Chemicals in consumer products

Towards a safe and sustainable use

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"Fortunate as we are, we nevertheless cannot afford waste in consumption any more than we can afford inefficiency in business or Government. If consumers are offered inferior products, if prices are exorbitant, if drugs are unsafe or worthless, if the consumer is unable to choose on an informed basis, then his dollar is wasted, his health and safety may be threatened, and the national interest suffers."

– John F. Kennedy, Special Message to the US Congress on Protecting the Consumer Interest, March 15, 1962

This licentiate thesis consists of an introduction and the following papers:

I Molander L. and Rudén C. (2012). Narrow-and-sharp or broad-and-blunt – Regulations of hazardous chemicals in consumer products in the European Union. *Regulatory Toxicology and Pharmacology* 62: 523-531.

II Molander L., Breitholtz M., Andersson P.L., Rybacka A., Rudén C. (2012). Are chemicals in articles an obstacle for reaching environmental goals? – Missing links in EU chemical management. *Science of the Total Environment* 435-436: 280-289.

III Hansson S.O., Molander L., Rudén C. (2011). The substitution principle. *Regulatory Toxicology and Pharmacology* 59: 454-460.

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Abstract

Health and environmental risks associated with emissions of hazardous chemicals from articles, including everyday consumer products such as clothes and toys, have become widely acknowledged internationally, particularly in the EU. This thesis contributes to new understandings of how these risks are currently managed within the EU and recommends actions for ensuring a safe and sustainable use of chemicals in articles.

Paper I provides an overview and comparative analysis of regulatory strategies for managing risks of chemicals in articles in the EU. The in-depth analysis, which is focused on the Toys Safety Directive, the RoHS Directive, and REACH, shows that the legislations differ significantly. Differences include e.g. what criteria are used for the selection of substances to be targeted for regulation, and the kind of requirements and restrictions applied to the selected substances. It is concluded that product-specific directives are important complements to REACH in order to ensure a safe use of chemicals in articles.

Paper II evaluates to what extent the regulation of chemicals in articles under REACH is coherent with the rules concerning chemicals in the Sewage Sludge Directive (SSD) and the Water Framework Directive (WFD). The results show that the majority of the chemicals that are prioritized for phase-out under the WFD or for concentration restrictions in sludge and soil under the SSD are allowed to be used in articles according to REACH. In order to avoid end-of-pipe problems and to increase resource efficiency, it is argued that it is necessary to minimize the input of chemicals identified as hazardous to health or the environment into articles.

Paper III aims to clarify what the substitution principle means and how it can reasonably be applied as part of chemical policies. A general definition is proposed that gives equal weight to hazard, functionality and economical considerations, while at the same time recognizing that the aim of the substitution principle is to reduce hazards to human health and the environment. This paper also summarizes major methods to promote and implement the principle, discusses legislative approaches with regard to their ability to promote substitution of hazardous chemicals, and makes proposals for an efficient implementation of the principle.

Keywords: articles, consumer products, hazardous chemicals, risk management, chemicals regulation, REACH, substitution, regulatory toxicology, European Union

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Abbreviations

BBP	Benzyl butyl phthalate
BFR	Brominated flame retardant
BPA	Bisphenol A
CLP	Regulation on the Classification, Labelling and Packaging of substances and mixtures
CMR	Carcinogenic, Mutagenic, and Reprotoxic
CSA	Chemical Safety Assessment
DBP	Dibutyl phthalate
DEHP	Di(2-ethylhexyl)phthalate
DIBP	Diisobutyl phthalate
ECHA	European Chemicals Agency
EDC	Endocrine-disrupting chemical
ICCM	International Conference on Chemicals Management
L/NOAEL	Lowest/No Observed Adverse Effect Level
L/NOEC	Lowest/No Observed Effect Concentration
NGO	Non-Governmental Organisation
OECD	Organisation for Economic Co-operation and Development
PBDE	Polybrominated diphenyl ether
PBT	Persistent, Bioaccumulative, and Toxic
PCA	Principal Component Analysis
PCB	Polychlorinated biphenyl
PFC	Perfluorinated chemical
REACH	Registration, Evaluation, Authorisation and restriction of Chemicals
RoHS	Restriction of the use of certain Hazardous Substances
SAICM	Strategic Approach to International Chemicals Management
SSD	Sewage Sludge Directive
SVHC	Substance of Very High Concern
vPvB	very Persistent and very Bioaccumulative
WEEE	Waste Electrical and Electronic Equipment
WFD	Water Framework Directive

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Paper III
Hansson S.O., Molander L., Rudén C. (2011). The substitution principle. *Regul Toxicol Pharm* 59: 454-460.

1. Introduction

Only since 2009, when I started to work on what has now become this thesis, health and environmental risks associated with emissions of hazardous chemicals from articles, including everyday consumer products such as clothes, toys and electronics, have become widely acknowledged internationally, particularly in the European Union (EU). Risks may be associated with all life cycle stages of an article and they are gaining increased attention in society – by scientists and regulators, as well as by politicians, NGOs and the general public. The use of hazardous chemicals in articles is recurrently being identified as an issue of emerging concern (e.g. Shubber, 2012; Swedish Chemicals Agency, 2012). In high-income countries, hazardous chemicals emitted from articles have been identified as one of the most important sources contributing to the human toxic burden (Massey et al., 2008; Swedish Chemicals Agency, 2011a).

As a consequence of the substantial increase in the consumption of articles during the last decades, their rapid turnover and ever more global trade, in combination with the complexity of articles with regard to the diversity of materials and chemical content, there is high pressure on chemical risk management to tackle associated risks and for risk assessment not to fall behind technological and economic developments (UNEP, 2012; MMB, 2012).

A number of risk reduction initiatives, both regulatory and voluntary, that directly target or are of relevance for chemicals in articles have been implemented in recent years as a response to this. Within the EU, the industrial chemicals legislation REACH (Registration Evaluation Authorization and restriction of Chemicals; Regulation (EC) No 1907/2006) is currently being implemented (EC, 2006). Although it first and foremost regulates chemical substances as such and chemical products, i.e. commercial mixtures, it includes and introduces certain new rules directed towards chemicals in articles. There are also international instruments that have called for more far-reaching and innovative policy solutions for managing risks of chemicals in articles, such as the United Nations' voluntary Strategic Approach to International Chemicals Management (SAICM). SAICM, which was adopted by the International Conference on Chemicals Management (ICCM) in 2006, has identified four emerging policy issues, all of which concern articles; the need for an internationally harmonized information system for chemicals in articles, hazardous substances within the life cycle of electrical and electronic products, nanotechnologies and nanomaterials, and lead in paint (Swedish Chemicals Agency, 2011b; Shubber, 2012).

Although this recognition of the risks posed by chemicals in articles has led to the introduction of new risk reduction measures during the last decade it is being stressed that existing regulatory restrictions and requirements are inadequate with regard to managing health and environmental risks of hazardous chemicals in articles in a way that ensures a safe and sustainable use.

1.1 Aims of this thesis

My PhD project concerns regulatory aspects of toxicology – spanning from risk assessment to risk management issues of hazardous chemicals in articles. This licentiate thesis is focused on how health and environmental risks associated with chemicals in articles are managed within the EU.

The overall aims of this thesis are to (1) identify strengths and shortcomings of current EU regulatory risk reduction strategies targeting chemicals in articles, (2) analyse implications for human health and the environment of these strategies, and (3) make recommendations that will help ensure a safe use of chemicals in articles in a sustainable way.

1.2 Definitions

In this thesis the terms *consumer product* and *product* are used synonymously with *article* as is defined as "an object which during production is given a special shape, surface or design which determines its function to a larger degree than does its chemical composition" according to REACH (Article 3.3). A *mixture* is used to denote a chemical product, i.e. a mixture or solution composed of two or more substances (REACH, Article 3.2).

2. Background

2.1 Chemicals in articles – A global concern

2.1.1 Production of chemicals and articles is increasing

During the second half of the 20th century, the global chemical production increased from around 7 million tons to over 400 million tons per year, and it is expected to continue to grow. In 2001, the Organisation for Economic Co-operation and Development (OECD) calculated that global chemical production would rise by an additional 85% between 1995 and 2020 (Swedish Chemicals Agency, 2010). It is estimated that over 100,000 chemical substances are commercially available on the global market (Swedish Chemicals Agency, 2011a). In the EU alone, around 143,000 substances had been pre-registered under REACH before the first registration deadline in November 2010 (ECHA, 2012). However, between 30,000 and 100,000 of these chemicals, which are produced or imported in above 1 ton/year, are estimated to be in commercial use[1] (Swedish Chemicals Agency, 2011b).

One important explanation of the increasing production of chemicals is the rapidly increasing production of articles (Swedish Chemicals Agency, 2011a). The international trade with articles has tripled since the 1970's (MMB, 2012), and there are now millions of articles on the global market. Information on which and how many of the commercially available chemicals are used in articles is to a great extent lacking (Swedish Chemicals Agency, 2011a).

Chemicals are present in articles for different reasons. They can for example be used as constituents for the manufacturing of materials, such as plastics, or added to the material in order to achieve certain functions or properties. Examples of such chemicals are perfluorinated chemicals (PFCs), which act as water- and grease repellents, and phthalates, which are used as plasticizers. Other applications include the treatment of articles with biocides and finishing with paints and lacquers. Traces of chemical substances used in the manufacturing process may also unintentionally remain in the finished article where it no longer serves any purpose. (Swedish Chemicals Agency, 2011b; MMB, 2012)

[1] The given span is for example due to the fact that one substance can be counted as a single substance in one estimation and as part of a group of substances that is counted as one substance in another estimation.

The increasing production of articles is closely related to our lifestyles. As our way of living and consuming has changed much during the last 50 years, chemical exposure has also changed. There has been a shift from exposure to a limited number of substances, mainly in the occupational setting, to exposure to numerous chemicals at the same time, where indoor environments and food have become important sources (Swedish Chemicals Agency, 2011a).

2.1.2 The life cycle perspective

Chemicals can be released from articles during all steps of the life cycle – manufacturing, use, waste handling and disposal and recycling – thereby posing a potential risk to human health and the environment (Figure 1).

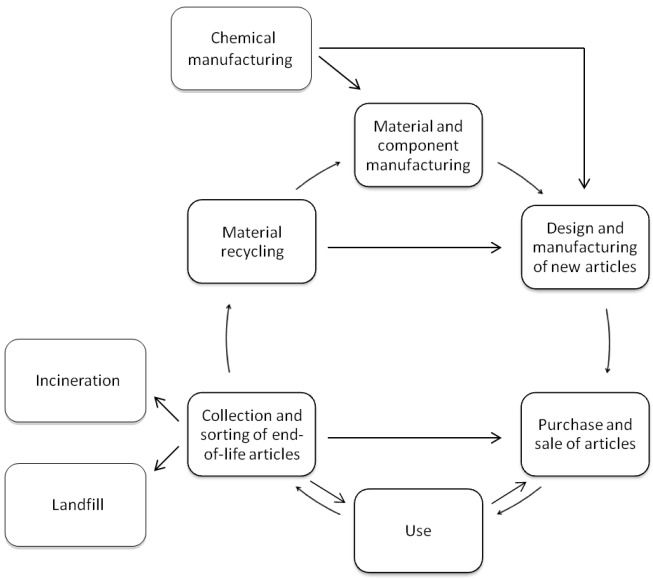

Figure 1: A simplified picture of the life cycle of chemicals used in articles. The figure is modified from the Swedish Chemicals Agency, 2011b.

During the use phase, chemicals can for example be released from articles through leakage of additive substances, washing and wearing or via the formation of small particles (Swedish Chemicals Agency, 2011b). Humans and non-target organisms in the environment may subsequently be exposed via several different routes. Humans can be orally exposed via food and drink, for example to chemicals that have migrated from food contact materials (Swedish National Food Agency, 2011).

Substances that come into contact with the skin may be dermally absorbed (Swedish Chemicals Agency, 2011b). Human exposure also occurs through inhalation of particles in air and dust. Organic chemicals, such as flame retardants that can be released from computers, TV sets and furniture, have for example been found to accumulate in indoor dust. Since children spend much time close to the floor, they are especially targeted by these chemicals (Mercier et al., 2011; de Wit et al., 2008).

Even if the chemical emission from a single article may be insignificant, the total emission of one chemical or the combined emissions of several chemicals may be important sources of environmental pollution and negative effects on ecosystems. Humans may subsequently be indirectly exposed via for example intake of food and water. (Swedish Chemicals Agency, 2011a) Emissions from articles incorporated or treated with hazardous chemicals may result in long-term exposure to humans and the environment. This includes articles with fast turnover, such as toys and clothes, as well as articles that stay in use for many years, such as building materials. Chemicals included in these materials can be more or less persistent, but also chemicals that degrade relatively rapidly can result in significant exposures if emissions occur continuously. Overall, the knowledge about the mechanisms involved in the diffuse emissions of substances from articles and consequent exposures of humans and the ambient environment is insufficient (Swedish Chemicals Agency, 2011b).

The fast turnover of articles causes increased resource consumption, generates hazardous wastes and prompts the need for safe and efficient recycling. Hazardous substances in waste may be released and pose risks via incineration or landfills, as well as in the recycling process (Swedish Chemicals Agency, 2011b). Risks to human health and the environment are difficult to assess due to the lack of information about the presence of hazardous substances in articles. Even if information is available, it is often not disseminated from producers and importers to the waste stage (Swedish Chemicals Agency, 2011b) as this is in most cases not required by law, e.g. REACH (EC, 2006). Thus, hazardous chemicals may be reintroduced to the market via reused and recycled materials and articles.

Environmental and health risks associated with the use of chemicals in articles is mainly a prioritized problem in the north-western part of the world, but there are also serious problems arising in the life cycle of articles that to a great extent target other parts of the world. Manufacturing of materials and articles that are sold and consumed on the European market primarily takes place outside the EU; often in countries having less restrictive and comprehensive chemical rules for protecting human health and the environment (MMB, 2012; Swedish Chemicals Agency,

2011b). In these countries, the manufacturing of articles may therefore result in unhealthy levels of occupational exposures and environmental releases of dangerous chemicals (e.g. Fick et al., 2009). Another stage of the article life cycle chain closely associated with health and environmental problems in low-income countries is the waste stage. Many end-of-life articles generated within the EU, such as waste electrical and electronic equipment, are being exported to countries where there are few risk management measures in place for minimizing negative impacts on human health and the environment (Ongondo et al., 2011). The *Basel Convention on the Transboundary Movements of Hazardous Wastes and Their Disposal* is thought to prevent this geographical injustice by prohibiting hazardous wastes to be exported from industrialized countries to low-income countries. Yet, there are serious risks to human health and the environment posed by the leakage of toxic chemicals from exported wastes. This is partly because the Basel Convention has not been ratified or strictly enforced by some major exporters of wastes, such as the United States (Hansson, 2009; Zhang et al., 2012).

2.1.3 Chemicals in articles and association to adverse outcomes

Humans of all ages, including children, pregnant women and other sensitive subpopulations, are continuously exposed to multiple chemicals at the same time, many of which are released from articles (MMB, 2012). How these combined exposures affect human health is to a great extent still unknown.

Biomonitoring studies of human exposure to chemicals in the environment have found that numerous chemicals representing different chemical classes are present in the human body at various levels (CDC, 2009; Woodruff et al., 2011). These include chemicals commonly incorporated in, and known to be released from, articles, such as brominated flame retardants (BFRs), perfluorinated chemicals (PFCs), bisphenol A (BPA) and phthalates, as well as banned but still widespread persistent environmental contaminants, e.g. polychlorinated biphenyls (PCBs). Analyses conducted on blood samples from three generations in thirteen EU member states showed for example that BFRs are detected in higher levels and more frequently in the blood of younger generations than in older generations (Watson, 2005 in Swedish Chemicals Agency, 2011b).

Research on male reproductive health conducted in Denmark and Finland has reported a relationship between levels of a group of brominated flame retardants, polybromintaed diphenyl ethers (PBDEs), in mothers' breast milk and

cryptorchidism[2] in their sons (Main et al., 2007). This relationship is also reported from animal experiments (Mori and Todaka, 2008). There is increasing concern that the growing and widespread use of chemicals, including their use in articles, may be linked to increases of for example several endocrine-related impairments in both human and wildlife populations:

> "Rates of endocrine diseases and disorders, such as some reproductive and developmental harm in human populations, have changed in line with the growth of the chemical industry, leading to concerns that these factors may be linked. For example, the current status of semen quality in the few European countries where studies have been systematically conducted, is very poor: fertility in approximately 40 % of men is impaired. There is also evidence of reproductive and developmental harm linked to impairments in endocrine function in a number of wildlife species, particularly in environments that are contaminated by cocktails of chemicals that are in everyday use. Based on the human and wildlife evidence, many scientists are concerned about chemical pollutants being able to interfere with the normal functioning of hormones, so-called endocrine-disrupting chemicals (EDCs), that could play a causative role in these diseases and disorders. If this holds true, then these 'early warnings' signal a failure in environmental protection that should be addressed." (EEA, 2012)

Significant adverse effects of a number of chemicals used in articles are reported from both *in vitro* and *in vivo* toxicity and experimental ecotoxicity studies, but many causes and relationships remain unexplained or in need of support by epidemiological studies (WHO, 2012). However, due to e.g. statistical constraints and the many confounding factors it is very difficult to link health impacts to exposure to a specific substance in epidemiological studies (Faustman and Omenn, 2001). Uncertainties inherent in the results are for example due to the fact that we are exposed to a mixture of chemicals, that people have different genetic traits and life style habits, and time latencies in the occurrence of negative health outcomes.

As the assessment of health and environmental impacts of chemicals involves many complex parameters and uncertainties, they are sometimes subject to both scientific and policy debates. Current such topics, which are closely related to articles being identified as an emerging issue, are the relevance of so-called low-dose[3] effects of EDCs reported in experimental studies for human health risk assessment, combination effects and risks associated with nanomaterials.

[2] In cryptorchidism, the testes have not descended in the scrotum by the time of birth (Mori and Todaka, 2008).
[3] Different definitions of *low-dose* exist, but often it refers to doses below the NOAEL or to doses in the range of typical human or environmental exposures (Vandenberg et al., 2012).

2.2 Risk assessment and risk management

In the risk decision process risk assessment and risk management have traditionally, and are still routinely, regarded as separated activities. Conducting a risk assessment (sometimes also called "safety assessment") means a structured review and evaluation of toxicological data for estimating health or environmental outcomes in relation to exposure to chemicals (WHO, 2004). Risk assessment is a conceptual framework often described as comprising three main steps (EC, 2003; WHO, 2004). The first step, the **effect assessment**, consists of the *hazard identification* and the *dose-response assessment*. This step identifies the type and nature of adverse effects that the substance has an inherent capacity to cause in an organism, population or sub-population. It also seeks to characterize the relationship between doses and effects, where the aim is often to identify the no observed adverse effect level (NOAEL) or the lowest observed adverse effect level (LOAEL). In environmental risk assessment, these levels are named no observed effect concentration (NOEC) and lowest observed effect concentration (LOEC), respectively. To extrapolate the effect levels (or no effect levels) identified in animal experiments to realistic human or environmental conditions, assessment factors are applied to account for e.g. differences between and within species, differences in exposure duration and uncertainties due to lack of data (van Leeuwen and Vermeire, 2007). The second step of the process is the **exposure assessment**, which is an estimation of the doses of the substance (or its derivatives) that the identified subjects are exposed to. The final step is the **risk characterization**, which is a qualitative or quantitative estimation of the probability of the incidence of known or potential adverse effects under defined exposure conditions.

These three steps are the same for both human health and environmental risk assessment, although there are some differences in practices within each step. A major difference, however, regards the aim. While human health risk assessment and risk management aims to protect the most sensitive individual, environmental risk assessment aims to prevent harm on the population-level in order to ensure that the function of ecosystems is protected.

Risk management decisions and actions do not only consider the outcome of the risk assessment, but in addition to toxicological aspects also considers economic, legal, social and technological implications.

Figure 2 visualizes how scientific data feed into the different steps of the risk assessment process and how risk assessment is connected to risk management.

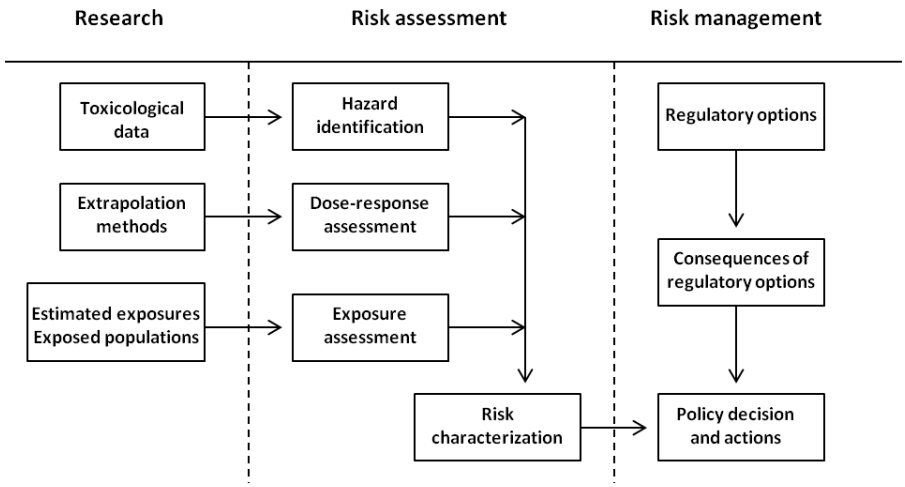

Figure 2: The structure of the risk assessment process, and its connection to risk management decision-making. The figure is modified from NRC, 1983.

Risk assessments are usually portrayed as purely scientific. However, in practice they are constantly framed by different prior normative assumptions. To increase the transparency of the process it has been argued that underlying assumptions should be made explicit (Wandall, 2004).

2.3 Risk reduction strategies

Both regulatory and voluntary strategies are used for managing health and environmental risks posed by hazardous chemicals emitted from articles. These may include bans or restrictions on certain substances, mixtures or uses, requirements, such as to disseminate information, and economic incentives for substituting hazardous chemicals to safer alternatives. Risk management strategies can vary substantially in aim, scope, design and effectiveness. Some instruments and strategies of relevance for chemicals in articles are briefly described and discussed below.

2.3.1 Regulatory instruments

While some chemical sectors are relatively well-regulated, regulations of industrial chemicals, and in particular the use of chemicals in consumer products, have been criticized for not being protective enough with regard to human health and the environment (e.g. Molander and Rudén, 2012; Molander et al., 2012).

During the last decade the EU chemicals legislation has essentially been completely renewed (Swedish Chemicals Agency, 2012). When REACH went into force on 1 June 2007 it replaced about 40 pieces of chemicals legislation and thereby also the previous differences in requirements for what was called ”existing” and ”new” chemicals. Important reasons behind the development of REACH was that data on chemical properties should be required for all industrial chemicals, irrespective of the date of their entry to the market, as well as shifting the responsibility for assessing the safety of the chemicals from authorities to the chemical producers and importers (MMB, 2012; Rudén and Hansson, 2006).

A central problem in chemicals control is, however, still that the required data on toxicological and ecotoxicological properties of chemicals are insufficient for enabling a robust health or environmental risk assessment (Rudén and Hansson, 2010). The data required by REACH to be submitted to the European Chemicals Agency (ECHA) is volume-dependent; the higher the production volume of the substance, the more information about the substance is required. For chemical substances produced or imported in less than 1 ton per producer or importer and year no data is required and for substances in the tonnage band between 1 and 10 tons the data requirements are very limited. This has the implication that a great number of chemicals can not be adequately risk assessed or classified according to the hazard criteria laid down in the European regulation on classification, labelling and packaging of substances and mixtures (CLP) (EC, 2008). The CLP hazard classifications are central in EU chemicals policy as they are often used as a basis for priority-setting of substances for restrictions and requirements under other legislations.

Another problematic issue for risk assessment and risk management is that information about the chemical content of articles is rarely available to regulators, professional buyers, or consumers (Swedish Chemicals Agency, 2011b; Molander and Cohen, in press). The assessment of human and environmental risks associated with the use of chemicals in consumer articles is thus often hampered by the lack of important information. The chemical safety assessment (CSA) that is required as part of the registration dossier under REACH for hazardous chemicals produced or imported in 10 tons or more annually, will generate such information for certain

uses (EC, 2006). Depending on how this requirement is implemented, the CSAs have the potential to be important in contributing to understanding the complex risk profiles of hazardous chemicals in different articles.

The identification of substances of very high concern (SVHCs)[4] and their entry into the so-called candidate list under REACH is an important tool that is available for risk reduction of chemicals in articles. The authorisation that is gradually required for the SVHCs also includes assessing if the substance can be accepted for use in articles produced within the EU (EC, 2006).

Besides being the basis for the authorisation process, the candidate list is also a tool for increasing and disseminating information on the presence of SVHCs in articles, particularly in the supply chain, but also to consumers upon request (EC, 2006). Since many supply chains are global, the information requirements connected to the SVHCs will have impacts also outside the EU. Although putting an SVHC on the candidate list does not automatically encompass any use restrictions, the list has been identified as influential in companies' work on substitution. The fact that the candidate list is regularly updated induces chemical companies to work proactively with substitution and to find out the chemical content of their articles. (Swedish Chemicals Agency, 2011b) However, considering the large number of chemicals in commercial use in the EU, the authorisation and information requirements apply only to a very small share; out of a thousand substances on the EU market, one has currently been identified as a SVHC (Swedish Chemicals Agency, 2011b).

In addition to REACH, a number of product-specific legislations have also been implemented during the last decade in the EU. These legislations regulate chemicals in different categories of articles, such as toys, electrical and electronic equipment, packaging materials and vehicles. Such product-specific rules have emerged gradually as a response to indications or occurrences of health or environmental problems. This reactive process has contributed to making EU chemicals legislations diverse and sometimes incoherent (Swedish Chemicals Agency, 2011b; Molander and Rudén, 2012; Molander et al., 2012).

The need for additional product-specific and targeted rules have, however, been stressed as a way to increase the protection of human health and the environment (e.g. Molander and Rudén, 2012). As part of the Swedish strategy for a non-toxic environment, it was recently suggested that new rules should be introduced in the EU concerning the use of dangerous chemicals in textiles. An important reason behind the proposal that stricter use restrictions and extended information

[4] The identification of a SVHC is based on hazard criteria for CMR cat 1 or 2, PBT, vPvB and/or substances "which give rise to an equivalent level of concern" (REACH, Art. 57).

requirement on chemicals in textiles is needed is that textiles constitute an article category which children come into close contact with and where exposure to dangerous chemicals may occur (MMB, 2012; Swedish Chemicals Agency, 2012).

Regulations that concern chemicals in articles are harmonized within the EU. It is therefore difficult for member states to introduce national rules, although it happens now and then when risks associated with chemicals in articles are assessed as unacceptable and not sufficiently managed by existing EU legislations (Swedish Chemicals Agency, 2011b). Denmark recently decided to ban four phthalates (DEHP, DBP, DIBP and BBP) from use in consumer products, including imported products, due to their endocrine-disrupting properties and potential for synergistic effects (EC, 2012). Another recent example is the extended use restrictions of BPA introduced in for example Denmark and Sweden to also include food packaging for children under three years of age in addition to the current EU ban on BPA in feeding bottles (Swedish Ministry of the Environment, 2012; Ministry of Food, Agriculture and Fisheries of Denmark, 2010; EC, 2011).

2.3.2 Voluntary approaches

To accelerate the work towards achieving a safe and sustainable use of chemicals in articles, voluntary approaches can be used to complement regulatory restrictions and bans. As a complement to mandatory rules, voluntary initiatives are thought to offer "win-win" outcomes where the regulators achieve for example environmental and health objectives to a lower enforcement cost and where the regulated community can take part in the development and implementation plans for reaching these objectives (Daley, 2007). Voluntary approaches include for example different kinds of information efforts. Information about the chemical content of articles is crucial for article-producing companies to be able to substitute the use of a hazardous chemical with a safer alternative substance or technical solution in the early stages of development and design or production of a material or component. (MMB, 2012)

Common voluntary information instruments are targeted information campaigns and positive labelling. These may increase the receivers' knowledge and perception of hazards and risks, and subsequently sometimes lead to changes in attitudes and behaviour, although results are divergent to what extent this is the case (e.g. Leire and Thidell, 2005). Consumers that are provided with information about the content of hazardous chemicals in articles in a user-friendly format may thus change their consumption patterns. Increased knowledge will enable consumers as well as purchasers, for example in procurement, to make more informed choices, take

precautionary actions and ask for or require alternatives. This will put pressure on producers and suppliers of articles and may ultimately result in the phase out of chemicals with unwanted properties. Voluntary information efforts may hence contribute to the development of a more sustainable production with regard to human health, the environment and the use of resources. (Swedish Chemicals Agency, 2011b)

In order to facilitate and encourage industry to move to safer substitutes there are voluntary initiatives that aim to evaluate the safety of alternative chemicals. One such example is the Substitution Support Portal (Subsport; http://www.chemsec.org/subsport), which among other things contains inspirational case stories on successful substitutions provided by companies. Besides identifying safer alternatives to hazardous chemicals, these approaches, known as alternative assessments, can also disseminate information about limitations of substitute chemicals for certain uses (Lavoie et al., 2010).

Voluntary initiatives may take the form of voluntary commitments, i.e. where it is optional to participate in a cooperation or sign an agreement, but once one has joined one is committed to follow the plans and work towards the goals agreed upon (Swedish Chemicals Agency, 2011b). SAICM is an example of such a voluntary commitment (SAICM, 2008). The overall aim of SAICM is to achieve the goal agreed upon in Johannesburg in 2002 at the World Summit on Sustainable Development that by 2020 chemicals should be "used and produced in ways that lead to minimization of significant adverse effects of human health and the environment" (SAICM, 2008; SAICM 2012). An important step towards this goal is that all actors, including consumers, have increased access to information on chemicals in products throughout their entire life cycle, including the waste stage, as outlined by Objective 15 of the SAICM Overarching Policy Strategy (SAICM, 2006).

Economic instruments have proven to sometimes constitute effective incentives for reaching environmental goals. The use of economic incentives, such as taxes and fees, has however been practiced only to a limited extent for minimizing the use of hazardous or untested chemicals. Internationally, existing chemicals control through economic incentives mainly concerns waste, packaging and single substances. The use of economic instruments for managing risks associated with the use of chemicals in articles is also possible, although it is more complicated than for single substances. The challenge is due to the limited knowledge of which articles contain hazardous chemicals and in what concentrations (Swedish Chemicals Agency, 2011b). Besides the recent ban of four phthalates in certain consumer products, Denmark has practiced the use of fees to regulate the use of phthalates in plastic

materials and different kinds of consumer products (Swedish Chemicals Agency, 2011c).

3. Preview of papers

Based on literature reviews, systematic and empirical analyses were conducted for the studies reported in Paper I, II and III. The literature mainly comprised of (1) scientific research in the area, (2) existing and proposed regulatory acts, and (3) guidance and policy documents. In Paper II, a principal component analysis (PCA) was conducted for quantitative pattern recognition in addition to the literature studies. The PCA was done by collaborative partners with expertise in the area, Patrik Andersson and Aleksandra Rybacka at Umeå University.

3.1 Paper I

This paper examines what strategies are in place for regulating risks associated with hazardous chemicals in consumer products in the EU for various categories of products. The focus is on toys as regulated by the Toys Safety Directive, electrical and electronic equipment as regulated by the Restriction of Hazardous Substances (RoHS) Directive, and most other articles as regulated by REACH. The paper discusses a number of implications for the protection of human health and the environment possibly resulting from these current risk management strategies, as well as providing recommendations for increased protection.

The three legislations differ significantly in several respects, including what criteria are used for the selection of substances to be targeted for regulation, the kind of requirements and restrictions applied to the selected substances, and what information reaches consumers with regard to chemical properties and content in the different article categories.

One of these differences concern how maximum chemical concentration limits are applied to articles. According to REACH, the concentration of a chemical is based on the weight of the entire complex article, while the concentration limits in the RoHS Directive apply to homogeneous materials in an article. As the concentration limit in REACH is connected to an information requirement, the interpretation has implications for the amount of information that reaches the end user. Another important difference is that all rules in the Toys Safety Directive and the RoHS Directive apply both to articles that are produced in the EU and to imported articles. On the contrary, particularly hazardous substances, so-called substances of very

high concern (SVHCs), contained in imported articles fall outside the authorisation requirement under REACH.

Many of the differences depend on the context in which the legislations were developed and passed. The differences, however, have the consequence that the same chemicals may be regulated differently when used in different articles. This can be problematic when those you especially want to protect, often children, are exposed to a chemical via various consumer products. Such a situation can for example be seen today for di(2-ethylhexyl)phthalate (DEHP) and BPA, where the latter was recently banned in baby bottles in the EU but is continued to be used in a variety of other products that children come into contact with in their everyday lives.

One conclusion is that product directives are important complements to REACH because they can be more specific and targeted in their restrictions. We suggest that it should be evaluated whether product-specific directives, similar to RoHS and the associated Waste Electrical and Electronic Equipment (WEEE) Directive, which regulates electrical and electronic products in the waste phase, could be suitable also for other products where hazardous chemicals are present and the use is widespread. Textiles and building products constitute such examples.

3.2 Paper II

Paper II studies to what extent REACH, which is the most comprehensive chemical legislation applicable to most of the articles on the European market, is coherent with the chemical restrictions and requirements in the Sewage Sludge Directive (SSD) and the Water Framework Directive (WFD), respectively. This was done against the background of the EU environmental policy, which states that environmental damage should be rectified at source and that preventive actions should be taken according to the precautionary principle. Translated into the context of chemicals in articles, those principles could arguably hold that the input of hazardous chemicals into articles should be avoided or minimized in order to prevent problems from arising at the end-of-pipe, which may contribute to difficulties in achieving environmental and health goals.

The coherence analysis shows that the majority of the chemicals or groups of chemicals that are prioritized for phase-out under the WFD or for concentration restrictions in sludge and soil under the SSD are allowed to be used in articles according to REACH. In addition, a principal component analysis (PCA) was conducted which shows that the chemicals that are regulated for use in articles

under REACH deviate from classical legacy environmental pollutants. This indicates a need for new methods for prioritizing of chemicals to be targeted for restrictions in articles, and perhaps also for screening methods to be revised in order for environmental research to focus on important sources of exposures. The incoherencies in which substances are prioritized and in the levels of restriction between REACH and the SSD and WFD are a possible obstacle for reaching environmental goals. They are also not in line with the EU environmental policy principles.

It is argued here that, in order to minimize risks associated with chemicals in articles to or via the environment, and at the same time enable recycling of materials free from hazardous substances and increase resource efficiency, (1) the prioritization of which substances should be targeted by the restrictions and requirements concerning articles under REACH should to a greater extent take into account substances that have been identified as priority substances by the WFD or through other means as posing a risk to or via the environment, (2) suppliers should be required to declare the chemical content of articles to make the tracing and management of the sources of many environmental pollutants easier, and (3) the authorization requirement under REACH should also target SVHCs in imported articles.

3.3 Paper III

The purpose of this paper is to clarify what the substitution principle means and how it can reasonably be applied as part of chemicals policies.

A number of different definitions of the substitution principle exist, many of which emphasize that functional equivalence of the substitute is a decisive factor for substitution to take place or not. Here we propose a general definition that gives equal weight to hazard, functionality and economical considerations, while at the same time recognizing that the aim of the substitution principle is to reduce hazards to human health and the environment.

The EU legislations analyzed in Paper I are here evaluated with regard to their ability to promote substitution of hazardous chemicals to safer alternatives. Some legislations, e.g. the RoHS Directive, use what is here referred to as a substance-specific approach, i.e. they regulate substances that are explicitly listed. This approach will have a direct effect on information dissemination and substitution of hazardous chemicals in articles as the responsible agent needs to assure that the listed substances are not used. The disadvantage is that it does not, by itself, create

incentives for generating information and for substitution to take place beyond what is currently required. As an alternative, a criteria-based approach can be used, i.e. where a set of criteria needs to be applied in order to identify substances for regulation. As opposed to substance-specific risk reduction strategies, its strength is that it includes processes both for identifying and restricting substances of concern. However, such an approach risks becoming complex, and includes several processes that could be both time- and resource consuming. One process that runs this risk is the REACH authorization process.

It is also recognized that substitution of substances as such and in mixtures is supported by current legislations to a greater extent than substitutions of substances used in articles.

Furthermore, this paper summarizes major methods, both regulatory and voluntary, to promote and implement the principle. A critical problem for substitution work and for chemical risk management in general, is that many companies do not have access to adequate information about the chemical contents of the materials that they use. Thus, among the methods that promote substitution are those that include the increase of availability of toxicity data and information on the chemical composition of materials. To make informed decisions on risk reduction, including decisions on substitution, it is essential that available knowledge about the properties of chemicals, and the content of products, is disseminated to relevant actors. Other methods to stimulate substitution include e.g. providing information about successful substitution projects, listing unwanted substances, banning dangerous substances, and introducing economic incentives.

To enable efficient implementation of the substitution principle it is here concluded that actual or expected legislations are important drivers, and that regulations should not be too detailed on what substances to substitute in order to put pressure on companies to take initiatives themselves. However, a more systematic evaluation of the effects of substitution-promoting measures is needed.

4. Discussion

As shown in Paper II, the great majority of the commercially available chemicals in the EU are not restricted for use in articles, including substances that are considered especially hazardous, such as carcinogenic, mutagenic and reprotoxic (CMR) substances, EDCs and strongly sensitizing chemicals (Swedish Chemicals Agency, 2011b). When assessing human health and environmental risks, it is also of importance to take into account the substances' persistence and potential to bioaccumulate in biota. A preliminary inventory done in 2011 of the chemical properties of the about 100 chemicals present in highest average net amounts in articles made of plastics, textiles and rubber in Sweden[5] showed that almost one fourth of these chemicals were known persistent, bioaccumulative and toxic (PBT) substances or structurally resembled chemicals with PBT properties.

Lack of protective legislations can cause problems in all life-cycle stages of an article. Although this thesis mainly analyzes and discusses strengths and shortcomings of how risks associated with hazardous chemicals in articles are managed *after* incorporation in or addition to different materials, one overall conclusion that follows from Papers I-III is that hazardous chemicals should be avoided already at the stage of production. This would also improve the protection of the health of the workers and the surrounding environment involved at the earlier stages of an article's life cycle.

The emphasis on preventive and precautionary actions in the EU environmental policy is also supported by the Council conclusions on sustainable materials management and sustainable production and consumption, which were adopted in December 2010 by the EU environmental ministers. They emphasize the importance of the European Commission's strategy for a "resource-efficient Europe" to also include measures for reduced use of hazardous substances in materials and for avoidance of recirculation of these substances. (Swedish Chemicals Agency, 2011b) As is also pointed out in Paper II, the presence of harmful chemicals in articles makes it difficult to reuse and recycle materials and other end-products, such as sludge and ash, without reintroducing new risks to

[5] The data is retrieved from the Commodity Guide database, constructed by the Swedish Chemicals Agency. The Commodity Guide is a publicly available database, which contains information on what chemicals different materials and articles might contain and in what concentrations. The information is based on a Danish comprehensive survey asking manufacturers about the composition of their products and data provided by Statistics Sweden (The Commodity Guide: https://webapps.kemi.se/varuguiden/default.aspx).

human health and the environment. There is a need to promote green, or sustainable, chemistry efforts, i.e. to manufacture and use less harmful substances.

Increased data requirements on chemical properties and uses and improved transfer of such information in the supply chain to reach all actors would enable a more meaningful assessment of hazards and risks as well as a better targeted risk management of an article's all life cycle stages. As is emphasized in Paper III, the main responsibility for preventing risks of negative impacts on human health or the environment rests with the producing or importing companies. They are responsible for the generation and gathering of toxicity and exposure data in order to characterize risks, provide information relevant for safe handling and substitute hazardous substances by safer alternatives.

The scope of this licentiate thesis is mainly focused on chemicals management within the EU, however, it is important to note that the trade with articles is global and thus chemicals control within the EU is not only a regional matter, but one that affects and is affected by international conditions. More and more of the production of chemical products and articles is located in areas with fast economic growth, such as parts of Asia and Latin America, where chemicals control is less restrictive than in the EU (Swedish Chemicals Agency, 2011a).

The complex nature of the risks associated with chemicals present in articles requires a combination of different risk reduction strategies in order to be managed sufficiently. These could include both regulatory and voluntary measures that are of both international and regional character, as well as being general or specific in targeting chemicals in articles for restrictions and requirements. One of the conclusions in Paper I, that there is a need for specific rules for certain types of articles, arguably for textiles and building materials, is also highlighted in and supported by the Swedish Chemicals Agency's comprehensive review of EU legislations related to chemicals control (Swedish Chemicals Agency, 2012).

4.1 Conclusions and recommendations

Based on the results from Papers I-III, three main conclusions and recommendations are that:

(1) The complex nature of health and environmental risks associated with chemicals in articles requires a combination of regulatory risk reduction strategies that are of both general character and specific in targeting chemicals in articles for restrictions and requirements.

(2) Requirements on the generation of effect and exposure data, information on the chemical content of articles and information dissemination need to be increased. This will facilitate substitution of hazardous chemicals to safer alternatives and enable supply chain actors and other stakeholders to improve the management of risks.

(3) A life cycle perspective needs to be introduced to chemicals control for it to be effective towards reaching the EU environmental objectives. To obtain improved resource efficiency and a sustainable development it is necessary to minimize the input of hazardous chemicals into articles. This will help ensure that environmental goals can be met and that waste and other end-products can be reused and recycled without harming human health or the environment.

5. Future work towards a PhD thesis

A contributing factor to why chemicals in articles have become a prioritized issue is likely the recognition that low doses may result in adverse health and environmental outcomes. EDCs constitute one group of chemicals that have shown to produce known or potential adverse effects at doses below current reference doses and at environmentally relevant levels (Vandenberg et al., 2012). Many chemicals identified as being of concern in articles have endocrine-disrupting properties. A few chemicals exhibiting such properties have already been touched upon in this thesis, e.g. BPA, nonylphenol and octylphenol, for which incoherencies in substance priority and restrictions between REACH and the WFD were identified in Paper II. These are widely used in consumer products and/or widespread environmental contaminants.

My next two papers will concern risk assessment practices relevant for chemicals in articles, with a focus on EDCs. More specifically, the first paper will involve an in-depth and systematic study of low-dose toxicity studies of BPA as part of the need to develop appropriate and sensitive criteria for identification of EDCs as well as for the refinement of the BPA risk assessment. This study aims to characterize the low-dose endpoints with regard to e.g. the nature and distribution of reported effects, at what dose levels the studied effects are reported, and the occurrence of non-monotonic dose-response relationships. In the second paper we will suggest criteria for the evaluation of reliability and relevance of non-guideline studies, as well as developing guidelines for reporting of such studies. The aim is to enable a better use of non-guideline data in risk assessments.

This work, which is already ongoing, is performed in collaboration with researchers at the Institute of Environmental Medicine (IMM), Karolinska Institutet.

References

Centers for Disease Control and Prevention (CDC), 2009. Fourth national report on human exposure to environmental chemicals. Available at: http://www.cdc.gov/exposurereport (accessed 2012-09-25).

Daley D.M., 2007. Voluntary approaches to environmental problems: Exploring the rise of nontraditional public policy. *The Policy Studies Journal* 35(2): 165-180.

de Wit C., Thuresson K., Björklund J., 2008. Brominated flame retardants and perfluorinated compounds in air and dust from indoor environment in Stockholm. Institutionen för Tillämpad Miljövetenskap, Stockholms Universitet. Stockholms stads rapportserie Nya gifter – nya verktyg. ISSN: 1653-9168.

European Chemicals Agency (ECHA), 2012. Pre-registered substances: http://echa.europa.eu/web/guest/information-on-chemicals/pre-registered-substances (accessed 2012-10-20).

European Commission (EC), 2003. European Commission Technical Guidance Document in Support of Commission Directive 93/67/EEC on Risk Assessment for New Notified Substances and Commission Regulation (EC). No 1488/94 on Risk Assessment for Existing Substances, Part II.

European Commission (EC), 2006. Registration, evaluation, authorisation and restriction of chemicals (REACH). Regulation (EC) no 1907/2006 of the European Parliament and of the Council. Off. J. Eur. Commun. L396, 1-849.

European Commission (EC), 2008. Classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006 Regulation (EC) No. 1272/2008 of the European Parliament and of the Council. Off. J. Eur. Commun. L353, 1–1355.

European Commission (EC), 2011. Commission Directive 2011/8/EU of 28 January 2011 amending Directive 2002/72/EC as regards the restriction of bisphenol A in plastic infant feeding bottles. Off. J. Eur. Union, L 26/11, 1-11.

European Commission (EC), 2012. Communication from the Commission - SG(2012) D/5564. Notice banning the import and sale of products intended for indoor use which contain the phthalates DEHP, DBP, BBP, and DIPB, and products which contain these substances in parts of the products which may come into

contact with skin or mucous membranes: http://ec.europa.eu/enterprise/tris/pisa/app/search/index.cfm?fuseaction=pisa_notif_overview&iYear=2012&inum=124&lang=EN (accessed 2012-09-25).

European Environment Agency (EEA), 2012. The impacts of endocrine disrupters on wildlife, people and their environments – The Weybridge+15 (1996-2011) report. EEA Technical report, No 2/2012. Luxembourg: Publications Office of the European Union. ISSN: 1725-2237

Faustman E.M. and Omenn G.S., 2001. Risk Assessment. In: Casarett & Doull's toxicology. The basic science of poisons. 6th ed. Klaassen C.D. Macgraw-Hill. ISBN: 0-07-112453-5.

Fick J., Söderström H., Lindberg R.H., Chau D.N.P., Tysklind M., Larsson D.G.J., 2009. Contamination of surface, ground, and drinking water from pharmaceutical production. *Environmental Toxicology and Chemistry* 28: 2522-2527.

Hansson S.O., 2009. Waste management. In: Callicott J.B. and Frodeman R., Eds. 2009. Encyclopedia of environmental ethics and philosophy. Vol. 2. Gale, Cengage Learning, USA.

Hansson S.O., Molander L., Rudén C., 2011. The substitution principle. *Regulatory Toxicology and Pharmacology* 59: 454-460.

Lavoie T.E., Heine G.L., Holder H., Rossi S.M., Lee II E.R., Connor A.E., Vrabel A.M., Difiore M.D., Davies L.C., 2010. Chemical alternatives assessment: enabling substitution to safer chemicals. *Environmental Science & Technology* 44: 9244–9249.

Leire C. and Thidell Å., 2005. Product-related environmental information to guide consumer purchases – a review and analysis of research on perceptions, understanding and use among Nordic consumers. *Journal of Cleaner Production* 13: 1061-1070.

Main K.M., Kiviranta H., Virtanen H.E., Sundqvist E., Tuomisto J.T., Tuomisto J., et al., 2007. Flame retardants in placenta and breast milk and cryptorchidism in newborn boys. *Environmental Health Perspectives* 115(10): 1519-1526.

Massey R.I., Hutchins J.G., Becker M., Tickner J., 2008. Toxic substances in articles: The need for information. Copenhagen: The Nordic Council of Ministers, 2008, TemaNord 2008:596.

Mercier F., Glorennec P., Thomas O., Le Bot B., 2011. Organic contamination of settled house dust, a review for exposure assessment purposes. *Environmental Science & Technology* 45: 6716-6727.

Miljömålsberedning (MMB), 2012. Miljömålsberedningens expertgrupp om farliga ämnen i produkter och varor -Underlag till Miljömålsberedningens arbete med en strategi för en giftfri miljö. Draft report in Swedish.

Ministry of Food, Agriculture and Fisheries of Denmark, 2010. Danish ban on bisphenol A in materials in contact with food for children aged 0-3: http://www.fvm.dk/Default.aspx?ID=18488&PID=169747&NewsID=6014 (accessed 2012-09-25).

Molander L. and Cohen A.K., in press. EU and US regulatory approaches to information on chemicals in products: Implications for consumers. Forthcoming in *European Journal of Risk Regulation*.

Molander L. and Rudén C., 2012. Narrow-and-sharp or broad-and-blunt – Regulations of hazardous chemicals in consumer products in the European Union. *Regulatory Toxicology and Pharmacology* 62: 523-531.

Molander L., Breitholtz M., Andersson P.L., Rybacka A., Rudén C., 2012. Are chemicals in articles an obstacle for reaching environmental goals? – Missing links in EU chemicals management. *Science of the Total Environment* 435-436: 280-289.

Mori C. and Todaka E., 2008. Environmental contaminants and children's health, Sustainable health science for future generations. Center for Preventive Medical Science, Chiba University, Japan. MARUZEN PLANET Co.,Ltd.

National Research Council (NRC), 1983. Risk assessment in the federal government – managing the process. National Academy Press, Washington D.C., USA. ISBN: 0-309-03349-7.

Ongondo F.O., Williams I.D., Cherrett T.J., 2011. How are WEEE doing? A global review of the management of electrical and electronic wastes. *Waste Management* 31(4): 714-730.

Rudén C. and Hansson S.O., 2006. Improving REACH. *Regulatory Toxicology and Pharmacology* 44(1): 33-42.

Ruden C. and Hansson S.O., 2010. Registration, Evaluation, and Authorization of Chemicals (REACH) is but a first step - How far will it take us? Six further steps to

improve the European chemicals legislation. *Environmental Health Perspectives* 118(1): 6-10.

Shubber H., 2012. Strategic Approach to International Chemicals Management – Development and opportunities. In: Wexler P., van der Kolk J., Mohapatra A., Agarwal R., Eds, 2012. Chemicals, Environment, Health – A global management perspective. CRC Press, Taylor & Francis Group. ISBN: 978-1-4200-8469-6.

Strategic Approach to International Chemicals Management (SAICM), 2006. Draft overarching policy strategy, SAICM/ICCM.1/3, Dubai. Available at: http://www.chem.unep.ch/ICCM/meeting_docs/iccm1_3/3%20OPS%20E.pdf (accessed 2012-09-25).

Strategic Approach to International Chemicals Management (SAICM), 2008. SAICM Information bulletin No I. Available at: http://www.saicm.org/documents/Publications/SAICM%20Information%20Bulletin%20No%201%20Jan%202008.pdf (accessed 2012-09-23).

Strategic Approach to International Chemicals Management (SAICM), 2012. Introducing SAICM: http://www.saicm.org/index.php?option=com_content&view=article&id=72&Itemid=474 (accessed 2012-09-26).

Swedish Chemicals Agency, 2010. Chemical industry from an economic perspective – Development trends in the world, the EU and Sweden in 2010. Rapport 5/10. Available at: http://www.kemi.se/sv/Innehall/Publikationer/Rapporter/

Swedish Chemicals Agency, 2011a. Handlingsplan för en giftfri vardag 2011-2014 – Skydda barnen bättre. In Swedish. Available at: http://www.kemi.se/documents/publikationer/trycksaker/handlingsplan-giftfri-vardag.pdf (accessed 2012-09-205)

Swedish Chemicals Agency, 2011b. Kemikalier i varor – Strategier och styrmedel för att minska riskerna med farliga ämnen i vardagen. Rapport 3/11. In Swedish. Available at: http://www.kemi.se/sv/Innehall/Publikationer/Rapporter/

Swedish Chemicals Agency, 2011c. Internationell förekomst av ekonomiska styrmedel på kemikalieområdet. PM 1/11. In Swedish. Available at: http://www.kemi.se/sv/Innehall/Publikationer/PM/

Swedish Chemicals Agency, 2012. Bättre EU-regler för en giftfri miljö – rapport från ett regeringsuppdrag. Rapport 1/12. In Swedish. Available at: http://www.kemi.se/sv/Innehall/Publikationer/Rapporter/

Swedish Ministry of the Environment, 2012. Government prohibits bisphenol A in baby food bottles: http://www.sweden.gov.se/sb/d/15926/a/190565 (accessed 2012-09-25).

Swedish National Food Agency, 2011. Riskprofil för material i kontakt med livsmedel. Rapport 5. In Swedish. Available at: http://www.slv.se/sv/grupp3/Rapporter/Kemiska-amnen/

United Nations Environment Programme (UNEP), 2012. Global Environmental Outlook (GEO) 5. Environment for the future we want. Chemicals and Waste. ISBN: 978-92-807-3177-4.

Vandenberg L.N., Colborn T., Hayes T.B., Heindel J.J., Jacobs Jr. D.R., Lee D.-H., et al., 2012. Hormones and endocrine-disrupting chemicals: Low-dose effects and non-monotonic dose responses. *Endocrine Reviews*, doi: 10.1210/er.2011-1050

van Leeuwen, C. J. and Vermeire, T. G., Eds. 2007. Risk Assessment of Chemicals: An Introduction. Springer. ISBN: 1402061013.

Wandall B., 2004. Values in science and risk assessment. *Toxicology Letters* 152(3): 265-272.

Watson G., 2005. Detox Campaign, Generation X – Result of WWFs European Family Bio-monitoring Survey. Världsnaturfonden WWF.

Woodruff T.J., Zota A.R., Schwartz J.M., 2011. Environmental Chemicals in Pregnant Women in the US: NHANES 2003-2004. *Environmental Health Perspectives* 119(6), 878-885.

World Health Organization (WHO), 2004. International Program on Chemical Safety (IPCS). IPCS Harmonization Project. IPCS Risk Assessment Terminology. Available at: http://www.inchem.org/documents/harmproj/harmproj/harmproj1.pdf (accessed 2012-09-26)

World Health Organization (WHO), 2012. Endocrine disrupters and child health – Possible developmental early effects of endocrine disrupters on child health. Geneva, Switzerland: WHO Document Production Services. ISBN: 978 92 4 150376 1.

Zhang K., Schnoor J.L., Zeng E.Y., 2012. E-waste recycling: Where does it go from here? *Environmental Science & Technology* 46: 10861-10867.