

## The EU Exposure Assessment Toolbox

*An Approach to Harmonise Exposure Assessment in the EU,  
Using the **Toolbox** of the **European Information System** on risks from chemicals  
released from consumer products and articles'  
"EIS-ChemRisks"*

## Outline & Status

February 2006

D. Papameletiou\*, A. Arvanitis, I. Biavetti, Y. Bruinen de Bruin, C. del Pozo, P.J. Hakkinen, M. Lahaniatis, V. Reina and A. Zenié

European Commission, Joint Research Centre, Institute for Health and Consumer Protection, Physical and Chemical Exposure Unit, Ispra, Italy

---

**\*Contact person for correspondence:**

Demosthenes Papameletiou, Ph.D.;

European Commission, Joint Research Centre (JRC), Institute for Health and Consumer Protection (IHCP), Physical and Chemical Exposure Unit,

TP 281, I-21020 Ispra (VA) Italy;

Tel. +39. 0332. 78 5282 (direct)/Tel. +39. 0332. 78 9952 (secretariat)

[demosthenes.papameletiou@jrc.it](mailto:demosthenes.papameletiou@jrc.it)

<http://www.jrc.cec.eu.int/eis-chemrisks>





## Rationale and Objectives

Exposure information on chemicals related to consumer products and articles (e.g. toys and textiles) is difficult to find or missing altogether, and this is often a major bottleneck in developing safety and risk assessments. The need to build knowledge and develop European and global infrastructure, methods and tools for understanding the reasonably foreseeable uses and misuses, and accidental consumer exposure is becoming increasingly important. Experiences arising from the implementation of the General Product Safety Directive (GPSD, 2001/95/EC) and the adoption of the proposal for a EU regulatory framework for the Registration, Evaluation and Authorization of Chemicals (REACH) on 29 October 2003 emphasise this need. This led the European Commission's DG SANCO (Health and Consumer Protection Directorate General) and the Joint Research Centre (JRC) to launch the 'European Information System on risks from chemicals released from consumer products and articles' (EIS-ChemRisks) in 2003 with the aim to provide tools and reference data that enable harmonised exposure assessment procedures for consumer products and articles in the EU.

## Deliverables

A key deliverable of EIS-ChemRisks is the "**EU Exposure Assessment Toolbox**". It was developed over the period 2003 – 2005 and represents an infrastructure to systematically support the exchange of information on exposure issues among stakeholders - such as industry, governmental bodies, research organizations and Non Governmental Organisations (NGO's). At present, the toolbox includes the following **integrated relational databases/tools** designed to act as a **reference system**:

- ❑ **ExpoData** (storage of chemical specific exposure data, such as substance usage in specific products/articles and their typical concentrations, physical/chemical properties of substances, etc.),
- ❑ **EU-ExpoFactors** (storage of non-chemical specific exposure data, such as human body weight and breathing rates for various types of consumers, residential air exchange rates for various types of apartments and homes, etc.),
- ❑ **ChemTest** (Exposure Testing Methods, such as methods to quantify emission of volatile chemicals from a consumer product, etc.),
- ❑ **ExpoModels** (storage of existing Exposure Models and Algorithms, such as an algorithm for assessing dermal exposure to a chemical in a product used for a household cleaning task, etc.),
- ❑ **ExpoHealthData** (storage of Human Health Data associated to Exposure, such as physician reports in publications of human skin irritation and sensitisation associated with a particular chemical used in consumer products and articles, etc.),
- ❑ **ExpoScenarios** (storage of existing exposure assessments and scenarios for particular consumer products and articles and their chemicals, together with an standardised, user friendly process to develop new exposure assessments, etc.).

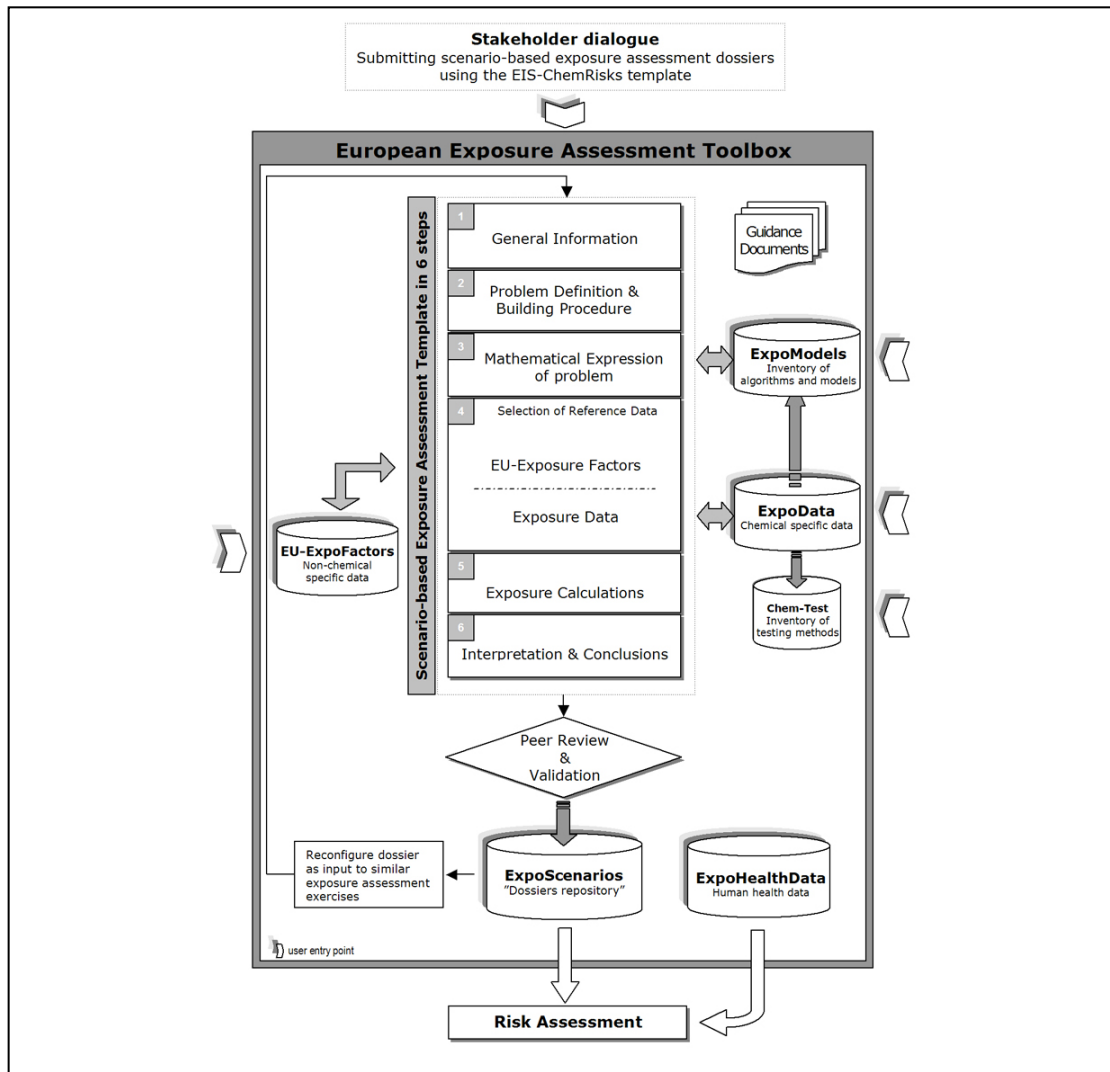
The integration of the above databases/tools into the Toolbox and the methods applied to establish harmonised exposure assessment are illustrated in **Figure 1**. To date, the system development and pilot operation included data processing from over 4400 documents into the different databases to develop and test the following toolbox functionalities:

- ❑ A central user interface,
- ❑ Product and data-specific taxonomies (classification/categorization),
- ❑ Tool-specific data input, and "knowledge-based" analysis/indexing,



- ❑ Tool-specific “knowledge-based” data queries,
- ❑ Tool-specific automatic reports,
- ❑ “Standard format” for developing “scenario-based exposure assessment dossiers,”
- ❑ Web online access and operation.

At present, the Toolbox represents a unique reference system for Exposure Scenarios that have been applied in risk assessments at world scale. Currently, it is being tested internally at the JRC and by selected experts with the scope of providing broad stakeholder access during 2006.



**Figure 1:** The European Exposure Assessment Toolbox of EIS-ChemRisks. Exposure assessment carried out by stakeholders, are formatted using the EIS-ChemRisks “standard” format”; the so-called “scenario-based exposure assessment dossier”. These dossiers undergo peer-review and expert Committees validation and are stored in the “ExpoScenarios” tool. This tool is a unique reference system on Exposure Scenarios applicable for various assessment needs. Overall, the toolbox is used to retrieve existing reference information or to develop novel assessments using existing reference data. For further information see: <http://www.jrc.cec.eu.int/eis-chemrisks/toolbox.cfm> .



## Harmonisation of exposure assessments using the toolbox facilities

There is a major overlap in exposure assessment data and tools needed by diverse policy areas, for example human physiological factors, time use factors, life styles, exposure scenario building procedures, etc. Currently, there is no infrastructure to harmonise this. To respond to this challenge, EIS-ChemRisks offers the Toolbox to support implementation of EU policies on exposure assessment, by providing a unique reference system that comprehensively covers the data and information resources needed in exposure assessments of chemicals in consumer products and articles.

The Toolbox was designed within EIS-ChemRisks with an open architecture; it is modular and easily adaptable to specific needs arising from the implementation of particular policies, in various areas, such as product safety (the GPSD, General Product Safety Directive), chemicals (the forthcoming REACH policy), food/feed controls/contact materials (882/2004/EC, 2002/72/EC, etc.), cosmetics (Directive 76/768/EEC), etc.

The Toolbox design was based on the development of **standard data taxonomies, reference data, assessment procedures and common formats** to be shared by different policy areas.

**Data-taxonomies:** The development of taxonomies for exposure data categories is based on close co-operation with the WHO/International Program on Chemical Safety (IPCS), which established the 'Glossary of Key Exposure Assessment Terminology'. EIS-ChemRisks fully supports the further development of this "Glossary" which makes the Toolbox attractive for application at a global scale. Taxonomies relevant to consumer products were added, and are being further refined in co-operation with stakeholders in the frame of sectorial/thematic (textiles, non-woven products, etc.) workshops. Using standard taxonomies allows information on exposure scenarios, exposure data, exposure factors, testing methods, and exposure models and algorithms to be indexed and made retrievable in a standardized manner (see **Figure 2**).

**Standard format for building and assessing exposure scenarios:** A major harmonisation tool developed by EIS-ChemRisks is a 'standard format' for developing, reviewing, retrieving presenting and harmonising results of scenario-based exposure assessment (see **Figure 3**).

The EIS-ChemRisks standard 'scenario-based-exposure-assessment-dossier' format is proposed as a common tool to harmonise the exposure assessment practices of various policies (such as GPSD and REACH). As illustrated in **Figure 1**, the structure of the standard format for exposure assessment dossiers assists stakeholders in the development of dossiers, and reviewers to follow the working steps and information flow described below:

1. General information: identification of stakeholder and issue in question  
↓
2. Scenario Definition & Building Procedure  
↓
3. Mathematical expression of the exposure scenario  
↓
4. Selection of reference data  
↓
5. Exposure assessment calculations  
↓
6. Interpretation of the results



The standard format provides detailed checklists and guidance for all of the above six working steps to assist stakeholders to understand the data requirements. It is designed to be configured and accommodate the **level of detail** required by a specific policy or other risk assessment needs.

The screenshot shows the 'Advanced Search' interface of the EEA Toolbox. The interface is divided into several sections: 'Search for:' (Dossier references, Assessment Results, Exposure Data), 'Title of the Dossier' (text input), 'Chemical' (dropdown menu with a list of chemicals including Formaldehyde, Diethylstilbestrol, etc.), 'Total Exposure' (dropdown menu), 'Source' (Exposure Source Type, Product Category, Product Sub-Category, Product, Related Source(s)), 'Risk Management Measures' (Risk Management Measures Class, Risk Management Measures), 'Target/Subject' (radio buttons for newborn, infant, children, adults, no choice), 'Microenvironment' (radio buttons for indoor, outdoor), 'Geographic Applicability' (radio buttons for World-wide, EU wide, specific country/ies, specific region/state/s, specific city/ies), and 'Exposure Data' (checkboxes for Dermal EXPOSURE, Inhalation EXPOSURE). Annotations on the right side of the screenshot point to specific sections: 'Indexing: knowledge based analysis and storage of information (taxonomies, IPCS/WHO glossary)' points to the top of the search interface; 'Substances' points to the 'Chemical' dropdown; 'Uses Exposure categories' points to the 'Source' section; 'Articles' points to the 'Product' dropdown; 'Risk Management Measures' points to the 'Risk Management Measures' section; and 'Scenario Settings' points to the 'Target/Subject', 'Microenvironment', and 'Geographic Applicability' sections.

**Figure 2:** “Indexing Tool” using standard taxonomies for information (product/material categories, exposure data on chemicals/agents) to be stored in a Toolbox Reference Database (illustrated example taken from ExpoData).



“Average Daily Adult External Exposure to Dyestuffs from Textiles Over a Normal Lifetime of Use”											
<p>■ <b>Source document:</b> Extractability of Dyestuffs from Textiles Over a Normal Life Time of Use. ETAD Project G 1033, March 1997</p> <p>■ <b>Disclaimer:</b> This EIS-ChemRisks Exposure Assessment Dossier refers only to information from the original document related to the chemical, the particular product and exposure activity highlighted in the title.</p>											
General Information	<table border="1"> <thead> <tr> <th colspan="2">GENERAL INFORMATION</th> </tr> </thead> <tbody> <tr> <td>Purpose</td> <td>Providing technical resources for use in proactive assessments and to support stakeholder dialogue. Reasonably Foreseeable Consumer Exposure</td> </tr> <tr> <td>Stakeholder/Rapporteur of the source documents</td> <td>Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) Other Stakeholders involved: Ciba Spezialitätenchemie AG Colors, CH - 4002 Basel (Schweiz)</td> </tr> <tr> <td>Issue at Stake</td> <td>Concerns about possible consumer risks resulting from exposure to dyed textiles</td> </tr> <tr> <td>Review level/Review documentation</td> <td>[not specified]</td> </tr> </tbody> </table>	GENERAL INFORMATION		Purpose	Providing technical resources for use in proactive assessments and to support stakeholder dialogue. Reasonably Foreseeable Consumer Exposure	Stakeholder/Rapporteur of the source documents	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) Other Stakeholders involved: Ciba Spezialitätenchemie AG Colors, CH - 4002 Basel (Schweiz)	Issue at Stake	Concerns about possible consumer risks resulting from exposure to dyed textiles	Review level/Review documentation	[not specified]
	GENERAL INFORMATION										
Purpose	Providing technical resources for use in proactive assessments and to support stakeholder dialogue. Reasonably Foreseeable Consumer Exposure										
Stakeholder/Rapporteur of the source documents	Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD) Other Stakeholders involved: Ciba Spezialitätenchemie AG Colors, CH - 4002 Basel (Schweiz)										
Issue at Stake	Concerns about possible consumer risks resulting from exposure to dyed textiles										
Review level/Review documentation	[not specified]										
Scenario Building Section	<table border="1"> <thead> <tr> <th colspan="2">SOURCE/PRODUCT</th> </tr> </thead> <tbody> <tr> <td>Textile</td> <td>Clothing/Apparel</td> </tr> </tbody> </table>	SOURCE/PRODUCT		Textile	Clothing/Apparel						
	SOURCE/PRODUCT										
	Textile	Clothing/Apparel									
	<table border="1"> <thead> <tr> <th colspan="2">AGENT/CHEMICAL</th> </tr> </thead> <tbody> <tr> <td colspan="2">C.I. Disperse Yellow 3 [CAS# 2832-40-8], C.I. Disperse Blue 3 [CAS# 2475-46-9], and C.I. Acid Red 114 [CAS# 6459-94-5]</td> </tr> </tbody> </table>	AGENT/CHEMICAL		C.I. Disperse Yellow 3 [CAS# 2832-40-8], C.I. Disperse Blue 3 [CAS# 2475-46-9], and C.I. Acid Red 114 [CAS# 6459-94-5]							
	AGENT/CHEMICAL										
	C.I. Disperse Yellow 3 [CAS# 2832-40-8], C.I. Disperse Blue 3 [CAS# 2475-46-9], and C.I. Acid Red 114 [CAS# 6459-94-5]										
	<table border="1"> <thead> <tr> <th colspan="2">GENERIC EXPOSURE SCENARIO</th> </tr> </thead> <tbody> <tr> <td>Wearing of a textile</td> <td><b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.</td> </tr> </tbody> </table>	GENERIC EXPOSURE SCENARIO		Wearing of a textile	<b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.						
	GENERIC EXPOSURE SCENARIO										
	Wearing of a textile	<b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.									
	<table border="1"> <thead> <tr> <th colspan="2">TARGET/SUBJECT</th> </tr> </thead> <tbody> <tr> <td>Consumer</td> <td>Adult</td> </tr> </tbody> </table>	TARGET/SUBJECT		Consumer	Adult						
TARGET/SUBJECT											
Consumer	Adult										
<table border="1"> <thead> <tr> <th colspan="2">MICROENVIRONMENT</th> </tr> </thead> <tbody> <tr> <td colspan="2">[not specified]</td> </tr> </tbody> </table>	MICROENVIRONMENT		[not specified]								
MICROENVIRONMENT											
[not specified]											
<table border="1"> <thead> <tr> <th colspan="2">GEOGRAPHIC APPLICABILITY</th> </tr> </thead> <tbody> <tr> <td colspan="2">[not specified]</td> </tr> </tbody> </table>	GEOGRAPHIC APPLICABILITY		[not specified]								
GEOGRAPHIC APPLICABILITY											
[not specified]											
<table border="1"> <thead> <tr> <th colspan="2">SEASONAL APPLICABILITY</th> </tr> </thead> <tbody> <tr> <td colspan="2">[not specified]</td> </tr> </tbody> </table>	SEASONAL APPLICABILITY		[not specified]								
SEASONAL APPLICABILITY											
[not specified]											
<table border="1"> <thead> <tr> <th colspan="2">EXPOSURE ACTIVITY</th> </tr> </thead> <tbody> <tr> <td>Wearing of a textile</td> <td><b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.</td> </tr> </tbody> </table>	EXPOSURE ACTIVITY		Wearing of a textile	<b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.							
EXPOSURE ACTIVITY											
Wearing of a textile	<b>Note from the Source Document:</b> Wearing of a textile under normal conditions of usage, including while perspiring.										
<table border="1"> <thead> <tr> <th colspan="2">CHEMICAL RELEASE, EXPOSURE PATHWAY, EVENT &amp; ROUTE</th> </tr> </thead> <tbody> <tr> <td>Chemical Release</td> <td>Dyestuff is extracted from the textile by perspiration. It is assumed that the maximum amount of dyestuff that can migrate from a textile to the skin is given by the amount that can be extracted by the perspiration simulants.</td> </tr> <tr> <td>Exposure Pathway</td> <td>From textiles to skin. Perspiration is an exacerbating factor.</td> </tr> <tr> <td>Exposure Event</td> <td>Contact between textile and skin</td> </tr> <tr> <td>Exposure Route</td> <td>Dermal exposure to dyes released during the wearing of clothing. The study was intended to cover the external exposure from the wearing of textiles under normal conditions of usage, including while perspiring.</td> </tr> </tbody> </table>	CHEMICAL RELEASE, EXPOSURE PATHWAY, EVENT & ROUTE		Chemical Release	Dyestuff is extracted from the textile by perspiration. It is assumed that the maximum amount of dyestuff that can migrate from a textile to the skin is given by the amount that can be extracted by the perspiration simulants.	Exposure Pathway	From textiles to skin. Perspiration is an exacerbating factor.	Exposure Event	Contact between textile and skin	Exposure Route	Dermal exposure to dyes released during the wearing of clothing. The study was intended to cover the external exposure from the wearing of textiles under normal conditions of usage, including while perspiring.	
CHEMICAL RELEASE, EXPOSURE PATHWAY, EVENT & ROUTE											
Chemical Release	Dyestuff is extracted from the textile by perspiration. It is assumed that the maximum amount of dyestuff that can migrate from a textile to the skin is given by the amount that can be extracted by the perspiration simulants.										
Exposure Pathway	From textiles to skin. Perspiration is an exacerbating factor.										
Exposure Event	Contact between textile and skin										
Exposure Route	Dermal exposure to dyes released during the wearing of clothing. The study was intended to cover the external exposure from the wearing of textiles under normal conditions of usage, including while perspiring.										
<table border="1"> <thead> <tr> <th colspan="2">RISK MANAGEMENT MEASURES</th> </tr> </thead> <tbody> <tr> <td colspan="2"> </td> </tr> </tbody> </table>	RISK MANAGEMENT MEASURES										
RISK MANAGEMENT MEASURES											
Exposure Modelling Section	<table border="1"> <thead> <tr> <th colspan="2">EXPOSURE MODEL</th> </tr> </thead> <tbody> <tr> <td>Exposure Concept</td> <td>The migration rate of dyes from textiles was measured under simulated experimental conditions. To simulate one wearing event, the textile tissues were eluted in a simulant perspiration solution (eye bath liquor ratio 1:20) at 40°C for 1 hour. A 50 wearing/washing cycle was considered to represent the product lifecycle and was simulated using standard washing procedures (MTCC standard and ISO 105 C06 A1 S) repeated 28 times to produce migration results from aged textiles. This procedure delivered experimental values of "Average Product Lifetime Daily Migration Rate" which was used in calculations to estimate an "Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime"</td> </tr> <tr> <td>Mathematical Expression/Algorithm</td> <td>Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight]</td> </tr> </tbody> </table>	EXPOSURE MODEL		Exposure Concept	The migration rate of dyes from textiles was measured under simulated experimental conditions. To simulate one wearing event, the textile tissues were eluted in a simulant perspiration solution (eye bath liquor ratio 1:20) at 40°C for 1 hour. A 50 wearing/washing cycle was considered to represent the product lifecycle and was simulated using standard washing procedures (MTCC standard and ISO 105 C06 A1 S) repeated 28 times to produce migration results from aged textiles. This procedure delivered experimental values of "Average Product Lifetime Daily Migration Rate" which was used in calculations to estimate an "Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime"	Mathematical Expression/Algorithm	Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight]				
	EXPOSURE MODEL										
Exposure Concept	The migration rate of dyes from textiles was measured under simulated experimental conditions. To simulate one wearing event, the textile tissues were eluted in a simulant perspiration solution (eye bath liquor ratio 1:20) at 40°C for 1 hour. A 50 wearing/washing cycle was considered to represent the product lifecycle and was simulated using standard washing procedures (MTCC standard and ISO 105 C06 A1 S) repeated 28 times to produce migration results from aged textiles. This procedure delivered experimental values of "Average Product Lifetime Daily Migration Rate" which was used in calculations to estimate an "Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime"										
Mathematical Expression/Algorithm	Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight]										
Data Selection from reference DBs	<table border="1"> <thead> <tr> <th colspan="2">CHEMICAL SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT</th> </tr> </thead> <tbody> <tr> <td>Concentration of chemical in the product</td> <td>10 - 351 [µg/cm<sup>2</sup>] Method Applied: concentrations were not measured but estimated on the basis of the dyestuffs used during the dyeing procedures for the preparation of the test samples</td> </tr> <tr> <td>Chemical Release/Emission Rate</td> <td>0.005 - 0.067 [µg/cm<sup>2</sup> day] Average Product Lifetime Daily Migration Rate for dyes from textiles Method Applied: Determination of the extractable amount of dyestuff from textiles. ETAD in-house Method.</td> </tr> </tbody> </table>	CHEMICAL SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT		Concentration of chemical in the product	10 - 351 [µg/cm <sup>2</sup> ] Method Applied: concentrations were not measured but estimated on the basis of the dyestuffs used during the dyeing procedures for the preparation of the test samples	Chemical Release/Emission Rate	0.005 - 0.067 [µg/cm <sup>2</sup> day] Average Product Lifetime Daily Migration Rate for dyes from textiles Method Applied: Determination of the extractable amount of dyestuff from textiles. ETAD in-house Method.				
	CHEMICAL SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT										
	Concentration of chemical in the product	10 - 351 [µg/cm <sup>2</sup> ] Method Applied: concentrations were not measured but estimated on the basis of the dyestuffs used during the dyeing procedures for the preparation of the test samples									
	Chemical Release/Emission Rate	0.005 - 0.067 [µg/cm <sup>2</sup> day] Average Product Lifetime Daily Migration Rate for dyes from textiles Method Applied: Determination of the extractable amount of dyestuff from textiles. ETAD in-house Method.									
	<table border="1"> <thead> <tr> <th colspan="2">NON CHEMICAL-SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT</th> </tr> </thead> <tbody> <tr> <td>Duration of Exposure Activity</td> <td>50 [wearings]</td> </tr> <tr> <td>Product Lifetime</td> <td>50 [wearings/washing cycles]</td> </tr> <tr> <td>Surface Area of Exposure</td> <td>1 [m<sup>2</sup>] <b>Note from the Source Document:</b> a reference body exposure surface area of 1 m<sup>2</sup> is rather high and not typical for direct skin contact with dyed cloths. The TGD does not have a default value for this. See Pages 236 - 237 (Volume 1, Appendix II).</td> </tr> <tr> <td>Body Weight of an adult</td> <td>70 [kg] <b>Note from the Source Document:</b> This is the default adult body weight for use in the European Union provided in the European Commission's Technical Guidance Document in Risk Assessment (2003 TGD, Page 220, Appendix II of Volume 1)</td> </tr> </tbody> </table>	NON CHEMICAL-SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT		Duration of Exposure Activity	50 [wearings]	Product Lifetime	50 [wearings/washing cycles]	Surface Area of Exposure	1 [m <sup>2</sup> ] <b>Note from the Source Document:</b> a reference body exposure surface area of 1 m <sup>2</sup> is rather high and not typical for direct skin contact with dyed cloths. The TGD does not have a default value for this. See Pages 236 - 237 (Volume 1, Appendix II).	Body Weight of an adult	70 [kg] <b>Note from the Source Document:</b> This is the default adult body weight for use in the European Union provided in the European Commission's Technical Guidance Document in Risk Assessment (2003 TGD, Page 220, Appendix II of Volume 1)
NON CHEMICAL-SPECIFIC EXPOSURE DATA USED IN THE ASSESSMENT											
Duration of Exposure Activity	50 [wearings]										
Product Lifetime	50 [wearings/washing cycles]										
Surface Area of Exposure	1 [m <sup>2</sup> ] <b>Note from the Source Document:</b> a reference body exposure surface area of 1 m <sup>2</sup> is rather high and not typical for direct skin contact with dyed cloths. The TGD does not have a default value for this. See Pages 236 - 237 (Volume 1, Appendix II).										
Body Weight of an adult	70 [kg] <b>Note from the Source Document:</b> This is the default adult body weight for use in the European Union provided in the European Commission's Technical Guidance Document in Risk Assessment (2003 TGD, Page 220, Appendix II of Volume 1)										
Exposure Estimation	<table border="1"> <thead> <tr> <th colspan="2">EXPOSURE ASSESSMENT CALCULATIONS</th> </tr> </thead> <tbody> <tr> <td colspan="2">Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight] = [ 0.005 - 0.067 [µg/cm<sup>2</sup> day]] x [ 1 [m<sup>2</sup>] ] / [ 70 [kg] ] = 0.71 - 9.7 [µg/ kg BW day]</td> </tr> </tbody> </table>	EXPOSURE ASSESSMENT CALCULATIONS		Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight] = [ 0.005 - 0.067 [µg/cm <sup>2</sup> day]] x [ 1 [m <sup>2</sup> ] ] / [ 70 [kg] ] = 0.71 - 9.7 [µg/ kg BW day]							
	EXPOSURE ASSESSMENT CALCULATIONS										
	Average Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime = [Average Product Lifetime Daily Migration Rate] x [Exposure Surface Area] / [Body Weight] = [ 0.005 - 0.067 [µg/cm <sup>2</sup> day]] x [ 1 [m <sup>2</sup> ] ] / [ 70 [kg] ] = 0.71 - 9.7 [µg/ kg BW day]										
<table border="1"> <thead> <tr> <th colspan="2">EXPOSURE ASSESSMENT RESULTS</th> </tr> </thead> <tbody> <tr> <td>Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime</td> <td>1 [µg/ kg BW day] 0.71 - 9.7 [µg/ kg BW day]</td> </tr> <tr> <td></td> <td><b>Note from the Source Document:</b> Average Value <b>Note from the Source Document:</b> Range</td> </tr> </tbody> </table>	EXPOSURE ASSESSMENT RESULTS		Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime	1 [µg/ kg BW day] 0.71 - 9.7 [µg/ kg BW day]		<b>Note from the Source Document:</b> Average Value <b>Note from the Source Document:</b> Range					
EXPOSURE ASSESSMENT RESULTS											
Daily Dermal Exposure to Dyestuffs from Textiles Over Product Lifetime	1 [µg/ kg BW day] 0.71 - 9.7 [µg/ kg BW day]										
	<b>Note from the Source Document:</b> Average Value <b>Note from the Source Document:</b> Range										
<table border="1"> <thead> <tr> <th colspan="2">COMPARISON WITH OTHER ASSESSMENTS</th> </tr> </thead> <tbody> <tr> <td>BgVV, Germany (1998)</td> <td>71.4 - 2507 [µg/ kg BW day] <b>Note from the Source Document:</b> Range of values obtained using a default migration factor of 0.1% per day</td> </tr> </tbody> </table>	COMPARISON WITH OTHER ASSESSMENTS		BgVV, Germany (1998)	71.4 - 2507 [µg/ kg BW day] <b>Note from the Source Document:</b> Range of values obtained using a default migration factor of 0.1% per day							
COMPARISON WITH OTHER ASSESSMENTS											
BgVV, Germany (1998)	71.4 - 2507 [µg/ kg BW day] <b>Note from the Source Document:</b> Range of values obtained using a default migration factor of 0.1% per day										

**Figure 3:** EIS-ChemRisks standard format for developing and presenting a “scenario-based exposure assessment dossier”. Different slots exist providing information and guidance on exposure scenario building, on exposure modelling, on data selection from reference databases, and on calculating, presenting and comparing exposures.



The potential of this tool to harmonise exposure was demonstrated by the implementation within the toolbox of about 400 case studies from international risk assessments, from the following sources:

- ❑ EU [European Commission Risk Assessment Reports, and resources obtained at the National level from Danish EPA, Dutch National Institute for Public Health and the Environment (RIVM), German Bundesinstitut fuer Risikobewertung (BfR), etc.],
- ❑ USA [U.S. EPA's Voluntary Children's Chemical Evaluation Program (VCCEP); Consumer Product Safety Commission (CPSC), etc.],
- ❑ Health Canada (Priority Substances Lists 1 and 2),
- ❑ Australia [National Industrial Chemicals Notification and Assessment Scheme (NICNAS)],
- ❑ Industry and other non-governmental organizations, e.g., the European Apparel and Textile Organisation (EURATEX/GUT), Ecological and Toxicological Association of Dyes and Organic Pigments Manufacturers (ETAD), Human and Environmental Risk Assessment (HERA) project, and the European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC).

### **Sectorial Stakeholder dialogue approach using the toolbox as an assessment and communication tool**

Using the standard EIS-ChemRisks exposure assessment format in a systematic way in the EU offers numerous advantages, in particular:

- ❑ Stakeholders have a clear guidance on how to develop, present, and review exposure assessment dossiers,
- ❑ The toolbox introduces a systematic procedure for scenario building and reviewing at the sectorial level (textiles, toys, etc.),
- ❑ The scenario building approach provides easily understood links between a scenario and the model(s)/algorithm(s) and data used for an assessment,
- ❑ Central submission and review of standard formatted exposure assessment dossiers allows development of a sustainable system for data collection and validation generating input to the reference tools of the "EU Exposure Assessment Toolbox",
- ❑ It allows storage and retrieval of exposure assessment dossiers and of exposure data in centralized data bases,
- ❑ The procedures for selection and use of reference data by stakeholders become transparent,
- ❑ The review and validation work of standard formatted exposure assessment dossiers using reference data becomes easier,
- ❑ Reviewed and validated dossiers enjoy benefits in terms of wide-scale acceptability and communication strength,
- ❑ Validated dossiers represent "reference material" available for common use,
- ❑ An overall decrease of time and costs for the development and review of dossiers by stakeholders through sharing common formats, tools, and data,
- ❑ It is designed to be configured and accommodate the level of detail required by a specific policy or other risk assessment need.

EIS-ChemRisks has been developing the toolbox concept together with stakeholders in the so-called "sectorial workshops". These workshops are coordinated by sectorial Task Force



groups, representing interests across the supply chain and across different institutional backgrounds, including Authorities, Industry, NGOs and Academia. The main objective of the stakeholder dialogue is to ensure that all relevant knowledge is shared and to discuss priorities regarding exposure assessment. The toolbox provides the framework for the exchange and review of this information. Regarding communication to the citizen, a multi-step approach is applied:

- ❑ First step: communication and dialogue among stakeholders to develop assessments,
- ❑ Second step: peer review by thematic experts and validation by Scientific Committees of the European Commission,
- ❑ Third step: Communication to the citizen.

## Conclusions and Outlook

The prototype development and pilot work on the EU Exposure Assessment Toolbox have demonstrated the feasibility of establishing a “first of its kind” common reference system for harmonised exposure assessment in the EU, and beyond:

- ❑ To date, the Toolbox represents a unique reference system for Exposure Scenarios that have been applied in risk assessments at world scale,
- ❑ The toolbox is designed to support the implementation of EU policies that require exposure information by offering tools, data and guidance to the stakeholders concerned, including Industry, Authorities, NGO's and Academia,
- ❑ The essential feature of the toolbox is the open architecture that makes it interoperable across several policy areas. This is achieved by establishing common terms of reference for exposure assessment, including standard data taxonomies, reference data/methods/models, assessment procedures and common assessment formats,
- ❑ The demonstration results, based on more than 400 exposure assessment case studies, show that the common formats developed under EIS-ChemRisks, efficiently harmonise assessments carried out under different circumstances at world scale,
- ❑ The system offers unique cost/effectiveness advantages if it becomes a common exposure assessment standard to all relevant policies and users.

The EIS-ChemRisks sectorial stakeholder dialogue approach using the toolbox as the data exchange, assessment and repository system is offered to:

- ❑ The user societies for several purposes, such as, to develop “reference material” available for common use, internal company assessment, supply chain communication, policy compliance, etc
- ❑ Policy makers to benefit from the stakeholder dialogue and to prioritise the relevant exposures to be assessed, in the frame of policy implementation (such as REACH, GPSD, etc.).

On-going work is focused to identify and introduce into the toolbox relevant worldwide information on consumer exposure to chemicals from publicly available risk assessments and to provide broad stakeholder access in 2006.

Future work in EIS-ChemRisks will be focused on the deployment of the EU Exposure Assessment Network - which has the aim to represent the user society of the EU Exposure



Assessment Toolbox and to ensure that its design and contents meet the user needs - and in testing the implementation of the toolbox at large scale at themes relevant to several policy areas. JRC proposes the concept of outsourcing the operation of the toolbox to competent Institutions in the EU, as a means of developing a sustainable project in terms of cost/benefit. JRC proposes to maintain the co-ordination and to ensure the secretariat, training and helpdesk functions. To this end, a call for tenders is currently under publication in the Official Journal of the European Commission.