National Institute for Public Health
and the Environment
Ministry of Health, Welfare and Sport

Hazardous substances in textile products

RIVM Report 2014-0155

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Colophon

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Consumenten komen dagelijks in contact met textiel, bijvoorbeeld via kleding en beddengoed. De bezorgdheid bestaat dat textiel stoffen bevat met eigenschappen die een risico zouden kunnen vormen voor de gezondheid, zoals huidallergie. Een aantal kleurstoffen mag inmiddels niet meer in textiel worden gebruikt.

Het RIVM heeft in dit verband een methode ontwikkeld waarmee een rangorde kan worden gegeven aan stoffen die in de Europese wetgeving REACH staan geregistreerd voor gebruik in textiel. Op basis van deze prioritering kan worden bepaald van welke stoffen het belangrijk is een risicobeoordeling uit te voeren. Keuzes voor deze prioritering zijn ontleend aan de registratiegegevens over het gebruik van de stof: zit de stof in het eindproduct van textiel of wordt deze tijdens het productieproces van het textiel gebruikt? Daarnaast is gekeken naar classificatie van de gevaarseigenschappen zoals huidallergie of kanker. Ten slotte is de hoogte van de blootstelling waarboven effecten op de gezondheid niet kunnen worden uitgesloten (drempelwaarde) van belang.

Met de methode zijn 788 individuele stoffen geïdentificeerd, waarvan 32 stoffen de hoogste prioriteit kregen. De meeste stoffen met zo'n hoge prioriteit waren kleurstoffen en vlamvertragers. Van tien van deze hoog-prioritaire stoffen is nader onderzocht of de registratiegegevens in REACH informatie over de blootstelling bevatten. Deze informatie bleek weinig specifiek te zijn, waardoor een goede risicoschatting niet mogelijk is.

Hoewel de methode geschikt is gebleken voor de prioritering, geeft het RIVM enkele aanbevelingen om de methode verdere uit te werken en te valideren. Zo is een realistisch model voor blootstellingschattingen nodig om een risicobeoordeling van gevaarlijke stoffen te kunnen uitvoeren. De belangrijkste beperking om deze blootstelling en een risicoschatting te kunnen maken is het gebrek aan stofspecifieke gegevens over de mate waarin stoffen aanwezig zijn in textiel en eruit vrijkomen tijdens het gebruik.

Ten slotte is de hoogte van de blootstelling waarboven effecten op de gezondheid niet kunnen worden uitgesloten (drempelwaarde) van belang.

Kernwoorden: textiel, prioriteringsmethode, blootstellingschatting

Abstract

Consumers have daily dermal contact with textile articles, through clothing and matrasses for example. There is a concern that textiles contain hazardous substances that pose a risk to human health, such as skin sensitization. Some dyes are already restricted for use in textiles.

RIVM has developed a prioritization method for substances in textiles that are registered in the European legislation REACH based on their hazard characteristics. Prioritization depends on the use of the substances, e.g. only in the production process or present in textile article. In addition, the classification of the substances into categories such as carcinogen or skin sensitization, and potency were also included for prioritization.

This method identified 788 individual substances, 32 of which had the highest priority scores. Most substances with a high priority were dyes and flame-retardants. An in-depth assessment was performed for ten of the high-priority substances. Information available in the REACH registration dossier was not specific enough to perform a risk assessment.

Although it has some drawbacks, this method seems to be a solid for indicating high-priority substances registered under REACH. Recommendations are given for further development and validation. A realistic exposure model is needed to perform a risk assessment for hazardous substances in textiles. Substance-specific information on the concentration and release from textiles is required.

Keywords: textile, prioritization method, exposure assessment

Contents

Summary

Exposure to hazardous substances used or present in textiles can occur daily due to daily use, the large area of contact and the long duration of contact with textiles such as clothing and bed covers. For this reason, the textile article group is considered the most relevant article group in the chemical risk assessment for consumers. Some azo dyes, for example, were previously identified as being a risk to consumers and/or workers via dermal exposure and were therefore restricted for use in textiles. There is concern that other hazardous substances are being used in textiles as well and could pose a risk to consumers.

First, reports by other organizations were reviewed in order to obtain background information on how textiles are manufactured and which chemical substances are used in the different processes. The production of textiles involves a long process that includes many steps, e.g. production of textile, manufacture of yarns and pre-treatment, dyeing, printing and finishing processes. In each step of the process, different substances are used.

Then, a prioritization method was set up to identify hazardous substances used in textile products and registered under REACH. For this report, hazardous substances are substances classified as carcinogen, mutagen, reproductive toxic, acute dermal toxic, skin sensitizers and Specific Target Organ Toxicity (STOT) – repeated exposure (RE). These substances were given priority scores based on their classification, potency (using DNEL/DMELs) and use categories (in textiles).

The query search in the REACH registration database resulted in 788 individual substances. Out of these, based on the priority scoring system, two substances had the highest priority score of 4, nine substances had a priority score of 5 and 21 substances a score of 6. Most substances with the highest priority score were dyes and flame-retardants, which corresponds with the findings reported by other organisations reviewed for this report. It was beyond the scope of this report to further compare the overview tables from the reviewed reports with the priority table that was obtained with the search method. It is recommended, however, that the results be compared further for the validation of the prioritization method.

Ten substances from the high-priority list were further assessed for the presence of an exposure assessment in the chemical safety reports (CSRs) provided for registration in REACH. This consumer exposure assessment is present in five of ten cases. Two of the substances are placed on the market in low tonnages, which means no exposure assessment is required. Information on the amount used in a textile and released from a textile is often absent in the REACH registration database. In three out of ten cases, a consumer exposure assessment was missing without supporting information. In the other CSRs, the exposure assessment contained default values as provided by the ECETOC TRA v3 consumer exposure tool. In two out of the five substances with a consumer exposure assessment, specific values were included without supporting information. In one of the cases looked at here, measured data were provided or used in the exposure assessment

In conclusion, substances were prioritized from the REACH registration database based on hazard classification, potency and use. Prioritization based on exposure was not possible. Although it has some drawbacks, this method seems to be a solid method for indicating high priority substances registered under REACH.

Finally, a request was made for a feasibility study to be conducted whether the available RIVM Emission tool is suitable for assessing exposure to substances from textile products via the skin. This model was developed to assess exposure to substances migrating from solid materials. To use the RIVM Emission tool, a number of parameters must be known or estimated, such as the concentration in the product, which is usually not (publicly) available. In addition, to realistically model dermal exposure from substances in products via contact with the skin, the processes of internal transport of the substance in the products and the processes of mass transfer to the skin should both be included. At present, little is known about the processes of mass transfer to the skin. It seems that migration may be determined by mass transfer (by solution in sweat or skin, or by evaporation and subsequent transfer to the skin). From this it can be concluded that the diffusion-based modelling as employed in the current RIVM Emission tool is not exactly applicable to the estimation of migration rates of substances from textiles.

It has been concluded that the developed method for the prioritization of substances in textiles within the REACH registration database is suitable. The absence of substance-specific data on the presence and release of substances from textiles is the main shortcoming for estimating the exposure and the risk. However, some recommendations with regard to the exposure scoring have been discussed. It is recommended for validation that the results of this prioritization be compared with the prioritized substances in reports from other organizations. In addition, it is considered important that a realistic method for the exposure and risk assessment of substances in textiles be developed.

Samenvatting

Consumenten kunnen dagelijks blootgesteld worden aan gevaarlijke stoffen in textiel door langdurig en veelvuldig gebruik en het grote contactoppervlakte aan producten zoals kleding, handdoeken en beddengoed. Hierdoor wordt textiel gezien als potentieel meest relevant wat betreft blootstelling. Sommige azo-kleurstoffen zijn al eerder geïdentificeerd als een risico voor consumenten en werkers vanwege blootstelling via de huid en daarom zijn deze kleurstoffen verboden voor het gebruik in textiel. Er bestaat echter bezorgdheid dat andere gevaarlijke stoffen gebruikt worden in textiel en een risico kunnen vormen voor consumenten.

Allereerst is een aantal onlangs verschenen rapporten bekeken om achtergrondinformatie te verkrijgen over textielproducten; welke chemische stoffen gebruikt worden in de verschillende processen. De productie van textiel is lang en bevat verschillende stappen, van het verkrijgen van vezels, het creëren van draden tot voorbehandeling, kleuren, printen en afrondings-processen. In elk van deze stappen worden verschillende chemicaliën gebruikt. Daarnaast is er een prioriteringsmethode ontwikkeld om gevaarlijke stoffen die geregistreerd staan in REACH voor het gebruik in textiel te kunnen identificeren. Voor dit rapport zijn gevaarlijke stoffen die stoffen die geclassificeerd zijn als carcinogeen, mutageen of reprotoxisch (CMR stoffen), acuut dermaal toxisch, huid-sensibiliserend of specifiek doelorgaan toxisch (STOT) – herhaalde blootstelling (RE). Stoffen die een of meerdere van deze classificaties bezitten kregen een prioriteitsscore. Daarnaast werden prioriteitsscores toegekend voor potentie (gebruikmakend van DNEL/DMEL) en gebruikscategorie, e.g. toepassing in productieproces (PC) of aanwezig in eindproduct (AC).

De zoekmethode leverde 788 individuele stoffen op, hiervan vielen twee stoffen in de groep met de hoogste prioriteitsscore en 30 stoffen in de een en twee na hoogste groepen. De meeste stoffen met een hoge prioriteitsscore waren kleurstoffen en vlamvertragers. Dat resultaat komt overeen met de rapporten die als achtergrondinformatie dienden. Het viel buiten het doel van dit rapport om de overzichtstabellen uit deze rapporten in detail te vergelijken met de hoog prioritaire stoffen uit het huidige rapport. Tien hoog prioritaire stoffen zijn gekozen om meer informatie te verkrijgen. Voor deze stoffen is gekeken naar de aanwezigheid van een blootstellingsbeoordeling in een zogenoemd Chemical Safety Report (CSR) die door de registrant opgesteld moet worden. In vijf van de tien CSRs is een blootstellingschatting aanwezig. Informatie over de hoeveelheid van de stof die gebruikt wordt in textiel en informatie over de hoeveelheid die uit textiel vrijkomt ontbreekt in de meeste registratiedossiers. In twee van de vijf blootstellingschattingen was gebruik gemaakt van de standaardwaarden die in de ECETOC TRA v3 tool gebruikt worden voor het schatten van consumentenblootstelling. Voor twee stoffen werden specifieke waarden gebruikt zonder informatie over de herkomst. Slechts in één registratie van de onderzochte tien stoffen was gemeten data aanwezig om een realistische blootstellingschatting te kunnen uitvoeren. In drie van de CSRs was zonder uitleg geen verplichte blootstellingschatting aanwezig, voor twee stoffen was geen blootstellingschatting verplicht door het gebruik in een laag tonnage.

Ook was gevraagd een haalbaarheidsstudie uit te voeren of de beschikbare RIVM Emissie tool geschikt is om blootstelling te kunnen schatten aan stoffen die vanuit textiel naar de huid migreren. Informatie die noodzakelijk is om de

Emissie tool te kunnen gebruiken is vaak niet (publiekelijk) beschikbaar, zoals de concentratie van de stof in textiel. Om een realistische schatting te kunnen uitvoeren is zowel het transportproces van de stof in textiel als de mass transfer van de stof uit textiel naar de huid van belang. Op dit moment is er weinig bekend over het proces van de massa transfer van een stof naar de huid. Omdat migratie van een stof naar de huid waarschijnlijk bepaald wordt door deze massa transfer is een blootstellingschatting zoals die uitgevoerd kan worden met de RIVM Emissie tool op dit moment niet geschikt voor de blootstellingschatting van stoffen uit textiel.

Geconcludeerd kan worden dat de prioriteringsmethode binnen REACH ontwikkeld in het huidige rapport geschikt is voor het prioriteren van stoffen aanwezig in textiel. Voor de validatie van deze methode wordt het aanbevolen de hoog prioritaire stoffen te vergelijken met de stoffen die uit eerdere rapporten als hoog prioritair geacht worden. Daarnaast is het van belang een realistisch model te ontwikkelen om een blootstellingsbeoordeling en risicobeoordeling te kunnen uit voeren naar gevaarlijke stoffen aanwezig in textiel. Het ontbreken van stof specifieke gegevens over de aanwezigheid en het vrijkomen van stoffen uit textiel is de grootste beperking voor het uitvoeren van een schatting van de blootstelling en een risicoschatting.

1 Introduction

1.1 Motivation

Textiles are a heterogeneous group of products and consist of clothing, household linens and bedding, curtains, wall coverings, rugs and carpets and are widely used in industry. Contact with textiles is unavoidable as we wear clothing, sleep underneath blankets and dry ourselves with towels. Because of the large area of contact, the long duration of the contact and the daily instance of contact, dermal exposure to substances in textiles is considered one of the most relevant from all articles. However, the exposure also depends on the release of the substance from the article. In addition, the toxicological properties of the substance also determine the risk. This report therefore focuses on hazardous substances which, for this report, are defined as substances classified as carcinogen, mutagen, reproductive toxicity, acute dermal toxicity, skin sensitizers and as Specific Target Organ Toxicity (STOT) – repeated exposure (RE). Chemical exposure to hazardous substances from textiles is considered very relevant in risk assessment, justifying the focus on the textile article group in this report.

Clothing is an important sector of the European textile market (45%), whereas household (20%), interior (10%) and technical (18%) textiles are also significant in terms of mass. Average apparent annual consumption was estimated to be 9,547,000 tonnes of textile products (19.1 kg/citizen per year), 6,754,000 tonnes of which are clothes and 2,793,000 tonnes of which are household textiles (JRC Impro 2014).

Assessing the risk of substances in textiles is considered important but has proven to be difficult (KEMI 2013). Textiles pose multiple challenges for risk management, due to their production in developing countries, their circulation in globalized trade, rapid turnover, technological development, and intimate appreciation of the consumers. Article 25 (and recital 27) of the Regulation 1007/2011/EU on textile fibre names and related labelling and marking of the fibre composition of textile products requires the European Commission to assess the hazardous substances used in textile products and, in particular, to carry out a study to evaluate whether there is a causal link between allergic reactions and the chemicals substances or mixtures used in textile products in order to prepare, where appropriate, legislative proposals in the context of existing EU legislation. A study investigating the link between allergic reactions and substances used and remaining on finished textile products was recently published (RPS 2013) at the request of the European Commission and may serve as the basis for any legislative proposals and risk management measures.

Different member states (Finland and Denmark, among others), as well as NGOs such as Greenpeace, have published reports on the possible hazardous chemicals in clothing (Assmuth 2011, Danish EPA 2014, Greenpeace 2012). A position paper on hazardous chemicals in products and the need for enhanced EU regulation was published recently (ANEC 2014). The ANEC paper concluded that REACH does not and will not compensate for insufficient provisions regulating chemicals in consumer products – particularly articles, because articles, mainly imported ones, are barely covered by REACH.

1.2 Aim of the study

At request of the NVWA, this report focuses on the identification and prioritization of substances in textiles which may have an adverse effect on the health of consumers and which have not already been regulated. These substances may be subject to enforcement research or regulation by the European Commission or one of the member states.
The following action was requested:

- perform an exploratory search on substances used in textiles registered under REACH and propose a prioritization for substances in textiles based on information gathered on toxicity and estimated consumer exposure,
- perform a feasibility study on the use of the RIVM Emission Tool for the exposure assessment of substances in textiles,
- assess the feasibility of a risk assessment for a number of the prioritized substances.

Due to the limitations of the assignment, the focus of this exploratory report is the development of the prioritization model and the feasibility of performing exposure and risks assessments using available RIVM models and REACH dossiers. Although substances used in textiles present risks for human health and the environment, this report focuses only on consumer exposure and the accompanying health risks to consumers in their use of textiles.

2 Set-up of the study

2.1 Introduction

This report contains a method for the prioritization of substances used in textiles and registered under REACH. In addition, several reports published by other organizations on the identification and prioritization of hazardous substances used in textiles were reviewed in order to get a first impression of the hazardous chemicals used in textiles. Using the available RIVM Emission Tool, the feasibility of an exposure assessment was assessed and additional information was collected for a sample of the substances with the highest priority in order to assess the feasibility of a risk assessment. Various steps are therefore being taken:

- Gathering background information on the manufacture and use of substances in textiles, as well as on the regulation concerning textile products (Chapter 3);
- Conducting a review of different reports on chemicals used in textiles that have been published in recent years (Chapter 4);
- Constructing a method for the prioritization of substances registered under REACH, results and the identification of the prioritized substances and the collection of toxicological data (Chapter 5);
- Conducting a feasibility study for an exposure and risk assessment (Chapter 6).

2.2 Background information on the manufacture, use and regulation of substances in textiles (Chapter 3)

As a first step, background information on the manufacture and use of substances in textiles was obtained. Hazardous substances are used in all steps of the textile manufacturing process. Textiles can be dyed, printed, coated and finished. The choice of the processing steps and the choice of substances are fibre-specific. The textile manufacturing process will be explained in the first part of Chapter 3.
In addition, information on the current legislation regulating substances in textiles is listed, as is EU (REACH) and Dutch legislation, as well as voluntary initiatives.

2.3 Review of external reports (Chapter 4)

A number of recently published reports (up to September 2014) on substances used in textiles and their related health risks are reviewed in Chapter 4. The reports were selected based on their focus on consumer exposure to hazardous substances in textiles:

- Greenpeace; Toxic Threads: The Big Fashion Stitch-up (2012)
- Finnish Environment Institute; Case study on textiles (Assmuth 2013)
- Swedish chemicals agency (KEMI); Hazardous chemicals in textiles (2013, 2014)
- RPS advies- en ingenieursbureau (RPS); Study on the link between allergic reactions and chemicals in textile products (2013)
- Bundesinstitut für Risikobewertung (BfR); Introduction to the problems surrounding garment textiles (2012, 2013)

These reports were used to obtain background information on substances with high priority scores but not registered under REACH (references provided in Chapter 4).

It was beyond the scope of this report to make an extensive comparison of the lists of substances in the above-mentioned reports with the list obtained through the constructed prioritization method.

2.4 Constructing a method for the prioritization of chemicals registered under REACH, results and the identification of these prioritized substances and the collection of toxicological data (Chapter 5)

The risk of substances present in and released from textiles (limited to clothing textiles) depends on the hazard properties (type of effects), the potency (DNEL/DMEL) of the substance and the amount of the substance released from the textile. Within the REACH registration database of the European Chemical Agency (ECHA), it is possible to perform a search on hazard properties and potency, but not on estimated exposure. It is possible to search for use of a substance in textiles. As a result, the prioritization of the substances for risks via exposure to textiles will be based on the type of effects (hazard classification), the potency of the substance to induce adverse effects and their use in textiles. Hazard, potency and use will be given scores and these scores will be combined, resulting in groups of substances with a priority score ranging between 3 and 14. Substances with the lowest scores (scores 4, 5 and 6) and having the highest priority were assessed further for existing restrictions. From these high priority substances, ten substances were chosen – exposure to which was estimated based on substance function – for an assessment of the feasibility of conducting a risk assessment. Information on hazard and exposure was obtained from Chemical Safety Reports (CSRs) downloaded from the confidential REACH registration database. Obtained information was verified for confidentiality on the website of ECHA and confidential information was provided in the confidential Annex.

2.5 Feasibility of an exposure assessment using the Emission tool and feasibility study regarding a risk assessment for substances in textiles (Chapter 6)

The RIVM Emission tool was developed to assess exposure to substances migrating from solid materials and to estimate the emission of a substance into the air (Delmaar 2010). The extent to which this existing model may be useful in estimating the migration of substances from textiles to the skin was explored. Next to that, information from CSRs was the basic input for the feasibility study regarding a risk assessment. CSRs should include an exposure assessment when consumer exposure is expected. This exposure assessment may be a worst-case scenario and registrants may refine this to produce a more realistic scenario. Several CSRs were assessed concerning whether the information provided by the registrants is suitable for an exposure assessment.

3 Manufacture and regulation of textiles

3.1 Chemicals in textiles

The production of textiles is a complex process and includes many steps (Figure 1). In each step of the process, different substances are used. The first steps are the production of textiles from natural fibres (such as wool or cotton) or synthetic fibres (such as polyester) and the manufacture of yarns from these fibres. Fabrics are produced from the yarns using different technologies such as weaving, knitting or braiding. These fabrics can then go through pre-treatment, dyeing, printing and finishing processes (KEMI 2013).

In the pre-treatment process, the textile is prepared for the dyeing, printing and finishing steps. The choice of processing steps and the choice of substances is fibre-specific. Natural fibres need more chemical treatment – such as in order to make the fabric soft or shrink-proof – than synthetic fibres, which need more antistatic treatment than other materials. Pre-treatment can be chemical, mechanical, wet or thermal. Apart from the cleaning effects, the pre-treatment of textiles increases the absorption of dyes and improves the wettability or stability of the material (Assmuth 2011).

3.1.1 Dyeing and printing

The dyeing of textiles is performed using dyes (soluble in its vehicle) and pigments (insoluble in its vehicle). Almost all dyes used in textile industry are synthetic organic compounds. Colourizing with dyes is based on physic-chemical equilibrium processes, namely diffusion and sorption of the dye molecules or ions. These processes may be followed by chemical reactions in the fibres. In a well-managed dyeing process, 70-95% of the dyeing agents attach to the fibre and the rest are channelled to waste water treatment. Pigments are attached into the fabric using a binding agent or applied using a printing method. Approximately half of all textile printing is performed using pigment printing technology, in which the pigment has no affinity with the fibre. For this reason, a binder and fixating agent must be added to the printing paste. The type and quantity of dyes, chemicals and auxiliaries (surfactants, dispersing agents, etc.) depends on the product quality. The most common coloured articles are socks, pantyhose and wool knitwear (KEMI 2013, Assmuth 2011).

3.1.2 Coating and finishing

Finishing improves the products' functionality, maintenance and comfort in use. The finishing of textiles can be divided into chemical, mechanical (gives a special brightness to the textile) and physical processes. The chemical treatment of textiles is necessary for:

- easy-care (shrink resistance);
- softening;
- water-proofing, repellent, antimicrobial treatment;
- fire-proofing, stain-proofing;
- the appearance, for example through bleaching.

Substances can also be added to textiles for protection during storage and transport, especially for long journeys. These substances can be directly applied to the textile or contained in separate bags with the packaging. Treatment of the container itself with substances requires labelling the container, but this does

not apply if the textile in the containers is treated before loading (KEMI 2013, Assmuth 2011).

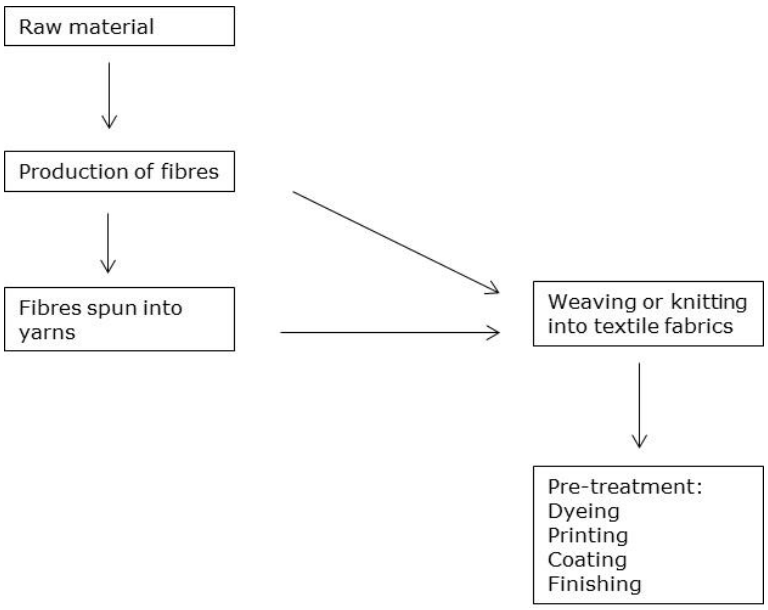


Figure 1. A simplified schematic diagram of the textile manufacturing process

3.2 Legislation on the use of substances in textiles

3.2.1 REACH Regulation (EU) No 1907/2006

In Europe, REACH (Registration, Evaluation, Authorization and Restriction of Chemicals) covers the registration, evaluation, authorization and restriction of chemicals produced or imported in the EU over 1 tonne per annum. The registration of substances used in imported articles is not a requirement under REACH. However, notification is required for Substances of Very High Concern (SVHC, according to Annex XIV in REACH) present in articles above 0.1%. Under REACH, companies have become largely responsible for the safety assessment of substances and the classification and labelling of substances. They are obligated to provide the European Chemicals Agency (ECHA) with all the required information on these substances. In the registration procedure, the manufacture or import of substances in quantities of 1 tonne or more per year and the legal entity need to be registered. This registration should include the substance's use in articles when relevant. Upon registration in volumes above 10 tonnes per year, a chemical safety assessment has to be provided. This includes the life-cycle approach of the substance, including risks from its use in articles. The assessment is intended to guarantee the safe use of the substance (REACH Regulation (EU) No 1907/2006).

However, for certain substances with specific toxicological properties, substitution is preferred and the authorisation of the use is required when substitution is not feasible. The first step on route to the authorization process is to identify those substances that may have serious effects on human health or the environment. A substance can be identified as a SVHC, after which the substance is placed on the Candidate list. Substances with hazard properties that meet the criteria for classification as being carcinogenic, mutagenic or reproduction toxic (1A or 1B, according to CLP), or persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB) according to

REACH Annex XIII can be identified as SVHCs. In addition, substances identified as an equivalent concern on a case-by-case basis, via REACH article 57f, can be placed on the candidate list. Once a substance has been added to the candidate list, there is a requirement to communicate information on any presence of the substance above a concentration of 0.1% in articles, including textiles. KEMI expects that, in practice, the list will be interpreted by a large part of the textile industry as a 'prohibition' list and consequently the substances will be phased out voluntarily (KEMI 2013). If given a high priority, substances on the candidate list can be placed on Annex XIV of REACH and, as a result, these substances may only be applied in authorized uses.

A restriction of a substance ensues from any condition for limitation of or concerning its manufacture, use or placement on the market. Restrictions under REACH permit risk management measures beyond those already implemented by manufacturers, importers and downstream users. Restrictions can also impose a harmonized level of risk management measures that applies to all manufacturers, importers, downstream users and distributors of a substance. A list of substances that are restricted for use in textiles under REACH is provided in Table 1.

Table 1: Substances restricted for use in textiles (REACH Annex XVII)

Substance	**Restriction**
Mercury compounds	In the impregnation of heavy-duty industrial textiles and yarn intended for their manufacture.
Tris(2,3 dibromopropyl) phosphate	Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
Tris(aziridinyl)phosphinoxide	Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
Polybromobiphenyls; Polybrominated biphenyls (PBB)	Shall not be used in textile articles, such as garments, undergarments and linen, intended to come into contact with the skin.
Organostannic compounds	Dioctyltin (DOT) compounds shall not be used after 1 January 2012 in the following articles for supply to or use by the general public, such that the concentration in the article, or a part thereof, is greater than the equivalent of 0.1 % by weight of tin: — textile articles intended to come into contact with the skin
Cadmium	Equipment and machinery for the production of textiles and clothing
Azocolourants and Azo dyes	Concentration of 0.003 % by weight in the articles or in the dyed parts thereof, according to the testing methods listed in Appendix 10, shall not be used in textile and leather articles which may come into direct and prolonged contact with the human skin or oral cavity. Concentration greater than 0.1 % by weight, whereby the substance or the mixture is intended for colouring textile and leather articles
Nonylphenol Nonylphenol ethoxylates	Shall not be placed on the market or used as substances or in mixtures in concentrations equal to or

	greater than 0.1 % by weight for the following purposes: textiles and leather processing except: — processing with no release into waste water, — systems with special treatment whereby the process water is pre-treated to remove the organic fraction completely prior to biological waste-water treatment (degreasing of sheepskin);
Dimethylfumarate (DMF)	Articles or any parts thereof containing DMF in concentrations greater than 0.1 mg/kg shall not be placed on the market.
phthalates (or other CAS- and EC numbers covering the substance): Di-'isononyl' phthalate (DINP) Di-'isodecyl' phthalate (DIDP) Di-n-octyl phthalate (DNOP) Bis (2-ethylhexyl) phthalate Dibutyl phthalate (DBP) Benzyl butyl phthalate (BBP)	Toys and childcare articles containing these phthalates in a concentration greater than 0.1 % by weight of the plasticized material shall not be placed on the market. For the purpose of this entry, 'childcare article' shall mean any product intended to facilitate sleep, relaxation, hygiene, the feeding of children or sucking on the part of children.
Diphenylether, octabromo derivative	Articles shall not be placed on the market if they, or flame-retardant parts thereof, contain this substance in concentrations greater than 0.1 % by weight.
Monomethyl-dibromo-diphenyl methane bromobenzylbromotoluene, mixture of isomers Trade name: DBBT	Articles containing the substance shall not be placed on the market.
Monomethyl-dichloro-diphenyl methane Trade name: Ugilec 121 Monomethyl — tetrachlorodiphenyl methane Trade name: Ugilec 141	Articles containing the substance shall not be placed on the market.

Note: some of the restrictions are not aimed specifically at textile articles, but rather to articles in general.

3.2.2 *Textile names and labelling Regulation 1007/2011/EU*

Article 25 of the Regulation 1007/2011/EU on textile fibre names and related labelling and marking of the fibre composition of textile products requires the European Commission to assess the hazardous substances used in textile products. Many textiles are imported to Europe from non-European countries, such as Bangladesh and India (RPS 2013). As a result, the information on substances used in these textiles and their concentration is very limited. It is therefore difficult to regulate and manage the chemicals used in the production of textiles. The European Union conducted a study (RPS 2013) on the correlation between allergic reactions and the chemicals used in textiles. This study provided suggestions for legislative and non-legislative actions. It is not known whether these suggestions have led to further actions.

3.2.3 *Dutch Legislation- 'Warenwet'*

In addition to the European legislation, the Netherlands has two specific restrictions on the use/presence of formaldehyde and pentachlorophenol in

textiles. Formaldehyde has a limit of 120 ppm in clothing after the first washing. Pentachlorophenol is restricted in trade products in the Netherlands above 5 mg/kg (Dutch legislation; "Warenwet" assessed October 2014).

3.2.4 Biocides Regulation (EU) 528/2012

Biocides can be applied to textiles with a specific intention, such as to serve an antibacterial function. Under the Biocidal Product Regulation (BPR, Regulation (EU) 528/2012) this type of specific use requires authorization, including a risk assessment indicating safe use and therefore whether any possible risks to consumers have already been sufficiently controlled. Therefore, biocides are beyond the scope of this study.

3.2.5 POP Regulation (EC) 850/2004

Persistent organic pollutants (POPs) are substances that persist in the environment, i.e. bioaccumulate, are transported across international boundaries far from their sources and pose a risk to the environment as well as to human health. POPs are characterized by low water solubility, high lipophilicity, semi-volatile, high molecular weight and stability. The objective of the regulation (EC) 850/2004 is to protect human health and the environment by prohibiting, phasing out as soon as possible, or restricting the production, introduction to the market and use of these substances. Some of the substances on this list are also used for the production of textiles. On this regulatory list are substances such as:

- Insecticides and pesticides; aldrin, dieldrin, lindane
- Hexachlorobenzene
- Polychlorinated biphenyls (PCBs)
- Dichlorodiphenyltrichloroethane (DTT)
- Dioxins
- Hexabromocyclododecane (HBCD)
- Polycyclic aromatic hydrocarbons (PAHs)
- Polybromodiphenyl ethers (PBDEs)
- Perfluorooctane sulphonic acid (PFOS) and derivatives.

3.2.6 ECO-labelling initiatives (self-regulation)

- Oeko-Tex Standard 100 is a global health label for textile raw materials and finished products. The label guarantees that the finished product does not cause allergies or other health problems to the consumers (OEKO-Tex 2014).
- Global Organic Textile Standard (GOTS) was developed with the aim of defining requirements that are recognized worldwide that ensure the organic status of textiles from the harvesting of the raw materials through environmentally and socially responsible manufacturing all the way to labelling in order to provide credible assurance to the consumer. Only textiles produced and certified according to the provisions of the standard can carry the GOTS label, e.g. textiles must be made of organic fibres. In addition, there are criteria for the processing and manufacturing of textiles (non-exhaustive list provided here):
    - All chemical inputs (e.g. dyes, auxiliaries and process chemicals) must be evaluated and meeting basic requirements on toxicity and biodegradability /eliminability;
    - Prohibition of critical inputs such as toxic heavy metals, formaldehyde, aromatic solvents, functional nano particles, genetically modified organisms (GMO) and their enzymes;
    - The use of synthetic sizing agents is restricted; knitting and weaving oils must not contain heavy metals;

  - Azo dyes that release carcinogenic amine compounds are prohibited;
  - Discharge printing methods using aromatic solvents and plastisol printing methods using phthalates and PVC are prohibited;
  - Technical quality parameters must be met (rubbing, perspiration, light and washing fastness and shrinkage values);
  - Raw materials, intermediates, final textile products as well as accessories must meet stringent limits regarding unwanted residues (GOTS 2006).
- The zero discharge of hazardous chemicals (ZDHC) Joint Roadmap is an ambitious cooperation of companies such as Adidas, H&M, C&A, Nike, Puma and Li Ning. They made a commitment towards the zero discharge of hazardous chemicals for all products in the supply chain by 2020. The list includes both the final products and the chemicals used during the textile production. In particular, they prioritized the chemical classes that exhibit persistent, bioaccumulative and/or toxic characteristics: CMR, PBT, vPvB or endocrine disrupting substances. Restricted substances and groups of substances are:
  - Alkylphenol and alkylphenol ethoxylates
  - Chlorobenzenes and chlorotoluenes
  - Chlorophenols
  - Dyes (azo, navy blue colorant, carcinogenic (or equivalent concern), disperse (sensitizing))
  - Flame retardants
  - Glycols
  - Halogenated solvents
  - Organotin compounds
  - Polycyclic aromatic hydrocarbons
  - Perfluorinated and polyfluorinated chemicals
  - Phthalates including all other esters of ortho-phthalic acid
  - Total heavy metals
  - Volatile organic compounds (ZDHC 2013).

4 Overview of reports on substances in textiles

A number of reports published recently on substances used in textiles and their related risks are reviewed. For the current report, a selection was made focussing on consumer exposure.

4.1 Toxic Threads: The Big Fashion Stitch-up (Greenpeace 2012)

Greenpeace has investigated clothing purchased worldwide from authorized retailers that has been manufactured according to the garments' labels. The garments investigated included jeans, trousers, T-shirts, dresses and underwear and were made from both artificial and natural fibres. All the samples were tested for nonylphenol ethoxylates (NPEs). Dyed garments were also tested for azo dyes. Plastisol prints were tested for phthalates. In addition, a subset of 63 products (out of 141 products) was investigated using a broader screening to identify other substances, such as alkanes, benzyl benzoate and benzophenone, among others.
NPEs were found in 63% of all items tested. All of the brands included in the study had one or more products that contained detectable levels of NPEs. Phthalates were detected in all 31 samples of the plastisol printed fabric. Very high concentrations were found in four of the samples, at levels of up to 37.6% by weight, indicating their deliberate use as plasticizers. Two products contained azo dyes releasing cancer-causing amines within regulatory limits. The most commonly found 'other chemicals' were alkanes and benzyl benzoate.

4.2 Study on the link between allergic reactions and chemicals in textile products (RPS 2013)

At the request of the European Commission, this study was designed to investigate the link between allergic reactions and the chemicals used and that remained on finished textile products. The study aimed to provide a priority list or overview table of (sensitizing and irritating) substances in order to consider risk management measures in the context of existing EU legislation and non-legislative risk management measures. This has been done by evaluating the available scientific literature and epidemiological information combined with information collected from industry via questionnaires on the uses of the allergenic chemical substances in textile products.
RPS found it difficult to determine the prevalence of contact dermatitis resulting from substances found in textiles. Some disperse dyes (most reported allergic reactions have been reactions to disperse dyes, which are loosely held on the fabric structure and so easily rub off on the skin) in textiles can result in allergic contact dermatitis in sensitized persons, which account for around 2/3 of all textile-related cases of allergy. These dyes include Disperse Orange 1, Disperse Orange 3, Disperse Red 1, Disperse Red 17, Disperse Blue 3, Disperse Blue 35, Disperse Blue 85, Disperse Blue 106, Disperse Blue 124, Disperse Yellow 3, Disperse Red 1, Disperse Red 17 and Disperse Brown 1.
Three categories are suggested for prioritizing the (sensitizing) substances used in textile products:

1. Substances classified as sensitizers included in the classification and labelling (CLP) inventory and intended to remain on the finished textile products.

2. Substances with a harmonized classification as sensitizer under CLP and not intended to remain, yet remaining on finished textile and causing textile allergies
3. Substances with a harmonized classification as irritant under CLP and intended to remain on finished textile products

The report suggests different types of regulatory and non-regulatory actions. Also, assumptions and limitations in the study were given, e.g. the study does not include allergic reactions caused by textile materials themselves (such as wool) and the study does not include a risk assessment of chemical substances. Market data on actual quantities of the chemical substances used that remain on the textile is lacking.

4.3 Case study of textiles (The Finnish Environment Institute; Assmuth 2011)

The aim of this report was to identify and describe deficiencies in the risk management of chemicals in textile articles and to evaluate and propose ways to improve this risk management. The case study was scoped to comprise all life cycle stages of textiles, from the manufactured fabric, e.g. pre-treatment, to the dyeing and finishing of the fabric or textile.
It was concluded that the risks associated with chemicals in textiles are challenging. Because the textile and clothing industry is an important sector, there are vital interests at stake. The report identifies possibilities for the improved risk management of chemicals and textiles. These include regulatory measures, such as improved implementation of regulations already enacted, regulatory risk assessment and the evaluation of alternative management policies and public information provided by authorities to consumers in general and to specific groups. The report also identifies measures for enterprises and co-governance, such as active compliance with regulatory requirements, the development of environment-friendly textile products and processes, the development of consumer information, the extension of eco-labelling and joint campaigns for the environment friendly choice and use of textiles.
A variety of harmful chemicals is still used in textiles around the world and endangers human health. These include persistent organic pollutants such as Triclosan and PBDE, toxic chlorinated aliphatic industrial chemicals, endocrine modulating industrial chemicals such as phthalates, carcinogenic organic compounds such as azo dyes, sensitizing organic compounds, biocides and heavy metals and elements (see Table 2).

Table 2: Substances from textiles that cause risks to humans according to the Finnish Environment Institute (Assmuth 2011)

Chemicals (class)	**Uses**	**Exposure routes**	**Ecological risk**	**Human health risks**	**Benefits**	**Risk distribution***	**Un-certainties**	**Management implications**
Persistent organic pollutants								
PBDEs, HBCD	++	Diet, inhalation (dust), etc.	+++	++	Fire safety	Prolonged, long-range	++	Restrictions
SCCPs	++	Diet, inhalation (dust), etc.	+++	++	Technical	Prolonged, long-range	+	Restrictions
TBT compounds	+	Diet	+(+) (repro)	+	Technical	Median-range	++	Restrictions (targeted)
PFOS, etc. PFCs	++ outside EU	Diet, inhalation	++(+)?	+ (also indirect)	Technical (cooling)	Long-range lagged (O3)	++	More global control
PeCP	++ outside EU	Diet	+ (also PCDD/Fs)	+ (also PCDD/Fs)	Technical (preservation)	Median-range precursor	+	Restrictions import
PBBs, PCBs	++ outside EU	Diet	+(+) PCB reduced	+(+) PCB reduced	None (PCBs substituted)	Long-range/young	++ (+ for PCBs)	Phased out, dioxin links
Triclosan	++	Diet, dermal	+(+) aq. bacteria	+(+) cancer, hormonal	Aesthetic (odour)	Chronic also indirect	+(+)	More global control
Toxic Chlorinated aliphatic industrial chemicals								
1,2-DCE, DCM	++	+ inhalation	-	+	Technical	Immediate	+	Reduce use
TCEe								
TeCEe	+ (dry cleaning)	+ inhalation	-	+ (worker) cancer	Technical/safety (non-flamm)	Immediate	+	Reduce use (cleaning)
1,4-DCB	++	+ inhalation	+	+	Tech/ preservative	Intermediate	+	

Endocrine modulating industrial chemicals (in addition to some of the POPs above)								
DEHP/ phthalates	++	inhalation, diet	++	+(+) reprod.	Technical	Infants and embryos	++	Substitution
NP/NPEOs AP/APEOs	++	inhalation, diet	++ (textile share)	+(+) reprod.	Technical, also aesthetic (dye)	Infants and embryos	++	substitution
Carcinogenic organic compounds								
Azo dyes (some)	++ outside EU	Dermal, diet, inhalation	(-)	++ (cancer)	Limited aesthetic	Chronic	++	Global control, substitution
Sensitizing organic compounds								
Formaldehyde	+++	inhalation	-	+++ (also workers)	Technical +safety aesthetic	Immediate	+ (expo)	Further reduction
Isocyanates	++/ water-proofing	inhalation	(-)	++ acute also chronic	Technical	immediate	+	Further reduction
Biocides (other than those above; including pesticides, herbicides and other Plant Protection Products)								
DMF	++ (non-EU furniture)	Contact volatile	+	++ skin burns, rash	Technical (preservative)	Acute and allergic	+	Reduced in EU
Aldicarb, parathion	+++ (fibre production)	+++ cotton aggregation	+++	+++	Pest control	Cultivation areas	+ (++ for far risks)	Biological/integration Pest control
Toxic heavy metals and elements								
Cd, Hg, Pb, As	++	inhalation (dust)	+	+ fraction of total intake	Technical, aesthetic (dyes)	Prolonged, chronic	+(++ for expo)	More global control
Cr, Ni	++	Direct contact	-	++ allergies cancer	Technical, aesthetic (dyes)	Prolonged chronic	+ (++ for expo)	Improved implement
Nano-elements	+ (increasing)	?	? – also indirect	? also indirect	Technical, environ benefits	unknown	+++	Regulations to be given
Other textile constituents and textile treatment chemicals								
Perchlorate	++	Diet, inhalation	+	+ thyroid	Technical	Acute mainly	+	Improved implementation
PVC	+++	Indirect	+ (also	+ (reaction	technical	Indirect	+	To be considered

			physical)	products)				

+/++/+++ indicates rather/relatively/very significant

*Risk distribution defines transport, period of time and use (for detailed explanation see Assmuth 2011)

PBDEs; Polybrominated diphenyl ether, HBCD; Hexabromocyclododecane, SCCP; Short-chained chlorinated paraffin, TBT; Tributyltin (oxide), PFOS; Perfluorooctane sulphonate / Perfluorinated sulphonates, PFC; Perfluorinated compound, 1,2-DCE; 1,2-Dichloroethene, DCM;dichloromethane, TCE; Trichloroethene (also abbreviated TCEe to distinguish from trichloroethanes), TeCEe; Tetrachloroethene (also abbreviated TeCEe to distinguish from tetrachloroethanes), 1,4 DCB; 1,4-Dichlorobenzene, DEHP; di(2-ethylhexyl) phthalate, NP/NPEO; nonylphenol ethoxylates, DMF; dimethylfumarate, PVC; Polyvinyl chloride, Cd; cadmium, Hg; mercury, Pb; lead, As; arseni , Cr; chromium, Ni; nickel

4.4 Hazardous chemicals in textiles – report of a government assignment (Swedish Chemicals Agency, KEMI 2013)

The Swedish Chemicals Agency (KEMI) has investigated which chemicals with hazardous properties are used in the textile production and, has produced a list of hazardous chemicals in the final textile product. The discussion is mainly focused on the Textile Fibre Regulation (EC No1007/2011) as the main regulatory option, with some alternative ways given to regulate chemicals. The potential human health and environmental impacts, as well as possible economic impacts are described. KEMI recommends that the regulation of chemicals in textiles should be based on the intrinsic properties of the substances, e.g. to regulate hazardous chemicals in textiles according to textile fibre names and fibre composition. This implies that new articles are to be added to the existing regulation on Textile Fibres. KEMI proposed regulation at three different levels:

1. Regulation without limited restrictions;
2. Regulations with limited restrictions;
3. Procedure for including other substances or groups of substances and for lowering the maximum allowed concentration level.

The substances that were found in a survey of textile analyses conducted during the years 2005-2012 were perfluorinated compounds, phthalates, heavy metals, flame retardants, isocyanates, organic tin compounds, antibacterial substances, free arylamines from disperse dyes and allergenic disperse dyes. Also, some organic compounds such as formaldehyde and various glycols were found in textiles. The report contains a non-exhaustive list of 165 chemicals that may be found in the final textile product. Risk assessments are available for 54 substances from this list. For most of the cases, exposure scenarios related to consumers are lacking. Exposure scenarios from textiles were available for only nine substances out of the 54 (Table 3).

Table 3: Substances for which textile risk assessments have been performed according to KEMI (2013)

Substance	**Textile-related function**	**Exposure scenario/risk**
1-vinyl-2pyrrolidone	UV curing of inks and coating	Available measurements indicated that the residual levels are below detectable levels; consumer exposure is considered negligible.
o-anisidine	Pigments or dyes based on o-anisidine	Dermal (skin contact with printed packing and foils and dyed textiles) and oral (sucking on textiles); identified risk for consumers
Acrylonitrile	Largest use is production of acrylic and modacrylic textile fibres, used in clothing, domestic and industrial textiles	Dermal and inhalation; negligible overall risk but acrylonitrile is a non-threshold carcinogen and therefore there's a need for limiting the risks
Tris(2-chloroethyl)phosphate (TCEP)	Flame-retardant plasticizer	Inhalation, dermal and oral; no identified risks
Decabromodiphenyl ether (DecaBDE)	Flame-retardant	Dermal; although no data on leaching was available dermal contact was

		expected to be very low
Antimony trioxide	Flame-retardant	Dermal, oral; no identified risks
Hydrogen peroxide	Textile bleaching by consumers	Dermal, inhalation, oral; concerns for eye irritation/corrosivity during bleaching
Hexabromocyclododecane (HBCDD)	Textile coating agent, flame-retardant	Oral, inhalation; no identified risks
Alkanes, C10-13, chloro (SCCP)	Production of flame-retardants, water repellent and rot-preventing finishes	Inhalation, dermal; no identified risks

Recently, KEMI published a new report with the aim of identifying hazardous substances in textile articles with a potential risk to humans or the environment. Briefly, approximately 3,500 substances were identified as relevant for use in textiles, approximately 2,000 of which were not yet registered under REACH. About 10 per cent of the 2,400 substances that were further investigated were considered to be a potential concern with respect to human health. The majority of these substances were direct dyes or acid azo dyes and fragrances (KEMI 2014; an incomplete summary).

4.5 Introduction to the problems surrounding garment textiles – Bundesinstitut für Risikobewertung (BfR 2012 and 2013)

The BfR working group on textiles published a review (BfR 2012) on the most relevant dangerous substances found in textiles and leather, the regulation of such substances and the exposure assessment. In the summary below, information from the minutes of the working group's meeting held in October 2013 is included (BfR 2013) as well.
The working group has provided an assessment of a number of substances used in textiles and leather (Table 4), although the selection of these substances is not clear. Approximately 1-2% of the contact allergies (skin sensitization) are caused by exposure to textiles. Within the groups of substances present in textiles, dyes are the main sensitizers. There are 49 dye substances known to have caused skin sensitisation via textiles, eight of which should not be used for textiles according to the BfR (Table 5). Some dyes show cross-reactivity with other dyes and with p-phenyldiamine (CAS 106-50-3). Research showed that some of these dyes, including DB 106 and DB 124, have a very high potential for skin sensitization compared with the other substances. The lowest effective dose was 0.003% or 0.75 µg/cm^2. Most of these substances are included in the restriction lists of several voluntary labels.

A standardized method for determining the release of dyes from textiles in artificial sweat shows that between 0.1 to 300 µg per 500 cm^2 is released in 4 hours at 37°C. The highest release of 400 µg per simulated wear event represents 0.18% of the available dye and results in an external surface – related dose of 0.7 µg/cm^2. Higher exposures would be possible due to errors in the dying process or due to mechanical effects during the use of the textiles. Results taken from a wear simulator indicate higher releases under such circumstances. Release is reduced after multiple cycles of washing and use. After five washings, the release is reduced by a factor of 3 and is less than 10% after 28 cycles. The average release over time of the available data shows exposure between < 0.005 – 0.067 µg/cm^2. This results in an external dermal

exposure of < 0.71 to 9.7 µg/kg bw assuming 1 m^2 of contact area and 70 kg of body weight. However, for skin sensitization, the high initial exposure is probably determinative. Overall, the available information on dyes is limited and even worse for processing aids.

BfR proposes a worst-case exposure model (first use) (which is more a descriptive exposure scenario) based on the amount of dye per kg textile using a default body weight of 60 kg, 100 g textile per 1 m^2, a contact area of 1 m^2 and a release rate of 0.5% for dyes, 2% for hydrophilic processing aids and 0.1% for hydrophobic processing aids. The average exposure is 10% at the first exposure. However, these estimations can be adapted based on the specific circumstances, such as in case of processing errors.

Based on the available toxicological data (mutagenicity and skin sensitization of substances with dermal penetration potential) for dyes and processing aids applied by German industry, the BfR does not expect systemic toxicity. However, in case of erroneous processing a risk cannot be excluded. A risk for skin sensitization cannot be excluded.
The BfR recommended that dyes named in Table 5 and the carrier 1,2,4-trichlorobenzene should not be used.

Table 4: Dangerous substances in textiles and leather according to the BfR (BfR 2013)

Substance	**CAS number**	**Use**	**concern**	**Risk**	**Cases**	**regulation**	**remark**
Formaldehyde	50-00-0	textile finishing, shrink resistance	Carcinogenicity and skin sensitization	skin sensitization	only historic cases but no new cases	restricted in several countries, including Germany and the Netherlands	formaldehyde is released from formaldehyde derivates
glyoxal (ethanedial)	107-22-2	textile finishing, shrink resistance	mutagenicity and skin sensitization	skin sensitization	no cases known	not regulated	glyoxal is released from derivates. Not used in Germany
Flame retardants	group	flame retardant	Various	Various	not stated	some flame retardants are restricted	Up to 20% in textiles. Replaced with salts with low dermal absorption
Antimony compounds (antimony trioxide)	group	flame retardant, catalyst	not stated	assessment indicates no risk	not stated	not regulated	Release data available
Carrier (organic solvents) 1,2,4-trichlorobenzene	group 120-82-1	solvent for dyes	not stated	a risk is expected	not stated	not regulated but should be according to the BfR	A proposal for SVHC based on equivalent concern (environmental) was not accepted.
organo-tin compounds	group	biocide	various	a risk is expected	not stated	Some but not all are restricted	
UV-filter	group	UV-filter	not stated	not stated	not stated	not regulated	
Perfluoric compounds	group	hydrophobicity	various	a risk is not expected	not stated	PFOS restricted PFOA is SVHC	Used as polymers. PFOS and PFOA replaced with FTOHs.
Biocides	group	biocide	various	assessed before authorization	not stated	Restricted according to the biocide	substances include permethrin, triclosan,

						regulation	silver and its compounds
Dyes	various	dyeing	carcinogenicity, mutagenicity, skin sensitization	not stated	not stated	certain azo dyes are restricted	main concern is dispersive dyes because of the limited binding to textile and the good dermal absorption
Nano particles	group	various	oral and inhalatory exposure	not stated	not stated	not regulated	Includes substances such as sliver, titan dioxide, zinc dioxide, silica.
silver and nano silver compounds	group	biocide	bacterial resistance	not stated	not stated	partly regulated via the biocide regulation	The use of nano silver is being replaced with ionic silver.
Dioxins	group	contamination	Various	not expected	not stated	Restricted in Germany	
Residues of cleaning products	group	cleaning	Various	None	only very limited cases of skin sensitization	not regulated	
Fabric conditioner and hygiene conditioner	group		various	skin sensitization	a risk is expected	not regulated	These conditioners are applied after washing and not removed. Includes benzalkoniumchloride and isothiazolinones

Table 5: Potentially sensitizing dyes that should be restricted according to BfR (2012)

Colour Index Name	CAS number	Abbreviation	type of dye
Disperse blue 1	2475-45-8	DB 1	Anthraquinone
Disperse blue 35	12222-75-2	DB 35	Anthraquinone
Disperse blue 106	12223-01-7 68516-81-4	DB 106	Azo dye
Disperse blue 124	61951-51-7 15141-18-1	DB 124	Azo dye
Disperse yellow 3	2832-40-8	DG 3	Azo dye
Disperse orange 3	730-40-5	DO 3	Azo dye
Disperse orange 37/76	12223-33-5 51811-42-8 13301-61-6	DO 37	Azo dye
Disperse red 1	2872-52-8	DR 1	Azo dye

4.6 Other initiatives on the risk of substances in textiles

Due to limited time, other initiatives on the risk of hazardous substances in textile products are only mentioned briefly below.

Survey of selected allergenic, disperse dyes in clothes (Danish EPA 2014)
Based on a literature review, the Danish EPA concludes that the limited number of available studies indicate that there is limited use of dyes that are considered as health hazardous or allergenic. In addition, information from the Danish National Allergy Center indicates that allergy related to textiles is rare, with only two cases of textile dye allergy out of 1,000 persons tested. Questionnaires showed that the companies demand that their suppliers must meet various standards of Oeko-Tex®, Global Organic Textile Standard (GOTS), the European Ecolabel or the Nordic Ecolabel that have a number of black lists. They have no or limited information regarding the substances that are used in the textiles. The Danish EPA determined the level of a number of disperse dyes in clothes which come into close skin contact with dark or luminous colours from synthetic textiles (mainly polyester) that were manufactured outside Europe (31 items). The items were tested for 23 disperse allergenic dyes including all allergic dyes identified by the BfR. None of the tested dyes where detected in the tested clothing. The results indicate that the use of dyes with allergic properties is very limited.

Identification of non-regulated aromatic amines of toxicological concern which can be cleaved from azo dyes used in clothing textiles (Bruschweiler 2014)
The Swiss Federal Office of Public Health identified a high number of non-regulated aromatic amines based on their potential formation via enzymatic cleavage from known azo dyes. Forty-three aromatic amines were prioritized based on the available human health data. For 22 aromatic amines the presence

in clothing was determined. In 26 of the 153 samples, one or more non-regulated aromatic amines (eight out of 22) were detected. They concluded that there is a gap in toxicological information on aromatic amines and that there is a gap in the regulation of aromatic amines/azo dyes present in textiles (Bruschweiler 2014).

5 Prioritization of substances in textiles registered under REACH

5.1 Prioritization of substances of risk in textiles

The risk presented by substances present in and released from textiles (clothing) depends on the hazard properties (type of effects), the potency (DNEL/DMEL) of the substance and on the amount released from the textile. The prioritization of the substances for risks via exposure to textiles will be based on the type of effects (hazard classification), the potency of the substance to induce adverse effects and the estimated exposure.

5.1.1 Selection of hazardous substances

The classification can be used as an indicator of the hazard and the DNEL (Derived No Effect Level) or DMEL (Derived Minimal Effect Level) as an indicator of potency.
As clothing is used directly on or close to the body, the dermal route is considered most relevant (scenario 1). The main focus is on the hazard classes with effects after repeated exposure, which is likely with use of textiles (Table 6). The second relevant scenario is a child mouthing a part of the clothing (scenario 2). For some substances, the oral absorption may be much higher than the dermal absorption. Although, there may be some substances which are relevant for the oral scenario but not relevant for the dermal scenario, the focus of this report lies on dermal exposure to substances from textiles. No scenario for exposure is included, since high vapour pressure substances would have been evaporated during cleaning and storage steps, and the formation of aerosols from clothing during use is unlikely (Table 7).

Table 6: Hazard classes that are considered relevant for the prioritization of substances in textiles

Hazard class	**Remark**
Carcinogenicity	All categories
Mutagenicity	All categories
Reproductive toxicity	All categories
Specific Target Organ Toxicity – repeated exposure (STOT RE)	All categories
Acute dermal toxicity	Acute endpoint, but often the only dermal-specific data available
Skin sensitization	Dermal route

Table 7: Human health hazard classes that are considered less relevant for the prioritization of substances in textiles

Hazard class	**Remark**
Acute oral and inhalation toxicity	Other route
STOT SE	The available information for this hazard class is very limited and therefore not reliable.
Skin corrosion and irritation	This effect is caused by a relatively high local concentration that is not expected due to slow release from the textile.
Eye irritation	Exposure of the eye to substantial amounts released from textiles is not expected.
Respiratory sensitization	The release of substantial amounts of volatile substances over a longer period is unlikely as these would have escaped already during production, cleaning and storage. Furthermore, only a part of the released vapour will be inhaled.
Aspiration hazard	This involves access to the lungs due to low viscosity. It is not relevant since oral exposure will mainly involve a combination of saliva and the released substance that will have a normal viscosity.

The following DNEL/DMELs are considered relevant for consumer exposure from textiles (ECHA 2012a):

- General population/dermal/systemic/long term
- General population/oral/systemic/long term

The use of a DNEL for local effects was also considered to cover substances that induce skin sensitization. However, since this DNEL was only available for very few substances, the parameter was not used for prioritization.

5.1.2 *Use categories and scores for exposure*

REACH requires registrants to provide information on all the uses of the substance. This is done in a standardized way using a use description system in which product categories (PC) and articles categories (AC) indicate the type of products or articles in which the substance is either used or present. However, the substance may not necessarily be present in the final article (Chapter R.12; Use Description System: ECHA 2012a).
Two IUCLID descriptors in the REACH registration are relevant for use in textiles:

- article category AC5 (Fabrics, textiles and apparel) in the section on consumers.
- product category PC34 (Textile dyes, finishing and impregnating products; including bleaches and other processing aids) in the section on consumers.

However, mindful of the many gaps in registration dossiers, it was considered better to include the same product category for industrial use and professional use as well. In addition, SU5 (sector of use = manufacture of textiles, leather, fur) was considered, but was not included because this was considered comparable to PC34.

Environmental Release Codes (ERCs) were considered as well. However, the link between ERCs and specific PC/AC codes of interest is missing. Furthermore,

ERCs do not distinguish between release processes within one PC/AC code and thus lack discrimination for priority setting.

Another IUCLID parameter that could be used is the technical function of the substance, because some of the technical functions, such as dye, may give an indication of the possible release from the textile. Little is known, however, about the correlation between the migration of a substance within the textile product, the release of the substance from the textile and thus possible dermal exposure and the technical function of the substance. In addition, currently no method is available to use this parameter in prioritization. Not all technical functions are directly related to AC/PC codes and this is often confidential information within the REACH registration database.
As a rough prioritization, the following approach is considered for substances with PC34 (substance used in the market sector including textile treatment products):

- group 1 AC5 and/or PC34 score 1
- group 2 PC34 score 4

For substances with a PC34 description, it is not certain whether the substance is still present is the final article. Therefore, when substances are only described with a PC34 score, they are given priority score 4. Substances with PC34 combined with the AC5 descriptor are given a lower score meaning a higher priority, as are those substances only described with an AC 5 score.

The exposure to substances from textiles depends on several factors, including:

- the amount present in the textile (mg/cm^2 or mg/kg textile)
- the release from the textile matrix into medium (sweat or saliva)

Exposure parameters are available from the REACH registration database. Use-specific exposure information is required, depending on produced tonnage per year and the classification of the substance. However, this information is only available in the Chemical Safety Reports (CSRs) and cannot be retrieved automatically. Other exposure indicators were considered too a-specific for exposure, so no exposure parameters were used for the prioritization.

5.1.3 Scores for hazard and potency

5.1.3.1 Hazard

The scores for hazard in the prioritization are based on the prioritization scheme set up for consumer exposure and human health in the RIVM report on "Prioritization in processes of the European chemical substances regulations REACH and CLP" (Schuur & Traas 2011) with adaptions as described below for the scenarios specific to substances in textiles. Lower scores indicate effects that are considered more adverse effects.

- group 1 CM 1A/1B score 1
- group 2 M2 + R 1A/1B + acute dermal 1 score 2
- group 3 C2 + R2 + STOT RE 1 + acute dermal 2 score 3
- group 4 STOT RE 2 + Skin sensitizer + acute dermal 3/4 score 4
- group 5 no classification score 5

5.1.3.2 Potency

The potency of the substances will be determined for the oral and dermal route (separately) based on the lowest DNEL of the two routes for systemic effects:

- group 1 DNEL/DMEL <0.1 mg/kg bw/day score 1
- group 2 DNEL/DMEL <1 mg/ kg bw/day score 2
- group 3 DNEL/DMEL 1-10 mg/ kg bw/day score 3

- group 4 DNEL/DMEL 10-100 mg/ kg bw/day score 4
- group 5 DNEL/DMEL >100 mg/ kg bw/day score 5

No DNEL or DMEL score 3

A lower systemic long-term DNEL/DMEL for the general population means a higher potency and therefore a lower score. Scoring of the DNELs in five groups differs from the scoring system reported in the REACH prioritization report (which used three levels) because information on the distribution was available on the current set of DNEL/DMELs of substances in textiles. This distribution was established in retrospect to optimise the potency ranges in order to differentiate.

5.1.4 Combination of hazard and exposure scores

The hazard and the potency scores will be combined (added) resulting in nine groups with a value ranging from 2 to 10 for each route, e.g. dermal or oral. The highest value of both routes is used for prioritization. The exposure is divided into two groups with a value of 1 or 4.

Overall, prioritization is based on a combination of the exposure group and the potency group by adding both values. The lowest value indicates the highest priority as seen in Table 8.

Table 8: Prioritization values, lowest value indicates highest priority

Hazard group/ Exposure group	2	3	4	5	6	7	8	9	10
1	3	4	5	6	7	8	9	10	11
4	6	7	8	9	10	11	12	13	14

5.1.5 Search description

The query tool in the REACH registration database (IUCLID version 5) was used to select hazardous substances in textiles. To cover all relevant endpoints, the following search criteria were chosen:

- use in textiles (PC34 and AC5) combined with the hazard classes mentioned;
- use in textiles combined with the hazard statements (H phrases) mentioned;
- use in textiles combined with DNEL/DMEL.

Due to limitations on the number of parameters in the query tool, seven separated queries were performed. Search profiles were prepared and tested in a small version of the IUCLID database and exported and run in the REACH registration database in the dossiers section. Annex I of this report shows hazard categories and hazard statements that were selected to represent the most relevant risk of substances in textiles, as well as the queries used to search in the REACH registration database.

5.2 Results query and prioritization scores

Substances registered for use in textiles were selected from the REACH registration database based on use in the production (PC34) or presence in the article (AC5) and the hazard classification. In the query, the DNELs for systemic effects after dermal and oral exposure were retrieved. The query search resulted in 788 individual substances. Scores for "exposure" (1 for PC34 and 4 for PC34) and hazard (category and potency) were ascribed to these substances. This resulted in sum scores between 4 and 14 (Table 9). The results of the search show that two substances have the highest priority score of 4 (Table 9). Nine

substances have a priority score of 5 and 21 substances a score of 6. Most substances with the highest priority scores were dyes and flame-retardants.

Table 9: Results of the query search with priority scores for hazardous substances with AC5 and PC34

Priority score	**N of substances**
4	2
5	9
6	21
7	40
8	139
9	114
10	68
11	126
12	162
13	83
14	24

The substances with the highest priority scores (scores 4, 5 and 6) were assessed for existing restrictions. The two substances with the highest score were already restricted, with a maximum content limit of 0.1% in consumer articles. From the nine substances with a priority score of 5, four were regulated and two were classified due to contamination. The substances classified due to contaminants were excluded for further assessments. Only one substance within the group of priority score 6 was already regulated (Table 10). The information for eight substances with the highest priority score was confidential.
For two substances with priority score 5 (zinc oxide and cobalt titanite green spinel), the classification used in the prioritization was based on the presence of an impurity with a harmonized classification for a CMR property above the generic concentration limit. The substance without this impurity would have had a lower priority and the impurity was probably also not determinative for the DNEL as derived by the registrant since these impurities are mostly present at a low concentration and CMR classification is not based on potency. For this report, this was only checked and adjusted for the substances with the highest priority score. The score for zinc oxide and cobalt titanite green spinel would be 7 without this impurity. Therefore, these two substances are considered to be not of the highest priority.
The scores of cobalt dichloride and cobalt sulphate are not affected by the presence or absence of the nickel impurity. The complete list of substances and their prioritization are not provided because it contains confidential information. Confidential Annex II shows a complete overview of Table 10.

Although it was beyond the scope of this report to further compare the overview tables selected from the reviewed reports (Chapter 4) with the priority table as obtained with the search method described here, a superficial check was performed. From the presented prioritization method, most substances with the highest priority score were dyes and flame-retardants. From this priority list, eight are present on the list of 299 substances indicated by KEMI to be of potential concern for human health (KEMI 2014). Most of the reports (BfR 2012, Assmuth 2012) show the presence of various dyes in clothing, although in a recent report of the Danish EPA none of the tested allergic dyes were detected in the tested clothes (Danish EPA 2014). The recommendation is to further compare the results for validation of the prioritization method.

Table 10: Substances with highest priority scores based on use in the production (PC34) or presence in the article (AC5) and the hazard classification. Obtained information is verified for confidentiality on the ECHA website.

Name	**CAS number**	**EC number**	**Classification**	**Priority score**	**DNEL dermal systemic (mg/kg bw/day)**	**DNEL oral systemic (mg/kg bw/day)**	**Notes**
Dibutyltin dilaurate	77-58-7	201-039-8	Muta 2 Repr 1B STOT RE 1 Skin Sens 1	4	0.08	0.002	Restriction Annex XVII REACH; 0.1% consumer articles
Dibutyltin oxide	818-08-6	212-449-1	Muta 2 Repr 1B STOT RE 1 Skin Sens 1	4	0.08	0.002	Restriction Annex XVII REACH; 0.1% consumer articles
Zinc oxide	1314-13-2	215-222-5	Repr 1A STOT RE 2	5 (7 without impurity)	83	0.83	Lead impurity
Cobalt titanite green spinel	68186-85-6	269-047-4	Carc 1A STOT RE 1 Skin Sens 1	5 (7 without impurity)	Na	na	Nickel impurity; Only DNEL for inhalation
Methanaminium, N-[4-[[4-(dimethylamino)phenyl]phenylmethylene]-2,5-cyclohexadien-1-ylidene]-N-methyl-, acetate	41272-40-6	255-288-2	Repr 2 Skin Sens 1	5	0.07	0.07	dye, malachite green acetate
tris[2-chloro-1-(chloromethyl)ethyl] phosphate	13674-87-8	237-159-2	Carc 2	5	0.017	0.017	TDCP flame retardant; RAR assessed
Confidential 1	confidential	confidential	confidential	5	Na	na	Confidential
Dioctyltin bis-(ethylmaleate)	68109-88-6	268-500-3	Repr 2 STOT RE 1	5	0.022	0.0004	Restriction Annex XVII REACH; 0.1% consumer articles

Dioctyltin laurate	3648-18-8	222-883-3	confidential	5	Na	0.0005	Restriction Annex XVII REACH; 0.1% consumer articles
Phenol, isopropylated, phosphate (3:1)	68937-41-7	273-066-3	Repr 2 STOT RE 2	5	2.08	0.04	Flame retardant polyvinyl
Tris(methylphenyl) phosphate	1330-78-5	215-548-8	Repr 2	5	1.25	0.05	Flame retardant
Confidential 2	Confidential	Confidential	Confidential	6	Na	na	Confidential
Dicyclohexyl Phthalate	84-61-7	201-545-9	Repr 2 Skin Sens 1	6	0.25	0.25	Plasticizer, Repro classification under assessment by RAC
Diisobutyl phthalate	84-69-5	201-553-2	Repr 1B	6	Na	0.21	plasticizer, Authorization list Annex XIV REACH
N,N-diethylaniline	91-66-7	202-088-8	STOT RE 2	6	0.027	0.053	Intermediate
Confidential 3	Confidential	Confidential	Confidential	6	Na	na	Confidential
2,2'-iminodiethanol	111-42-2	203-868-0	STOT RE 2	6	0.07	0.06	Manufacture of dyes, additive textile chemicals
Bis(2-ethylhexyl)phtalate (DEHP)	117-81-7	204-211-0	Repr 1B	6	0.72	0.036	Restriction Annex XVII REACH; 0.1% toys and child care articles Authorization list Annex XIV REACH
Antimony Trioxide	1309-64-4	215-175-0	Repr 1A Carc 2 STOT RE 2	6	168.6	168.6	Flame retardant The Repr 1A classification is only applicable to certain forms of the substance with high lead oxide content.

Divanadium pentaoxide	1314-62-1	215-239-8	Muta 2 Repr 2 STOT RE 1	6	Na	na	Intermediate
1,1'-(1,1-dimethyl-3-methylene-1,3-propanediyl)bisbenzene	6362-80-7	228-846-8	Skin sens 1 STOT RE 2	6	0.08	0.08	-
Cobalt dichloride	7646-79-9	231-589-4	Carc 1A 1B Muta 2 Repr 1B Skin sens 1 STOT RE 2	6	Na	0.0209	Used as humidity indicator (combination with silica). The Carc 1A classification is based on the presence of nickel in some forms.
Cobalt sulphate	10124-43-3	233-334-2	Carc 1A 1B Muta 2 Repr 1B Skin ses 1 STOT RE 2	6	Na	0.025	Used for the manufacture of pigments. The Carc 1A classification is based on the presence of nickel in some forms.
Hexabromocyclododecane	25637-99-4	247-148-4	Repr 2	6	1020	0.102	Authorisation list Annex XIV REACH, flame retardant
Benzenamine, reaction products with aniline hydrochloride and nitrobenzene, hydrochlorides	101357-16-8	309-913-1	STOT RE 2	6	0.07	0.07	Confidential
Confidential 4	Confidential	Confidential	Confidential	6	Na	na	Confidential
Confidential 5	Confidential	Confidential	Confidential	6	Na	na	Confidential
Confidential 6	Confidential	Confidential	Confidential	6	Na	na	Confidential
Confidential 7	Confidential	Confidential	Confidential	6	Na	na	Confidential
TE_FAT40812/A_03-05-0479_IT_EC445-040-3_CAS577954-20-2_RED TZ 5271	577954-20-2	445-040-3	Skin sens 1	6	0,833	0,083	Dye

Confidential 8	Confidential	Confidential	Confidential	6	Na	na	Confidential
Tetrakis (hydroxymethyl) phosphonium chloride, oligomeric reaction products with urea (Monomer)	27104-30-9	500-057-6	Repr 2 Skin sens 1	6	Na	na	Flame retardant

Na: no hazard identified

6 Exposure assessment of substances in textiles; usability of the Emission Tool

6.1 Human exposure; release of substances from textiles

Clothes can protect the skin from environmental influences and help to regulate skin temperature and skin moisture, but they can also pose a threat to the health of people. Substances in textiles interact with skin functions in a dynamic pattern. Thermo-regulation, mediated by local blood flow and the evaporation of sweat, is an important subject for textile-skin interactions. Mechanical properties such as the roughness of the fabric surface are responsible for non-specific skin reactions such as wool intolerance. The skin is also an important immune organ with non-specific and specific activities. Antimicrobial textiles may interfere with non-specific defence mechanisms such as the skin microflora. The interaction of clothing with the immune system may lead to allergic contact dermatitis (RPS 2013, Wollina 2006).

Direct exposure via the skin takes place when consumers use textiles. High body temperature and body moisture are factors that may increase the transport of the substances from the textile to the skin. Direct exposure can also take place when children suck on textiles.

Human exposure to substances in textiles depends on various properties, e.g. the amount used and the release rate of the substance. Some dyes, e.g. direct and acid dyes, bind very loosely to the fibres and therefore easily migrate to the skin. Disperse dyes are strongly bound to fibres, although low quality dyeing can decrease this binding and increase human exposure. Substances that are highly water-soluble are removed during the washing process. Volatile substances evaporate between the treatments before the finished product appears. Auxiliary chemicals are used to facilitate processes without being incorporated in the material and should be removed after use. This means that most surfactants, emulsifiers and other water-soluble substances are normally washed out before consumer use, if effective washing is performed. Substances such as pigments, plasticizers and flame-retardants are strongly bound to textile fibres, so human exposure is only expected in fibre-bound form due to wear and tear (RPS 2013).

BfR proposed a worst-case exposure scenario for the estimation of dyes and processing aids in textiles. This model is based on the amount of dye per kg textile using a default value for body weight (60 kg), 100 g textile per $1m^2$ of contact area and a release rate of 0.5% for dyes, 2% for hydrophilic processing aids and 0.1% for hydrophobic processing aids. Exposure to textile substances such as dyes is almost impossible to predict because it depends on various variables, including the type of dye, dye concentration, fixation on the substrate and use. Furthermore, dermal absorption varies per substance, depending on the need for internal or external exposure (Krätke and Platzek 2004, BfR 2013). An assessment of this model was not part of this study, but could be considered in a follow-up report.
As an example, Zeilmaker (1999) described experiments in which the leaching of azo dyes from clothing and footwear was determined using synthetic sweat. Zeilmaker assumed that the cumulative amount of the dye that was released during wearing of the product was equal to 10 times the leaching of the unwashed product. Leaching factors depended on the type of azo dye and the

type of material, and ranged from 0.0005 g/g out of underwear to 0.037 g/g out of lining of a coat. It should be noted here that the experimental setup probably overestimated the leaching of these substances during sweating (Zeilmaker 1999).

6.1.1 Worst-case exposure assessment under REACH

Estimation of consumer exposure to chemicals in textiles under REACH can be conducted in accordance with the REACH guidance (Chapter R.15; Consumer Exposure Estimation: ECHA 2012b). Applicants can use the ECETOC TRA v3 tool for the assessment of safe use of the substance. This tool describes a (worst-case) scenario using defaults for estimating dermal exposure to substances released from a textile product (article code AC5). No scenario is provided for product code PC34.

The algorithm used is:

Exposure (mg/kg bw/day) = (PI * CA * TF * FQ * TL *D *1000) / BW

Where PI is product ingredient in g/g, CA contact area cm^2, TF unitless transfer factor, TL thickness of the layer in cm, D density in g/cm^3 and 1,000 a conversion factor mg/g divided by body weight in kg.
Clothing is specified as a subcategory under article code AC5 with the following defaults:

- PI 0.43 g/g (based on plasticizers in plastics; worst-case choice)
- CA 14315 cm^2 wearing clothes covering whole body except feet, hands and head
- TF 1 default unitless
- FQ 1 event/day
- TL 0.01 cm default for non-fixed materials (textile)
- D 1 g/cm^3
- 1000
- BW 60 kg (adult)

Registrants are allowed to adjust these default values when substance-specific information for a more realistic scenario is available. An assessment of this model was not part of this assignment but could be considered as a follow-up.

6.2 Usability of the RIVM Emission Tool in exposure assessment

A feasibility study was requested into whether the available RIVM Emission Tool is suitable for assessing exposure to substances from textiles. The Emission Tool was developed to assess exposure to substances migrating from solid materials. This model has been applied to estimate emissions of the substance into air (Delmaar 2010) and to evaluate the plausibility of the ECETOC TRA consumer exposure model for dermal contact with products (Delmaar 2012). In the next section, the extent to which this model may be useful in estimating the migration of substances from textiles to the skin is explored.

6.2.1 Migration of substances from products to the skin

Two processes typically determine migration of substances from products to the skin. Firstly, the substance is transported in the product to the product surface. Secondly, from the surface the substance may be transferred to skin. This second process (the mass transfer) may take place via different intermediate media (see Figure 2), also described in Schneider (1999). The substance may evaporate from the product and come into contact with the skin as a vapour/gas concentration in air. Alternatively, the substance may be transferred to sweat on

the skin. Finally, the substance may transfer to the skin directly upon dermal contact with the product. Direct transfer may either be onto the stratum corneum or, as suggested in Weschler and Nazaroff (2008), into a lipid layer on the skin. Via which of these pathways exposure takes place will likely depend on physical-chemical substance properties, e.g. lipid or water solubility, vapour pressure, affinity of the substance with sweat and the textile.

For substances that are not embedded in the product material but are, for example, applied as a surface coating, the diffusional transport within the material may not be relevant. In this case, migration is mostly determined by the mass transfer from the product surface to the skin.

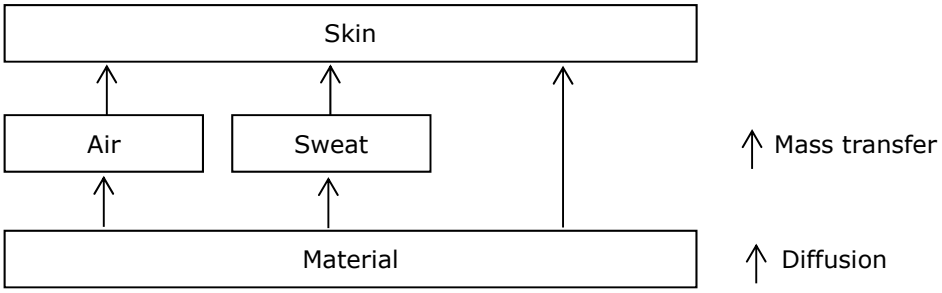


Figure 2. In the migration of a substance from a material to the skin, two phases can be distinguished. First is the diffusion of the substance in the material to the material's surface. From there the substance is transferred to the skin. This mass transfer can take place via air after evaporation, via solution in sweat on the skin, or directly into or onto the skin (Delmaar 2010).

6.3 Modelling dermal exposure from products and articles

To realistically model dermal exposure from substances in products in contact with the skin, both processes of internal transport of the substance in the product and mass transfer to the skin should be included. At present, however, little is known about the processes of mass transfer to the skin.
The transport of substances in the product material, on the other hand, is well-understood. Physics-based diffusion models have been developed and tested for a variety of substances and materials. These models have been described in Delmaar (2010) and have been implemented in the RIVM 'emission tool'. This computer program has been made publically available by the RIVM at www.consexpo.nl.
The RIVM emission tool describes the emission of substances from materials into indoor air. The diffusional transport of the substance in the material, however, is expected to be similar to a case of dermal exposure.

In addition to the development of the RIVM emission tool, the applicability of the diffusion models for dermal exposure assessment has been explored in Delmaar (2012). In this paper, the plausibility of the ECETOC TRA (ECETOC 2012) dermal exposure model was investigated by comparing this model with the potential migration on basis of diffusion alone. In this application of the diffusion model, the mass transfer of the substance to the skin was assumed to be immediate and complete. It was acknowledged that such an approach may overestimate exposure in those cases where incomplete mass transfer limits the migration to the skin. A similar approach can be used to employ the emission model to

estimate migration from textiles (i.e. migration from textiles may be estimated by the emission from diffusion alone).

6.4 Applying the RIVM Emission Tool to estimate the migration of substances from textiles

As described above, modelling the dermal migration is currently hampered by an insufficient understanding of the mass transfer from the product surface to the skin. In its current state, the emission tool may be used to model the potential release of chemicals from textiles based on the amount of substance that diffuses from the textile to the textile's surface, assuming that the transfer from the surface to the skin is complete. This approach may overestimate migration rates in those cases in which migration is limited by the mass transfer rather than the diffusion in the textile.
To use the RIVM emission tool, a number of parameters have to be known or estimated. Most notably, the diffusion coefficient of the substance in the product D [m^2/s], the substance concentration in the product Co [g/m^3] and the dimensions of the product such as its thickness L [m] and its surface area S [m^2]. Most of these parameters will be only approximately known in practical applications. For the diffusion coefficient D, however, very few data will be available. The value of D will depend on both the substance and the material in which the substance diffuses. In the report by Delmaar (2010), data on critical exposure parameters was collected, including available measured data on diffusion coefficients. The data did not include information on substances in textiles, but did include measurements of low molecular weight substances in carpets, which is assumed here to be a reasonable surrogate for textiles. Values for the diffusion coefficient range from about 5×10^{-12} (styrene in nylon carpet) to 4×10^{-8} m^2/s (n-octane in carpet).
Information on the diffusion coefficient may be used to estimate migration that results from diffusion in a textile. As an example, the total migration of a substance is modelled for three textiles:

1) Clothing
2) Bedding
3) Mattress

The migration is expressed per cm^2 of skin-product contact area and as a fraction of the total initial concentration of a substance – i.e. the result will be a fraction of the initial concentration that migrates per cm^2. From this modelled relative migration RE, the total migration may be calculated as:

$$A_{migr} = Co \times RE \times S_{contact}$$

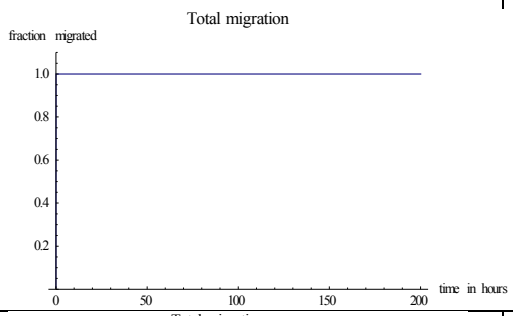
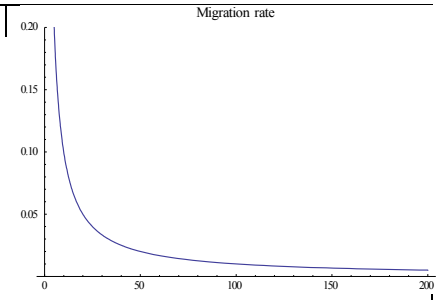
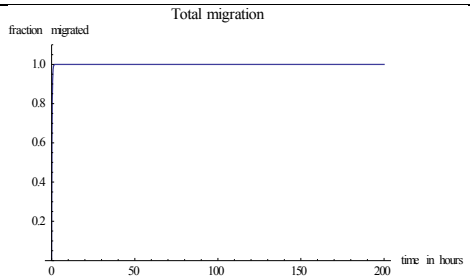
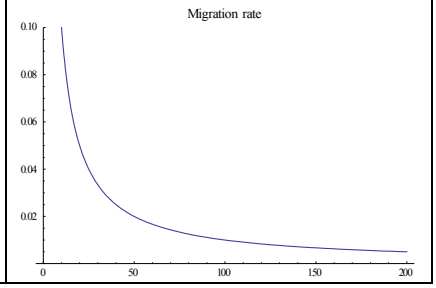
where A_{migr} is the total amount migrated and $S_{contact}$ is the total product-skin contact area.

The following thicknesses were assumed for the textile products:

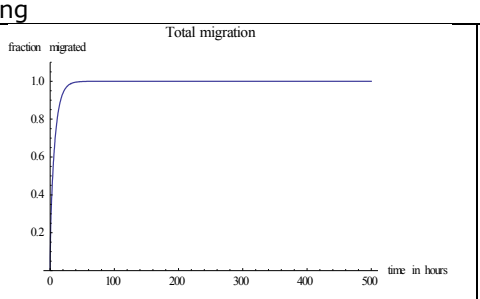
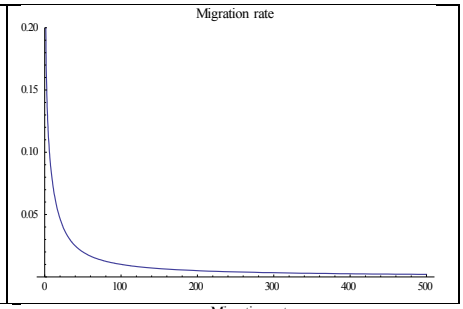
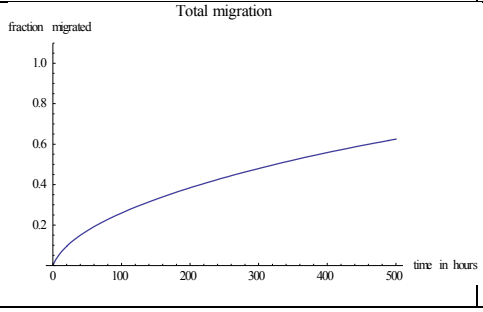
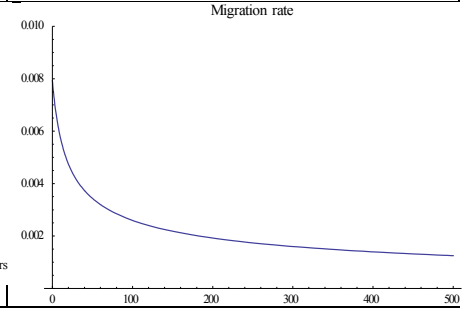
Clothing	1 cm
Bedding	5 cm
Mattress	20 cm

The emission is modelled for the upper and lower bound for the diffusion coefficient D (i.e. 5×10^{-12} and 4×10^{-8} m^2/s) to provide insight into the range of emissions that can be expected in reality. Results are presented as total migration after a time t and as an emission rate (migration per cm^2, per hour).

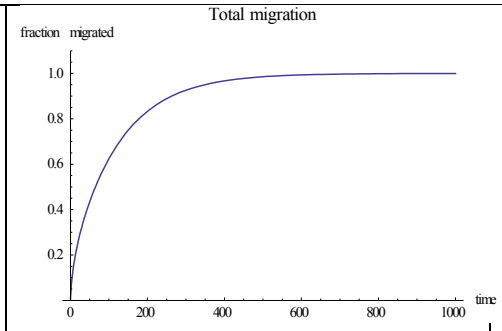
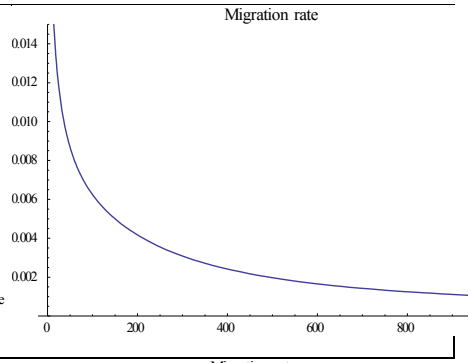
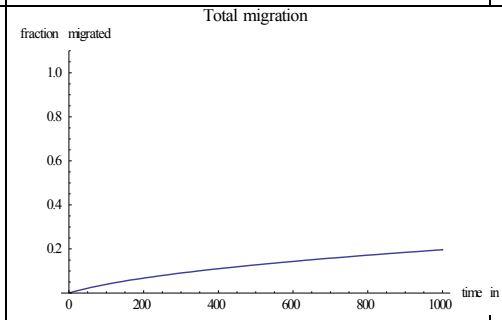
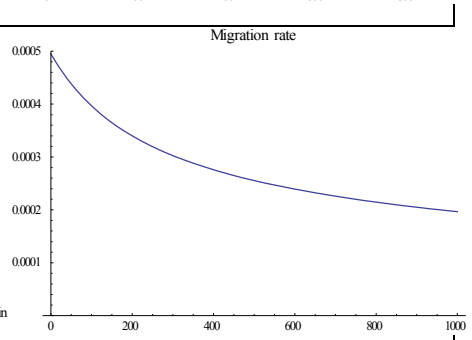
Clothing

D= 4x 10^{-8} m^2/ s		
D= 5x 10^{-12} m^2/s		

Bedding

D= 4x 10^{-8} m^2/ s		
D= 5x 10^{-12} m^2/s		

Mattress

D= 4x 10^{-8} m^2/ s		
D= 5x 10^{-12} m^2/ s		

From the model simulations, it follows that migration as predicted by the diffusion modelling and the range of diffusion coefficients assumed is relatively fast. For clothing, it is predicted that 100% of the substance will have migrated within 100 hours of contact time at most (but much faster for the higher diffusion coefficient). Only in the case of the mattress is the migration predicted to last for a substantial duration (more than 500 hours of contact).

Therefore, it seems that diffusion is probably not a rate-limiting step in the migration of substances from textiles and that, in reality, migration may be determined by mass transfer (i.e. by solution in sweat or skin, or by evaporation and subsequent transfer to the skin). From this, it can be concluded that diffusion-based modelling, as is employed in the current emission model, is not very well applicable to the estimation of migration rates of substances from textiles.

6.5 In-depth assessment of substances with high priority scores

Based on the outcome of the prioritization as described in paragraph 5.2, ten high-priority substances were selected for the feasibility of a risk assessment.

- Dibutyltin dilaurate (CAS 77-58-7; EC 201-039-8)
- Malachite green acetate (CAS 41272-40-6; EC 255-288-2)
- Confidential substance 1
- Dioctyltin laurate (CAS 3648-18-8; EC 222-883-3)
- 2,2 iminodiethanol (CAS 111-42-2; EC 203-868-0)
- Bis (2-ethylhexyl)phthalate (DHEP) (CAS 117-81-7; EC 204-211-0)
- Antimony Trioxide (CAS 1309-64-4; EC 215-175-0)
- Hexabromocyclododecane (HBCDD) (CAS 25637-99-4; EC 247-148-4)
- Confidential substance 2
- Confidential substance 3

The aim of the in-depth assessment is for the exposure estimation to be obtained only manually by opening the CSRs. This is necessary because exposure assessment is a crucial part of a risk assessment next to hazard identification. A second aim is to verify the classification of the substances and the DNELs. The in-depth assessment for the ten substances listed above was focused on the textile-specific information.
The substance information is retrieved from confidential CSRs, unless indicated otherwise, and therefore an overview of the estimation of consumer exposure per substance is provided in confidential Annex III.

Summarizing
A consumer exposure assessment for the ten substances in textiles chosen from the substances with the highest priority score is present in the CSR in three cases (REACH registration dossiers). In addition, for one substance an exposure and risk assessment was available in the Substance Evaluation (2,2-iminodiethanol). For DEHP, the non-acceptance of the restriction proposal for articles based on a combination of four phthalates shows that the exposure from textiles does not result in a risk. Because two of the substances are used in low tonnages, no exposure assessment is required. In three out of ten, a consumer exposure assessment was missing without supporting information. Information on the amount used in the textile and released from the textile was, in all investigated cases, absent in the REACH registration data.
In the other CSRs, the exposure assessment contained default values as provided by the ECETOC TRA v3 consumer exposure tool (shown above in paragraph 6.1.1). In two out of the three substances with a consumer exposure assessment, specific values were included, without supporting information. In one of the cases, measured data were provided or used in the exposure assessment.

7 Discussion and conclusion

7.1 Hazardous substances in textiles

Many substances are used for the manufacture of textile products and some of the most hazardous substances, such as azo dyes, are regulated or prohibited in order to prevent human exposure. Some of these substances have been registered under REACH, also with respect to use in textiles. However, it is thought that not all substances used and present in textiles are currently registered because they are manufactured in low tonnages or the substances are present in imported textile articles from non-European countries. A recent publication by KEMI showed that approximately 3,500 substances were identified as relevant for use in textiles, approximately 2,000 of which were not yet registered under REACH (KEMI 2014). There is a concern that there are hazardous substances used in the manufacture of textiles that could be a risk to consumers. A number of recently published reports raised concerns that hazardous substances are still present in textile products being placed on the market (overview in Chapter 4). For example, Greenpeace found nonylphenol ethoxylates in 63% of the tested clothes (Greenpeace 2012). A restriction of this substance based on environmental concerns is under discussion, with the following opinion given by RAC and SEAC: Textile articles or textile parts of articles that can be washed in water during normal or reasonably foreseeable conditions of use shall not be placed on the market if the total concentration of these substances in the textile article or textile parts of articles is equal to or higher than 0.01% by weight (ECHA 2014). BfR identified a number of skin sensitizing dyes, based on human cases, used in clothes (BfR 2012). The Danish EPA tested 31 textiles manufactured outside Europe and detected none of the tested dyes, including the dyes mentioned in the BfR report (Danish EPA 2014). Approximately 10 per cent of the 2,400 substances that were further investigated by KEMI were considered to be of potential concern for human health, the majority being dyes and fragrances (KEMI 2014). A separate risk assessment cannot be performed for all these substances, which raises the question of whether there is a possibility of prioritizing hazardous substances used in textiles that are registered in REACH.

7.2 Prioritization of hazardous substances used in textiles registered in REACH

Prioritization method

In this report, a method was developed in order to be able to prioritize hazardous substances in textiles registered under REACH. Within the REACH registration database, extensive toxicological information is available, such as toxicological tests, hazard classification, etc. Data on the use of a substance in different manufacturing stages and consumer articles are also present. This information is in part publicly available on the ECHA website, mostly toxicological data, although information on exposure assessment is only provided in a confidential CSR.

Using the developed method, substances are identified and prioritized based on their use in the manufacture of textiles or their presence in textiles, the type of effects (hazard) and potency. Preferably, exposure estimates would have been used instead of information on use. However, exposure information was not available for automated screening in the REACH registration database. As a

consequence, the level of exposure was not used in the priority setting, even though it is a crucial part of risk-based priority setting. Basically, the priority setting is based predominantly on hazard, although two classes for exposure were applied. AC5 was given a higher priority score than PC34 because substances with an AC5 code are in the final product and therefore consumers can come into direct contact with these substances. With regard to the substances with a PC34 code, it is unknown whether these remain in the final product, so they are given a lower priority score. This ensures substances as dyes a relatively higher score than those substances only used as an intermediate.

The focus of the priority setting was on dermal exposure to substances from textile products. However, oral DNELs also were taken into account because, for many substances, this is the only DNEL available. On the hazard part of priority setting, in addition to the systemic DNELs/DMELs, local DNELs for the skin sensitizing properties would also be of added value for the prioritization and risk assessment. However, REACH does not explicitly require potency information for skin sensitizing substances and, consequently, local DNELs were only available for a very limited number of substances. As a result, a risk assessment for local effects is also often not possible. It appears that REACH is not the legal framework that ensures protection against the skin sensitizing effects from substances present in textiles.
A second drawback of searching only in REACH registrations is the fact that substances that are only produced and used in textiles outside the EU or in low tonnage are not registered and are consequently missed.
It is important to note that articles treated with biocides, such as antibacterial sport clothes, are not registered under REACH and will therefore not be prioritized, although consumer exposure might be relevant. However, because the use of biocides in treated articles requires authorization, this risk is considered to be controlled.

Results of the prioritization
The query search performed in the summer of 2014 resulted in 788 individual substances with priority scores of between 4 and 14. Overall, 32 substances were identified with a high priority (score 4, 5 or 6). Most substances with the highest priority score were dyes and flame-retardants.
Two substances can be excluded because the classification was based on impurities, e.g. without the impurity they would have a priority score of 7. However, these impurities need to be prioritized as separate substances in order to prevent underestimation.
In addition, four organotin compounds can be excluded because of the existing regulation for textiles (e.g. limit on concentration of 0.1% in textile articles), resulting in 26 priority substances. It was beyond the scope of this report to perform a risk assessment based on the 0.1% limit for the concentration of these substances to exclude possible health risks for consumers.
A number of phthalate plasticizers were identified as substances with a high priority score. Phthalates are used in the plastisol printing of textiles. Recently, Denmark proposed restricting the use of four different phthalates in articles that come into contact with the skin. However, the RAC concluded that the phthalates do not pose a risk because the available biomonitoring data showed that a combined exposure did not exceed the DNEL (ECHA RAC decision 2012). So the phthalates that were part of the restriction proposal (Bis(2-ethylhexyl)phthalate (DEHP), benzyl butyl phthalate (BBP), dibutyl phthalate (DBP) and diisobutyl phthalate (DIBP)) can also be excluded.

The presence of several substances with an existing regulation for use in textiles in the highest priority groups confirms that the query identifies relevant substances with the highest combination of the chosen hazard and potency. According to the registration, these substances are still being used in textile products. Performing a risk assessment in combination with measurements of these substances in textile products can exclude exposure and health risks for consumers.

Discussion
Using the classification of substances as a hazard parameter has a drawback. For some substances, compositions are placed on the market containing impurities, resulting in an additional classification that is not applicable to the other forms of the substance, e.g. lead impurity in zinc oxide or nickel impurity in cobalt titanite green spinel. This will always result in an over-classification of the substance. Correction of the priority scores can only be performed via manual screening of the results. Note that the impurity should also be assessed for risks to consumers via textiles.
Attention should be paid to the fact that hazard classification, except in the case of harmonized classification, and DNELs are determined by registrant. This possibly leads to an under or over-classification of the priority scores of substances. In addition, classification and DNELs may differ between registrants. When performing an in-depth risk assessment, the classification and the DNELs could be verified.

It is currently not possible to refine the search with the query with additional parameters, e.g. exposure assessments, in the REACH registration database. Developing a query for hazardous substances in textiles based on exposure would be an improvement, but searching, for example, for amounts released from the textile or the expected consumer exposure to a substance can only be performed manually by searching in the CSR. In addition, as shown below, such information is not always available. Another criterion that could be used is the technical function of the substance because some of the technical functions, such as dyes, may give an indication of the possible release from the textile. However, currently no method is available to use this parameter in prioritization. Refining the search based on physical-chemical properties – e.g. low molecular weight substances penetrate the skin better or high vapour pressure inhalation exposure instead of dermal exposure – could also be a possibility. Due to the exploratory character of this study, the usefulness of this criterion is not included in the present report.

A number of reports published recently on substances used in textiles and their related risks were reviewed focusing on consumer exposure. Recently, the Swedish Chemical Agency (KEMI) has indicated 3,500 substances as relevant for use in textiles, approximately 8% of which (299 substances) were considered to be of potential concern for human health. From the list of substances with a high priority from the present study (Table 10), eight are present on this list of 299 substances reported by KEMI. Although very interesting, it was beyond the scope of this report to further assess where these differences come from.
Most of these reports show the presence of various (restricted) substances in clothing, with allergenic (disperse) dyes being the most mentioned as highest priority (see Table 5). For this group of substances, EU regulation could be expected. This group of substances, however, is self-regulated by most retailers and, in a recent report of the Danish EPA, none of the tested allergenic dyes were detected in clothing (Danish EPA 2014). This indicates that the self-regulation has at least been partly successful. These allergic disperse dyes were

not prioritized from the REACH registrations because they are currently not registered due to use in low tonnage.
The report of BfR (2012) provided a first-tier exposure assessment and concluded that a risk for skin sensitization, especially, cannot be excluded for certain substances. Other reports did not provide exposure assessments or migration and release data. Several reports state that this is not possible due to the absence of available measurements or exposure data. The different focus and methodology of the reports leads to non-comparable outcomes. Whereas Greenpeace tested clothes and found, say, NPEs (possibly restricted at 0.01% by weight in textiles due to environmental protection) in 63% of all items tested, some reports performed case studies which resulted in substances that possibly constitute risks for humans without testing whether these substances remain in the finished textiles.

Overall, most of the identified or prioritized substances were based on hazard assessment only because of the limited availability of exposure data. Data on the concentration of substances in the final textile product are missing, only a limited number of measurements are available (Danish EPA 2014). Migration and release data of a substance from different textile products are rare. There is a lack of experimental data on skin penetration and models for a realistic exposure assessment of substances in textiles are currently not suitable. Therefore, self-regulation in textiles is based on hazard instead of on the risk and is already applied by most retailers in order to protect consumers from a possible risk presented by hazardous substances. Still, some allergic disperse dyes are identified as the most likely candidates for EU regulation.

7.3 In-depth assessment of some high-priority substances

Information in the CSRs submitted under REACH is, in almost all of the ten substances, checked insufficiently to perform a complete human risk assessment. Although toxicological information such as DNELs is present in the registration, information on consumer exposure is in most cases limited:

- For one substance out of ten, enough information was available to perform an exposure assessment that was based not only on default values. Consumer exposure was mostly assessed by using the defaults from the ECETOC TRA tool, which in one case was altered without explanation.
- In some CSRs, it was noted that dermal exposure in consumers was not expected due to no expected release of the substance from the textiles. Regrettably, no reference was given for this conclusion on release.
- Real residue concentrations are not provided and the degree of release may vary considerably between substances.
- For some substances, information on the amount of a substance present in textiles was available, which could be used to improve the exposure and risk assessment.

The available information is limited for substances with an intended function in the finished product, such as dyes or flame-retardants, and even worse for processing aids. Release rates will be lower after repeated washing. Higher release rates are expected from poorly dyed textiles or intensively worn clothes (BfR 2012). Defaults can be used as worst-case assumptions if no other values are available, but the recommendation is to measure for highly prioritized substances in textiles in order to establish the presence, release and migration of the substance in the finished textiles. BfR proposed default values, depending on the amount present in the textile, that can be used for dyes and hydrophilic

or hydrophobic textile auxiliary (BfR 2012), thereby making it possible to make a small distinction in the exposure assessment.

7.4 Feasibility of exposure assessment with RIVM Emission Tool

The use of the RIVM emission model to estimate migration rates for textile products was explored. As this model does not include the mass transfer from the material surface to the skin, the estimated migration represents a conservative estimate of the migration. In reality, the migration may be significantly lower when migration is limited by the mass transfer.
A second limitation in the approach is the paucity of data on the diffusion of substances in textiles. Diffusion coefficients of small molecular weight substances in carpets where used as surrogate data. These provide a large range of the possible values the diffusion coefficient of substances in textiles might take on, but cannot be considered an appropriate estimate for a specific substance/textile combination. In addition, the true range of possible diffusion coefficients may easily be underestimated because the range of surrogate data itself was derived from a limited sample.
Given the lack of data and the limitations in the modelling, the model does not seem to be suitable for estimating specific migration rates.
Generic conservative values (i.e. reasonable upper bounds) of the migration for all substance/textile combinations may be estimated using a reasonably high estimate of the diffusion coefficient, but as was seen from the model simulations presented above, this approach will likely result in very (possibly unrealistically) high migration estimates.
In order for the diffusion models to be usable for migration estimation, at least one of two things has to be addressed:

1) Realistic, substance/textile-specific data for the diffusion coefficient needs to be available.
2) The models should be expanded with a plausible description of the mass transfer phase. This would have to include transfer via air and sweat, and the direct transfer of the substance to the skin (either to the stratum corneum or into the skin lipid layer).

From this, it can be concluded that diffusion-based modelling, as is employed in the current emission model, is not very well applicable to the estimation of the migration rates of substances from textiles.

7.5 Conclusions

- *Prioritization method*
  Substances were prioritized from the REACH registrations based on hazard classifications for CMR properties, repeated dose, acute dermal toxicity and skin sensitization, and their potency (by using the DNEL/DMELs) and their use in textiles (by PC and AC code). Although prioritization based only on local effects such as skin sensitization and on exposure was not possible, this method seems to be a solid method for indicating high priority substances registered under REACH.

- *In-depth assessment*
  The in-depth assessment of the possible risks of exposure for consumers due to hazardous substances present in textiles is difficult due to limited (publicly) available data and exposure estimation. Information on the presence of substances in imported textiles is mostly missing and toxicological information on these products is generally absent. From the small proportion of substances used in textiles that have been registered

under REACH, it has been learned that probably, in most cases, information on exposure is very limited in the CSRs. It is therefore difficult, if not impossible, to focus on the possible risks resulting from the use of such substances in textiles because safety assessments are often missing.

The required chemical safety assessment in the REACH registration database for the use of substances in textiles was lacking or was of insufficient quality. In most of the ten substances assessed, the exposure assessment was absent, based on assumptions, defaults or limited data. Also local effects like skin sensitization were not assessed. A risk assessment based on the available data was therefore not feasible for most substances.

- *Overview reports*
  An overview of the published reports revealed the presence of various allergenic (disperse) dyes in clothing (Table 5) as a relevant risk that is not yet regulated. For this group of substances, EU regulation could be expected using existing legislation as indicated in Article 25 of the Regulation of Textile Fibres (EU No 1007/2011).

- *Feasibility RIVM emission tool*
  The available RIVM emission tool, in its current form, is not suitable for the exposure assessment for substances found in textiles, but could be useful when experimental data on migration and measurements on concentration in the textile product are provided.

7.6 Recommendations

- *Prioritization method*

To improve the prioritization method, some follow-up steps are suggested:

- Combine information on substances gathered in the reports that were reviewed and information from industry with the substances registered under REACH to get a more complete overview of substances found in textiles and their prioritization.
- Explore the possibility of refining the exposure scoring based on the physical chemical properties (molecular weight or vapour pressure) of the substances.
- Explore the possibility of refining the exposure scoring based on the technical function of the substance in textile products.

- *In-depth assessment*

One of the ten selected substances chosen for an in-depth assessment is registered as being present in the textile product and release of the substance was expected. The exposure assessment in the CSR was performed using adjusted default values in the ECETOC-TRA consumer exposure tool leading to a RCR below 1, indicating no exposure for consumers. This default value was altered without explanation. Based on the type and function of the substance, release was expected and it is recommended that this substance be reviewed more in-depth to see whether a substance evaluation may be required.

Furthermore, an in-depth risk assessment could be performed for the substances with high priority, but

- containing an impurity,
- < 0.1% presence of those substances restricted for use in textiles.

When the in-depth assessment shows that the REACH requirements have not been fulfilled, regulatory action should be considered. The presence and quality of an available safety assessment for the use of substances in textiles in the CSRs can be enforced by legal authorities. Specifically for those substances that pose a risk, the CSRs need to be enforced and additional information can be requested from the registrant to demonstrate safe use, for example via substance evaluation.

- *Exposure assessment*

Information on exposure is considered to be the most important information to improve the exposure and risk assessment of substances in textiles. The following actions could be considered to obtain exposure information:

- Measurements of the concentration, the migration of the substance in the textile and its migration to the skin in order to perform a realistic exposure assessment. Information on amount of substances used, on release and on migration may also be obtained from industry. Other member states have also performed either measurements or first-tier risk assessments. Contacting these parties could help in developing a method for exposure assessment.
- Assessment of other exposure models for usability for the exposure to substances released from textiles, such as the above-mentioned BfR migration model (BfR 2012) and ECETOC TRA.

Feasibility study for the development of an exposure model for substances released from textiles.

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Annex I Hazard categories, statements and query

Detailed information on the query as used in IUCLID 5 for the prioritization of hazardous substances in textiles.

Table Ia: Hazard categories and statements used for query search

Hazard categories	**Hazard statements**
Acute dermal toxicity Skin sensitization 1, 1A, 1B Germ cell mutagenicity 1A, 1B, 2 Carcinogenicity 1A, 1B, 2 Reproductive toxicology 1A, 1B, 2 Specific Target Organ Toxicity (STOT) – repeated exposure 1, 2	H310: fatal in contact with skin H311: toxic in contact with skin H312: harmful in contact with skin H313: may be harmful in contact with skin H317: may cause an allergic skin reaction H340: may cause genetic defects H341: Suspected of causing genetic defects H350: May cause cancer H351: Suspected of causing cancer H360: May damage fertility or the unborn child H361: Suspected of damaging fertility or the unborn child H362: May cause harm to breast-fed children H372: Causes damage to organs through prolonged or repeated exposure H373: May cause damage to organs through prolonged or repeated exposure

These were divided into four hazard sub-queries:

Query 1: Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard Categories/ Carc. 1A|Carc. 1B|Muta. 1A|Muta. 1B|
OR
Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard statements/ H340: May cause genetic defects|H350: May cause cancer

Query 2: Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard Categories/Muta. 2|Repr. 1A|Repr. 1B|
OR
Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard statements/ H310: Fatal in contact with skin.|H341: Suspected of causing genetic defects|H360: May damage fertility or the unborn child|.

Query 3: Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard Categories/Muta. 2|Repr. 1A|Repr. 1B|
OR
Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard statements/ H310: Fatal in contact with skin.|H351: Suspected of causing cancer |H361: Suspected of damaging fertility or the unborn child.|H362: May cause harm to breast-fed children.|H372: Causes damage to organs through prolonged or repeated exposure.

Query 4: Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard Categories/ Skin Sens. 1|Skin Sens. 1A|Skin Sens. 1B|STOT Rep. Exp. 2
OR
Add query block: Substance/ 2 Classification & Labelling and PBT assessment/ 2.1 GHS/ Classification/ Hazard statements/ H311: Toxic in contact with skin.|H312: Harmful in contact with skin.|H317: May cause an allergic skin reaction.|H373: May cause damage to organs through prolonged or repeated exposure.

In addition, three potency sub-queries were used:

Query 5a: Add query block: Substance/ 7 Toxicological information/ Σ Toxicological information/ General Population/ dermal/ systemic/ long term: Hazard assess. Conclusion/ DNEL (Derived No Effect Level)|DMEL (Derived Minimum Effect Level)/ > 0 mg/kg bw/day

Query 5b: Add query block: Substance/ 7 Toxicological information/ Σ Toxicological information/ General Population/ dermal/ local/ long term: Hazard assess. Conclusion/ DNEL (Derived No Effect Level)|DMEL (Derived Minimum Effect Level)/ > 0 mg/cm^2

Query 5c: Add query block: Substance/ 7 Toxicological information/ Σ Toxicological information/ General Population/ oral/ systemic/ long term: Hazard assess. Conclusion/ DNEL (Derived No Effect Level)|DMEL (Derived Minimum Effect Level)/ > 0 mg/kg bw/day

Data derived from the seven queries used in IUCLID were processed in Excel resulting in one datasheet combining all available substances and their identifiers, with detailed information and scores on exposure, hazard and potency properties, together with the final priority score.

RIVM

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