Framework for combining REACH and national regulations to obtain equal protection levels of human health and the environment in different countries — Comparative study of Denmark and Korea

Jihyun Lee, Anders Brandt Pedersen, Marianne Thomsen*

Department of Environmental Science, Faculty of Science and Technology, Aarhus University, Frederiksborgvej 399, 4000 Roskilde, Denmark

ABSTRACT

The aim of this paper is to present a conceptual framework for a systems approach to protect the environment and human health by taking into account differences in the cumulative risks of total human exposure in a territorial context. To this end the measures that are available and that can be included in REACH exposure scenarios in order to obtain territorially relevant chemical safety assessments (CSAs) were explored. The advantage of linking the REACH exposure scenarios with background environmental quality data reported under other national regulations is discussed. The main question is how REACH may be improved to protect the environment and human health inside and outside the EU. This question is exemplified in a comparative case study of two countries, Denmark and Korea, each with its own set of different environmental qualities and national regulations. As a member of the EU Denmark is obliged to adopt REACH, while Korea implemented REACH to improve the competitiveness of Korean industry within the EU market. It is presented how differences in national regulations and environmental qualities in these two countries affect background human exposure concentrations. Choosing lead as a model compound, the territorial differences in background exposure to endocrine and neurological interfering stressors were modelled. It is concluded that the different territorial soil and air lead pollution levels contribute differently to the total childhood lead exposure in the two countries. As such, the probability of the total exposure from air and soil exceeding 10% of the provisional Total Daily Intake (PTDI) is estimated to be 55.3% in Denmark and 8.2% in Korea. The relative contribution from air inhalation and soil ingestion to childhood lead exposure is estimated to be 1—99% in Denmark while it is 83—17% in Korea.

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1. Introduction

Chemicals are widely used in our daily life, almost everywhere and in everything. To control and protect human health from chemical exposures, regulators need scientific input regarding potential harmful impacts of the chemicals on the market and in the environment. Additionally, to set appropriate standards for the environment, products and food, decision-makers need an answer to the following question: what is the risk of the substance? Basically, risk is defined as a function of hazard and exposure. In practice, assessing risk is a complex matter: we are exposed to a wide range of substances, some with similar, some with different toxic effects. We are exposed through multiple exposure routes

(i.e. inhalation, ingestion and dermal contact), and exposure originates from multiple sources within the working and living environment, all complicating the exposure scenarios (Boriani et al., 2011, 2013; Boogaard et al., 2011; Soerensen et al., 2010a,b; Thomsen et al., 2006, 2008, 2012). Therefore, assessing and managing cumulative risks from multiple sources and stressors pose a challenge in the regulation of chemicals (Assmuth et al., 2010). International organizations and national governments have used various risk assessment tools for setting policy goals, analysing cost-benefit aspects, and evaluating substitutes and alternatives (EEB, 2005; NRC, 2009; WHO, 2012). One example is the European Community regulation on chemicals and their safe use, called REACH (Registration, Evaluation and Authorization of Chemicals) (EC, 2006a). When it entered into force in June 2007, REACH was considered the world's strictest regulation on toxic chemicals (San Francisco Chronicle, 2006 and Section 3.1). The REACH regulation aims to 1) *improve the protection of human health and the environment from the risks that can be posed by chemicals*; 2) *enhance the*

* Corresponding author. Tel.: +45 871 58602; fax: +45 46301212.
  E-mail addresses: jile@dmu.dk (J. Lee), apd@dmu.dk (A.B. Pedersen), mth@dmu.dk (M. Thomsen).

competitiveness of the EU chemicals industry, a key sector for the economy of the EU; 3) *promote alternative methods for the assessment of hazards of substances*, and 4) *ensure the free circulation of substances on the internal market of the European Union* (EC, 2006a, Title I, Chapter 1, Article 1.1)). The introduction of REACH has wide-reaching impacts on chemical risk governance as it has shifted the burden of proof from authorities to industrial sectors, following the principle of 'no data − no marketing' (Assmuth et al., 2010). Industries outside the EU have to evaluate and document the level of risk associated with chemical substances in products prior to their import into the EU market (KMOE, 2012a). Furthermore, the risks associated with manufacture, use and any release to the environment after use have to be documented prior to marketing. As such, the REACH regulation is expected to influence the chemical substance flow in products inside and outside the EU; and thereby, environmental quality and human exposure, not only within EU countries but also in non-EU countries exporting their products to the EU market.

In respect to the first aim of REACH, which is to improve the protection of human health and the environment from risks that can be posed by chemicals, a broader perspective taking into account environmental health (EH) is needed (Barouki et al., 2012; WHO, 1999, 2011b). The health of human beings is influenced by the quality of the surrounding environment and the services provided by ecosystems in the region they live in. While ecosystems were formerly assumed to possess unlimited capacity to assimilate waste, it is now evident that the sustainability of ecosystems is threatened by degradation and not only by overexploitation of resources (Rockström, 2009). Historical, existing and emerging pollutants may also affect environmental quality and cause environment and human health problems (Bester et al., 2008; Pizzol et al., 2011; Thomsen et al., 2012). Therefore, REACH should take into account the differences in territorial environmental qualities caused by historical and existing industrial activities as well as the resulting differences in background exposure levels to present a worst-case exposure scenario and adopt a precautionary approach to deriving the predicted environmental concentration (PEC) values. Only by applying such a systemic approach to the REACH exposure scenario will REACH be able to document its progress towards the aim of improved protection of environment and human health.

Pollutants from human activities that were, and are presently, being used and released are continuously moving through the human and natural environment, while being transported and transformed in abiotic and biotic processes. As such, chemicals may degrade or accumulate according to persistence, fate, transport, and the detoxifying capacity of the natural system (Boriani et al., 2013; Pizzol et al., 2012; Thomsen et al., 2012; Vorkamp et al., 2009). The transport routes of hazardous substances to the environment, humans and other non-target organisms/populations as well as the combined effects from multiple exposures are difficult to evaluate and prevent by means of a single regulatory tool. This means that REACH alone cannot cover all sources of exposure or mixture toxicity (Assmuth et al., 2010). In this regard a systems approach is needed in order to solve the present EH problems (e.g. KMOE, 2011c; Danish Government, 2003, 2010; Thomsen et al., 2008; WHO, 1999). To fulfil the goals of REACH and to maximize the potential of REACH in contributing to improved protection of the environment and human health, the possibility of including local environmental quality data in the REACH exposure assessment tool for deriving PECs is reviewed in this paper. In order to verify the relevance of taking into account differences in territorial background exposure concentrations, the local environmental quality data are compared which are reported under existing national regulations and also needed in order to obtain an estimate of

territorial total exposure. The case of two countries were discussed; Denmark, which as an EU country is required to implement the REACH regulation and Korea, where the REACH regulation is implemented voluntarily to make Korean industry competitive in the EU market. Finally, a conceptual framework is proposed for a systems approach capable of monitoring, verifying and assessing future EH problems upon the release of new chemicals into different territorial background contamination levels within human and natural systems.

2. Methods

Firstly (Section 3), it is reviewed which transport pathways and routes of exposure that are, and are not, included in the guidelines describing the REACH exposure assessment tool (Section 3.1). Next, other national regulations and environmental management tools that may provide input data for quantifying background environmental quality for inclusion in REACH exposure scenarios are reviewed (Section 3.2). Then a conceptual framework for a systems approach to include background environmental quality as part of the chemical safety assessment (CSA) under REACH is presented (Section 4). With reference to the situation of globally applied, harmonized environmental policies, the chemical regulations and environmental management tools in Denmark and Korea are reviewed (Section 5), which share the same aim as REACH, i.e. to protect environmental and human health from the risks of being exposed to hazardous pollutants (KMOE, 2011c; The Danish Government, 2003). First, environmental quality standards are compared for substances included in the national regulations for the protection of air, water (drinking, surface and groundwater) and soil quality in Denmark and in Korea (Section 5.1). Then the environmental monitoring data reported nationally (Section 5.2), and the levels of soil, water and air emissions reported under the PRTR (Pollutant Release and Transfer Register) regulation are compared with reference to the national environmental qualities and quality standards in the two countries (Section 5.3). Using lead as an example, it is shown that population background exposure in relation to national regulatory standards varies, which verifies the need for a holistic systems approach to be able to support REACH in reaching the goal of better and equal protection of the environment and human health at a territorial level. Lastly, children's lead exposure, via the environment, inhalation and soil/dust ingestion, in urban areas of these two countries was calculated by applying the Monte Carlo method for comparing environmentally conditioned childhood exposure levels, presented in Section 5.4.

3. REACH and other national regulations

Several national regulations exist aiming to protect the environment and human health. While REACH focuses attention on better control of the continued flow of chemicals within the European market, other national environmental regulations, e.g., the Water Framework Directive, the new Soil Directive and the Air Pollution Directive as well as the pollutant Release and Transfer Registers (PRTR), have been established to protect and improve environmental quality (EC, 2000, 2006b, 2008a, 2012b). In addition, mandatory regulatory instruments, such as environmental impact assessment (EIA) and strategic environmental assessment (SEA) and, most recently, the European environmental liability directive (ELD) are tools to control, prevent and alleviate impacts from industrial activities on the surrounding environment (EC, 1997, 2001, 2004). Similarly, a number of voluntary environmental management programs exist, such as certifications released in connection with the family of ISO 14000 regulations (e.g. Stevens et al., 2012). More recently extended to include the eco-management and audit

scheme EMAS and the eco-label award scheme, both of which are voluntary; although a legally binding reporting scheme with external audit is required to obtain the EMAS certification (EC, 2009, 2010). In this paper the focus is only on national legally binding regulations for which data are assumed available and ready for use in terms of quantified environmental quality data in a territorial context; the latter being of relevance for quantification of the total ecosystem level and human background exposure to support REACH in deriving PECs for appropriate total exposure from single chemicals and mixtures (Backhaus and Faust, 2012).

3.1. Completeness of the REACH exposure scenario

The European chemical legislation REACH (1907/2006/EC) entered into force in 2007 and streamlined and improved the former EU legislative framework on chemicals (EC, 2006a, 2012a). By amending and repealing several former directives and regulations — including the areas of risk assessment of existing and new substances, their classification, and safety data sheets — REACH can be considered a very complex regulation relating to chemical risk (Assmuth et al., 2010). Under REACH, a CSA is required only if a substance is manufactured or imported at/or above 10 tonnes per year. If a substance meets the criteria for classification as 'dangerous' in accordance with Regulation (EC) No. 1272/2008, or if it is persistent, bioaccumulative and toxic, or very persistent and very bioaccumulative, the chemical safety report has to include an exposure assessment and a risk characterization for manufacture and all identified uses of the substance (REACH Art. 14.4). Within these restrictions of knowledge (Soerensen et al., 2010a,b), the risks of chemical exposure are considered to be controlled when the predicted exposure levels (PEC) do not exceed the derived no effect levels (DNEL). If the risk characterization under the CSA indicates that the applied risk management measures and operational conditions, both for workers and consumers, are not adequate to control risks (PEC/DNEL > 1), the exposure estimation may need to be refined and re-evaluated until the PEC is under DNEL (REACH Annex I 5.1.1). However, iterative risk assessment seems more a single-chemical desktop exercise characterized by a 'linear business as usual' and 'close to source' responsibility of the producer. This approach gives little or no attention to the nature of cumulative risks from long-term accumulation of dispersive chemicals in the environment.

An exposure assessment describes the sources, pathways (the courses an agent takes from the source to the target), and routes (the way an agent enters a target after contact, e.g. ingestion, inhalation, or dermal absorption) (ECHA, 2012; Soerensen et al., 2010a,b; Thomsen et al., 2008; Zartarian et al., 2005). In REACH guidance on information requirements and CSA (ECHA, 2012), risk characterization for humans should "document the outcome of the combined risk via all pathways for the different populations separately, and combined (i.e., cumulative for workplace, exposure from consumer products and via the environment)" (Appendix to Part F, F.10.1.1). The guidance also includes detailed provisions regarding exposure assessments (Part D on exposure scenario building and in-depth guidance in R.12 to R.18). In particular, an exposure scenario includes a description of operational conditions, including the manufacturing, processing and use processes, the activities of workers or consumers, and the duration/frequency of the exposure to humans and the environment. It also includes risk management measures to reduce/avoid direct and indirect exposures of humans and the environment (REACH Annex I 5.1.1). Estimated human exposure contains different phases of activity (preparatory, application, post-use and post-application), all exposure routes (inhalation, dermal and oral), and acute/chronic exposure (ECHA guidance R.14 and R.15). In addition to this, indirect exposure via the environment is supposed to be calculated (ECHA guidance R.16). This indirect exposure is assessed both at the local and regional scale. The local area is the vicinity of single point sources and the region is a larger area which includes all point sources and emissions from widely dispersive uses of the chemical subject to the assessment in that area. The conditions of these areas are assumed in ECHA guidance to represent generic worst-case scenarios. The regional concentrations are used as 'background concentrations' in the calculation of PEC_{local} and added to the local concentrations close to the point source ($PEC_{local} = C_{local} + PEC_{regional}$) for a single chemical; i.e. the chemical under assessment. As such, there seems to be great potential to improve exposure assessments by integrating national and local policy regulations and monitoring programs with precautionary measures of risks of total exposure from chemical mixtures (COM, 2012).

Fig. 1 shows the specification of human exposure for consumers who represent the general public. The pathways shaded grey are covered by REACH exposure assessment as included in the ECHA guidance and reporting tool (ECHA, 2012; CHESAR, 2012).

As shown in Fig. 1, the grey REACH exposure assessment scenario includes exposure to a substance which is emitted to the environment by ongoing or planned activities of the registrant (pathway 1.1.2, 2.1.2) and exposure to the same substance which is transported from other regions (the third pathway of 1.1.1 and 2.1.1). For workers, the principle is the same, but exposure from product use (pathway 1.2, 2.3 and 3.2) is replaced by exposure from their working conditions. The risks for the environment cover the aquatic, the terrestrial and the atmospheric compartment and the microbiological activity in sewage treatment systems (CHESAR, 2012).

The ECHA guidelines for the quantification of exposure scenarios have been extended to include cumulative exposure by including indirect exposure via the environment and food (ECHA guidance R.16). However, as shown in Fig. 1, there are still other indirect exposure pathways that are not covered in REACH exposure assessment. Background environment quality is a combination of historical (accumulated) pollution and pollutants emitted by several facilities or different uses of substances. As the focus of REACH is the risk of a single substance from an identified use, cumulative risks, including risks from accumulated historical pollutants and from total emissions by several registrants, are not assessed under current REACH regulation (Assmuth et al., 2010; Groβ et al., 2011). As such, current REACH exposure assessment scenarios do not include all sources and pathways of exposure; even in a single-chemical approach assuming independent mode of action, background exposures from historically accumulated chemicals are missing. However, other regulatory frameworks and tools which have similar goals as REACH may provide input data for quantifying the contribution from background environmental exposure in a territorial context and work in synergy with REACH exposure scenarios. Appropriate background exposure data from these sources would allow for a single registrant to add source-specific data to the extended exposure scenario for use in cumulative exposure assessment.

3.2. National regulatory frameworks and tools for EH management

The Kiev protocol is the first legally binding international instrument on global pollutant release and transfer registers (PRTR). PRTR is a national/regional environmental database of pollutants released to environmental media (air, water and soil) and transferred off-site for treatment or disposal (UNECE, 2012; OECD, 2012a). As the information in PRTR is publicly available, this system is not only used for assisting governments to track the generation and release of pollutants and to set priorities for pollution
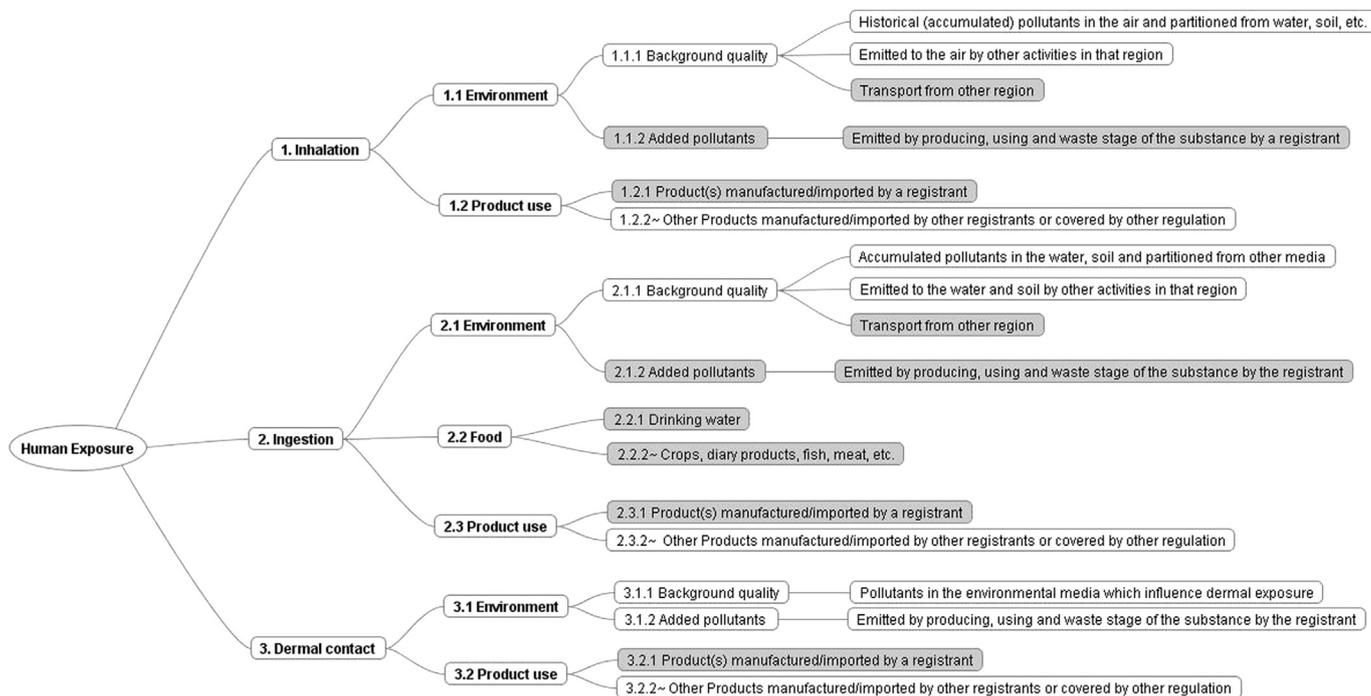
Fig. 1. Different routes, pathways and sources contributing to total human exposure. The pathways shaded grey are covered by the exposure assessment under REACH, while uncoloured pathways are not taken into account in REACH exposure scenario assessment (software used: FreeMind).

intervention policies, but to put pressure on industries not to be identified as among the biggest polluters (UNECE, 2012; EC, 2007). The PRTR regulation upon proper integration with other chemical regulations may provide input data to improve the REACH exposure scenario (cf. Section 6).

Life cycle assessment (LCA) is a voluntary tool to describe and analyse the life cycle environmental impacts of a product, system or technology; ideally from the extraction of resources, through production, use, and recycling, up to final disposal (Askham, 2012; JRC, 2010; Potting and Hauschild, 2006). However, like the REACH regulation, LCA does not take into account absolute measures of environmental quality in time and place, nor the cumulative risk from accumulation of the pollution and background environmental quality. One way to improve information on territorial background human exposure may be realised by embedding PRTR (pollutant release and transfer registers) in the new extended global EMS tool, EMAS III (Eco-Management and Audit Scheme, Regulation (EC) No 1221/2009) and combining this with data from national environmental monitoring programs.

Contrary to LCA, Environmental Impact Assessment (EIA) and Strategic Environmental Assessment (SEA) aim to protect the productivity and capacity of natural systems to maintain their ecological processes and functions by comparing different project/policy alternatives (UNEP, 2004; US CEQ, 1969). By integrating the principles of sustainable development into country policies and programs, the environmental effects of plans (e.g. land use development) and programs (e.g. waste management) are taken into consideration in SEA (OECD, 2006a; EC, 2001). Prior to the implementation of planned projects, programs and policies, EIA identifies the environmental, socioeconomic and human health impacts of projects, programs and policies. EIA may be used to implement legally binding international environmental agreements for the prevention of environmental degradation; for example, for hazardous chemicals, EIA is mandatory in Europe for landfill sites, incineration plants and chemical manufacturing facilities (EC, 1997; Gonzáles et al., 2008). Even though EIA/SEA have contributed to

more informed decision-making, assessment of cumulative impacts of long-term chemical exposure lags behind; probably due to inadequate understanding of long-term background exposures, environmental degradation and human health (UNEP, 2004). Adoption of the environmental liability directive (EC, 2004), supports greater acknowledgement of the interrelatedness between environmental quality, ecosystem services and human health and thereby the need for combined information and knowledge to increase action in the direction of better protection of the environment and human health (Smolders et al., 2008).

3.2.1. Denmark

In Denmark, after the 1960s, when environmental problems became a political issue, environmental regulation was established systemically (Christiansen, 1996; Pedersen, 2010). The Danish Ministry of the Environment (DMOE) and the Danish Environmental Protection Agency (DEPA) were founded in 1971 and 1972, respectively. In 1973, the first Danish framework act for environmental protection, "The Environmental Protection Act" was implemented. Today, Danish requirements for air quality are based on EU provisions (DEPA, 2011). Regarding water quality, there are five relevant EU directives (Nitrates, Water Framework, Groundwater, Drinking Water and Pesticides) and national quality standards for soil and groundwater are set up to protect human health (DEPA, 2010). Environmental control monitoring data in different media, groundwater, air, surface water, soil and sediment, are reported according to existing regulations (DMOE, 2012; NERI, 2010a, 2010b, 2010c; GEUS, 2012). Denmark follows the E-PRTR system, the European Pollutant Release and Transfer Register. E-PRTR (Regulation (EC) No 166/2006), which replaces the previous European Pollutant Emission Register (EPER) and is the new Europe-wide register system under the directive on Integrated Pollution Prevention and Control (IPPC). As REACH was adopted by the EU, Denmark has been implementing REACH since 2007 and strongly prioritizes endocrine disruptors, combination effects and chemicals in consumer products (The Danish

Government, 2010). Denmark imports a large share of its industrial products of which the synthetic chemical content is now controlled by REACH to protect consumers' exposure and, therefore, the main emission source from consumers' consumption may be the end-of-life products, i.e. the waste management system (SD, 2010).

3.2.2. Republic of Korea

Korea has experienced comprehensive industrial change since the state-led industrialization efforts of the 1960s (KMOE, 2012b). With rising concerns about environmental pollution issuing from the rapid industrialization and urbanization processes, the Korean Environmental Conservation act was enacted in 1977 and the Environmental Agency was established in 1980 under the Ministry of Health and Society and upgraded to the Korean Ministry of Environment (KMOE) in 1990. The Framework Act on Environmental Policy was enacted in 1990 and the environmental quality standards for air and surface water were established by this act (KMGL, 2011a). The quality standards for drinking water, groundwater and soil are set by separate laws, focussing specifically on each of the separate environmental media (KMGL, 2010, 2011b, 2011c). KMOE and research institutes under KMOE collect environmental quality data for air, surface water, groundwater, soil and sediments (KEC, 2012; NIER, 2012a, 2012b; KMGL, 2011d). When Korea became a member of OECD in 1996, PRTR was launched by means of a legal groundwork (amending the "Toxic Chemicals Control Act"). Today, in contrast to Denmark, manufacturing and energy-intensive facilities, e.g. in the shipbuilding industry and steel production, are still predominant in Korea, and the chemical industry has grown rapidly too (OECD, 2006b; KMOE, 2011a). As the EU is Korea's second largest export destination (14% in 2000), the Korean government responded very actively to the EU's REACH system and supports domestic companies in relation to REACH registration (KOSTAT & EUROSTAT, 2012). Korea's main imports are raw materials — petroleum, iron, gas, coal, etc — and major export products are industrial products such as electrical machinery, vehicles, and manufactured chemicals (KOSTAT & EUROSTAT, 2012). Therefore, compared with Denmark, the total emission from manufacturing and industrial use to the local environment may be much higher.

4. Systemic approach to protecting human health and the environment

Evaluating the total EH impact seems almost impossible as this would cover all areas of human activities that release pollutants, the environmental system as a container and/or reactor of those pollutants as well as the resulting impact on human health and the environment. In spite of several international and national regulations trying to control the emission of chemicals to the environment, total concentrations of pollutants in environmental media and biota are still increasing, as evidenced by the environmental burden of disease (e.g. WHO, 2011a; Pizzol et al., 2011). Materials, nutrients and substances within the natural system are circulated throughout environmental media and biota, as are pollutants. The concentration of persistent chemicals in the environment will increase steadily if environmental media are not remediated and/or emission rates are not reduced to a level that is lower than the chemical degradation rate in the environment. And countries experience different levels of environmental quality according to their historical and existing pollutant emission intensity (ECHA guidance R.17).

In order to improve the protection of human health and the environment, and to enhance the competitiveness of the chemical industry in a sustainable way, we need to assess and intervene against further increases in the cumulative risks of chemicals. One way would be to prevent further accumulation of persistent chemicals in the environment; i.e. maintaining the total level of exposure to humans and the environment below the level of adverse health effects — if indeed it is possible to define an 'acceptable level' such as this. A systems approach, integrating information from a number of regulatory instruments and management tools, may provide an estimate for the total substance flow crossing the human—environment system interface, making it possible to assess cumulative risks. Fig. 2 illustrates the raw material flows provided by the ecosystem and transformed and processed within the human system in different stages; planning, production, consumption, and waste treatment (in rectangles shaded grey). Fig. 2 also shows the regulatory instruments and management tools (in rounded rectangles), including environmental standards, PRTR, environmental monitoring, EIA/SEA,
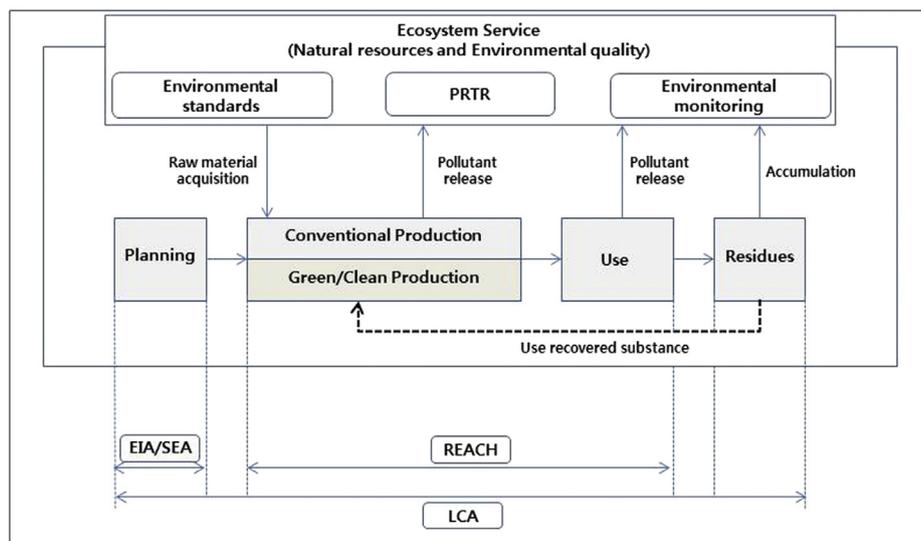

Fig. 2. Systemic approach to monitor, verify and report chemical flows to obtain a better protection level of human health and the environment. Arrows represent material and substance flows.

REACH and LCA, designed to control the use of chemicals and to maintain and improve environmental quality.

The preservation of ecosystem services, including natural resources and environmental quality, relies on maintaining a healthy ecosystem and controlling pollution emissions so that the intensity of pollutant release is below the detoxification capacity of natural systems. As shown in the upper box of Fig. 2, standards for the environment, e.g. air, soil and water, are regulatory goals designed to protect the health of human beings and ecosystems. The data reported under PRTR give information about the quantities of pollutants released and transferred by industries. The effectiveness of environmental management systems is documented within environmental monitoring programs, as monitored environmental quality reflects the aggregated level of pollutants released from historic and existing emission sources.

In order to assess the environmental effect of human activities, there are tools to control governmental/industrial projects and activities, as described in Section 3. In Fig. 2, EIA and SEA are suggested EMS tools that can be implemented to adopt a precautionary approach in the planning of new industrial activities. For the production stage and transportation for use, REACH is a tool to regulate the use of hazardous chemicals on the basis of risk to human health and the environment. Even though LCA is not legally binding, through EMAS III, industries and governments may apply the life cycle perspective approach to assess environmental performance and impacts through all the different stages of human activities.

In order to preserve ecosystem services (and thereby human health), environmental quality presumably needs to be maintained within the levels set by regulatory standards. And, to assess cumulative risks as precisely as possible, background environmental monitoring and PRTR data may be taken into account as a basis for impact/risk assessment under EIA/SEA and REACH. Furthermore, in order to avoid the accumulation of pollutants in environmental media, design for reuse and clean technology may reduce pollutant release (the dotted circular arrow connecting residues with green/clean production in Fig. 2). In a sustainable industrial system, with balanced material flow and substance exchange between the human and natural system, REACH may ensure the quality of products produced from secondary raw materials (ECHA, 2010). Additionally, tools to make industry financially liable for environmental pollution, e.g. the European environmental liability directive (ELD), can contribute to preventing damage to the environment and health risks arising from environmental contamination.

Regarding the marketing of new chemicals, GIS-based approaches to SEA combined with territorial environmental quality data (e.g. EC, 2007; Gonzáles et al., 2011) may support industrial symbiotic networks which exchange resources in order to protect and/or improve the ecosystem services. Essentially, REACH can move the assessment closer to the real world by taking into account background environmental quality and contribute to the sustainability of industrial systems by including the whole material flow in a life cycle perspective and adopting a more precautionary approach with regard to similar modes of action of chemical mixtures.

5. Data and results

An efficient way to take into account differences in background exposure in different territories in CSAs is to include background environmental quality data. In order to verify the relevance of taking into account differing territorial background exposures in the REACH exposure scenario, a comparative case study of the environmental quality standards, monitored environmental quality and reported PRTR data in two countries (Denmark and Korea) have been explored and are presented below.

5.1. Environmental quality standards

According to EU directives, environmental quality standards are established for twelve pollutants in air, 33 priority substances in surface water and 53 substances/parameters in drinking water (EC, 2011, 2008b, 1998). Furthermore, Danish quality standards exist for 58 substances in soil and 56 substances in groundwater (DEPA, 2010). In Korea, environmental quality standards exist for seven pollutants in air and 25 pollutants/criteria in surface water (KMGL, 2011a), 57 items in drinking water (KMGL, 2010), 19 pollutants in groundwater (KMGL, 2011b) and 21 pollutants in soil (KMGL, 2011c).

Table 1 shows the air quality standards of Denmark and Korea (NERI, 2010a; KEC, 2012). In order to compare the data, the unit used for air quality standards in Korea is converted from ppm to $\mu g/m^3$. As observed from Table 1, among the eight substances in Korean air quality standards, five of the Danish air quality standards, i.e. in case of SO_2, CO, NO_2, O_3 and PM_{10}, are about 1.1–1.5 times stricter than those in Korea.

When comparing quality standards for water and soil for selected heavy metals, the differences are more pronounced, as may be observed from Table 2. Table 2 shows some of the water and soil quality standards for five selected heavy metals. The Danish freshwater quality standards for lead, mercury and cadmium are 7, 20 and 55 times stricter, respectively, compared to Korea. For drinking water, Denmark has higher quality standards than the EU with regard to groundwater used as drinking water, i.e. 1.25–50 times stricter, while Korea has adopted drinking water quality standards similar to the EU. Like for the water compartments, soil quality standards for Denmark are stricter than in Korea, with the exception of chromium which is a factor 4 lower than for similar land use in Denmark.

5.2. Environmental monitoring data

With regard to the most recent environmental monitoring data available from Denmark and Korea, air and sediment data are explored. For freshwater and groundwater, concentrations of hazardous chemicals such as heavy metals and PAHs are under the detection limit and therefore less relevant for comparison. For soil, while there is a nationwide monitoring system in Korea (NIER, 2012b), as presented in Table 3, a similar monitoring database in Denmark is still under establishment and planned to be finished in 2014 (personal communication, DEPA, June 2012).

Table 4 shows the average air qualities for Korea and Denmark for the substances subject to regulatory quality standards (NERI, 2010a; KEC, 2012).

Table 1
Air quality standards in Denmark and Korea, provided as average concentration levels [$\mu g/m^3$].

Quality goals	SO_2[a]	CO[a]	NO_2	O_3[a]	Bz	Pb	PM_{10}	$PM_{2.5}$	Cd[b]	As[b]	Ni[b]
EU/Denmark	125	10,000	40	120	5	0.500	40	25	0.0050	0.0060	0.0200
Korea	143	11,000	62	129	5	0.500	50	25			

[a] Concentration for SO_2 is an average for 24 h and concentrations for CO and O_3 are averages for 8 h.
[b] For these 3 items, target value enters into force 31.12.2012 (EC, 2011).

Table 2
Water and soil quality standards in Denmark and Korea, provided as average concentration levels.

Quality goals	Water (µg/L)						Soil (mg/kg)	
	Freshwater		Drinking water			Groundwater	KOR[e]	DK
	KOR	DK(=EU)	KOR	EU	DK[c]	KOR[d]		
Pb	50	7.2	10	10	1	100	200	40
Cd	5	0.09[a]	5	5	0.5	10	4	0.5
As	50	–	10	10	8	50	25	20
Hg	1[b]	0.05	1	1	0.1	1	4	1
Cr(VI)	50	–	50	50	1	50	5	20

[a] This is the quality standard for 'Class 3' (the middle range level among 5 classes) (EC, 2008b).
[b] By law, the quality standard is zero for these compounds. This is the limit of detection (KMGL, 2011a).
[c] The provided quality standards refer to groundwater used as drinking water (DEPA, 2010).
[d] These standards are for residential purposes including laundry, dishes, and toilets. When groundwater is used for drinking, it is subject to the standards for drinking water (KMGL, 2011b).
[e] The soil contamination standards in Korea are divided into three categories, in accordance with the land use. In this table, the standards for region 1 (for rice paddies, fields and school sites) are shown (KMGL, 2011c).

In Denmark, the annually reported concentrations of SO_2, CO and Pb are less than 10% of the air quality standards. For concentrations of NO_2, the concentration at street sites (traffic sites) is 1.025 times higher than the quality standard (40 µg/m³). In Korea, the concentrations of SO_2 and CO are lower than the regulatory quality standards, while, similar to Denmark, the annual concentration of NO_2 in areas of traffic is 1.4 times higher than the Korean quality standards. Korean particulate matter in air, PM_{10}, monitored in urban and traffic areas is 1.06 and 1.2 times higher than the quality standards. Ozone levels in air are comparable between the two countries, while the Korean air concentrations for SO_2, CO, NO_2, Pb and PM_{10} exceed the Danish levels; concentration levels being from 1.4 up to 13.2 times higher compared to Denmark. Regarding air pollution levels, sediment pollution levels for selected metals seem to be comparable between the two countries except for chromium and zinc. Table 5 shows the concentrations of heavy metals in sediments of freshwater (NERI, 2010b, 2010c; NIER, 2012b).

In contrast to the air pollution levels in the two countries, there seems to be a tendency for the sediment concentration levels of cadmium, mercury and zinc to be slightly higher in Denmark compared to Korea; i.e. 1.6–2.6 times higher than those in Korea. Only for chromium is a higher pollution level observed in Korean freshwater sediments, i.e. 2.3–2.8 times higher than in Denmark.

5.3. PRTR emission data

The Pollutant Release and Transfer Register (PRTR) contains data on the amounts of pollutants released to air, water and land at facility level as well as off-site transfers of waste and of pollutants in wastewater covering 91 key pollutants in the EU and 388 substances in Korea, including heavy metals, pesticides, greenhouse gases and dioxins. While the E-PRTR system includes greenhouse gases and nutrients that can cause eutrophication, the Korean PRTR system does not include these.

Table 6 shows the total amount of PRTR data for Korea and Denmark in 2009. In Denmark, 234 facilities reported pollutant emissions to the environment, 1 facility reported pollutant transfer and 265 facilities reported waste transfer data covering about 35

pollutants (EEA, 2012). In Korea, 2917 facilities reported pollutant emission and transfer data for 212 chemical substances (KMOE, 2011b). In the Danish data, the emissions of CO_2, CH_4, NO_2 and SO_2 to air are not included in Table 6 because these pollutants relate mainly to climate change and are not included in the Korean PRTR reporting system. The amount of emission to water and the transfer of total organic carbon, total nitrogen and total phosphorus in Denmark are also excluded in Table 6 because these three substances mainly relate to eutrophication, and they are not included in the Korean PRTR reporting system either.

As observed from Table 6, the total amount of PRTR-reported data in Demark is 13,200 tonnes, which is 2.25% of that in Korea. Total area and population of the two countries are 43,000 km² and 5.5 million in Denmark and 100,000 km² and 48.7 million in Korea (OECD, 2012b, 2012c). Therefore, the annual quantities of PRTR reported chemicals released directly to the environment and/or transferred per capita and per area are 2.4 kg/person and 307 kg/km² in Denmark and 12.0 kg/person and 5856 kg/km² in Korea. This indicates that the existing Korean industrial emission intensity to the environment is 5 times higher per capita and 19 times higher per area than in Denmark.

5.4. Frequency analysis of environmental quality data and childhood lead exposure in Denmark and in Korea

In order to verify the existence of different territorial environmental qualities and, i.e., background human exposure levels, the total childhood exposure from lead pollution data in Korean and Danish air and soil is compared.

To verify the extent to which territorial differences in environmental quality and resulting human exposure are relevant to take into account in potential future improvements to REACH exposure scenarios, standard deviations of the average reported values in Tables 3 and 4 were derived. Average concentration levels of lead and physiological parameters for children, including standard deviation of the lognormally/normally distributed data are provided in Table 7.

Data on the concentration of lead in the air (Pb_{air}) are based on the measurements from the most recent available data reported by

Table 3
Soil monitoring data for Korea in 2010 [mg/kg].[a]

Number of sites	Cd	Cu	As	Hg	Pb	Cr(6+)	Ni	PCB	Benzene	Toluene	Ethyl-benzene	Xylene	Phenol
1521	1.094	19.934	4.821	0.030	26.763	0.142	12.579	0.000	0.001	0.003	0.000	0.003	0.001

[a] Since 2010, the monitoring method for five heavy metals has changed from extraction to total concentration (NIER, 2012b). In order to calculate children's lead exposure and compare this with Danish urban data in Section 5.4 the data in 2010 have been used.

Table 4
Air quality in Denmark and Korea in 2009 [μg/m³].

Average conc.		SO_2	CO	NO_2	O_3	Bz	Pb	PM_{10}	$PM_{2.5}$	Cd	As	Ni
Denmark	Urban		229	17	52		0.004	21	14	0.0015	0.0004	0.0029
	Traffic	3	462	41	36	1	0.005	28	18	0.0015	0.0005	0.0036
	Rural		210	10	58		0.004	18	14	0.0015	0.0005	0.0018
Korea	Urban	16	691	51	52		0.050[a]	53				
	Traffic	17	928	87	32			60				
	Rural	6	492	14	74			45				
	Background	7	500	11	91			49				

[a] The average Pb concentrations of 12 major cities in Korea (KMOE, 2010).

the national monitoring programs in the two countries (NERI, 2010a; KMOE, 2010). In order to compare urban air quality, the data of urban and traffic areas in Denmark were selected and data for twelve cities in Korea were used. For the concentration of lead in soil (Pb_{soil}) in Korea, monitoring data from residential, school and park areas in the year 2010 constituted 563 sites with a total of 1521 sampling sites. These were chosen for the purpose of comparability with Danish monitoring data. As Danish nationwide soil monitoring data are not available, the most recent and representative monitoring data from housing and recreational areas in Copenhagen and in the city of Ringsted in 2002 and 2003 were used (Falkenberg et al., 2004). For physiological parameters, recommended values from the US EPA for children between 3 and 6 years old were used, assuming that no difference exists among physiological standard conditions in the USA, Denmark and Korea (US EPA, 2008).

5.4.1. Environmental quality frequency analysis

Frequency distribution of air and soil quality data (Figs. 3 and 4) as well as total daily intake (Fig. 5) from these two sources was calculated by using a Monte Carlo analysis. The frequency analysis is a simplified technique based on frequency factors depending on the distributional assumption that is made and, in this case, the mean and variance of the log transformed raw data (e.g. Cheng et al., 2007; Ott, 1990). As the concentrations of substances in the environment are usually lognormally distributed (Ott, 1990), the logarithms data of environmental concentrations were used for the Monte Carlo analysis. The Monte Carlo model was set up to run 10,000 trials and, for each trial, input parameter values for equation (1) were selected randomly within the value ranges shown in Table 7. Figs. 3 and 4 show the resulting frequency distribution of the lead concentration in air and soil of urban residential areas in Denmark and Korea. In the Monte Carlo analysis, environmental concentration values were selected randomly 10,000 times among

the normal distribution, with the average and standard deviations shown in Table 7. The X-axis is the concentration value which the Monte Carlo method chose and the Y-axis is the frequency of that concentration value in 10,000 times of being selected. By adding all the frequency values above the specific level of the X-axis, which means the area of the graph, we can calculate the probability of each distribution exceeding this environmental concentration. The sum of the Y-axis values for all X value ranges, which means the total area of the graph, should be 1. Calculation of the area was based on these frequency values. However, in order to show only the difference in environmental concentrations and daily intake levels between Denmark and Korea, the frequency value (Y-axis) was normalized by dividing frequency by the maximum value of each distribution in Figs. 3–5.

In Fig. 3, the probability of air concentration exceeding 0.5 μg/m³, the air quality standard in Denmark and Korea, is very low in both countries because the area of frequency above 0.5 μg/m³ is 0% in Denmark and 0.03% in Korea. However, with the level of 0.0097 μg/m³, which is the 99.9th percentile upper distribution data in Denmark, the area of Korean air concentration distribution above this value is 0.9997. This means that more than 99.97% of people in residential areas in Korea may be exposed to lead above 0.0097 μg/m³. On the other hand, when looking at Fig. 4, the probability of soil concentrations exceeding the Danish quality standard limit of 40 mg/kg is 76% for Denmark as opposed to 18% in Korea. Furthermore, approximately 12% of Danish lead soil concentration distribution is estimated to be above the Korean soil quality standard of 200 mg/kg, while only 0.04% is estimated to be above that concentration in Korea.

5.4.2. Daily intake frequency analysis

The daily lead intake via air inhalation (box 1.1.1, Fig. 1) and soil ingestion (part of box 2.1.1, Fig. 1) are estimated according to equation (1):

$$\text{Daily intake via the air and soil}\left(\frac{\mu g}{\text{kg bw}\cdot\text{day}}\right) = Pb_{air}\left(\frac{\mu g}{m^3}\right) \times \frac{\text{Inhalation rate}\left(\frac{m^3}{\text{day}}\right)}{\text{Body weight(kg)}} + Pb_{soil}\left(\frac{\mu g}{g}\right) \times \frac{\text{Ingestion rate}\left(\frac{g}{\text{day}}\right)}{\text{Body weight(kg)}}$$

(1)

Table 5
Stream and lake sediment monitoring data in Denmark and Korea in 2009 [mg/kg].

Median conc.	Pb	Cd	As	Hg	Cr	Zn	Ni
DK (stream)	15.9	0.72	13.7	0.09	17.5	125	18.3
DK (lake)	29.1	0.691	7.63	0.104	14.1	162	13
KOR (stream + lake)	25.6	0.4	11.3	0.04	39.9	77.9	17.4

As in the environmental quality frequency analysis above, the Monte Carlo method was used by running the equation (1) 10,000 times, selecting input values from lognormally distributed soil and air concentration data and normally distributed physiological data as provided in Table 7. Fig. 5 shows the result of this analysis, i.e. the probability distributions of daily intake of lead via the soil ingestion

Table 6
PRTR data in Denmark and Korea in 2009

	Total area (km²)	Total population	Total PRTR (kg/yr)	Emission (kg/yr)			On-site landfills (kg/yr)	Transfers (kg/yr)
				Air	Water	Total		
Denmark	43,000	5,519,000	13,199,480	11,076,031[a]	21,015[b]	11,097,045	–	2,102,435[b]
Korea	100,000	48,747,000	585,614,448	46,857,837	130,750	46,988,587	10,861,225	527,764,636

[a] This does not include CO_2, CH_4, NO_2 and SO_2, which are not included in Korean PRTR data.
[b] These amounts are after exclusion of the emission of TOC (Total Organic Carbon), TN (Total nitrogen) and TP (Total Phosphorus).

and air inhalation for children living in urban areas in Denmark and Korea. The resulting frequency distribution was compared to the acceptable daily intake value of 3.57 μg lead per kg body weight per day (μg/kg bw/day). This value was derived by using a former PTWI (Provisional Tolerable Weekly Intake) value, 25 μg/kg bw/week, suggested by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). It should be mentioned that since the 73rd report of JECFA in 2010, showing that even this former PTWI value is associated with a decrease of childhood IQ (Intelligence quotient) and increased systolic blood pressure in adults, the PTWI value for lead is under discussion; although a new provisional value for the PTWI has not yet been adopted (IPCS, 2012). As such, a PTDI (Provisional Tolerable Daily Intake) value for lead was derived from the former JECFA PTWI value for the purposes of our analysis, resulting in an acceptable daily intake value, i.e. PTDI, of 3.57 μg/kg bw/day.

Human exposure to lead occurs mainly via food and water, but exposure via the environment, air, dust and soil is also a contributing factor; especially during childhood where up to 50% of total exposure, especially in contaminated areas, occurs via the environment (EFSA, 2010). Reflecting this, the estimated daily intake of lead via the soil and air in Denmark and in Korea is compared with an estimated maximum allowable fraction of the PTDI corresponding to 50% and 10% of the PTDI; i.e. 1.785 and 0.357 μg/kg bw/day, respectively.

Fig. 5 shows that the probability of children's exposure through inhalation and soil/dust ingestion exceeding 50% of PTDI is about 5% in Denmark, while it is close to zero in Korea (0.01%). The probability of exposure exceeding 10% of PTDI is estimated to be 55.3% in Denmark and 8.2% in Korea. The distributional contribution to Danish childhood exposure via inhalation and soil ingestion, respectively, is estimated to be 1% versus 99%. In comparison, Korean childhood exposure via inhalation represents 16.8% and the exposure via soil/dust ingestion represents 83.2% of the total air and soil exposure.

6. Discussion

By including existing chemicals and new chemicals under a single management system, and sharing information with several interest sectors such as manufacturers, downstream users and the public, the introduction of REACH has comprehensive impacts on

chemical risk governance, shifting the burden of proof from authorities to industrial sectors. Therefore, REACH has been accepted as an improvement to chemical risk governance.

However, in order to protect the health of inhabitants, the boundary of REACH needs to be extended to support sustainable ecosystem services such as non-polluted top soils, clean water and air. By failing to take into consideration the cumulative risks from different sources and pathways, such as territorial environmental background exposures, intake from daily food consumption, use of products containing the same substance and several substances which have similar modes/mechanisms of action, the current REACH system has limitations when it comes to maintaining and improving ecosystem service in a sustainable way. Instead of adding more complexity to REACH, revising the current system and linking it with other already existing regulations and management tools, such as EIA/SEA, PRTR and environmental monitoring systems as illustrated in Fig. 2, would be a more practical way to improve the whole management system in a systemic way (Assmuth et al., 2010). One possible way forward would be for the REACH exposure scenario to include environmental monitoring or PRTR emission data generated by national/local governments, to assess background exposure levels, and for national/local governments to use the information collected under REACH for EIA/SEA in order to reduce uncertainties (EC, 2012c).

In this paper, the exposure routes and pathways included in REACH are analysed and a systemic approach is presented which can enable REACH, national regulations and environmental management tools to work together. It is also shown how data not currently considered in the present REACH system can be used to assess the exposure from the territorial background environment. Several sources of environmental monitoring data (i.e. for air, water, soil, sediment) provide a measure of current environmental quality. The difference between policy goals, environmental quality standards, and present environmental quality clearly illustrates differences in exposure from the background environment.

Table 7
Air and soil lead concentration and childhood physiological parameters for Monte Carlo analysis.

	Input parameters	Unit	Median	Stdev	Distribution
Lead conc.	Pair (DK)	μg/m³	0.005	0.0011	Log normal
	Pair (KR)	μg/m³	0.0495	0.0388	Log normal
	Psoil (DK)	μg/g	104.36	105.28	Log normal
	Psoil (KR)	μg/g	26.56	18.14	Log normal
Physiological	Body weight	kg	18.6	3.9	Normal
parameter	Inhalation	m³/day	10.9	2.7	Normal
(3–6 yrs)	Soil ingestion	g/day	0.1	–[a]	–[a]

[a] In this paper, soil ingestion rate was regarded as constant, using the rounded value of the total soil and dust ingestion rate (US EPA, 2008).

Fig. 3. The estimated distributions of urban air lead concentration.
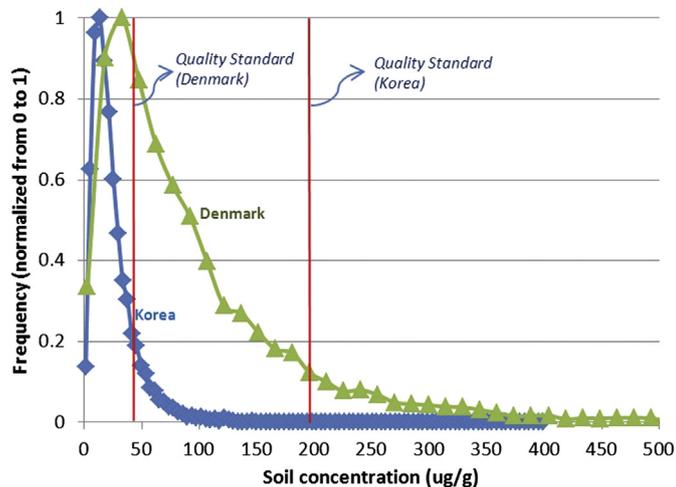
Fig. 4. The estimated distributions of soil lead concentration.

The average concentrations of air pollutants in Korea, for SO_2, CO, NO_2, Pb and PM_{10}, which reflects a part of the current emission to the environment, are from 1.4 to 13.2 times higher than those in Denmark. On the other hand, heavy metal concentrations in sediments of surface water in Denmark, which may reflect historical accumulation, are from 1.6 to 2.6 times higher than concentrations in Korea. Considering that Danish drinking water supply is based on groundwater (DMOE, 2012), background exposure to historical accumulation should be considered when evaluating the risk of drinking groundwater. While in Korea, as shown in PRTR data, current emission levels of several pollutants from industry are much higher (up to 44 times in total amount and 19 times per area, excluding substances related with climate change and eutrophication) than in Denmark. Among these, many substances are not included in air quality standards in Korea and thus not monitored nationwide under the current monitoring system. Even though the concentration of several hazardous chemicals such as heavy metals and PAHs in environmental media is often under the detection limits, especially for surface and groundwater, this does not mean that the concentration of these substances is zero. PRTR data can be used for estimating the exposure from the territorial background environment as a substitute for the missing monitoring data. Substances reported by PRTR emitted to the environment may
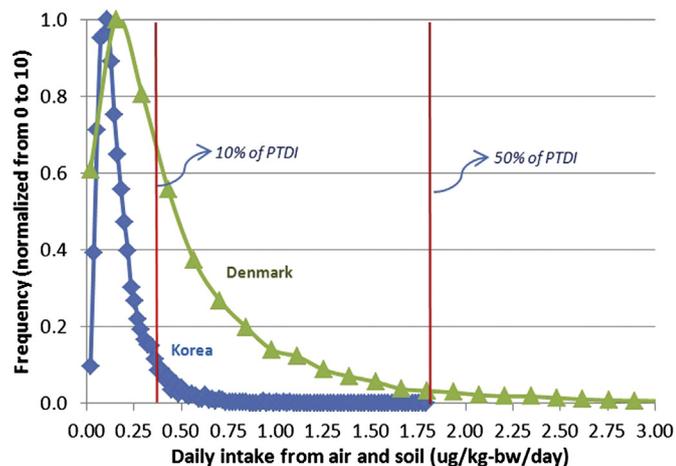
accumulate in biota over the long term. Therefore, by using similar modelling methods to those used in the current REACH environmental exposure assessment, PRTR data can be used to predict regional concentrations (PEC_{local}) that not only include the emission from a registrant but also historical and existing emission levels associated with the specific area. In order to use PRTR data in REACH CSA, the harmony between these two regulatory systems should also be considered. For example, just one out of 14 chemicals in the list of substances subject to authorization under REACH (Annex XIV), bis(2-ethyl hexyl) phthalate (DEHP), and 21 out of 56 chemicals in the list of dangerous substances, mixtures and articles for restriction (Annex XVII) are included in the E-PRTR (EC, 2006a, 2006b). Needless to say, systematic and representative monitoring, verification and reporting of existing and historical pollution are needed in order to evaluate cumulative risks of chemicals in a way that reflects real exposure situations. Assessing exposure of single substances released from multiple uses, exposure to multiple substances with similar mode/mechanism of action, and assessing impacts and exposures to different population groups (i.e. children) are also needed to improve the CSAs under REACH (EC, 2012c; Groβ et al., 2011; Toenning et al., 2009).

This study has shown that different territorial soil and air lead pollution levels and source intensities result in significant differences in the source contribution to childhood lead exposure between Denmark and Korea. Overall, the frequency analysis shows the differences in terrestrial background environmental quality between the two countries which in turn result in different background childhood exposure levels. Approximately 55% of children in residential areas in Denmark and 8% in Korea may be exposed to lead above 10% of the PTDI value via the environment. Considering the results of studies about lead intake via food, children in Denmark are exposed to approximately 0.44 µg/kg bw/day (12% of PTDI) of lead, while the exposure level is 1.03 µg/kg bw/day (31% of PTDI) in Korea (EFSA, 2010; KFDA, 2010). The background lead exposure level may increase when these values of exposure via food are taken into account. In addition, if we combine the exposure to other substances which have a similar mode/mechanism of action, then the total risk will increase again. The result of this study shows a need to apply a more systemic and precautionary approach to REACH by taking territorial differences in environmental qualities into account.

7. Conclusion

The existing exposure scenario assessment under REACH is not complete with regard to human exposure from the background environment, which may differ by territory as a reflection of both historical and existing pollutant emissions. In order to protect human health and the environment, REACH needs to evaluate the cumulative impacts of chemicals and contribute to the sustainability of the industrial system by taking into account the whole material flow in a life cycle perspective. A systems approach, linking REACH to supporting data on background exposures such as environmental monitoring and PRTR data, would allow for a more thorough EIA-based evaluation prior to authorization of additional chemical industrial activities. Extended system boundaries to document action to decrease background concentrations and promote no-risk for future generations call for a territorial whole-system chemical risk assessment in a life cycle perspective, as illustrated by the systemic approach (see Fig. 2). In applying this type of approach, REACH may be able to provide cumulative risk assessments that are closer to real exposure situations and include differences in territorial environment quality. This would allow materials to flow in a more circular way. As shown in the case studies of Denmark and Korea, countries have different background

Fig. 5. The estimated distribution of children's daily intake of lead through air inhalation and soil/dust ingestion.

environmental quality due to different emission histories and different industrial structures and scales. The model-based study shows that the background exposure to lead via the environment, which REACH currently does not include, may be substantial for children in these countries. In order to assess the risks of chemicals, these background exposure levels and territorial differences should be taken into consideration in REACH. Data from environmental monitoring and PRTR may be used to derive total background human exposure and thereby the predicted exposure levels as defined within REACH.

Acknowledgement

References

Askham, C., 2012. REACH and LCA—methodological approaches and challenges. The International Journal of Life Cycle Assessment 17, 43–57.

Assmuth, T., Hilden, M., Craye, M., 2010. Beyond REACH: roadblocks and shortcuts en route to integrated risk assessment and management of chemicals. Science of the Total Environment 408, 3954–3963.

Backhaus, T., Faust, M., 2012. Predictive environmental risk assessment of chemical mixtures: a conceptual framework. Science of the Total Environment 46, 2564–2573.

Barouki, R., Gluckman, P.D., Grandjean, P., Hanson, M., Heindel, J.J., 2012. Developmental origins of non-communicable disease: implications for research and public health. Environmental Health 11, 42. http://dx.doi.org/10.1186/1476-069X-11-42.

Bester, K., Scholes, L., Wahlberg, C., McArdell, C.S., 2008. Sources and mass flows of xenobiotics in urban water cycles—an overview on current knowledge and data gaps. Water Air & Soil Pollution 8, 407–423.

Boogaard, P.J., Hays, S.M., Aylward, L.L., 2011. Human biomonitoring as a pragmatic tool to support health risk management of chemicals — examples under the EU REACH programme. Regulatory Toxicology and Pharmacology 59, 125–132.

Boriani, E., Mariani, A., Baderna, D., Moretti, C., Lodi, M., Benfenati, E., 2011. ERICA: a multiparametric toxicological risk index for the assessment of environmental healthiness. Environment International 36 (7), 665–674.

Boriani, E., Badermo, D., Benfenatti, E., Thomsen, M., 2013. Application of ERICA index to evaluation of soil ecosystem health according to sustainability threshold for industry impact. Science of the Total Environment 443, 134–142.

Cheng, K.S., Chiang, J.L., Hsu, C.W., 2007. Simulation of probability distributions commonly used in hydrological frequency analysis. Hydrological Processes 21 (1), 51–60.

CHESAR, 2012. Chemical Safety Assessment and Reporting Tool, Ver2.0. http://chesar.echa.europa.eu/ (accessed July 2012).

Christiansen, P.M., 1996. Governing the Environment: Politics, Policy, and Organization in the Nordic Countries. Nordic Council of Ministers, p. 368.

COM, 2012. 252 Final. Communication From the Commission to the Council. The combination effects of chemicals. Chemical mixtures, Brussels, 31.5.2012. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2012:0252:FIN: EN:PDF (accessed August 2012).

DEPA, 2010. Danish Environmental Protection Agency, List of Quality in Relation to Contaminated Land Drinking Water Quality Standards. http://www.mst.dk/NR/rdonlyres/95F9ABE9-485B-4D83-A3FF-62E420A5BE8D/0/Kvalitetskriter-ierjord_og_drikkevandfinaljuni2010.pdf (accessed July 2012).

DEPA, 2011. Air Pollution Monitoring Program: Danish Air Quality Regulation. http://www.mst.dk/English/Air/air_pollution_monitoring_programme/ (accessed July 2012).

DMOE, 2012. Danish Ministry of Environment, Danish Lessons: Water Supply in Denmark. Available at: http://www.geus.dk/program-areas/water/denmark/vandforsyning_artikel.pdf (accessed July 2012).

EC, 1997. Council Directive 97/11/EC of 3 March 1997 Amending Directive 85/337/EEC on the Assessment of the Effects of Certain Public and Private Projects on the Environment. http://ec.europa.eu/environment/eia/full-legal-text/9711.htm (accessed July 2012).

EC, 1998. Council Directive 98/83/EC on the Quality of Water Intended for Human Consumption. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX: 31998L0083:EN: NOT (accessed July 2012).

EC, 2000. Directive 2000/60/EC of the European Parliament and of the Council, Establishing a Framework for Community Action in the Field of Water Policy. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: L:2000:327:0001: 0072:EN: PDF (accessed July 2012).

EC, 2001. Directive 2001/42/EC of the European Parliament and of the Council, on the Assessment of the Effects of Certain Plans and Programmes on the Environment. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX: 32001L0042:en:NOT (accessed July 2012).

EC, 2004. Directive 2004/35/EC of the European Parliament and of the Council, on Environmental Liability with Regard to the Prevention and Remedying of Environmental Damage. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32004L0035:EN: NOT (accessed August 2012).

EC, 2006a. Directive Regulation (EC) No 1907/2006 of the European Parliament and of the Council, Concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), Establishing a European Chemicals Agency, Amending Directive 1999/45/EC and Repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as Well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC. http://echa.europa.eu/web/guest/regulations/reach/legislation (accessed August 2012).

EC, 2006b. Regulation (EC) No 166/2006 of the European Parliament and the Council, Concerning the Establishment of a European Pollutant Release and Transfer Register and Amending Council Directives 91/689/EEC and 96/61/EC. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32006R0166: EN: NOT (accessed August 2012).

EC, 2007. Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 Establishing an Infrastructure for Spatial Information in the European Community (INSPIRE).

EC, 2008a. Directive 2008/50/EC of the European Parliament and of the Council, on Ambient Air Quality and Cleaner Air for Europe. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: L:2008:152:0001:0044:EN: PDF (accessed July 2012).

EC, 2008b. Directive 2008/105/EC of the European Parliament and of the Council on Environmental Quality Standards in the Field of Water Policy. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: L:2008:348:0084:0097:EN: PDF (accessed July 2012).

EC, 2009. Regulation (EC) No 1221/2009 of the European Parliament and of the Council, on the Voluntary Participation by Organisations in a Community Eco-management and Audit Scheme (EMAS). http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: L:2009:342:0001:0045:EN: PDF (accessed July 2012).

EC, 2010. Regulation (EC) No 66/2010 of the European Parliament and of the Council, on the EU Ecolabel. Available at: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ: L:2010:027:0001:0019:EN: PDF (accessed July 2012).

EC, 2011. Air Quality Standards. http://ec.europa.eu/environment/air/quality/standards.htm (accessed July 2012).

EC, 2012a. REACH − Registration, Evaluation, Authorisation and Restriction of Chemicals. http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm (accessed July 2012).

EC, 2012b. The Implementation of the Soil Thematic Strategy and Ongoing Activities. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0 046:EN: NOT (accessed July 2012).

EC, 2012c. Communication from the Commission to the Council, the Combination Effects of Chemicals, Chemical Mixtures, COM(2012) 252. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:52012DC0252:EN: NOT (accessed July 2012).

ECHA, 2010. Guidance on Waste and Recovered Substances. http://echa.europa.eu/documents/10162/13632/waste_rec_en.pdf (accessed July 2012).

ECHA, 2012. Guidance on Information Requirements and Chemical Safety Assessment. http://echa.europa.eu/web/guest/guidance-documents/guidance-on-information-requirements-and-chemical-safety-assessment (accessed July 2012).

EEA, 2012. The European Pollutant Release and Transfer Register, E-PRTR Data. http://prtr.ec.europa.eu/AreaOverview.aspx (accessed July 2012).

EEB, 2005. EU Environmental Policy Handbook, a Critical Analysis of EU Environmental Legislation. European Environmental Bureau. http://www.eeb.org/publication/policy_handbook.html (accessed July 2012).

EFSA, 2010. Scientific opinion on lead in food. European Food Safety Authority. EFSA Journal 8 (4), 1570. http://www.efsa.europa.eu/en/scdocs/doc/1570.pdf (accessed July 2012).

Falkenberg, J.A., Thomsen, A.D., Persson, B., Schmidt, T.S., Andersen, J.S., 2004. Diffus jordforurening og kulturlag. DEPA. Environmental project no. 912. http://www2.mst.dk/udgiv/publikationer/2004/87-7614-214-0/pdf/87-7614-215-9.pdf (accessed July 2012).

GEUS, 2012. Groundwater Monitoring in Denmark. http://www.geus.dk/publications/grundvandsovervaagning/grundvandsovervaagning-uk.htm (accessed July 2012).

Gonzáles, A., Gilmer, A., Foley, R., Sweeney, J., John, F., 2008. Technology-aided participative methods in environmental assessment: an international perspective, Computers. Environment and Urban Systems 32, 303–316.

Gonzáles, A., Gilmer, A., Foley, R., Sweeney, J., Fry, J., 2011. Applying geographic information systems to support strategic environmental assessment. Journal of Environmental Impact Assessment Review 31, 368–381.

Groß, R., Bunke, D., Gastiser, S., 2011. Basic principles for the development of a concept for environmental exposure assessments of single substances released from multiple uses under REACH. Umweltbundesamt. ISSN: 1862-4804. www.umweltdaten.de/publikationen/fpdf-l/4183.pdf (accessed July 2012).

IPCS, 2012. Evaluations of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) for Lead. The International Program on Chemical Safety. http://apps.who.int/ipsc/database/evaluations/chemical.aspx?chemID=3511 (accessed July 2012) Bottom of Form.

JRC, 2010. LCA Tools, Service and Data. http://lca.jrc.ec.europa.eu/lcainfohub/lcaPage.vm (accessed July 2012).

KEC, 2012. Korea Environment Corporation, Air Korea. www.airkorea.or.kr (accessed July 2012).

KFDA, 2010. Human Risk Assessment of Heavy Metals in Food for Safety Management Systems. National Institute of Food and Drug Safety Evaluation. http://www.kfda.go.kr/index.kfda?searchkey=title:contents&mid=56&searchword=???&pageNo=1&seq=16682&cmd=v (accessed July 2012).

KMGL, 2010. Korean Ministry of Government Legislation, Enforcement Regulation of Drinking Water Standards and Inspection. http://www.law.go.kr/lsSc.do?menuId=0&p1=&subMenu=1&nwYn=1&query=%EB%A8%B9%EB%8A%94%EB%AC%BC+%EC%88%98%EC%A7%88%EA%B8%B0%EC%A4%80+&x=0&y=0#liBgcolor0 (accessed July 2012).

KMGL, 2011a. Framework Act on Environmental Policy. http://www.moleg.go.kr/english/korLawEng?pstSeq=52614&rctPstCnt=3&searchCondition=AllButCsfCd&searchKeyword=Framework+Act+on+Environmental+Policy (accessed July 2012).

KMGL, 2011b. Ground Water Act. http://www.law.go.kr/lsSc.do?menuId=0&p1=&subMenu=1&nwYn=1&query=%EC%A7%80%ED%95%98%EC%88%98%EB%B2%95&x=0&y=0#liBgcolor0 (accessed July 2012).

KMGL, 2011c. Soil Environment Conservation Act. http://www.moleg.go.kr/english/korLawEng?pstSeq=52630&rctPstCnt=3&searchCondition=AllButCsfCd&searchKeyword=Soil (accessed July 2012).

KMGL, 2011d. A Plan for Rivers and Lakes' Sediment Monitoring System. http://www.law.go.kr/admRulInfoPWah.do?admRulSeq=2000000016405 (accessed July 2012).

KMOE, 2010. Environmental Statistics Yearbook 2010. http://webbook.me.go.kr/DLi-File/pdf/2011/02/5254874.pdf (accessed July 2012).

KMOE, 2011a. White Paper of Environment 2010. http://www.keep.go.kr/portal/board/view.act;jsessionid=0211515B88185A576D4258015DEDF9F1?boardId=envBuk&atclNum=6057 (accessed July 2012).

KMOE, 2011b. Korean Ministry of Environment, PRTR Report 2009. http://ncis.nier.go.kr/prtr/ (accessed July 2012).

KMOE, 2011c. The Korea National Environmental Health Action Plan (2011—2020). http://me.go.kr/web/92/me/deptdata/deptDataUserView.do?inpymd=20110311154000&level1=A1&decorator=me&level2=A105&level3=A10501 (accessed July 2012).

KMOE, 2012a. REACH Helpdesk. http://www.reach.me.go.kr/eng/ (accessed July 2012).

KMOE, 2012b. History of MOE. http://eng.me.go.kr/content.do?method=moveContent&menuCode=abo_his_history (accessed July 2012).

KOSTAT, EUROSTAT, 2012. The European Union and the Republic of Korea: a Statistical Portrait, 2012 ed., ISBN 978-92-79-20835-5. http://epp.eurostat.ec.europa.eu/portal/page/portal/product_details/publication?p_product_code=KS-32-11-816 (accessed July 2012).

NERI, 2010a. The Danish Air Quality Monitoring Programme, Annual Summary for 2009. NERI Technical Report no.799. http://www2.dmu.dk/Pub/FR799.pdf (accessed July 2012).

NERI, 2010b. Soeer 2009. NOVANA. NERI Technical Report no. 803. http://www2.dmu.dk/Pub/FR803.pdf (accessed July 2012).

NERI, 2010c. Vandloeb 2009. NOVANA. NERI Technical Report no. 804. http://www2.dmu.dk/Pub/FR804.pdf (accessed July 2012).

NIER, 2012a. Water Information System. http://water.nier.go.kr (accessed July 2012).

NIER, 2012b. Soil and Groundwater Information System. http://sgis.nier.go.kr.

NRC, 2009. National Research Council: Committee on Improving Risk Analysis Approaches Used by the U.S. EPA, Science and Decisions: Advancing Risk Assessment. The National Academies Press, ISBN 0-309-12047-0.

OECD, 2006a. Applying Strategic Environmental Assessment, Good Practice Guidance for Development Co-operation, ISBN 92-64-02657-6. http://www.oecd.org/document/23/0, 3746, en_2649_34421_45703137_1_1_1,00.html (accessed July 2012).

OECD, 2006b. Environmental Performance Reviews: Korea (2006), ISBN 9264024042. http://www.oecd.org/document/27/0, 3746, en_2649_34307_37435483_1_1_1,00.html (accessed July 2012).

OECD, 2012a. Introduction to Pollutant Release and Transfer Registers (PRTRs). http://www.oecd.org/document/22/0, 3746, en_2649_37465_47616790_1_1_1_37465,00.html (accessed July 2012).

OECD, 2012b. Country Statistical Profile: Denmark. Available at: http://www.oecd-ilibrary.org/economics/country-statistical-profile-denmark_20752288-table-dnk (accessed July 2012).

OECD, 2012c. Country Statistical Profile: Korea. Available at: http://www.oecd-ilibrary.org/economics/country-statistical-profile-korea_20752288-table-kor (accessed July 2012).

Ott, W.R., 1990. A physical explanation of the lognormality of pollutant concentrations. Journal of the Air & Waste Management Association 40 (10), 1047—3289.

Pedersen, A.B., 2010. The fight over Danish nature: explaining policy network change and policy change. Public Administration 88 (2), 346—363.

Pizzol, M., Christensen, P., Schmidt, J., Thomsen, M., 2011. Impacts of "metals" on human health: a comparison between nine different methodologies for Life Cycle Impact Assessment (LCIA). Journal of Cleaner Production 19, 646—656.

Pizzol, M., Bulle, C., Thomsen, M., 2012. Indirect human exposure assessment of airborne lead deposited on soil via a simplified fate and speciation modelling approach. Science of the Total Environment 421—422, 203—209.

Potting, J., Hauschild, M.Z., 2006. Spatial differentiation in Life Cycle Impact Assessment. A decade of method development to increase the environmental realism of LCIA. The International Journal of Life Cycle Assessment 11 (Special Issue 1), 11—13.

Rockström, J., 2009. A safe operating space for humanity. Nature 461, 472—479.

San Francisco Chronicle, 2006 (December 14). European Parliament OKs World's Toughest Law on Toxic Chemicals/30,000 Substances to Be Regulated — U.S. Will Be Affected. downloaded 29.06.2012 at: www.sfgate.com.

SD, 2010. Statistics Denmark, Statistical Yearbook 2010, 114th ed., ISBN 978-87-501-1844-2. http://www.dst.dk/yearbook (accessed July 2012).

Stevens, P.A., Batty, W.J., Longhurst, P.J., Drew, G.H., 2012. A critical review of classification of organisations in relation to the voluntary implementation of environmental management systems. Journal of Environmental Management 113, 206—212.

Smolders, R., Casteleyn, L., Joas, R., Schoeters, G., 2008. Human biomonitoring and the inspire directive: spatial data as link for environment and health research. Journal of Toxicology and Environmental Health, Part B: Critical Reviews 11 (8), 646—659.

Soerensen, P.B., Thomsen, M., Assmuth, T., Grieger, K.D., Baun, A., 2010a. Conscious worst case definition for risk assessment, part I: a knowledge mapping approach for defining most critical risk factors in integrative risk management of chemicals and nanomaterials. Science of the Total Environment 408 (18), 3852—3859.

Soerensen, P.B., Giralt, F., Rallo, R., Espinosa, G., Münier, B., Gyldenkærne, S., Thomsen, M., 2010b. Conscious worst case definition for risk assessment, part II: a methodological case study for pesticide risk assessment. Science of the Total Environment 408 (18), 3860—3870.

The Danish Government, 2010. The Chemicals Action Plan 2010 — 2013. DEPA. http://www.mst.dk/English/Chemicals/chemicals_action_plan/ (accessed July 2012).

The Danish Government, 2003. Environment and Health Are Closely Related — Strategy and Action Plan to Protect Public Health Against Environmental Factors, ISBN 87-7972-932-0. http://www2.mst.dk/udgiv/publications/2003/87-7972-931-2/pdf/87-7972-932-0.pdf (accessed July 2012).

Thomsen, M., Sorensen, P.B., Fauser, P., Faber, J., Lahr, J., Peirano, P., Vernai, A.M., Strebel, K., Schlink, U., Porragas, G.E., Giralt i Prat, F., 2006. D1.2.4. Pre-selection of Scenario for Cumulative Risk Assessment — Documentation of the First Version of Selection Procedure Including Initial Uncertainty Evaluation. http://nomiracle.jrc.ec.europa.eu (accessed August 2012).

Thomsen, M., Frederiksen, M., Bach, H., Bonefeld-Jorgensen, E.C., Rastogi, S., Fauser, P., Krongaard, T., Soerensen, P.B., 2008. Conceptual framework for a Danish human biomonitoring program. Environmental Health: A Global Access Science Source 7, S1—S3.

Thomsen, M., Faber, J.H., Sorensen, P.B., 2012. Soil ecosystem health and services - evaluation of ecological indicators susceptible to chemical stressors. Ecological Indicators 16, 67—75.

Toenning, K., Jacobsen, E., Pedersen, E., Strange, M., Poulsen, P.B., Moeller, L., Boyd, H.B., 2009. Survey and Health Assessment of the Exposure of 2 Year-olds to Chemical Substances in Consumer Products. DEPA. Survey of Chemical Substances in Consumer Products No. 102. http://www2.mst.dk/udgiv/publications/2009/978-87-92548-82-5.pdf (accessed July 2012).

UNECE, 2012. Kiev Protocol on Pollutant Release and Transfer Registers. http://www.unece.org/env/pp/prtr.html (accessed July 2012).

UNEP, 2004. Environmental Impact Assessment and Strategic Environmental Assessment: Towards an Integrated Approach, ISBN 92-807-2429-0. http://www.unep.ch/etb/publications/envImpAsse.php (accessed July 2012).

US CEQ, 1969. The National Environmental Policy Act of 1969, Council on Environmental Quality. http://ceq.hss.doe.gov/nepa/regs/nepa/nepaeqia.htm (accessed July 2012).

US EPA, 2008. Child-specific Exposure Factors Handbook. US Environmental Protection Agency, Washington, D.C.

Vorkamp, K., Thomsen, M., Moeller, S., Falk, K., Soerensen, P.B., 2009. Persistent organochlorine compounds in peregrine falcon (Falco peregrinus) eggs from South Greenland: levels and temporal changes between 1986 and 2003. Environment International 35 (2), 336—341.

WHO, 1999. Overview of the Environment and Health in Europe in the 1990s. http://www.euro.who.int/document/e66792.pdf (accessed August 2012).

WHO, 2011a. Environmental and Occupational Cancers. Fact sheet No. 350. http://www.who.int/mediacentre/factsheets/fs350/en/index.html (accessed July 2012).

WHO, 2011b. Resolution. Action Plan for Implementation of the European Strategy for the Prevention and Control of Noncommunicable Diseases 2012—2016. http://www.euro.who.int/__data/assets/pdf_file/0017/150614/RC61_Res_03.pdf.

WHO, 2012. Risk Assessment. http://www.who.int/foodsafety/micro/riskassessment/en/index.html (accessed July 2012).

Zartarian, V., Bahadori, T., Mckone, T., 2005. Adoption of an official ISEA glossary. Journal of Exposure Analysis and Environmental Epidemiology 15, 1—5.