration: 60 Months

Organisation name of lead contractor for this deliverable: RIVM

Final version

Project co-funded by the European Commission with the Sixth Framework Programme (2002-2006)		
Dissemination Level		
PU	Public	
PP	Restricted to other programme participants (including the Commission Services)	
RE	Restricted to a group specified by the consortium (including the Commission Services)	X
CO	Confidential, only for members of the consortium (including the Commission Services)	

## Introduction

Today, risk assessments of chemical substances are often performed for one source of exposure and one route of exposure. However, a chemical that is present in consumer products is usually released from many different sources, and exposure can potentially occur via three different routes: oral, dermal or by inhalation. As a result, such a source-specific and route-specific approach can underestimate the health risks associated with exposure to the chemical substance. To provide a more realistic assessment of both exposure and risk, one of the aims of this work-package is to develop methods by which **aggregate** exposure to chemicals from consumer products can be assessed.

Very little, if any, information is available with regard to (chronic) health effects due to consumer product use. However, this does not imply that all consumer products are safe, especially when the chemical and not the product is considered. Therefore another challenge in this work-package is to extrapolate animal data to (human) health effects.

The aim of the present Chemicals Assessment Protocol is, first, to bring a definition of the issue that will be addressed and, secondly, to provide an overview of the methodology that will be used in order to perform a health impact assessment in the specific area of chemicals in consumer products. A consumer product is in general regarded as a product that can be purchased from retail outlets by members of the general public. Examples of consumer products are cleaning products, cosmetics, soft furnishings.

This Chemicals Assessment Protocol is seen as a 'living document' that will be regularly updated based on experience gained and feedback obtained from the practical case studies. It elaborates on the Policy Scoping Report of WP5.3 (2006).

## Contents

<b>1</b>	<b>The issue of chemicals in consumer products</b>	<b>4</b>
1.1	The issue to be assessed	4
	Chemical substances in consumer products	4
	Aggregate/Cumulative exposure assessments	5
1.2	The key stakeholders, and their interests	6
1.3	The policy context of chemicals in consumer products	6
	Current EU Policy	6
	The European Chemicals Bureau ( <a href="http://ecb.jrc.it/">http://ecb.jrc.it/</a> )	7
	Republic of Serbia's legislation	8
1.4	Policy scenarios that will be addressed	9
<b>2</b>	<b>Scope of the assessment</b>	<b>10</b>
2.1	The assessment framework	10
2.2	Key elements/relationships to be assessed	10
2.3	Target area	12
2.4	Target time period	12
2.5	Target population	13
2.6	Target consumer products	13
2.7	Target chemical substances	14
<b>3</b>	<b>The assessment methodology</b>	<b>15</b>
3.1	Source to exposure	16
	Aggregation of the exposure	16
	Method/Model/Tool	17
	Construction of exposure profiles and data needs	18
	Details on first tier assessment	21
	Possible indicators	23
3.2	From Exposure to health effects	23
	Possible indicators	25
3.3	Health effects to impacts and costs	25
	Health indicators	25
	Disability Adjusted Life Years - DALY's	26
	Possible indicators	27
<b>4</b>	<b>Anticipated limitations of the assessment</b>	<b>28</b>
4.1	Major sources of uncertainty	28
	Exposure	28
	Toxicity	29
	Health impact	29
4.2	Gaps in the assessment	29
4.3	Expected problems in the assessment process and possible solutions	30
<b>5</b>	<b>Reporting and communication</b>	<b>30</b>

# 1 The issue of chemicals in consumer products

## 1.1 The issue to be assessed

Nowadays, people spend most of their time in indoor environments making indoor climate quality a very important issue for public health. Many consumer products are used indoors in households, and as such represent potential sources of pollution. Indeed, by using a product, a consumer can be exposed to chemical substances at several points in their use: during their use, after use, and through secondary exposures to use by others within the same household.

At present the safety of chemicals in products is assessed on a product basis. Assessments are then usually chemical-specific, route-specific and source-specific. Using this type of approach can possibly lead the assessor to an under-estimation of the risk of using a certain substance, as it only takes into account one source of exposure.

According to the GPSD, products have to be safe and, in general, the exposure to the same substance via various products is not assessed. Also, for biocides, safety assessment is also usually carried out on a product basis, and the issue that consumers can be exposed to the same chemical via other products is ignored. In the Existing Chemicals Framework, consumer exposure is assessed for various products. However, when the weight fraction of the chemical in the product or the final exposure to the chemical is low, the exposure scenario is not taken into account. Possible exposure via various products will be mentioned, but is not added up. For this aggregate exposure, it would be interesting to include all possible, even (very) small, exposures. Under the new European chemicals legislation, REACH, industry is obliged to identify appropriate risk management measures to ensure safe use of chemicals (for workers, consumers and man exposed indirectly via the environment). Exposure scenarios for identified uses have to be safe. However, how to assess total exposure is not clear yet.

Today, there are a number of tools (models, software) available that allow the user to assess exposure to chemicals from consumer products. These tools implement the usual chemical/route/source-specific approach. The only area where aggregation techniques are implemented and used is the field of risk assessment of pesticides in the USA.

While the need for aggregation is becoming increasingly recognised, the overall aim of this WP is to design and implement methodologies and tools to assess risks due to aggregate and cumulative human exposure to chemicals in consumer products; and to perform a health impact assessment. These assessments will be realised assuming a normal use of the consumer products.

In this report, aggregate exposure has to be understood as exposure to a single chemical substance via relevant routes, pathways, and sources; while cumulative exposure relates to an aggregate exposure to multiple chemicals having a common toxicological mechanism.

The methodologies and tools which will be developed in WP3.5 will be tested with chemical substances that are frequently found in consumer products, and that have different health impacts.

### Chemical substances in consumer products

Consumer products are considered in their everyday use and/or contact. Examples are: household cleaning products (detergents), paints, varnishes, lacquers, cosmetics, fragrances, air fresheners, pesticides, furniture and soft furnishings (carpets, rugs ...), electronic devices (computers, TV ...), building materials, textiles ...

This WP uses the definition that is given in the European Technical Guidance Document on Risk Assessment, which is: “A consumer product is in general regarded as a product that can be purchased from retail outlets by members of the general public.”  
In principal, drugs, food, alcohol and tobacco are out of the scope of this WP.

Concerning ‘substance’, ‘preparation’ and ‘article’ terms, the definitions used in REACH are adopted. These are the following (from the Draft Technical Guidance Document on requirements for substances in articles -Reach Implementation Project 3.8 - Final Report):

Substance: According to Article 3(1), the definition of substance says “Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition”.

Preparation: According to Article 3(2), “Preparation means a mixture or solution composed of two or more substances”.

Article: According to Article 3, the article definition says: “Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition”.

#### Aggregate/Cumulative exposure assessments

One of the first steps in the health impact assessment in this project is to perform aggregate and cumulative exposure assessment for chemicals in consumer products.

The Exposure Assessment Terminology Working Group who worked on the IPCS Risk Assessment Terminology Report found that “in most instances where the terms appear, ‘aggregate’ and ‘cumulative’ are used as adjectives to modify ‘exposure’ or ‘dose’ without further elaboration. Often, ‘aggregate’ and ‘cumulative’ seem to be used interchangeably, suggesting

- (1) Exposures that are from multiple sources, received via multiple exposure pathways, or doses received through multiple routes;
- (2) Exposures or doses that accumulate over time, often over a lifetime; or
- (3) Exposures or doses from more than one chemical or stressor simultaneously or sequentially.

As a result, both terms have not been included in the IPCS glossary. According to this glossary, in the *Framework for Cumulative Risk Assessment* (US EPA 2002), the US Environmental Protection Agency uses ‘aggregate’ as a term referring to the risks over time from multiple sources, pathways, and routes *for a single chemical or stressor*, reserving ‘cumulative’ for assessments where (aggregate exposures or doses for) multiple chemicals or stressors are evaluated together.

The following definitions from the *Framework for Cumulative Risk Assessment* are adopted in this WP:

Aggregate exposure: The combined exposure of an individual (or defined population) to a specific agent or stressor via relevant routes, pathways, and sources.

Aggregate risk: The risk resulting from aggregate exposure to a single agent or stressor.

Cumulative risk: The combined risks from aggregate exposures to multiple agents or stressors.

From our research so far, cumulative risk assessment appears to be possible only for four groups of pesticides: organophosphates, N-methyl carbamates, triazines and

chloroacetanilides. As such, the WP is very ambitious in including an assessment of the cumulative risk for substances other than these.

The focus of the assessment will be on estimating aggregate exposure/risks and, if there are any resources remaining, on attempting to assess cumulative exposure/risks or identify research needs in this field.

## 1.2 The key stakeholders, and their interests

The key stakeholders in this assessment are likely to be as follows:

- Risk assessors and risk managers (e.g. some partners of the WP3.5, public health agencies...) - They have to assess (and manage) human exposure and risks due to chemical substances contained in consumer products (e.g. formaldehyde in many different products like detergents, VOCs in construction materials, glycol ethers in paints...). They often have to deal with the lack of data (volumes, exposure data in particular) and confidentiality issues;
- Civil society stakeholders - They express concerns related to health effects of chemicals in products; e.g. formaldehyde in air fresheners, VOCs in building materials, parabens in cosmetics, phthalates in toys, flame retardants such as DecaBDE in electronic devices... They urge for an improvement of the transparency of risk assessments, for better information of the consumers with regard to environment and health hazards and risks, and for the improvement and the harmonisation of labelling;
- Industry stakeholders - They may be, among others, trade associations, formulators, suppliers, retailers... Industry has to deal with different issues depending on where it is located on the supply chain and there is a strong need for a better information flow in this supply chain. Money (costs-benefits) issues and also confidentiality issues will arise in this group.

Annex A presents a table with examples of stakeholders that could be involved in the issue of chemicals in consumer products. Please, note that it does not mean that they have been involved in the preparation of this document. Interest or relevance of the first selection of chemicals was inquired to some of the stakeholders (see Policy Assessment Report).

In the following part, stakeholders might be asked to be involved in judging the first pass assessment. Stakeholders might give guidance on which subjects or outcomes they need more or other information. Other INTARESE WPs are supposed to provide guidance on stakeholder participation).

## 1.3 The policy context of chemicals in consumer products

### Current EU Policy

Different pieces of European legislation are related to the subject.

The General Product Safety Directive, GPSD (Directive 2001/95/EC of the European Parliament and of the Council of 3 December 2001 on general product safety) is aimed at ensuring that only safe products are sold on the EU market. The GPSD is intended to provide a high level of safety for products which are not already covered by a sector-specific legislation and it also complements some sector-specific legislation in case certain matters are not covered.

*"The GPSD aims at ensuring that consumer products placed on the EU market are safe. The objectives of the Directive are both to protect consumer health and safety and to*

*ensure the proper functioning of the internal market. In addition to the basic requirement to place only safe products on the market, producers must inform consumers of the risks associated with the products they supply".<sup>1</sup>*

EU policy on chemical substances aims to protect human health and environment from undesirable exposure to chemicals. The EU maintains that the objective of its policy is to encourage continued innovation in the chemicals industry, which is to the benefit of citizens of the EU.

Today, the four main legal instruments that compose the EU legislation on chemicals are<sup>2</sup>:

- The "Directive on Dangerous Substances" - Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances;
- The "Dangerous Preparations Directive" - Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations;
- "Existing" substances - Council Regulation (EEC) No 793/93 of 23 March 1993 on the evaluation and control of the risks of existing substances;
- The "Limitations Directive" - Council Directive 76/769/EEC of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations.

In February 2001, a White Paper on the Strategy for a future Chemicals Policy was issued by the Commission. After further developments and many discussions with the major stakeholders, it resulted in the adoption of the REACH proposal by the Commission on 29<sup>th</sup> October 2003. This proposal relates mainly to the four important legal instruments indicated above.

The REACH Regulation was formally adopted on December 18<sup>th</sup> 2006 by the Council, following the vote in second reading of the European Parliament on December 13<sup>th</sup> 2006. REACH will enter into force on June 1<sup>st</sup> 2007.

Under REACH, all manufacturers or importers should register their substances in a central database managed by the European Chemical Agency if they exceed a volume of 1 ton per year. Also, under REACH, manufacturers and importers are given greater responsibilities in the management of the risks from their chemicals and in the provision of information down the supply chain.

[The European Chemicals Bureau \(http://ecb.jrc.it/\)](http://ecb.jrc.it/)

The mission of the European Chemicals Bureau (ECB) is to provide scientific and technical support to the conception, development, implementation and monitoring of EU policies dealing with dangerous chemicals.<sup>3</sup>

The ECB develops methodologies and software tools in order to perform systematic and harmonised assessments of chemicals.

The activities of the ECB are mainly related to 4 areas: risk assessment; harmonization of testing methods; classification and labelling; and information exchange on the import and export of dangerous substances.

---

<sup>1</sup> [http://ec.europa.eu/consumers/cons\\_safe/prod\\_safe/gpsd/currentGPSD\\_en.htm](http://ec.europa.eu/consumers/cons_safe/prod_safe/gpsd/currentGPSD_en.htm)

<sup>2</sup> [http://ec.europa.eu/consumers/cons\\_safe/prod\\_safe/other\\_EU/chem\\_policy\\_en.htm](http://ec.europa.eu/consumers/cons_safe/prod_safe/other_EU/chem_policy_en.htm)

<sup>3</sup> [http://ecb.jrc.it/ASSESSMENT\\_OF\\_CHEMICALS/](http://ecb.jrc.it/ASSESSMENT_OF_CHEMICALS/)

Countries which are represented in the WP3.5 are: the Netherlands, the United Kingdom, France, Finland and the Republic of Serbia. The policy context presented so far has concentrated on the current situation in the four EU members states included in this grouping. An outline for the policy context in the Republic of Serbia, which is not yet a member of the EU, is presented below.

### Republic of Serbia's legislation

The Republic of Serbia belongs to the so-called Third Countries, which have special relationships with the EU concerning legislation. These legislations are different from EU countries. One of the main priorities notified in the Resolution of Accession of the Republic of Serbia to EU in 2004 was to harmonise the country's legislation with the current EU legislation. The Action plan for the harmonisation of the Republic of Serbia's legislation for 2005 contained a list of activities and achievements related to the preparation, the date of finalisation and the adoption of laws. The report on the harmonisation of legislation, which was finalised in 2006, describes the results and status of planned activities in 2005.

The Republic of Serbia's Law of Poisons ("Sl.list SRJ" no.15/95, 28/96 and 37/2002) will be replaced with a new Law on the Control of Chemicals, which is currently still in preparation. This law will ensure the control of chemicals, including control on their production, marketing, classification, packaging, and labelling, and on production and marketing restrictions relating to them.

The major goal of this chemicals legislation is to harmonise with the following EU Directives and Regulations: Council Directive 92/32/EEC, Council Directive 2004/10/EC, Council Directive 93/67/EEC, Council Directive 99/45/EC, Council Directive 87/71/EEC, Council Directive 81/437/EEC, Council Directive 76/769/EEC, Regulation (EEC) No 793/93, Regulation (EC) No 1488/94 and Regulation (EEC) 304/03.

Legislation related to biocidal products and plant protection products is also in the process of being harmonised with Directive 98/8/EC.

In 2005, the Law for Consumer Protection ("Sl.glasnik RS", no.79/2005) was adopted partly in order to harmonise national legislation with EU legislation. However, it has been recognised that there are some gaps in the harmonisation with the General Product Safety Directive.

The control of consumer products in the Republic of Serbia is mainly the responsibility of the Ministry of Health. The main laws regarding sanitary control are: Law of sanitary control ("Sl.glasnik RS", no. 125/2004), Law of sanitary requirements of food and articles of common use ("Sl. list SFRJ", no. 53/91 and "Sl. list SRJ", no. 24/94, 28/96 and 37/2002) and Law of sanitary control of food and articles of common use. ("Sl. Glasnik SRS" no. 48/77, 29/88, 44/91 and "Sl. glasnik RS" no. 48/94).

The characteristics of the chemical composition of articles in common use are defined in the Regulation of sanitary requirements of articles of common use that may be marketed ("Sl. list SFRJ", no. 26/83, 61/84, 56/86, 50/89 and 18/91), where articles of common use are defined as:

- 1) foil, cutlery and food packaging materials;
- 2) toys;
- 3) personal care products, cosmetics (face and body beauty products);
- 4) products for hygiene maintenance;
- 5) tobacco and tobacco kits.



#### 1.4 Policy scenarios that will be addressed

In terms of policy scenarios, this WP will primarily deal with the impact assessment of chemical substances in consumer products, assuming their current ranges of concentrations.

In addition, the impacts of the policy dealing with reduction of use and substitution of certain types of substances in consumer goods seem useful to be looked at in the WP.

The proposed work will thus include an assessment of the exposure/risks under an alternative policy context. For each selected substance, a reduction in concentration and/or restrictions on the use to certain specific applications may be investigated. In such cases, the WP could determine the potential health benefits of such policies; DALYs could be used, for example, as an indicator of impacts.

##### Remarks:

- In case of a chemical for which already legal measures are taken or known to be taken into the future, it would be best to estimate the “historical” exposure that most likely would lead to a conclusion of concern. This can be compared with the level supposed to be reached after implementation of the measure (zero or a limit value in certain products).
- It may be interesting to consider the case where we arrive at a conclusion of ‘no concern’ for all chemicals. In this case two options might be considered: first, to include a “fake” higher exposure using as example to be able to finish the process to the end and/or second, to start with a new chemical.

## 2 Scope of the assessment

### 2.1 The assessment framework

Figure 1 provides an overview of the assessment framework.

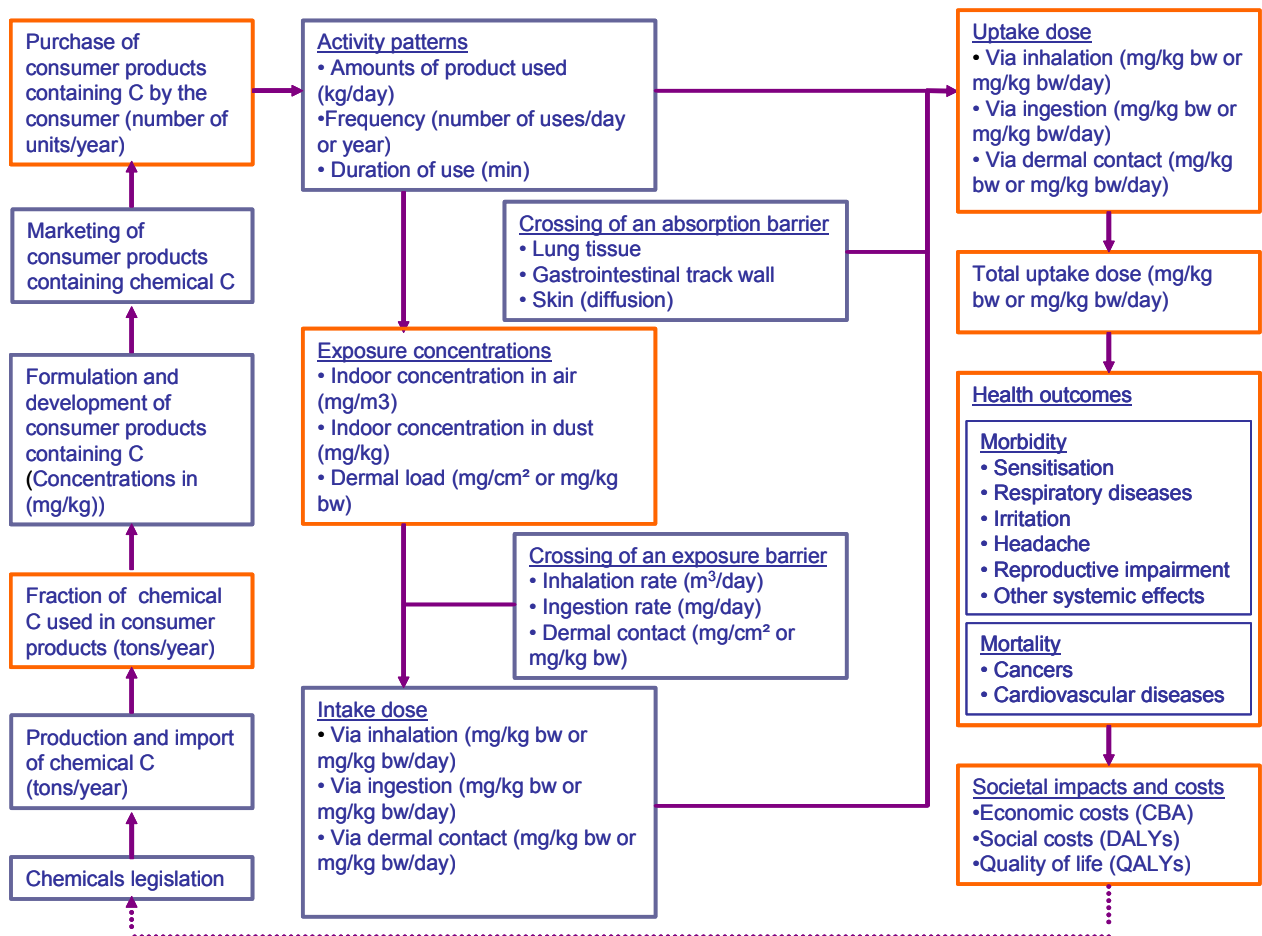


Figure 1 - Full chain approach for consumer exposure to household chemicals

### 2.2 Key elements/relationships to be assessed

This section details briefly what is meant by all the boxes in the framework diagram. Possible indicators for sources, exposure, health effects and impacts will be given and discussed in more details in Part 3 on the assessment methodology.

#### Research and Development and commercial interests

Innovation in Research and Development of new products, technologies and formulations can lead to the development of new chemical substances, new types of vectors and new types of products directly used by consumers. This increases the diversity of chemical substances on the market and thus can contribute to an increased exposure to chemicals. Technological and economic developments are then factors that motivate the marketing of new products which are new potential threats to consumers' health.

In addition, products are expected to exhibit a wide array of properties in addition to their main function, and this can only be achieved by the addition of many chemical substances (e.g. the main property of detergents is to clean - however they are also perfumed, require a certain viscosity that allows an easy application, they are stable for months/years... - all of this implies the addition of more chemical substances in the

product). One can see behind this that chemicals companies continually seek opportunities to formulate “new” products with new ways of marketing them. However, it can be also seen that society is increasingly demanding products suited to their own needs.

On the other hand, consumers are also becoming increasingly aware of the potential environmental and health impacts of certain consumer products (e.g. cleaning products, pesticides, etc...). Alternative “eco-friendly” products are gaining a substantial share of the market in Northern Europe. This encourages the development of less toxic compounds in preference to more toxic ones.

### Advertising

Usually the development and marketing of new products is supported by advertising (via all media like TV, radio, magazines...), which encourages people to consume, contributing then to the increase of consumer exposure to chemicals. For example, a driving force behind the development of cleaning products could be the ever-increasing advertising pressure to have clean and “bacteria-free” houses.

### Selling and purchase of consumer products

The marketing and the purchase of consumer products is mainly influenced by the points just mentioned above. The types of products purchased are also very much related to the age, socio-economic status, gender, ethnicity etc... of the purchaser. For instance, people from low-wages classes will probably buy cheaper products and maybe different products than people with higher wages. Also, for example, men and women will buy and use different products (e.g. cosmetics).

### Habits and trends in personal use

The usage of consumer products can be influenced by many different factors including:

- age;
- gender;
- type of area: rural/urban, north/south area;
- socio economic status;
- level of education / access to information;
- country-specific habits;
- labelling on the product;
- experience.

### Exposure

The main media exposure pathways to chemicals in consumer products are:

- Evaporation of chemical substances from the product → concentration in the air → exposure via inhalation;
- Direct application of the product on the skin → exposure via dermal contact (and possible hand-to-mouth contact);
- Emissions of chemical substances from the product → concentration in the air (inhalation exposure) → fall on the ground, in the house dust → exposure via ingestion and inhalation of and skin contact to house dust (children);
- Migration of chemical substances from the article → exposure via mouthing the article (ingestion) (children).

Remark: Concentrations of chemicals in air usually vary as a function of time and space.

Exposure can be strongly influenced by risk perception. Indeed, if consumers perceive risk to be sufficiently high, they will try to limit their exposure accordingly.

### Health effects

The main health effects potentially caused by chemicals in consumer products are:

- Morbidity - Chemicals in consumer products can cause acute effects (irritation, sensitization, headache...) and/or chronic effects (cancer);

- Mortality, as some substances such as pesticides, or some other substances that are classified as CMRs are present in consumer products and may cause fatality;
- Quality of life can be affected, as illnesses, for instance, induce an alteration of the quality of life.

### Societal impacts and costs

The impacts and the costs of health effects induced by the use of consumer products need to be assessed. They can be expressed as DALYs, QALYs etc...

Also the impacts of substitution and/or restriction of chemicals in products need to be taken into account.

Other points that might need some discussion are societal pressures and trends, chemical policy, chemical legislation, lobbying and commercial interests.

### 2.3 Target area

The geographical scale of the issue of chemicals in consumer products is from local to continental. It can be then Europe wide but the WP will may want to focus on some countries (Member States and others that are in Europe), depending on the quality (and detail) of information that can be retrieved.

The assessments may focus on four EU member states (France, The Netherlands, UK and Finland) and Serbia. These five countries are those represented by the partners involved in this WP.

### 2.4 Target time period

Definitions from the IPCS glossary:

Acute exposure: A contact between an agent and a target occurring over a short time, generally less than a day. (Other terms, such as "short-term exposure" and "single dose," are also used.)

Chronic exposure: A continuous or intermittent long-term contact between an agent and a target. (Other terms, such as "long-term exposure," are also used.)

For the exposure assessment, it is necessary to define whether the exposure that will be assessed is chronic or acute. The timescale on which the exposure assessment is realised is very much related to the toxicological endpoint of the substance which is studied. At first, the most critical effect (= the effect found at the lowest dose/concentration) has to be assessed. Then, for substances with acute toxicological endpoints, it will be more relevant to assess exposure on an acute timescale, like one hour or one day for example; whereas for substances with chronic critical endpoint, the timescale could be a year or a lifetime. Latency times, for examples for cancer, might need to be looked at.

If acute risks are considered in the assessment, it is necessary to build exposure profiles based on the time scale corresponding to the one of the toxicological endpoints. In other words, it implies, for instance, to build exposure profiles on an hour or a day basis, to indicate any temporal correlation or anti-correlation between different exposure events and also to consider that the exposure to a chemical resulting from a certain event can last for more than one day. This "history" of exposures would need to be taken into account for the following day's exposure profile, as recovery from certain acute effects (for example headaches, dizziness, irritation) may play a role as well.

As a result, aggregate exposure assessment to chemicals with acute effects is much more data demanding than exposure to chemicals with chronic effects. Probabilities of simultaneous use and "history" of the individual exposure events should be taken into account. This increases data needs and the difficulty of the assessment. Furthermore, the

addition (simultaneous use) might not be meaningful in all cases. Relevancy is higher for chronic exposure and their corresponding critical endpoints.

Discussions between WP3.5 partners on the type of effects (acute/chronic) that should be considered have led to the conclusion that the WP3.5 will focus on chronic exposure to chemicals.

If resources are sufficient, the acute issue will be dealt with by gathering more data and by further developing the methodology elaborated for the chronic issue.

## 2.5 Target population

From the review of tools and methodologies that aggregate human exposure to chemicals, the aggregation should be based on a person oriented approach, whatever the scope of the assessment is (screening type of refined assessment). There is a need to ensure consistency of exposure profile so that no unrealistic or unrepresentative combinations of exposure are taken into account. Exposure profiles should be built for a single person that could represent the entire population or that could be a realistic model of a person in the population.

## 2.6 Target consumer products

Different categorisations exist in order to classify consumer products; among them: the EU-TGD consumer preparations categories, the ECETOC-TRA 92 consumer product categories, the EIS-ChemRisks consumer products (preparations & articles) taxonomies, the Product categories in the BfR Database "GIFAS" (Reports of formulations for poison centres), the Health Canada Consumer Product Categories and Associated Sentinel Product Scenarios, the definitions of terms from the use/function classification in the IPCS INTOX Data Management.

First, one taxonomy has been chosen and then, a selection of product categories that are included in the scope of WP3.5 has been produced.

The categorisation indicated in the Technical Guidance Document on Risk Assessment Part I, Appendix II offers a product category list (see Annex B). It is proposed to use this categorisation as it is recommended by the European TGD on Risk Assessment.

The following categories will be taken into account in the WP 3.5 if relevant in exposure scenarios (for more details on the product categories, please refer to Annex B):

- Cleaner / Polish
- Adhesive / Sealant
- Painting material and additives
- Bleach / Disinfectant / Sterilizer
- Removers
- Textile chemical
- Vehicle maintenance
- Cosmetic / Personal hygiene product
- Toy / Joke / Children's plaything
- Other categories not mentioned otherwise

Concerning the biocidal products, product-types are defined in Annex V of Directive 98/8/EC (Refer to Annex C). Some biocidal products are intended to be included in the scope of WP3.5, when their influence is relevant in exposure scenarios. These product-types are:

- Product-type 1: Human hygiene biocidal products

- Product-type 2: Private area and public health area disinfectants and other biocidal products
- Product-type 3: Veterinary hygiene biocidal products
- Product-type 6: In-can preservatives
- Product-type 7: Film preservatives
- Product-type 8: Wood preservatives
- Product-type 9: Fibre, leather, rubber and polymerised materials preservatives
- Product-type 10: Masonry preservatives
- Product-type 12: Slimecidicides
- Product-type 14: Rodenticides
- Product-type 15: Avicides
- Product-type 16: Molluscicides
- Product-type 18: Insecticides, acaricides and products to control other arthropods
- Product-type 19: Repellents and attractants

## 2.7 Target chemical substances

*It has to be emphasized that the chemicals that have been selected do not aim at representing priority substances on a European scale (neither on a national scale). The aim of the selection was to identify substances to test a methodology, not to set up priorities.*

The method that has been used to select the chemical substances, which will be used to test the methodology, and the stakeholders, who have been involved in this step, are described in details in the Policy Scoping Report.

The following part quickly explains the method of selection of substances.

It has been decided to build a list of 10 substances for each country participating to the WP 3.5 (France, UK, The Netherlands, Republic of Serbia, and Finland) and to compare all these lists.

The criteria to select the substances in the lists were agreed as follows:

- The substance must be present in more than one product;
- Some exposure data have to be easily available;
- Information on the substance toxicity must be easily available;
- The substance can be a priority at a national or a European scale;
- Production quantities can be a criterion for inclusion in the list. However, substances in lower volumes can be of interest too.

Looking at the lists of each country, 3 (groups of) substances seemed to be of interest for nearly all partners:

1. Formaldehyde
2. Pyrethroids (pesticides)
3. Organophosphates (pesticides)

For the other substances, each (group of) substance has been discussed with participants.

The following ones have been selected:

4. Perfuming substances
5. Flame retardants
6. VOCs/VOS
7. Phthalates
8. Sodium hypochlorite

There was then a need to select one substance to represent each of the six selected groups. Each partner has been in charge of one group.

In order to select a substance in each group, it has been necessary to collect data on the substances and the following method has been agreed:

- List of possibly interesting chemicals (quick screen of literature for a given 'family')
  - Screen for existing risk assessments
  - Screen for crude toxicity data (the more toxic chemicals are more interesting)
  - Screen for exposure data (open literature or grey literature)
  - Screen for exposure data from specific consumer products
  - If possible assess the contribution of consumer products to total exposure (most interesting for the current exercise are the chemicals for which exposure to consumer products form the major source of exposure)
  - Screen type of products that the chemical is present in
- Choice of substance is combination of relative high toxicity, relative wide distribution in consumer products and relative large amount of information available.

For each step of this method, partners have indicated relevant sources of data. This constitutes a document which is regularly updated by partners and it allows a harmonisation of the work between WP3.5 partners.

Applying this method to each group of substance, the following substances have been pre-selected (see Policy Scoping Report):

**Formaldehyde** (CAS 50-00-0)

**Sodium hypochlorite** (CAS 7681-52-9)

**Permethrin** (CAS 52645-53-1)

**Malathion** (CAS 121-75-5) / **Chlorpyrifos** (CAS 2921-88-2)

**Isoeugenol** (CAS 97-54-1)

**Decabromodiphenyl ether** (CAS 1163-19-5)

**Toluene** (CAS 108-88-3)

**Di-n-butyl phtalate** (CAS 84-74-2)

Concerning the selection of chemical substances, the next step is the choice of four or five substances among these 9.

Criteria to be used in this selection are presence in a certain product group, critical endpoint, wide dispersive use, presence of primary (implemented for consumer product) or secondary (implemented for other (eg environmental) reasons) legislation.

The first phase of the project has showed that the methodology and choice of substances are inherently linked to each other. As the goal of the aggregate exposure assessment desires a certain methodology, available data on the selected substance will determine the possibilities. Developments in the methodology may also drive the selection of substances, since data requirements may change as well. As a matter of fact, the previous list may change as the methodology develops.

### **3** [The assessment methodology](#)

The assessment methodology for chemicals in consumer products follows the full-chain approach.

Each of the following parts relates to a step of this chain and each part includes a description of the methods/models, of the data and of the indicators that will be used in the assessment.

At first, the starting point should be made clear. Exposure estimates will be assessed for 2 situations: 1) the situation before a certain measure and 2) the situation after a measure. This measure might be a future/proposed one, possibly it is an already implemented (EU)-

measure. The measure might be focussed specifically on the substance in a consumer product, or it might be a measure meant for another purpose but also affecting the presence of a chemical in consumer products.

### 3.1 Source to exposure

#### Aggregation of the exposure

A report on how to aggregate human exposure to chemicals in consumer products has been issued and it presents an overview of the tools and methodologies that are available. One of the outputs of this report is the definition of steps for a typical aggregate exposure assessment:

1. Identify the sources and pathways of exposure;
2. Identify and define the populations of concern;
3. Construct the exposure profiles for individuals taken from these populations;
4. Aggregate the exposure per route for each individual from his exposure profile, on the timescales that are required for the assessment as dictated by the toxicological endpoints of the substance under consideration (e.g. daily intakes per route);
5. Construct appropriate time averages and population exposure measures from the individual exposure profiles. In this step, for instance, specific percentiles of the exposure within a population are determined, or sub-chronic or chronic exposures are derived from daily exposure values;
6. Integrate the exposures over the different routes, using an appropriate dose metric.

According to this report on aggregating human exposure to chemicals, the US EPA Office for Pesticide Programs suggests the use of two risk metrics:

- The 'total margin of exposure' ( $MOE_{tot}$ ) and;
- The 'aggregate risk index' (ARI).

The MOE is calculated by dividing the No-Observed-Adverse-Effect Level (NOAEL) by the estimated exposure for the considered route. The MOE for each route is compared with a reference or minimal MOE using an assessment or uncertainty factor (AF or UF (typically a factor of 100) which serves as a standard when ascertaining whether a given exposure is acceptable. To combine different MOEs into one, one uses the following equation:

$$MOE_{tot} = \frac{1}{\frac{1}{MOE_1} + \frac{1}{MOE_2} + \dots + \frac{1}{MOE_n}}$$

where  $MOE_1$ ,  $MOE_2$ , ...,  $MOE_n$  represent route specific (e.g. oral, dermal, inhalation) MOEs.

The  $ARI_{tot}$  is obtained when  $MOE_{tot}$  is divided by the UF:  $ARI_{tot} = \frac{MOE_{tot}}{UF}$

This approach is only valid when the uncertainty factor for each route is the same.

If this is not the case, the constituting MOEs should be normalized into an ARI first by dividing each MOE by its corresponding UF. In that case, the total ARI is obtained by:

$$ARI_{tot} = \frac{1}{\frac{1}{ARI_1} + \frac{1}{ARI_2} + \dots + \frac{1}{ARI_n}}$$



Figure 2 gives an overview of the conceptual model of the aggregation of exposure to chemicals in consumer products.

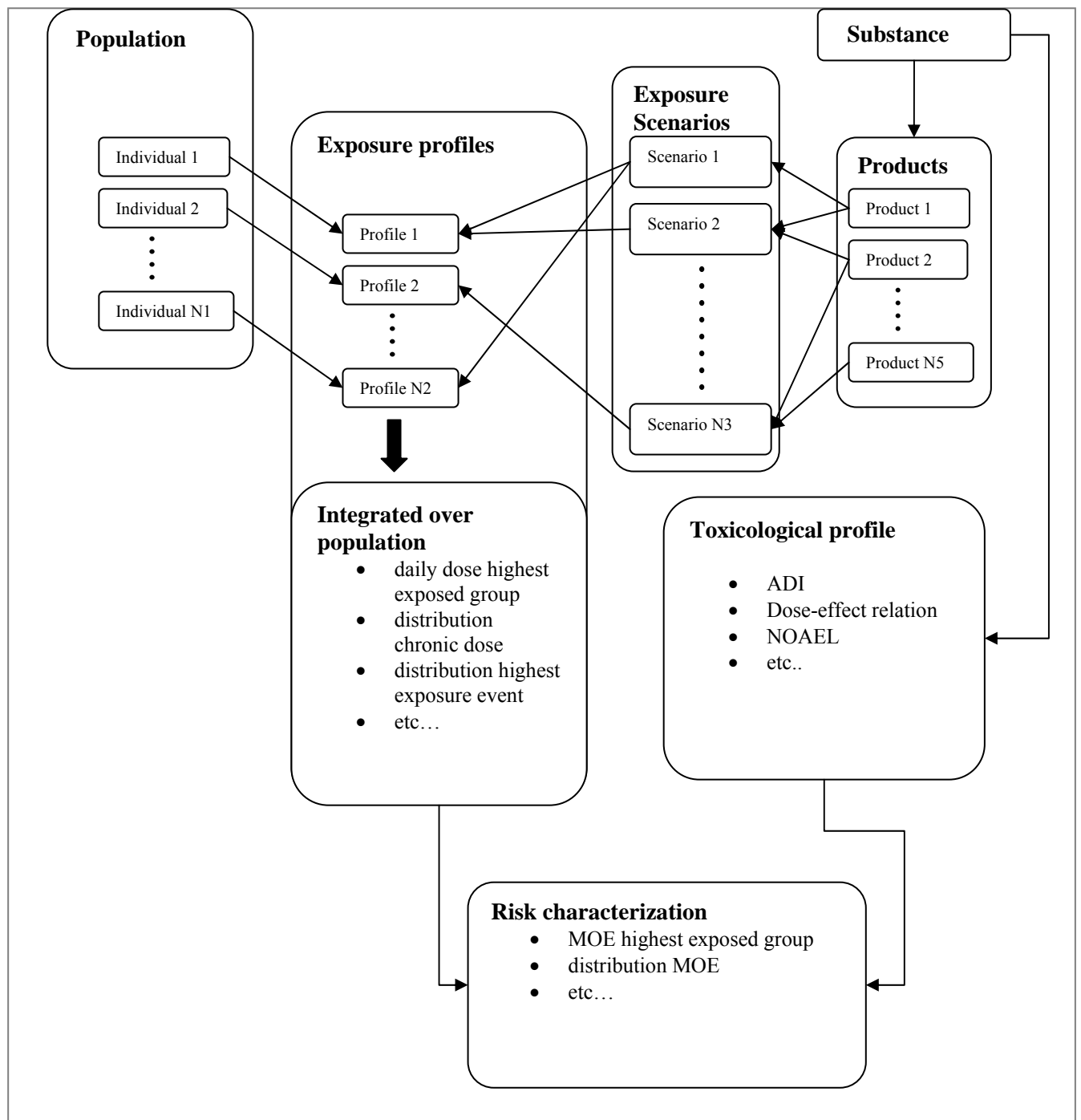


Figure 2: Conceptual model of the aggregation of exposure to chemicals in consumer products.

#### Method/Model/Tool

As direct measurements data of human exposure to chemicals in consumer products are scarce and costly, it is assumed that the exposure assessment will be performed via modelling.

If biomonitoring data are available, they will be used for comparison with the outputs of the modelling part. Contact with SP2 will be made on this issue during the first pass assessment.

In the report on aggregating human exposure to chemicals, several computer tools that assess consumer exposure to chemicals have been reviewed and described. The focus is on whether they are able to aggregate exposure from chemicals in multiple consumer products. This report presents several conclusions that can be directly used for the assessment of exposure in INTARESE WP3.5:

- "The level of detail with which aggregation is done should be dictated by the scope and purpose of the assessment."
- "Whatever the scope the assessment, the aggregation should be based on a person oriented approach."
- "The only area in which aggregation techniques are fully implemented and made use of is the field of exposure assessment to pesticides."
- "There is a number of specialized software tools available for the assessment of consumer exposures, but none of these implements or facilitates doing aggregate assessment."
- "At present risk assessment generally is performed on a product basis. Aggregate exposure to chemicals in multiple consumer products is currently hardly considered but should be taken into account to get insight whether actual risk is. A tool to perform aggregate exposure to consumer products needs to be developed."

The report emphasizes the fact that there is no tool available today to aggregate consumer exposure to chemicals in consumer products. It is proposed to use a tool that already exists and that assesses human exposure to consumer products and to use its outputs for the aggregation phase. This aggregation phase could be dealt with using excel sheets as a first step. The programme which is proposed to work with is ConsExpo.

This tool can be chosen for different reasons:

- it uses several models with different complexity levels which makes it useful for screening level assessments, but also for more detailed assessments (including distributional calculations);
- it uses a person oriented approach which is necessary as the exposure profiles will have to be constructed for a single person. As indicated earlier, this allows the elimination of any unrealistic or unrepresentative combination of exposure;
- it covers the 3 routes of exposure: oral, dermal and inhalation;
- it integrates the exposures across the different routes in order to obtain total internal doses;
- it covers a wide range of consumer products and pathways of exposure.

#### Construction of exposure profiles and data needs

It is proposed to proceed with a tiered approach to the assessment. The first tier would consist of a very crude deterministic assessment using conservative assumptions. If the result of this conservative exposure assessment is below a "safe" level, then it can be concluded that there is no concern related to the exposure to this substance for most of the population. If a level of concern is exceeded, the assessment should be refined; this would thus increase data needs and complexity of the model.

An exposure profile combines, for a hypothetical person, all of the exposure events involving different products which contain the same chemical substance.

The construction of exposure profiles will depend on the scope and on the purpose of the assessment. Three types of possible tiers are foreseen in the case of aggregate exposure to chemicals in consumer products. These are detailed below:

### A - Conservative screening assessment/chronic toxicity

This first tier is commonly seen as a quick and cheap step to indicate whether or not a more detailed approach is necessary.

The assessment is person-oriented and this person represents a (sub)-population. If one wants to assess the exposure of different groups of the population, the assessment needs to be repeated for other persons having different exposure profiles. Indeed, like for all exposure profiles, consistency is very important as this hypothetical person will not be exposed to all possible events. To take into account all the possible events, one can construct different exposure profiles which would reflect different sub-populations. In that sense, it may be relevant to realise a specific exposure assessment for vulnerable groups, such as children.

The basic data needs to construct an exposure profile for this type of assessment is:

- A listing of all the relevant products containing the chemical;
- The amount of the chemical that is contained in the product;
- Use data on the products: use description, amounts to be used, use frequencies;
- Basic population data: body weight, gender.

The exposure is calculated for each exposure scenario of an exposure profile. Depending on the time scale of the assessment, for instance on a yearly base, the exposure is averaged over each year, taking into account the frequency of such a scenario. For each scenario, the average exposure per route is estimated. Then, exposures are added per route over the different exposure scenarios, in an exposure profile. Aggregation can be finalised by adding the exposures over the different routes for each exposure profile.

The output of this assessment will be a conservative point estimate of the exposure of a hypothetical individual representing a group of the population. However, it will not give any information on the variation of the exposure among the sub-population that is studied, nor on how conservative the assessment is.

### B - More detailed assessment: population based/chronic toxicity

This is a more detailed population assessment. In this case, sub-populations are not represented by a single hypothetical individual, but rather by distributions of modelled individuals. These modelled individuals are characterised by specifying distributions of exposure determinants. For each sub-population this procedure can be repeated.

In this case also, only chronic toxicological endpoints are considered, the timescale of the exposure assessment can be e.g. a year. As a result, like in tier 1, it is not useful to have details on the temporal correlations between exposure events, as the exposure will be averaged on e.g. a year basis.

Compared to the previous tier, this assessment is more data demanding as data need to be provided under a distribution form. Identified data needs are:

- A listing of the products containing the chemical;
- The amount of the chemical that is contained in the product;
- Distributional information on product use:
  - Variation within the population of the amounts used per event;
  - Variation within the population of the number of products used;
  - Variation within the population in use frequencies;
  - (Anti)-correlations between the use of different products (e.g. an exposure profile containing an exposure scenario describing the use of a nail polish remover will have to contain also a scenario describing the use of a nail polish);
- Distributional information on anthropometric data;
- Distributional information on exposure factors.

Exposure is estimated for each exposure scenario. It is then multiplied by the exposure frequency and averaged over the timescale (e.g. a year). For each exposure profile, exposures arising from the exposure scenarios are added per route. Then they are added over the different routes to obtain a total average systemic exposure.

In this second tier, the way in which the aggregation is performed is quite similar to tier 1, except that distributions are used instead of point estimates (in tier 1) and that some correlations between exposure scenarios are taken into account.

The output of this type of assessment will be a distribution of the annual average aggregate exposure to a certain chemical substance. Unlike the approach used in tier 1, this approach allows an estimation of the variation of the exposure within the population and also an indication of how conservative the exposure estimate is by using a percentile of the output distribution, the percentage of the population which is exposed to a safe level can be known.

#### C - Highly detailed assessment: population based/acute and chronic toxicity

In addition to chronic toxicity, acute toxicological endpoints are also considered in this assessment. As indicated for the previous tiers, the timescale of the assessment has to correspond to the timescale of the effects. As a result, since acute effects will be taken into account in this tier, the timescale can be for instance on a day base.

For the construction of the exposure profiles, it is important at this stage to take into account the probability of using simultaneously (or on the same day) several products, and the fact that the use of a certain type of product may reduce the probability of use of another type of product. It may be important as well to consider the fact that exposure may last longer than one day after the end of the use of the product.

Data needed for this type of assessment have been identified:

- A listing of the products containing the chemical;
- The amount of the chemical that is contained in the product;
- Distributional information on product use:
  - Variation within the population of the amounts used per event;
  - Variation within the population of the number of products used;
  - Variation within the population in use frequencies;
  - (Anti)-correlations between the use of different products;
- Distributional information on anthropometric data;
- Distributional information on exposure factors;
- Probabilities that products are used simultaneously;
- Time profile of the individual exposure events.

The aggregation is carried out essentially in the same way as for the 2<sup>nd</sup> tier. Firstly, daily exposure (if the timescale is on a day basis) is calculated, per route, for each exposure scenario. Then daily exposures are summed per route over the different exposure scenarios, in an exposure profile. Finally, these exposures are integrated over the different routes using an appropriate risk metric. If necessary, the exposures can be averaged over longer exposure durations (e.g. a year).

The output of this type of assessment is then constituted by distributions of maximal acute exposures and of longer time averages of the population that is studied.

It is foreseen that the first pass assessment will start with a first tier assessment. Below, we propose different methods to perform a very crude first tier assessment.

## Details on first tier assessment

The choice of the method depends on which data will be most readily obtainable (or most reliably estimated). These methods are by no means the only ones possible, and many similar evaluations will probably be possible. Different approaches might be more appropriate for specific cases.

Exposures are evaluated as average daily doses. Depending on the toxicity profile of the substance and the product use, other time scales may be more appropriate.

1. Exposure is evaluated from the total amount of chemical released in consumer products each year and the size of the population that is exposed by assuming that all of the available chemical is actually taken up by the entire population.

That is,

$$D = \frac{A_{\text{tonnage}} \times f_{\text{consumer\_products}}}{W_{\text{body}} \times 365} \frac{1}{N_{\text{population}}}$$

2. Exposure is evaluated from a complete list of products that contain the substance and their composition.

$$D = \sum_{\text{products}} \frac{A_{\text{product}} \times f_{\text{weight}}}{W_{\text{body}} \times 365} \frac{1}{N_{\text{population}}}$$

3. Exposure is evaluated from a complete list of products that contain the substance, their composition and the use pattern of the products (amount used per use, use frequency)

$$D = \sum_{\text{products}} \frac{A_{\text{used}} \times f_{\text{weight}} \times f_{\text{intake}}}{W_{\text{body}}} \times n_{\text{use}}$$

4. A simplification of method 2) could be to categorize the products per product category, e.g. all toys or all carpets. Then assign each product category a share in the contribution to the total of substance usage (for instance, 35% of total DBP tonnage is used in toys), sum the amount per product category, and further assign each product category an average weight fraction.

$$D = \sum_{\text{products}} \frac{A_{\text{product\_categories}} \times f_{\text{weight\_categories}}}{W_{\text{body}} \times 365} \frac{1}{N_{\text{population}}}$$

5. An explicit method to evaluate the aggregate exposure from emission data is difficult to give, as this depends very much on the specific exposure scenario assumptions.

A general formulation would be something like:

$$D = \sum_{\text{products}} \frac{C_{\text{air}}(r_{\text{emission}}, \text{factors})}{W_{\text{body}} \times 365} \times t_{\text{contact, product}} \times R_{\text{inhalation}}$$

The unspecified factors will include data on ventilation, room sizes, sinks etc. The function C will also be very specific for the exposure scenario and might be

product dependent. (Note that this method is most suitable for volatile substances like VOCs etc.)

## Symbols

D	Average daily dose of substance in the target population ([mg]/[kg bw][day])
$A_{\text{tonnage}}$	Total tonnage of the substance used per year in the geographical area of interest - With: quantity used = quantity produced + quantity imported - quantity exported
$f_{\text{consumer\_products}}$	Fraction of the total tonnage $A_{\text{tonnage}}$ that is used in consumer products
$W_{\text{body}}$	(average) body weight of exposed person in the population.
$N_{\text{population}}$	Size of the exposed population
$A_{\text{products}}$	Total tonnage of a product used/sold per year in the geographical region of interest.
$f_{\text{weight}}$	Weight fraction of the substance in a product
$A_{\text{used}}$	Amount of product used per exposure event
$f_{\text{intake}}$	Fraction of the substance taken in during an exposure event - To be evaluated for specific scenarios using measurements or exposure models
$n_{\text{use}}$	(population average) Use frequency in times/day
$A_{\text{product\_categories}}$	Total tonnage of products in a products category
$f_{\text{weight\_categories}}$	Average weight fraction of substance in products of a category
$C_{\text{air}}$	Air concentration
$r_{\text{emission}}$	Emission rate of the substance from a product. Note that this is generally time-dependent
$t_{\text{contact,product}}$	Contact time with the exposure due to product (for inhalation: presence in the same space as the emitting product)
$R_{\text{inhalation}}$	Inhalation rate

## Data gaps

The evaluation of the exposure will likely suffer from a lack of reliable data on exposure factors. The most critical data needs per method are listed below:

1) For some substances, the total tonnage of substance might be known. The fraction  $f_{\text{consumer\_products}}$  of this amount that is used in consumer products, however, is generally not known. Also, the size of the population  $N_{\text{population}}$  must be known.

2) For some substances, lists of products containing the substances may be available. To complete the evaluation, the total amount (tonnage) of products used/sold  $A_{\text{products}}$  must be known.

Also the formulation of the product must be known.

In addition, the size of the population  $N_{\text{population}}$  must be estimated.

3) For some substances, lists of products containing the substances may be available. To complete the evaluation the total amount (tonnage) of products used/sold  $A_{\text{products}}$  should be known. In addition, (population) data on product use must be given. Specifically  $A_{\text{used}}$  and  $n_{\text{use}}$ .

4)  $A_{\text{product\_categories}}$ , total tonnage of products in a products category, and  $f_{\text{weight\_categories}}$ , average weight fraction of substance in products of a category, must be specified. This approach is similar to 2), but it might be that category-averaged data/estimates are more readily obtained.

5) For this approach, a complete list of products emitting the substance must be available plus the emission rates  $r_{\text{emission}}$ . Additional data on contact times etc would be needed but suitable values could be assumed in a first tier.

Obtaining appropriate values for the exposure parameters listed above is anticipated to be a significant challenge.

Several general approaches to obtain these data could be used (depending on the type of data):

- the development and execution of questionnaires
- analytical experiments
- the use of expert elicitation techniques
- locating and opening up new data sources
- personal estimation

Of course, for specific parameters there may be ad hoc methods that are more appropriate. Also, there may be methods not mentioned here that may be useful.

The use of personal estimation is the method most often used in absence of resources and time, but it might be an interesting challenge for the workgroup to try and use other methods first to obtain more realistic data.

Annex D gathers some sources of information that are useful when looking for the data needed for these types of exposure assessments.

### Possible indicators

Table 1: Examples of indicators that could be used to characterise sources and exposures

	Possible indicators
Source	<ul style="list-style-type: none"> <li>- Type of product(s)</li> <li>- Presence in the household</li> <li>- Quantity</li> <li>- Emission rate;</li> <li>- Presence/Absence of a substance in a product.</li> </ul>
Behaviour	<ul style="list-style-type: none"> <li>- Do people follow the instructions or not?</li> </ul>
Exposure	<ul style="list-style-type: none"> <li>- Measured concentration x time of the chemical in the room;</li> <li>- Measured concentration x time of the chemical in the breathing zone;</li> <li>- Modelled external concentration of the chemical (oral, inhalation, dermal);</li> <li>- Modelled internal concentration of the chemical (after uptake in gastro-intestinal tract, uptake from air in lungs, uptake through skin);</li> <li>- Measured internal concentration of the chemical (biomonitoring data).</li> </ul>

WP1.2 is in charge of the development of methods, tools and indicators for assessing the link between source and exposure and it will deliver a report on source-exposure models and methodologies. WP3.5 will also use this report and discuss how what is presented in it fits to the needs or how it could or could not be adapted to be used in the context of aggregate exposure assessment to chemicals in consumer products.

### 3.2 From Exposure to health effects

The extrapolation from exposure to health effects depends on:

- type of effect;
- exposure time: acute or chronic;
- non threshold or threshold;

- Route of exposure (if not similar route-to-route extrapolation should be performed if possible);
- Extrapolation from animal data (adverse effect) to the human situation (similar effect or related disease).

The step “From exposure to health effects” consists of integrating data on the dose-relationship of a chemical substance with the output of the exposure assessment in order to obtain a characterisation of the likelihood and the severity of the health effects.

Thus, first, it is necessary to get information on dose-response relationships and to perform an exposure assessment.

The method for quantifying the human health risks differs for carcinogenic and non carcinogenic substances.

### Carcinogenic substance

Different types of approaches exist in order to characterise risks due to carcinogenic substances

#### Approach 1

The risk estimate for this type of substance is expressed as the probability for an individual to suffer from an adverse effect: risk can be assessed as an excess individual lifetime cancer based on specified exposure.

Assuming linearity of the response at low doses, risk is estimated by using the following equation:  $Risk = LADD \times CSF$

Where:

Risk = probability of an individual to develop cancer

LADD = lifetime average daily dose (mg of substance/kg body weight/day)

CSF = cancer slope factor (mg of substance/kg body weight/day)<sup>-1</sup>

This equation usually does not give a “true” cancer risk estimate, but more an “upper bound” estimate; as the slope factor is usually derived from a conservative extrapolation to low doses.

#### Approach 2

This approach consists of the analysis of a margin of exposure (MOE). It can be used when the dose-response relationship is not linear or when the mode of action may have in theory a threshold.

### Non carcinogenic substances

For chemicals, with non carcinogenic effects, the assumption is that there is a level of exposure below which it is unlikely to experience adverse health effects. The important information consists then of safe levels of exposure and the critical effects associated with varying doses.

The exposure levels during a certain period of time are compared to a reference dose derived for a similar period of exposure. The risk estimate can be expressed as a “hazard

quotient” which is the ratio of exposure to toxicity:  $HQ = \frac{E}{RfD}$

Where

HQ = non cancer hazard quotient

E = Exposure level or intake in mg of substance/kg body weight/day

RfD = reference dose in mg of substance/kg body weight/day

HQ<1 suggests that exposures are unlikely to result in an adverse health effect



HQ>1 suggests that exposures may result in an adverse health effect

The margin of exposure (MOE) or margin of safety (MOS) approach can be also used for estimating risks from non carcinogenic substances. MOE and MOS are calculated as the

ration of toxicity to exposure:  $MOE(orMOS) = \frac{NOAEL}{E}$

Where

MOE = margin of exposure

MOS = margin of safety

NOAEL = no observed adverse health effect level in mg of substance/kg body weight/day

E = exposure level or intake in mg of substance/kg body weight/day

The No Observed Effect Level or Concentration (NOAEL or NOAEC) should be derived from available studies or from an existing risk assessment performed in another framework. The critical endpoint will be in most cases the endpoint with the overall lowest NOAEL.

In general, if the MOE (MOS) exceeds 100, it is considered that it is unlikely that exposures result in any adverse health effect. If the ratio is inferior to 100, it suggests that exposures may result in an adverse health effect.

Remark:

Non-threshold effects may also include (dermal or respiratory) sensitization.

Vulnerable groups

A specific attention should be given to vulnerable groups such as:

- Due to age: children and elderly people;
- Due to gender: maybe a differentiation between men and women, but the most vulnerable group is not known (also dependent on the toxicological endpoint of concern);
- Due to socio-economic status: low-wage families (we can wonder if cheap products can lead to a higher exposure to hazardous chemicals than more expensive ones);
- Pregnant women;
- Genetically susceptible groups?

Possible indicators

Table 2: Examples of indicators that could be used to characterise health effects

	Possible indicators
Health effects	<ul style="list-style-type: none"> <li>- Risk estimate of the disease associated with the exposure;</li> <li>Diseases could be: sensitisation, irritation, headache, reproductive impairment, cancer, cardiovascular impairment, respiratory illnesses, other systemic effects</li> <li>- Number of new cases of the disease per year (cancer cases);</li> <li>- Mortality from cancer;</li> <li>- Exceeding limit values.</li> </ul>

3.3 Health effects to impacts and costs

Health indicators

To monitor the health status of a population or to evaluate the consequences of trends or policy actions, several approaches can be envisaged. Over the years the reports about the health status of a population are changing with respect to the parameters applied. Traditionally mortality has been an important indicator of health. With the increasing life expectancy, public health attention shifted towards morbidity and health-related quality of life, in addition to mortality (Melse et al. 2000). This has led to the development of

parameters combining these traditional indicators into so called “composite health measures”.

At present a variety of these health indicators, pioneered by the QALY (Quality Adjusted Life Years), have been developed during the last twenty years and the most commonly referred to (acronyms in parenthesis) are known as “Healthy Life expectancy (HLE)”, “Quality Adjusted Life Years” (QALY’s), “Disability Adjusted Life Years” (DALY’s), “Health/Disability-Adjusted Life Expectancy”(HALE/DALE), ‘Healthy Year Equivalent’ (HYE), ‘Saved Young Life Equivalent’(SAVE), Willingness to Pay (WTP) and others.

The majority of these new combined health indicators have been developed to provide a “common currency” to assess the extent of the benefits gained from a variety of interventions in terms of health-related quality of life and survival. These indicators are primarily used in healthcare policy. They are also applied in health status and forecast reports (Murray and Lopez, 1996), in cost-utility analyses of interventions and they are essentially all based on clinically defined criteria. Application of these parameters in health impact assessment with respect to chemicals, if possible at all, is still in its infancy.

- QALY: Quality Adjusted Life Year, represents disease-specific health gain by taking into account both quantity and the quality of life generated by healthcare interventions. It is the arithmetic product of life expectancy and a measure of the quality of the remaining life-years.
- DALY: Disability Adjusted Life Year, represents disease-specific health loss as the sum of years of life lost (YLL) and years lived with disability (YLD) weighted for severity purposes.
- HYE: Healthy Year Equivalent, applies lifetime health profiles instead of disease specific quality parameters. Developed (Mehrez et al, 1989) for similar purposes as the QALY but it addresses some fundamental problems of the QALY. In theory superior to the QALY approach but practical implementation is considered doubtful.
- HALE/DALE: Health Adjusted Life Expectancy formerly called/started as Disability Adjusted Life Expectation, represents one of the most complex health indicators aiming to combine and summarize all states of health in one figure. Availability of data is one of the major problems calculating HALEs.
- SAVE: Saved Young Life Equivalent is an unity of measure of the yield of a healthcare system: one produces one SAVE if a young person is saved from a certain death with full reconstitution of its health.
- WTP: Willingness to Pay directly values health benefits in money but at present there is no consensus and the discussion is ongoing, both publicly and politically, about the amount of money serving as the equivalent of one QALY or DALY.

#### Disability Adjusted Life Years - DALY’s

Although originally developed as a public health proxy, the exploration of the DALY concept in integrated risk assessments has been started. Of all previously mentioned composite health measures, the DALY seems best suited for our purpose and may serve as a basis for comparing different estimated health losses (from different studies).

Essentially, the DALY combines the burden of disease caused by premature mortality and morbidity (non-fatal health outcomes) into one figure. In this figure, four important aspects of disease are incorporated: the number of people suffering from a disease, the severity of the disease, its mortality and the age at which mortality strikes. As originally described by Lopez and Murray (1997), the DALY is calculated by summing the number of years of life lost (YLL) due to premature death and the number of years lived with disability (YLD) attributable to a specific disease. The estimations are based on disease-specific epidemiological frequency data, expert derived disability weights (DW) and demographic data. The DW is a factor to express the severity of the disease. It has a range between 0 (perfect health-no disability) to 1 (death- maximum health loss, severest

disability). These factors are derived by panels of medical experts. The way DALY's are calculated can be illustrated with an example presented in Box 1.

**Box 1.**

A person develops lung cancer at the age of 45 and dies of it at the age of 59. The average life expectancy is set to 80 years. The number of years of life lost, YLL= 21 (80-59) and with a DW factor of 0.44 for lung cancer the number of years lived with disability, YLD=6.2 {0.44 x (59-45)}. So the total health loss for this person is calculated by YLL+YLD sums up to 27.2 DALY. When multiplied with the number of people having such a disease, a total number of DALYs can be estimated in the total population.

As previously mentioned, DALYs originate from health care policy making and applying those principles to the chemical risk analysis field may generate some specific problems like the lack of proper human data. For example translating information about 'liver damage' from animal experiments into human liver disease respectively into DALYs and employing DALYs within the (experimental animal) reproductive toxicological field are presenting major obstacles. These issues will become evident in the description of the case studies.

A common theme in public health policy-making is to take combined health measures, like the DALY, one step further by translating them into monetary units in order to convert cost-effectiveness analyses into cost-benefit analyses. However many different views, based on methodological and technical as well as on practical and ethical grounds, about the (im)possibilities to make this conversion (for example the choice which WTP-willingness to pay-equivalent for a QALY) do exist. Comparing different scenario's with DALYs as the common endpoint makes translation into monetary values redundant, because comparisons are directly made towards differences in health loss.

It is proposed to use in the first pass assessment the indicators presented above. Their relevancy to our approach for aggregate exposure assessment to chemicals will be discussed at the end of the first pass assessment.

WP1.4 addresses the issue of risk characterization and its outputs can be used in the scope of our case studies. They will be taken into account and their suitability to WP3.5 needs will be discussed at the end of the first pass assessment.

Socio-economic analysis for chemicals is under development for REACH at the moment. It is not yet clear how this will work out

**Risk perception**

Risk perception is the subjective judgment that people make about the characteristics and severity of a risk. Policy decisions might be greatly influenced by risk perception. Factors that are of importance in risk perception might be: a person's gender, age, education, previous familiarity with the risk, one's natural tendency to take or avoid risks and whether or not the person had children, and so on. There is a difference in risk perception between a professional assessing a risk and a concerned community affected by this risk.

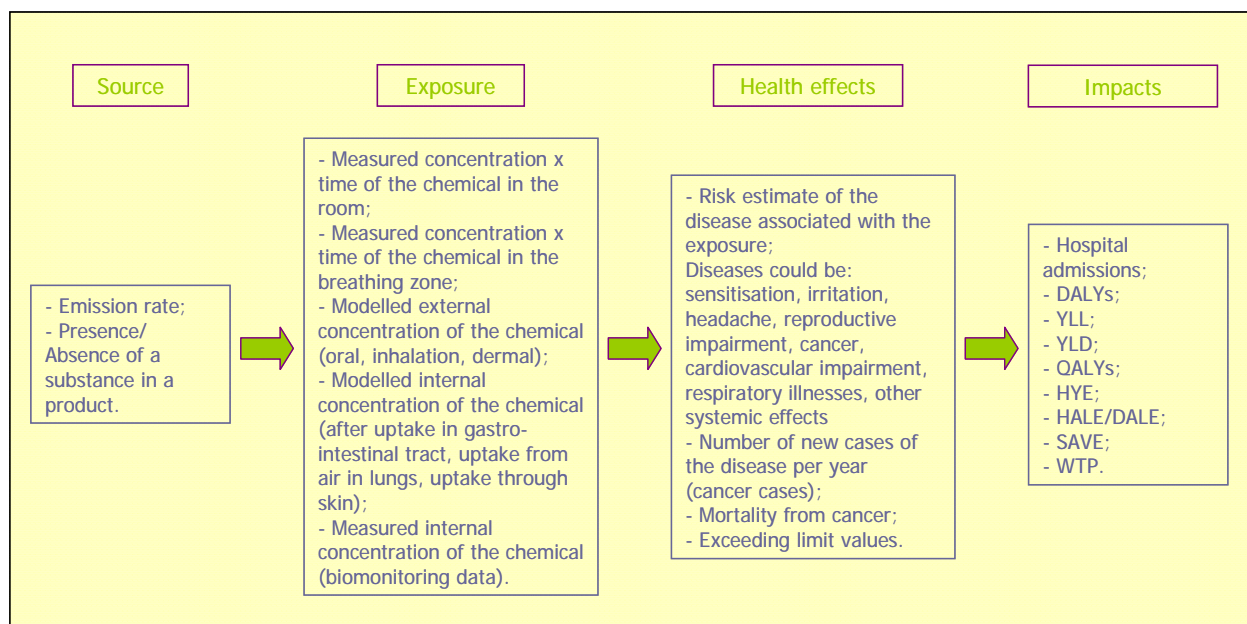
Possible indicators

Table 3: Examples of indicators that could be used to characterise impacts

	Possible indicators
Impacts	- Hospital admissions; - DALYs; - YLL;

	<ul style="list-style-type: none"> <li>- YLD;</li> <li>- QALYs;</li> <li>- HYE;</li> <li>- HALE/DALE;</li> <li>- SAVE;</li> <li>- WTP.</li> </ul>
--	---

Summary of some possible indicators:



## 4 Anticipated limitations of the assessment

### 4.1 Major sources of uncertainty

When assessing health impacts, some major sources of uncertainty can be identified. They have been grouped, depending on which step of the assessment they are related:

#### Exposure

- In case measured data are available, the source, sampling method, sampling time period, and/or analytical method of these measurements might differ, complicating the use for exposure assessment.
- When a calculation method or a model (like ConsExpo) is used to estimate an exposure, many assumptions have to be made. Assumptions are needed on frequencies of use, of time periods, of amounts etc... These are always made based on data if possible, and otherwise, assumptions are made based on expert judgment;
- Exposure estimations are almost always worst case estimations. In risk assessment for authorization purposes, this is a natural and desirable choice. In WP3.5 case studies, it is more desirable to have realistic average exposure estimates; in short, it is moving from a protective (risk) assessment towards a predictive (risk) assessment.
- In many cases, average exposures will be estimated. This is normal procedure in (protective) risk assessment. However, especially in case of acute exposure scenarios, peak exposures might be the interesting ones. For some products, health problems with consumers will be found in specific situations after peak exposures.

Also, one of the major sources of uncertainty in the process of consumer exposure assessment comes from the lack of data of different types:

- The composition of consumer products;
- The levels of production and importation of chemical substances;
- The amount of sold products;
- Consumers' behaviour;
- The pathway of release of the substance from the consumer products;
- The relative importance of the various pathways;
- The interactions between the chemicals in the products...

### Toxicity

Uncertainties are introduced when extrapolation is necessary from animal data to human data. In risk assessment (for reasons of prevention), in common cases, 10x10 is used as assessment factors. For health impact assessment, a more realistic choice might be more suitable, but is difficult to estimate. At present, safe limit values are derived from animal studies and using safety factors (or assessment factors, or uncertainty factors) extrapolated to a safe level for humans. So, it is relatively possible to state that below a certain level exposures are safe. But the other way around, to predict a human health outcome above a certain limit value is very uncertain.

Next to that, extrapolation from a toxic effect in animals to a disease in humans causes also some uncertainty.

### *Carcinogenicity*

- Uncertainty is introduced because the relevance for humans of the tumours found in animals is not always clear;
- Calculations can be performed using a linear scale for dose and carcinogenicity. This will be the choice in most cases for practical reasons, and because this is also commonly done in risk assessment. However, in risk assessment, it is attempted to protect the population and to prevent cancers. For health impact assessment, derivation of the results on a realistic base will be tried as much as possible;

### Health impact

- Defining a corresponding disease in humans (when calculating a DALY) from a (adverse) health effect determined in animals causes problems;
- Choosing a weighing factor for the effects brings (little) uncertainty to the assessment.
- Course of the disease is often unknown for allergies or some other health effects. Most cancers, however, are reasonably well described in terms of life expectancy, duration of illness etc.

## 4.2 Gaps in the assessment

Foreseen gaps in the assessment can be seen as consequences of the issue framing. Gaps can be determined as types of exposures that are left aside or also types of health effects.

In the case of chemicals in consumer products, gaps can be related to certain types of products that have been decided out of the scope of the WP3.5. For example, cigarette smoke and products like incense which are very complex mixtures of chemicals (the interaction of compounds being out of scope of the WP).

Concerning types of health effect, as described earlier, acute toxicological endpoints require more data than chronic effects. At the time of this assessment protocol, it is then foreseen to focus on chronic effects. If resources are remaining and if data is sufficient, then the issue of acute effects could be considered.

Finally, as indicated at the beginning of this report, the cumulative aspect will be left aside for the moment as there is not sufficient knowledge and resources in WP3.5 to develop methods dealing with this issue. Cumulative risk assessment is only possible for substances with a similar mode of action. For only a few groups of chemicals this approach is possible at the moment (such as pyrethroids, polychlorinated biphenyls and dioxins, .....

#### 4.3 Expected problems in the assessment process and possible solutions

One of the main expected problems in the assessment protocol is the lack of adequate data and the difficulties of access to data, as indicated in the sources of uncertainty. Due to confidential issues, it is very difficult to access data on the composition of consumer products and data on the amounts of sold chemical substances and products. Data on consumer behaviour are missing (quantity of product used, frequency of usage...). Also, information on how the substance is released from products and articles is missing. The interactions between the substances in the products/articles represent a significant challenge.

How to translate toxicity data obtained from animals to human health effects is another important challenge. Next to that, the translation of this health effect to a disease (in case of applying a DALY) might be challenging as well.

Concerning consumers' behaviour knowledge, a solution could consist of drawing up a proposal, at the end of the first pass assessment, for a EU-wide survey in order to collect data that could be used for a refined assessment.

## 5 Reporting and communication

For different policy scenarios, WP3.5 will assess consumer aggregate exposure to chemicals in consumer products. From these exposure assessments, health effects and impacts will be derived and a risk may or may not be perceived.

In case a risk is perceived, it may be important to involve stakeholders in order to discuss with them a way of reducing the exposure: the feasibility of banning the compound in certain products, of restricting the chemical compound to a maximum limit...

For enforcement purposes, limit values for chemicals in products are set for exposure for a single product. Then, the question also that arises is: what has to be done in case of an exposure to several products, each of them being below the limit value, but the total exposure exceeding the limit value? Will measures then affect the product with the highest exposure (but still below the limit value)? Will it be taken off the market?

In WP3.5, it is foreseen to involve stakeholders in the assessment but also in the discussion of the results. A guidance document to be issued by SP1 is expected on how to involve stakeholders, taking into account the national, internal, administrative and ethical rules that partners have to comply with.

A discussion on uncertainty will have to be included in the presentation and in the communication of the results of the assessment.

## Literature

[Commission Directive 93/67/EEC](#) of 20 July 1993 laying down the principles for assessment of risks to man and the environment of substances notified in accordance with Council Directive 67/548/EEC. OJ L 227, 08/09/1993 P. 0009 - 0018

[Commission Regulation \(EC\) No 1488/94](#) of 28 June 1994 laying down the principles for the assessment of risks to man and the environment of existing substances in accordance with Council Regulation (EEC) No 793/93 (Text with EEA relevance). OJ L 161 , 29/06/1994 P. 0003 - 0011

[Council Directive 67/548/EEC](#) of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances. OJ 196, 16.8.1967, p. 1-98

[Council Directive 76/769/EEC](#) of 27 July 1976 on the approximation of the laws, regulations and administrative provisions of the Member States relating to restrictions on the marketing and use of certain dangerous substances and preparations. OJ L 262, 27.9.1976, p. 201-203

[Council Regulation \(EEC\) No 793/93](#) of 23 March 1993 on the evaluation and control of the risks of existing substances. OJ L 84, 5.4.1993, p. 1-75

Delmaar JE, van Engelen, JGM (2006). Aggregating human exposure to chemicals. An overview of tools and methodologies. RIVM Report 630700001.

[Directive 98/8/EC](#) of the European Parliament and of the Council of 16 February 1998 concerning the placing of biocidal products on the market. OJ L 123 , 24/04/1998 P. 0001 - 0063

[Directive 1999/45/EC](#) of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations. OJ L 200, 30.7.1999, p. 1-68

[Directive 2001/95/EC](#) of the European Parliament and of the Council of 3 December 2001 on general product safety. OJ L 11, 15.1.2002, p. 4-17

[Directive 2004/10/EC](#) of the European Parliament and of the Council of 11 February 2004 on the harmonisation of laws, regulations and administrative provisions relating to the application of the principles of good laboratory practice and the verification of their applications for tests on chemical substances. OJ L 050, 20.02.2004, p. 44-59

[Directive 2006/121/EC](#) of the European Parliament and of the Council of 18 December 2006 amending Council Directive 67/548/EEC on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances in order to adapt it to Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) and establishing a European Chemicals Agency. OJ L 396, 30.12.2006, p 850-856

Melse JM, Essink-Bot ML, Kramers PG and Hoeymans N (2000). A national burden of disease calculation: Dutch disability-adjusted life-years. Dutch Burden of Disease Group. Am.J.Public Health 90[8], 1241-1247.

Murray CJL, Lopez AD (eds.) (1996). The global burden of disease: a comparative assessment of mortality and disability from disease, injuries, and risk factors in 1990 and projected to 2020. Cambridge (MA): Harvard University Press on behalf of the WHO and the World Bank.

Murray C J and Lopez AD (1997). Alternative projections of mortality and disability by cause 1990-2020: Global Burden of Disease Study. Lancet 349[9064], 1498-1504.

Policy Scoping Report (2006). INTARESE WP3.5 Household Chemicals.

[Regulation \(EC\) No 1907/2006](#) of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. OJ L 396, 30.12.2006, p. 1-849

[Regulation \(EC\) No 304/2003](#) of the European Parliament and of the Council of 28 January 2003 concerning the export and import of dangerous chemicals (Text with EEA relevance). OJ L 063 , 06/03/2003 P. 0001 - 0026

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

White Paper on the Strategy for a future Chemicals Policy COM (2001)88, February 2001. <http://ec.europa.eu/environment/chemicals/whitepaper.htm>



## ANNEX A

## Examples of Stakeholders

Industry stakeholders	CEPIC European Chemicals Industry Council	<a href="http://www.cefic.be/homepage/shwHomepage.asp">http://www.cefic.be/homepage/shwHomepage.asp</a> 'Cefic represents, directly or indirectly, about 29,000 large, medium and small chemical companies'
	EuroCommerce	<a href="http://www.eurocommerce.be">www.eurocommerce.be</a> 'Established in 1993, EuroCommerce represents the retail, wholesale and international trade sectors in Europe. Its membership of over 100 includes commerce federations in 28 European countries, European and national associations representing specific commerce sectors and individual companies.'
	EICTA European Information & Communications Technology Industry Association	<a href="http://www.eicta.org/">http://www.eicta.org/</a> 'EICTA is dedicated to improving the business environment for the European information and communications technology and consumer electronics (ICT and CE) sector, and to promoting the industry's contribution to economic growth and social progress in the European Union.'
	CEPE European Council of the Paint, Printing Ink and Artists' Colours Industry	<a href="http://www.cepe.org/">http://www.cepe.org/</a> 'The CEPE represents the interests of about 1100 paint and 75 printing ink and over 20 artists' colours companies at European level.' 'CEPE is a non-profit making organisation with the status of "association internationale sans but lucratif" (aisbl), which represents, promotes and protects the common interest of the European paint, printing ink and artists' colours industries.' 'CEPE works in close co-operation with the members - national associations and multinational companies - and makes use of their knowledge, experience and networks.'
	FormaCare	<a href="http://www.formaldehyde-europe.org/pages/">http://www.formaldehyde-europe.org/pages/</a> 'The FormaCare Sector Group is a recognised Cefic sector group, set up by the European formaldehyde producers to act as the official representative of the European formaldehyde manufacturers industry. Issues that the FormaCare Sector Group follows include Occupational Exposure Level (OEL) reductions, EU New Chemicals Management Policy and the Biocide Directive.'
	ESIG European Solvents Industry Group	<a href="http://www.esig.info/">http://www.esig.info/</a> 'Our mission is to support the sustainable and responsible use of oxygenated and hydrocarbon solvents through dialogue, information sharing and solutions that address health, safety and environmental aspects.'
	EFRA European Flame Retardants Association	<a href="http://www.cefic-efra.org">http://www.cefic-efra.org</a> 'EFRA's objectives are to promote fire safety, to coordinate studies and research relating to flame retardant chemicals, and to represent the flame retardant industry'
	AISE International	<a href="http://www.aise-net.org/">http://www.aise-net.org/</a> 'A.I.S.E. is the official representative body of this

	Association for Soaps, Detergents and Maintenance Products	industry in Europe. Its membership totals 35 National Associations in 33 countries, covering more than 900 companies ranging from small and medium-sized enterprises to large multinationals active both in the consumer goods market and the industrial & institutional domains.'
	COLIPA European Trade Association representing the interests of the cosmetic, toiletry and perfumery industry	<a href="http://www.colipa.com/site/index.cfm?SID=15588">http://www.colipa.com/site/index.cfm?SID=15588</a> 'The mission of COLIPA is to help maintain and develop a sustainable, competitive and respected industry in Europe by demonstrating the inherent value of our industry (as stated in our vision), by striving to create the most favourable economic and regulatory environment in which to operate and by advocating best practices; thereby ensuring that consumers benefit from continuously innovative and safe products.'
Civil Society Stakeholders	BEUC the European Consumers' Organisation	<a href="http://www.beuc.org">http://www.beuc.org</a> 'The European Consumers' Organisation, is the Brussels based federation of 40 independent national consumer organisations from the EU, accession and EEA countries. Our job is to try to influence, in the consumer interest, the development of EU policy and to promote and defend the interests of all European consumers.'
	EPHA European Public Health Alliance	<a href="http://www.epha.org/">http://www.epha.org/</a> 'The European Public Health Alliance represents over 100 non-governmental and other not-for-profit organisations working on public health in Europe.'
	WWF	<a href="http://www.wwf.org/">http://www.wwf.org/</a> 'The mission of WWF is to stop the degradation of the planet's natural environment, and to build a future in which humans live in harmony with nature, by: conserving the world's biological diversity, ensuring that the use of renewable natural resources is sustainable, reducing pollution and wasteful consumption.'
	Greenpeace	<a href="http://www.greenpeace.org/international/">http://www.greenpeace.org/international/</a> 'Greenpeace is a non-profit organisation, with a presence in 40 countries across Europe, the Americas, Asia and the Pacific.' 'We exist to expose environmental criminals, and to challenge government and corporations when they fail to live up to their mandate to safeguard our environment and our future.'
	ANEC	<a href="http://www.anec.org/">http://www.anec.org/</a> 'ANEC is the European consumer voice in standardisation, representing and defending consumer interests in the process of standardisation and certification, also in policy and legislation related to standardisation.'
	COFACE Confederation of Family Organizations in the European Union	<a href="http://www.coface-eu.org/">http://www.coface-eu.org/</a> 'COFACE is a non-political, non-religious-based organization which links together general and single-issue national family organizations. COFACE currently has 60 member organizations across the Member States of the European Union. As such, it gives a voice to many millions of parents and children.'
	Euro Coop	<a href="http://www.eurocoop.org/">http://www.eurocoop.org/</a>

	European Community of Consumer Cooperatives	<p>'Euro Coop. Four major objectives on behalf of consumers:</p> <ul style="list-style-type: none"> <li>- Centralise and diffuse information on current developments in economic and consumer policy issues which are of interest to members;</li> <li>- Constitute a forum for the regular exchange of information and the co-ordination of member organisations' common interests;</li> </ul> <p>Promote, defend and represent consumer interests at European level;</p> <ul style="list-style-type: none"> <li>- Represent the members at the European institutions in order to realise the previously mentioned social objective.' </li></ul>
Government stakeholders	ECB European Chemicals Bureau	<p><a href="http://ecb.jrc.it/">http://ecb.jrc.it/</a></p> <p>'The ECB provides scientific and technical support for the conception, development, implementation and monitoring of EU policies related to dangerous chemicals.'</p>
	DG SANCO The Health and Consumer Protection Directorate General	<p><a href="http://ec.europa.eu/dgs/health_consumer/index_en.htm">http://ec.europa.eu/dgs/health_consumer/index_en.htm</a></p> <p>'Over the years the European Union has established EU laws on the safety of food and other products, on consumers' rights and on the protection of people's health.'</p> <p>'The DG SANCO has the task of keeping these laws up to date. It is national, regional or even local governments in EU countries who actually apply the EU's health and consumer protection laws. It is their job to make sure traders, manufacturers and food producers in their country observe the rules. Nonetheless, part of our job is to check that this is really happening and that the rules are being applied properly in all EU countries.'</p>
	DG Enterprise	<p><a href="http://ec.europa.eu/dgs/enterprise/index_en.htm">http://ec.europa.eu/dgs/enterprise/index_en.htm</a></p> <p>'The Directorate-General for Enterprise and Industry is the driving force behind key Commission actions generating more favourable framework conditions for European business. We are working with the business community to help develop innovative, competitive and responsible enterprise and with Member States in implementing the Lisbon strategy in our Partnership for Growth and Jobs.'</p>

**ANNEX B**  
**Product category list (Technical Guidance Document, Part I)**

Category of Product/ general characterisation	Subcategories
<p><b>CLEANER / POLISH</b>            The category covers all products that are used in the household for cleaning, polishing and care. Some subcategories can be defined by different use characteristics. A comprehensive overview on household cleaners and its subcategories has been published by the IKW (IKW,2001)</p>	<ul style="list-style-type: none"> <li>• Cleaning of machines and vehicles (e.g. cars, bikes, motorbikes)</li> <li>• General household (All Purpose Cleaners)</li> <li>• Dish washing, manual</li> <li>• Dish washing, machine</li> <li>• Sanitary cleaners</li> <li>• Textile cleaners e.g. Powder Laundry Detergents, Laundry Liquid Detergents</li> <li>• Oven cleaners</li> <li>• Shoe and leather cleaner</li> <li>• Furniture cleaners</li> <li>• Drain cleaners</li> <li>• Metal cleaners</li> </ul>
<p><b>ADHESIVE / SEALANT</b>            The category covers all products that are used in the household as adhesives or sealants. Some subcategories can be defined by different use characteristics (The list of subcategories of adhesives has been prepared by the WHO/IPCS).</p>	<ul style="list-style-type: none"> <li>• General purpose adhesive</li> <li>• Floor covering adhesives</li> <li>• Dental plate cement</li> <li>• Fabric adhesive</li> <li>• Film cement, photographic</li> <li>• Leather adhesive</li> <li>• Metal adhesive</li> <li>• Paper adhesive</li> <li>• Plastic adhesive</li> <li>• Rubber adhesive</li> <li>• Wallboard joint cement</li> <li>• Wallpaper adhesive</li> <li>• Wood adhesive</li> </ul>
<p><b>PRINTING / WRITING MATERIAL</b>            The category covers all products that are used in the household for writing and printing. Some subcategories can be defined by different use characteristics: (The list of subcategories of adhesives has been prepared by the WHO/IPCS).</p>	<ul style="list-style-type: none"> <li>• Dye</li> <li>• Ink</li> <li>• Etching fluid</li> <li>• Correction fluid</li> <li>• Crayon</li> <li>• Pen marker</li> <li>• Toner</li> </ul>
<p><b>PAINTING MATERIAL AND ADDITIVES</b>            The category covers all products that are painted to an area for renewing, or to protect the areas against wetness or corrosion etc. Some subcategories can be defined by different use characteristics. The classification of subcategories has been prepared according to Baumann &amp; Muth (1997) and Bremmer and van Veen (2000a).</p>	<ul style="list-style-type: none"> <li>• Solvent based paint</li> <li>• Water based paint</li> <li>• Resin based paints</li> <li>• Aerosol paints</li> <li>• Paints for special purposes</li> <li>• Industrial paints</li> <li>• Varnish</li> <li>• Bleaching paints</li> <li>• Paints for conservation</li> <li>• Thinner</li> <li>• Paint remover</li> </ul>
<p><b>FUELS</b>            This category covers products that are used for feed machines (cars, motorbikes) or lamps or to lighten fires.</p>	<ul style="list-style-type: none"> <li>• Gasoline</li> <li>• Fuel oil</li> <li>• Liquid lamp oils and grill lighters</li> <li>• Solid grill lighters</li> </ul>

	<ul style="list-style-type: none"> <li>• Solid lighteners, other</li> </ul>
<p><b>BLEACH / DISINFECTANT / STERILIZER</b> The category covers all products that are used in the household as a bleach or for sterilisation. Some subcategories can be defined by different use characteristics.</p>	<ul style="list-style-type: none"> <li>• Bleaches</li> <li>• Sterilisers</li> </ul>
<p><b>REMOVERS</b> The category covers all products that are used in the household to remove substances, from surfaces and thus cleaning them. Some subcategories can be defined by different use characteristics:</p>	<ul style="list-style-type: none"> <li>• Adhesive/glue remover</li> <li>• Dye/ink remover</li> <li>• Seal remover</li> <li>• Polish remover</li> <li>• Limescale remover/descaler</li> <li>• Oil/grease remover</li> <li>• Rust remover</li> <li>• Stain remover</li> <li>• Wall paper remover</li> </ul>
<p><b>PHOTOGRAPHIC CHEMICAL</b> The category covers all products in the household that are referred to photography. Some subcategories can be defined by different use characteristics:</p>	<ul style="list-style-type: none"> <li>• Photographic chemicals</li> <li>• Photographic paper</li> </ul>
<p><b>TEXTILE CHEMICAL</b> The category covers all products that are exposure related to the use of textiles. Some subcategories can be defined by different use characteristics.</p>	<ul style="list-style-type: none"> <li>• Textile colours/dyes</li> <li>• Emission from textiles</li> <li>• Residues from cleaning textiles</li> <li>• Fabric softeners</li> <li>• Fire protecting agents in textiles</li> </ul>
<p><b>VEHICLE MAINTENANCE</b> The category covers all products that are used in the household to make vehicles (cars, bikes, motorbikes, caravans, boats etc.) ready for use. Cleaning is covered by the category "cleaner/polish". Some subcategories can be defined by different use characteristics:</p>	<ul style="list-style-type: none"> <li>• Lubricants</li> <li>• Repairing material</li> <li>• Antifreeze (vehicle)</li> <li>• Screen wash</li> <li>• Brake fluid</li> <li>• Fuel additive</li> <li>• Radiator fluid</li> <li>• Transmission fluid</li> </ul>
<p><b>COSMETIC / PERSONAL HYGIENE PRODUCT</b> The category covers all products that are used in the household to clean and care the body in particular e.g. hair and skin. Some subcategories can be defined by different use characteristics. Categories of cosmetics are extensively described by the compilation of cosmetic frame formulations (COLIPA, 2000). For composition of cosmetic products and for further use levels see also section 4.</p>	<ul style="list-style-type: none"> <li>• Rinse off products (e.g. Hand Dishwashing Liquids)</li> <li>• Non-rinse products</li> <li>• Spraying</li> <li>• Products that can contact mucous membranes</li> </ul>
<p><b>CONTAMINATION OF FOOD</b> The category covers exposures that can be referred to the consumption of food. In particular, it is referred to contaminations of food and is subcategorised to the different kinds of food. Most of the data referring to this type of exposure are available from food surveillance studies (e.g. BGVV, 1995).</p>	<p>Categories of food consumption should be taken according to the EFG food grouping system (EFCOSUM, 2001).</p> <ul style="list-style-type: none"> <li>• Contamination of food by processing and packaging material</li> </ul>
<p><b>AIR CONTAMINANT / POLLUTANT</b></p>	<ul style="list-style-type: none"> <li>• Furniture chemicals</li> </ul>

<p>The category covers all exposures that are referred to the emission of chemicals from materials in the household except textiles</p>	<ul style="list-style-type: none"> <li>• Building chemicals</li> <li>• Emissions from vehicles (e.g. cars)</li> </ul>
<p><b>TOY / JOKE / CHILDREN'S PLAYTHING</b> (Bremmer and van Veen, 2001)</p>	
<p><b>OTHER CATEGORIES NOT MENTIONED OTHERWISE</b></p>	<ul style="list-style-type: none"> <li>• Refrigerant, coolant</li> <li>• Solvent</li> <li>• Water softener</li> <li>• Aerosol propellant</li> <li>• Aquarium product</li> <li>• Art/craft material</li> <li>• Deodorizer/air freshener</li> <li>• Sports product</li> <li>• Swimming pool product</li> <li>• Waterproofing compound</li> <li>• Agricultural products other than pesticides</li> <li>• Medical devices</li> <li>• Piercings</li> </ul>

## ANNEX C

### Biocidal Product-Types and their descriptions as defined in Annex V of Directive 98/8/EC

#### MAIN GROUP 1: Disinfectants and general biocidal products

These product types exclude cleaning products that are not intended to have a biocidal effect, including washing liquids, powders and similar products.

##### *Product-type 1: Human hygiene biocidal products*

Products in this group are biocidal products used for human hygiene purposes.

##### *Product-type 2: Private area and public health area disinfectants and other biocidal products*

Products used for the disinfection of air, surfaces, materials, equipment and furniture which are not used for direct food or feed contact in private, public and industrial areas, including hospitals, as well as products used as algacides.

Usage areas include, *inter alia*, swimming pools, aquariums, bathing and other waters; air-conditioning systems; walls and floors in health and other institutions; chemical toilets, waste water, hospital waste, soil or other substrates (in playgrounds).

##### *Product-type 3: Veterinary hygiene biocidal products*

Products in this group are biocidal products used for veterinary hygiene purposes including products used in areas in which animals are housed, kept or transported.

##### *Product-type 4: Food and feed area disinfectants*

Products used for the disinfection of equipment, containers, consumption utensils, surfaces or pipework associated with the production, transport, storage or consumption of food, feed or drink (including drinking water) for humans and animals.

##### *Product-type 5: Drinking water disinfectants*

Products used for the disinfection of drinking water (for both humans and animals).

#### MAIN GROUP 2: Preservatives

##### *Product-type 6: In-can preservatives*

Products used for the preservation of manufactured products, other than foodstuffs or feedingstuffs, in containers by the control of microbial deterioration to ensure their shelf life.

##### *Product-type 7: Film preservatives*

Products used for the preservation of films or coatings by the control of microbial deterioration in order to protect the initial properties of the surface of materials or objects such as paints, plastics, sealants, wall adhesives, binders, papers, art works.

##### *Product-type 8: Wood preservatives*

Products used for the preservation of wood, from and including the saw-mill stage, or wood products by the control of wood-destroying or wood-disfiguring organisms.

This product type includes both preventive and curative products.

##### *Product-type 9: Fibre, leather, rubber and polymerised materials preservatives*

Products used for the preservation of fibrous or polymerised materials, such as leather, rubber or paper or textile products and rubber by the control of microbiological deterioration.

*Product-type 10: Masonry preservatives*

Products used for preservation and remedial treatment of masonry or other construction materials other than wood by the control of microbiological and algal attack.

*Product-type 11: Preservatives for liquid-cooling and processing systems*

Products used for the preservation of water or other liquids used in cooling and processing systems by the control of harmful organisms such as microbes, algae and mussels. Products used for the preservation of drinking water are not included in this product type.

*Product-type 12: Slimicides*

Products used for the prevention or control of slime growth on materials, equipment and structures, used in industrial processes, e.g. on wood and paper pulp, porous sand strata in oil extraction.

*Product-type 13: Metalworking-fluid preservatives*

Products used for the preservation of metalworking fluids by the control of microbial deterioration.

### MAIN GROUP 3: Pest control

*Product-type 14: Rodenticides*

Products used for the control of mice, rats or other rodents.

*Product-type 15: Avicides*

Products used for the control of birds.

*Product-type 16: Molluscicides*

Products used for the control of molluscs.

*Product-type 17: Piscicides*

Products used for the control of fish; these products exclude products for the treatment of fish diseases.

*Product-type 18: Insecticides, acaricides and products to control other arthropods*

Products used for the control of arthropods (e.g. insects, arachnids and crustaceans).

*Product-type 19: Repellents and attractants*

Products used to control harmful organisms (invertebrates such as fleas, vertebrates such as birds), by repelling or attracting, including those that are used for human or veterinary hygiene either directly or indirectly.

### MAIN GROUP 4: Other biocidal products

*Product-type 20: Preservatives for food or feedstocks*

Products used for the preservation of food or feedstocks by the control of harmful organisms.

*Product-type 21: Antifouling products*

Products used to control the growth and settlement of fouling organisms (microbes and higher forms of plant or animal species) on vessels, aquaculture equipment or other structures used in water.



*Product-type 22: Embalming and taxidermist fluids*

Products used for the disinfection and preservation of human or animal corpses, or parts thereof.

*Product-type 23: Control of other vertebrates*

Products used for the control of vermin.

## ANNEX D

### Exposure assessment to chemicals in consumer products

#### Sources of information

##### Screening for existing risk assessments

- \* ECB Internet site: <http://ecb.jrc.it/existing-chemicals/>
- \* The OECD HPV Chemicals Programme: for chemicals that have already been assessed see the OECD Integrated HPV Chemicals Database <http://cs3-hq.oecd.org/scripts/hpv/>
- \* [www.inchem.org](http://www.inchem.org)
- JMPR: Joint Meeting on Pesticide Residues → monographs of toxicological evaluations
- IARC: International Agency for Research on Cancer → summaries and evaluations
- EHC: Environmental Health Criteria → monographs
- JECFA: Joint Expert Committee on Food Additives → monographs and evaluations
- SIDS: Screening Information Data Set
- CICADs: Concise International Chemical Assessment Documents
- \* Risk assessment site (<http://risk.lsd.ornl.gov/>), which includes at least toxicity information
- \* Pesticide Awareness Network Factsheets - <http://www.pan-uk.org/>
- \* Health Canada Assessment reports for 1<sup>st</sup> and 2<sup>nd</sup> priority lists: [http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index\\_e.html](http://www.hc-sc.gc.ca/ewh-semt/contaminants/existsub/eval-prior/index_e.html)
- \* Opinions from the Scientific Committee on Consumer Products : [http://ec.europa.eu/health/ph\\_risk/committees/04\\_sccp/sccp\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/04_sccp/sccp_opinions_en.htm)
- \* Opinions from the Scientific Committee on Cosmetic Products and Non-food products intended for Consumers: [http://ec.europa.eu/health/ph\\_risk/committees/sccp/sccp\\_opinions\\_en.htm](http://ec.europa.eu/health/ph_risk/committees/sccp/sccp_opinions_en.htm)
- \* HERA Risk assessments: <http://www.heraproject.com/RiskAssessment.cfm>
- \* OECD SIDS (Screening Information Data Set): <http://www.inchem.org/pages/sids.html>
- \* Databases ESIS and IUCLID DS on: <http://ecb.jrc.it/esis/>
- \* Danish EPA reports: <http://glwww.mst.dk/homepage/> (→ Chemicals → Other chemicals → Chemicals in consumer products)

##### Toxicity data

- \* Toxnet (HSDB, Toxline, IRIS, ITER databases): <http://toxnet.nlm.nih.gov/>
- \* ATSDR:
  - Toxicological profiles: <http://www.atsdr.cdc.gov/toxpro2.html>
  - ATSDR ToxFAQs™ - <http://www.atsdr.cdc.gov/toxfaq.html#bookmark05>
  - MRLs list: <http://www.atsdr.cdc.gov/mrls.html>
- \* National Toxicology Program (NTP): <http://ntp-server.niehs.nih.gov/>
- \* TERA/ITER: [http://iter.ctcnet.net/publicurl/pub\\_search\\_list.cfm](http://iter.ctcnet.net/publicurl/pub_search_list.cfm)
- \* EU Technical Review Reports for Plant Protection Products (existing active substances): [http://ec.europa.eu/food/plant/protection/evaluation/exist\\_subs\\_rep\\_en.htm](http://ec.europa.eu/food/plant/protection/evaluation/exist_subs_rep_en.htm)
- \* Annex I of Directive 67/548/EEC which contains a list of harmonized classifications and labellings for substances or groups of substances, which are legally binding within the EU: <http://ecb.jrc.it/classification-labelling/>
- \* EXTTOXNET: Pesticide Information Profiles (PIPs) - <http://extoxnet.orst.edu/pips/ghindex.html>
- \* USEPA Factsheets: <http://www.epa.gov/oppsrrd1/REDS/factsheets>
- \* Scorecard Health Risk Assessments: <http://www.scorecard.org/>
- \* JMPR/IPCS Inchem International Chemical Safety Card (ICSC): <http://www.inchem.org/pages/icsc.html>

\* Agency for Toxic Substances and Disease Registry (ATSDR): Finalized Toxicological Profiles - <http://www.atsdr.cdc.gov/toxpro2.html#bookmark05>

### Exposure data (open literature or grey literature)

Search of articles with exposure data:

\* [www.scirus.com](http://www.scirus.com)

\* <http://scholar.google.com/>

\* [www.sciencedirect.com](http://www.sciencedirect.com)

\* Pubmed: <http://www.ncbi.nlm.nih.gov/entrez/query.fcgi>

\* <http://portal.isiknowledge.com>

### Data on products composition

According to the TGD Part I, the most logical sources to find data on the occurrence of the substance in products present on the European market are:

\* Dossiers provided by the producing/importing company(ies);

\* Product registers that are available in some countries.

Again, according to the TGD Part I, if these sources do not provide sufficient information other sources can be used such as:

\* (inter)national trade associations;

\* National consumer products inspectorates (Swedish, Norwegian, Danish products registers);

\* Poison control centres and case studies reported in the literature.

The diversity of consumer products does not allow for a single set of information sources, handbooks or databases to be consulted. Rather, it is necessary to explore which information sources apply to the substance of interest.

\* Section 5.3 of the TGD on Risk Assessment Part I - Appendix II: Composition tables for laundry and cleaning products

\* Household products database: <http://householdproducts.nlm.nih.gov/>

\* Safety datasheets for Procter and Gamble products sold in various European countries:

[http://www.scienceinthebox.com/fr\\_FR/product/productcompsitions\\_fr.html](http://www.scienceinthebox.com/fr_FR/product/productcompsitions_fr.html)

\* Full list of ingredients present in P&G (Procter & Gamble) laundry and cleaning products that are currently on sale in Europe:

<http://www.scienceinthebox.com/info-pg/index.html>

\* SPIN Database: <http://www.spin2000.net/spin.html>

\* "Cosmetic Frame Formulations" - January 2006 from COLIPA and EAPCCT

\* Hazardous chemicals in consumer products - Sept 2003 - TNO

<http://www.greenpeace.org.uk/MultimediaFiles/Live/FullReport/6043.pdf>

### Exposure factors

\* BfR (Bundesinstitut für Risikobewertung), Federal Institute for risk assessment:

[http://www.bfr.bund.de/cd/template/index\\_en](http://www.bfr.bund.de/cd/template/index_en)

\* RIVM factsheets: [www.consexpo.com](http://www.consexpo.com)

\* Some trade associations have provided data on product uses (amount, frequencies, use duration) for specific product categories that may be useful for estimating exposure. These data may be found in Appendix II (Section 5.3) of the TGD on risk Assessment Part I: tables that give information about use instructions and compositions of some laundry and house cleaning products, amounts and migration rate of textile dyes, amounts and frequency of use of cosmetic products.

\* HERA project: Human & Environmental Risk Assessment on Ingredients of Household Cleaning Products Guidance Document Methodology- February 2005: APPENDIX F - Table of Habits and Practices for Consumer Products in Western Europe

APPENDIX G - Consumer Exposure Factors

\* EXPOFACTS: "The European Exposure Factors (ExpoFacts) Sourcebook is a collection of statistics and references. It 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.": <http://cem.jrc.it/expofacts/>

\* Exposure parameters (dermal, oral, inhalation) in the report "Exposure and risk Screening Methods for consumer Product Ingredients" from the SDA (2005)

[http://www.cleaning101.com/files/Exposure\\_and\\_Risk\\_Screening\\_Methods\\_for\\_Consumer\\_Product\\_Ingredients.pdf](http://www.cleaning101.com/files/Exposure_and_Risk_Screening_Methods_for_Consumer_Product_Ingredients.pdf)

\* Consumption data about cosmetic products:

AISE - Association Internationale de la Savonnerie et de la Détergence

COLIPA - The European Cosmetic Toiletry and Perfumery Association

\* Section 5.2 of the TGD on risk Assessment Part I - Appendix II: anthropometric data (body weight, surface area, respiration volume, room volume, ventilation)

\* Section 5.3 of the TGD on Risk Assessment Part I - Appendix II:

**Table 8** Habits and practices for consumer products in Western Europe (AISE, 2002)

**Table 14** Typical use levels of cosmetics (Typical amounts per application and frequency of use of cosmetics)

**Table 15** Consumer exposure to textile dyes

\* The SCCNFP's Notes of Guidance for the testing of cosmetic ingredients and their safety evaluation (5<sup>th</sup> revision): Table 2 Calculation of the daily exposure to cosmetics using Colipa data (amount of substance applied, frequency of application, retention factor, daily exposure calculated)

\* US EPA NCEA (National Centre for Environmental Assessment) Exposure factors Handbook <http://www.epa.gov/ncea/efh/>

\* ECETOC (European Centre for Ecotoxicology and Toxicology of Chemicals) Exposure Factors Sourcebook for European Populations, with Focus on UK Data (Zaleski & Gephart, 2000): broad compilation of European exposure factors.

\* EIS-ChemRisks toolbox (JRC) Login is required

#### Note

\* A list of valuable sources on exposure data is given in the TGD - Part I - Appendix II (Section 6):

Abbreviation	Full title	Country	Remarks	Contact
AIHC	American industrial health council (1994). Exposure factors handbook	US	Anthropometric data on adults and children, behaviour data, given as distributions	Update coordinator, Suite 760, 2001 Pennsylvania Ave. NW, Washington DC 20006-1807
AUH	Standards zur Expositionsabschätzung	D	Compilation of anthropometric data, partly referred to other sources (US), focus on children	Dr. R Fehr, LAUG Bielefeld, Germany 49 521 8007 253

BgVV-ZEBS	Zentralstelle zur Erfassung und Bewertung von Stoffen in Lebensmitteln	D	Food monitoring, focus to Germany	Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany 49 1888 412 0
CEPA	Air toxic Hot Spots Program Risk Assessment Guidelines Californian Environmental Protection Agency.	US	Part IV Technical Support for Exposure Assessment and Stochastic Analysis	<a href="http://www.0ehha.ca.gov/air/hot_spots/finalStoc.html">http://www.0ehha.ca.gov/air/hot_spots/finalStoc.html</a>
CH-PR	Swiss product register	CH	Product information, given on request	Dr. J. De Peyer, Swiss Federal Health Office, Geneva
ECETOC	Exposure Factors Sourcebook for European Populations (with focus on UK data)	EU/ECETOC	Probability analysis Anthropometrics Time activity patterns	<a href="http://www.ecetoc.org">www.ecetoc.org</a>
IFL	Industrieverband Farben und Lacke	D	National industrial association, focus on paints, lacquers	Karistrasse 21 D-60329 Frankfurt 49 69 2556 0
IKW	Industrieverband Körperpflege und Waschmittel	D	National industrial association, focus on household preparations	Karistrasse 21 D-60329 Frankfurt 49 69 2556 0
IVA	Industrieverband Agrar	D	National industrial association, focus on agricultural preparations	Karistrasse 21 D-60329 Frankfurt 49 69 2556 0
PR-D	Product data base according to regulations of chemical law	D	Product information	Federal Institute for Health Protection of Consumers and Veterinary Medicine, Berlin, Germany 49 1888 412 0
PR-FIN (KETU)	Finnish product register	FIN	Product information	<a href="http://www.sttv.fi">www.sttv.fi</a>
PR-S	Swedish product register	S	Product information	<a href="http://www.kemi.se">www.kemi.se</a>

RIVM	Bremmer HJ, van Veen MP (2000b). Factsheet algemeen. Randvoorwaarden en betrouwbaarheid, ventilatie kamergroote, lichaamsoppervlak. RIVM report 612810009, factsheet algemeen	NL	General information, room volumes, room ventilation data	RIVM (2000)
RIVM-paint	Bremmer HJ, van Veen MP (2000a). Factsheet verf. Ten behoeve van de schatting van de risico's voor de consument.	NL	Use data on paints, paint classification, characterisation of paint use, focus to NL	RIVM (2000) Bilthoven, The Netherlands
RIVM-toys	Bremmer HJ, van Veen MP (2000a). Factsheet verf.	NL	Toys, characterisation of children, children's behaviour	RIVM (2000)
US EPA	Environmental Protection Agency (1997). Exposure Factors Handbook.	US	Substantial compilation of exposure factors	EPA (1997) <a href="http://www.epa.gov">www.epa.gov</a>
VCI	Verband der chemischen Industrie	D	National industrial association (all chemical industries)	Karlstrasse 21 D-60329 Frankfurt 49 69 2556 0