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Are chemicals in articles an obstacle for reaching environmental goals? — Missing links in EU chemical management

Linda Molander [a,*], Magnus Breitholtz [b], Patrik L. Andersson [c], Aleksandra Rybacka [c], Christina Rudén [a]

[a] Royal Institute of Technology, Dept. of Philosophy and the History of Technology, Teknikringen 78 B, 10044 Stockholm, Sweden
[b] Stockholm University, Dept. of Applied Environmental Science, 106 91 Stockholm, Sweden
[c] Umeå University, Dept. of Chemistry, 901 87 Umeå, Sweden

HIGHLIGHTS

- There is limited coherence in chemical prioritization between REACH and the WFD.
- This is not in line with the intentions of the EU environmental policy and the WFD.
- Chemicals regulated in articles deviate chemically from classical legacy pollutants.
- This warrants new tools to identify potentially hazardous chemicals in use.
- It is necessary to minimize the input of hazardous chemicals into articles.

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ABSTRACT

It is widely acknowledged that the management of risks associated with chemicals in articles needs to be improved. The EU environmental policy states that environmental damage should be rectified at source. It is therefore motivated that the risk management of substances in articles also takes particular consideration to those substances identified as posing a risk in different environmental compartments.

The primary aim of the present study was to empirically analyze 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). We also analyzed the chemical variation of the organic substances regulated under these legislations in relation to the most heavily used chemicals.

The results show that 16 of 24 substances used in or potentially present in articles and regulated by the SSD or the WFD are also identified under REACH either as a substance of very high concern (SVHC) or subject to some restrictions. However, for these substances we conclude that there is limited coherence between the legislations, since the identification as an SVHC does not in itself encompass any use restrictions, and the restrictions in REACH are in many cases limited to a particular use, and thus all other uses are allowed.

Only a minor part of chemicals in commerce is regulated and these show a chemical variation that deviates from classical legacy pollutants. This warrants new tools to identify potentially hazardous chemicals in articles. We also noted that chemicals monitored in the environment under the WFD deviate in their chemistry from the ones regulated by REACH.

In summary, we argue that to obtain improved resource efficiency and a sustainable development it is necessary to minimize the input of chemicals identified as hazardous to health or the environment into articles.

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1. Introduction

The increasing production and availability of chemicals on the global market, and their incorporation into millions of widely used articles, constitute a concern with regard to reaching the goals of EU environmental policy is to preserve, protect and improve the quality of the environment and to protect human health. It also sets great store by the prudent and rational use of natural resources. The environmental policy is based on the precautionary principle and on the principles that preventive action should be taken, that environmental damage should be rectified at source and that the polluter should pay

Abbreviations: BPA, bisphenol A; EQS, environmental quality standard; CMR, carcinogenic, mutagenic, reprotoxic; H/LPVC, high/low production volume chemical; NP, nonylphenol; OP, octylphenol; PBT, persistent, bioaccumulative, toxic; PCA, principal component analysis; pentaBDE, pentabrominated diphenyl ether; PFOS, perfluorooctane sulfonic acid; PS, priority substance; PHS, priority hazardous substance; POP, persistent organic pollutant; REACH, Registration, Evaluation, Authorization and Restriction of Chemicals; SSD, Sewage Sludge Directive; SVHC, substance of very high concern; vPvB, very persistent, very bioaccumulative; WFD, Water Framework Directive.

* Corresponding author. Tel.: +46 8 790 94 25; fax: +46 8 790 95 17.
E-mail address: linda.molander@abe.kth.se (L. Molander).

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(European Union, 2010). The environmental policy certainly sets ambitious goals for what should be accomplished within the EU in general terms.

Today, chemicals are found everywhere in our society and much of our well-being relies on their beneficial properties for use in e.g. construction materials, consumer articles and commercial mixtures such as pharmaceuticals, paint and cleaning agents. At the same time, some chemicals have properties that make them harmful to human health or the environment, meaning that their uses need to be restricted or prohibited. Considering the large number of industrial chemicals in use in the EU (around 143,000 chemicals pre-registered under REACH (ECHA, 2009)) it is of course a cumbersome task to obtain sufficient knowledge on unwanted properties and other relevant information for all these chemicals. It is for instance widely acknowledged that more information must be generated about the contents of chemicals in articles, to what extent and how they are emitted from these articles, and the resulting exposures of humans and the environment (Swedish Chemicals Agency, 2011).

As many chemicals, or their degradation products, emitted from articles sooner or later will reach the environment, e.g. via land application of treated sewage sludge or waste water (e.g. Benn and Westerhoff, 2008; Clarke and Smith, 2011), it is relevant to consider whether the substances identified as environmental contaminants are restricted for use in articles. Such an approach would be supported by the EU environmental policy that states that preventive actions should be taken and environmental damage should be rectified at the source (European Union, 2010).

Within the EU, the industrial chemical legislation REACH (Registration Evaluation Authorization and Restriction of Chemicals; Regulation (EC) No 1907/2006) is currently being implemented (European Commission, 2006). The majority of the rules set forth by REACH apply to chemical substances and mixtures produced or imported in more than 1 t per year and producer or importer. Articles, including consumer articles, are covered by REACH only to a limited extent. However, chemicals incorporated in articles constitute a major source of the global burden of toxic substances (Nordic Council of Ministers, 2008). It is emphasized that existing EU chemical legislations should be used in the first place to control risks to or via the aquatic environment posed by priority substances (PS) and priority hazardous substances (PHS) as identified under the Water Framework Directive (WFD) (Directive 2000/60/EC). Control mechanisms in EU chemical legislations, such as evaluation, authorization and restriction under REACH, should thus function as a net to prevent pollution or to reduce it at source, in order to avoid tackling pollution at the end of pipe (European Commission, 2011a, 2011b).

However, for chemicals having reached the environment, other rules become applicable, e.g. the rules for sludge and soil through the Sewage Sludge Directive (SSD) (Directive 86/278/EEC), and the WFD that sets criteria for water quality (Council Directive, 1986; European Commission, 2000). In 2005, EU Member States did a preliminary review of which water bodies are at risk of not reaching the WFD goal of "good status" by 2015, and it was estimated that on average about 40% of surface water bodies are at risk across the EU, and another 30% need additional data for adequate assessment (European Commission, 2008a). Substances found to pose a risk in or via surface waters and sludge and soil, e.g. as identified by the WFD and the SSD, may to some extent be explained by upstream regulatory drawbacks, e.g. in REACH.

1.1. Aims and scope

The primary aim of the present study was to empirically analyze to what extent the regulation of hazardous substances in articles under REACH is coherent with the restrictions under the Sewage Sludge Directive (SSD) and the Water Framework Directive (WFD). By coherence is here meant that the regulated substances and associated requirements or restrictions of the different legislations are consistent in relation to each other and at the same time effective in the work to achieve the far-reaching and ambitious policy related to environmental protection within the EU.

In case of incoherencies, a second aim was to provide recommendations on how the legislations could be better integrated to reduce articles as an important source of emissions of hazardous substances to the surrounding environment.

A third aim was to compare the chemical variation of the organic substances targeted by the three different legislations, and to relate these chemicals to the large variation of chemicals in commerce in the EU and to those identified as persistent organic pollutants (POPs) according to the Stockholm Convention.

2. Material and methods

A comparative analysis was conducted in three steps by:

(1) investigating the chemical variation of the organic substances regulated under the studied legislations in relation to the listed high and low production volume chemicals (H/LPVC) in the EU,
(2) identifying to what extent the substances that are regulated or that have been subject to review for possible inclusion in the SSD and the WFD are also regulated in articles under REACH, and
(3) analyzing if the requirements and restrictions associated with the overlapping substances (i.e. those regulated by both REACH and SSD/WFD) are coherent or not.

First, lists of the CAS numbers of the regulated substances under REACH, the SSD and the WFD, and in the case of the WFD also of the substances reviewed for inclusion, were compiled in Excel. The lists initially consisted of 168 different individual compounds, mixtures or groups of compounds (REACH: 118, SSD: 7, WFD: 60). The REACH list included the 84 substances of very high concern (SVHCs) currently on the candidate list (ECHA, 2012a) and the substances included in the list of restrictions (Annex XVII to REACH) for which a restriction of use in all or specific articles was stated. There are additional requirements under REACH that could potentially target the use of chemicals in articles (see Section 3.1), but since these do not identify specific chemical substances they were not included in the comparative analysis. The WFD list consisted of the 33 so-called priority substances (PS) (Annex II to Directive 2008/105/EC), 8 certain other pollutants and 13 substances/substance groups subject to review for possible identification as PS or priority hazardous substances (PHS) (Annex III to Directive 2008/105/EC). The SSD list comprised of seven heavy metals.

The chemical variation of the regulated compounds was compared with the variation of European H/LPVCs (step 1) (see Sections 2.2 and 2.3 for further description). This analysis was performed using calculated chemical descriptors and multivariate statistics for illustrating the coherence of commercial substances and those prioritized for restriction in articles under REACH and in the environment under the WFD and the SSD.

For the coherence analysis (steps 2 and 3) substances only regulated by REACH were excluded, as well as overlapping substances unlikely to be intentionally used or unintentionally present in articles. Six substances were selected among these for a more detailed description (case studies) of the coherence between the three chemical legislations (see Section 2.4 for further description).

2.1. Analyzed legislations

Although there are important product-specific directives in place in the EU regulating hazardous chemicals in certain categories of consumer products, such as the Restriction of Hazardous Substances (RoHS) Directive (European Council, 2003a; European Union, 2011) which applies to electrical and electronic equipment, and the Toys

Safety Directive (European Council, 2009), the present analysis is focused on REACH as it is the most comprehensive legislation applicable to all types of articles, such as textiles, construction products, electronics and furniture.

The SSD and the WFD were selected as they address chemical pollution in sludge and soil and in the aquatic environment, respectively; compartments where the bulk of chemicals, or their degradation products, eventually end up following diffuse emissions from articles. Waste regulations, e.g. the Waste Electrical and Electronic Equipment (WEEE) Directive (European Council, 2003b) and the Waste Framework Directive (European Commission, 2008b), were excluded from the comparative analysis because no specific substances are regulated or identified under these.

2.2. Analyzed data sets and chemical descriptors

The database of the European high and low production volume chemicals including 6657 discrete organic chemicals was retrieved according to Rännar and Andersson (2010).

The chemicals regulated or listed by the selected legislations were compiled in a database with names, CAS numbers and molecular structures denoted by their simplified molecular input line entry specification (SMILES), which were collected from the EPISuite database (US EPA, 2011). In case data were not found in the EPISuite database, it was retrieved from the QSAR Toolbox database (EINECS or ASCI names) or elsewhere. For organic salts counter ions were replaced by hydrogen whereas inorganics, metals, fibers, and so called substances of unknown or variable composition, complex reaction products or biological materials (UVCBs) were excluded to enable comparison with the chemicals of the H/LPVC database. This means that no substances regulated by the SSD were included in the comparison as only metals are covered by this legislation. In total 17 UVCBs and 8 fibers were excluded from the analysis (Table 1).

2.3. Principal component analysis

PCA is a powerful data extraction technique for pattern recognition analysis. The variance of a set of variables is explained by a number of independent orthogonal variables (principal components). Each principal component consists of a score and loading vector. Scores show locations of the samples, which can be used for detecting similarities or differences among objects (here chemicals), whereas loadings inform about the input of a descriptor (here chemical descriptors) in a given variable. PCA analysis was performed in SIMCA-P + 12.0.1 software. The number of components was defined based on their eigenvalue with a set criteria of >1.

2.4. Coherence analysis and case studies

For the coherence analysis, the Toxic Substances Portal (Agency for Toxic Substances and Disease Registry, 2012), and the REACH public database on Information on Chemicals (ECHA, 2012b) were used for identification of uses of the different chemicals. Searches in these databases were complemented with searches in the scientific literature and in risk assessment reports. Only chemicals relevant for articles (intentional or unintentional presence in finished articles) were selected for the coherence analysis. Chemicals mainly used in the production process, e.g. as catalysts, were included in the analysis when there was a reason to believe that they may be present in the finished article. Excluded chemicals mainly consisted of pesticides.

The requirements/restrictions for each substance/substance group were identified as being incoherent, limited in coherence or strongly coherent. Incoherent means that there are no requirements or restrictions under REACH with regard to use in articles for substances for which the WFD and/or the SSD lay down restrictions. Substances and associated restrictions were categorized as being of limited coherence when the restrictions only apply to specific uses, or when the requirements associated with a substance do not have an immediate effect upon its use, such as the obligation to provide information to consumers about the presence of SVHCs in articles upon request. In cases where both the end-of-pipe legislations, i.e. SSD and WFD, and REACH, which aims to manage chemicals in a preventive manner, restrict the same substance and to the same extent, they were considered to be strongly coherent.

During 2011 the European Commission did a review of Directive 2008/105/EC on priority substances (the EQS Directive) with the aim of identifying and prioritizing possible new PS/PHS for inclusion in the WFD. Annex III to the EQS Directive lists substances that are subject for possible inclusion in the WFD, and based on this list a new list of substances recommended for inclusion as PS and PHS was compiled (European Commission, 2012a). However, in the present analysis, all substances listed in Annex III are included, i.e. also those for which, after being reviewed by the Commission, it was concluded that more information was needed (i.e. zinc and its compounds) or not to take forward at present due to insufficient evidence (i.e. bisphenol A (BPA) and ethylenediaminetetraacetic acid (EDTA)).

Zinc (Zn), bisphenol A (BPA), nonylphenol (NP), octylphenol (OP), pentabrominated diphenyl ether (pentaBDE) and perfluorooctane sulfonic acid (PFOS) were selected from the dataset for case-studies with the aim to represent the different outcomes of the comparative analysis (Section 4.3). The case study chemicals were selected among the chemicals identified as being of relevance for use in articles (Table 2).

3. Background

3.1. REACH

REACH (Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorization and Restriction of Chemicals) aims at improved risk management of industrial chemicals produced in, or imported to, the EU (European Commission, 2006).

REACH primarily regulates industrial substances as such and mixtures, but to a more limited extent also chemicals in articles. A chemical substance can become regulated in articles under REACH if (1) it is intended to be released from the article "under normal or reasonably foreseeable conditions of use" and is produced or imported in an amount exceeding 1 t per year and producer or importer (Article 7), (2) it has been identified as a SVHC (Articles 7, 33, 57–60), or (3) it is included in REACH Annex XVII over restricted substances and uses.

The supplier of a substance identified as a SVHC and that is present in articles in concentrations exceeding 0.1% of the article's total weight is obliged to provide professional users with "sufficient information" for it to be handled in a safe way. As a minimum, the name of the substance must be provided. If requested, the same information should be given to consumers within 45 days (Article 33). ECHA should also be notified of the presence of a SVHC in an article (if concentration $>0.1\%$ and production/imported volume >1 t per year) if exposure to this substance cannot be excluded during normal or reasonably foreseeable conditions of use or disposal (Article 7).

Table 1
Substances excluded from the PCA analysis.

	Fibers	UVCB	Metals
REACH (118)	8	17	2
SSD (7)	0	0	7
WFD (60)	0	0	4

SVHCs will gradually be selected for authorization, which entails that the producers[1] of these substances must show that the risk of the substance and its uses will be "adequately controlled" and/or that socioeconomic considerations outweigh health and/or environmental risks (Article 60). Eighty four substances have so far been identified as SVHC (ECHA, 2012a) and fourteen of these have been identified by ECHA as priority substances to be included in the authorization list, Annex XVI (ECHA, 2012c).

Furthermore, if a substance classified as hazardous according to regulation (EC) no 1272/2008 on the Classification, Labelling and Packaging of substances and mixtures (CLP) (European Commission, 2008c) is present in an article and is produced or imported in at least 10 t per year, then that use could become affected by the requirement under REACH to conduct a chemical safety assessment (CSA). The purpose of the CSA is "to assess risks arising from the manufacture and/or use of a substance and to ensure that they are adequately controlled" (ECHA, 2010) and it should take into account the whole life cycle of the substance or mixture (Article 14). These rules are currently being implemented and the actual outcome of these requirements remains to be evaluated.

3.2. Sewage Sludge Directive

The aim of the Sewage Sludge Directive (SSD) (Directive 86/278/EEC) is to regulate the use of sewage sludge in agriculture in such a way as to prevent adverse effects on soil, vegetation, animals and man, while encouraging its correct use (paragraph 2). Special measures should be taken to ensure that humans and the environment are protected against harmful effects caused by uncontrolled use of sludge (Council Directive, 1986).

The SSD addresses pathogen reduction and the prevention of accumulation of heavy metals. It lays down limit values for seven heavy metals (cadmium, copper, nickel, lead, zinc, mercury and chromium) in both soil and sludge as these metals may be toxic to plants as well as constitute a health risk to humans through intake of crops. As of today, the SSD does not address organic persistent contaminants. When the limit values in soil are exceeded it should be prohibited to use sludge on that soil. The amount of heavy metals in sludge that is added to cultivated soils is also limited to prevent the soil limit values from being exceeded. The maximum quantities of these metals which may be applied to the soil each year are also stated (Article 4 and Annexes IA, IB and IC).

However, the European Commission is currently assessing whether the current SSD needs to be revised or not. Most Member States have already implemented stricter limit values for the seven heavy metals, as well as introduced requirements, either regulatory or voluntary, also for other contaminants (European Commission, 2008d, 2010a).

3.3. Water Framework Directive

The aim of the Water Framework Directive (WFD) (Directive 2000/60/EC) is to "establish a framework for the protection of inland surface waters, transitional waters, coastal waters and groundwater" in EU Member States (Article 1) (European Commission, 2000).

The environmental objectives set out in this directive require that "good chemical and ecological status" is ensured in surface water bodies as well as a "good chemical status" for groundwater (Article 4). The objective of good chemical status for the surface waters is defined by concentration limits set for a number of priority substances (PS). To date, there are 33 PS listed in Annex X of the WFD. The PS are chemical pollutants that have been identified through (more or less) comprehensive risk assessments as presenting a significant risk to or via the aquatic environment across the EU (Article 16). Among these, 13 have been identified as priority hazardous substances (PHS) based on their high persistence, bioaccumulation potential and toxicity or equivalent level of concern, consistent with the criteria for SVHC identification under REACH (Article 2). The Directive on priority substances (2008/105/EC) establishes the concentration limits, both annual average and maximum allowable concentrations, known as Environmental Quality Standards (EQSs), for the 33 PS.

The PS should be progressively reduced, and for those substances identified as PHS the aim is the cessation or phase out of emissions, discharges and losses within 20 years after the adoption of the substances to the priority list, i.e. by 2015 (Article 16). If one PS does not meet the EQS set for that substance, good chemical status is not thought to be achieved according to the principle of "one out–all out" (Annex V of the WFD and Article 1 of the EQS Directive).

Besides the priority substances, the WFD also requires that control measures are in place for a number of other pollutants, including organophosphorus compounds, metals and biocides that are discharged to water in "significant quantities". EU member states must set EQSs also for these so-called specific pollutants (Annex VIII). These are, however, not covered by the EQS Directive (European Commission, 2011a).

The European Commission is required to regularly review the list of PS/PHS and to identify new such substances (Article 16). In the recent, and first, review during 2011 of the EQS Directive particular consideration was given to the substances set out in Annex III of that Directive (European Commission, 2011a). The review also included proposals of reclassification of existing PS and PHS. In the review it was agreed that the methodology for prioritization of new PS/PHS under the WFD should take the SVHCs as identified under REACH into consideration. The proposed new substances and changes to existing substances are expected to be taken into consideration first in 2015 (European Commission, 2012b).

3.4. EU environmental policy

Articles 191 and 193 of the Lisbon Treaty provide the legal basis for the EU environmental policy (European Union, 2010). A number of action programs outline the framework for this policy, where the Sixth Community Environment Action Programme 'Environment 2010: Our future, our choice' provides the current framework for 2002–2012 (European Communities, 2002). This program emphasizes and promotes the polluter-pays principle, the precautionary principle, preventive actions, and the principle of rectification of pollution at source. It has four priority areas for action, which are climate change, biodiversity, environment and health, and sustainable use of natural resources and management of waste (European Communities, 2002).

The Sixth Community Environment Action Programme also provides the basis for the waste policy within EU. The main objectives of the current EU waste policy are to prevent the generation of waste and to promote re-use, recycling and recovery so as to reduce the negative environmental impact. Landfill should only be used when none of the other options are feasible. The long-term goal is for EU to become a "recycling society" that seeks to avoid the generation of waste as much as possible and use waste as a resource (European Commission, 2005).

4. Results

4.1. Chemical variation of prioritized chemicals

A PCA was calculated using estimated chemical descriptors for European high and low production volume chemicals (H/LPVCs), the PS and PHS chemicals identified by the WFD, SVHCs and chemicals restricted in articles (Annex XVII) under REACH, and chemicals defined by the Stockholm Convention as persistent organic pollutants (POPs) (UNEP, 2009). The score plot of the first two principal components (PC1 versus PC2) is shown in Fig. 1 where each triangle represents

[1] The authorization requirement only applies to SVHCs contained in articles produced within the EU. Imported articles containing SVHCs are thus exempted from this requirement.

Table 2
Substances and groups of substances potentially present in articles and coherence between associated requirements and restrictions under WFD, SSD and REACH.

Substance/substance group (CAS no.)	WFD and SSD requirements/restrictions	REACH requirements/restrictions concerning articles
Incoherence		
(1) Fluoranthene (206-44-0)	PS[a]	–
(2) Tributyltin-cation (36643-28-4): representative of tributyl compounds	PHS[b]	–
(3) Bisphenol-A (80-05-7)	Subject to possible inclusion in WFD (Annex III)	–
(4) Ethylenediaminetetraacetic acid (EDTA) (60-00-4)	Subject to possible inclusion in WFD (Annex III)	–
(5) Free cyanide (57-12-05)	Subject to possible inclusion in WFD (Annex III)	–
(6) Copper (7440-50-8)	Limit values for concentration in soil and sludge for agricultural use	–
(7) Zinc (7440-66-6)	Subject to possible inclusion in WFD (Annex III) Limit values for concentration in soil and sludge for agricultural use	–
(8) Cr(VI) (18540-29-9)	Limit values for concentration in soil and sludge for agricultural use	–
Limited coherence		
(9) Anthracene (120-12-7)	PHS	SVHC on the candidate list[c] (PBT)
(10) Benzene (71-43-2)	PS	Restricted in toys (Annex XVII)
(11) Cadmium and its compounds (7440-43-9)	PHS Limit values for concentration in soil and sludge for agricultural use	Shall not be used in articles produced from a number of plastic materials, such as PVC, in brazing fillers or in metal components of jewelry (Annex XVII)
(12) Chloroalkanes, C_{10-13} (85535-84-8)	PHS	SVHC on the candidate list (PBT and vPvB)
(13) 1,2-dichloroethane (107-06-2)	PS	SVHC on the candidate list (carcinogen, cat. 1B)
(14) Di(2-ethylhexyl)phthalate (DEHP) (117-81-7)	PS	SVHC in Annex XVI[d] (toxic for reproduction, cat. 1B) and restricted in toys and childcare articles (Annex XVII)
(15) Lead and its compounds (7439-92-1)	PS Limit values for concentration in soil and sludge for agricultural use	Lead compounds identified as SVHCs on the Candidate list: Lead dipicrate (CAS: 6477-64-1) Trilead diarsenate (3687-31-8) Lead diazide and lead azide (13424-46-2) Lead styphnate (15245-44-0) Lead chromate molybdate sulfate red (12656-85-8) Lead chromate (7758-97-6) Lead sulfochromate yellow (1344-37-2) Lead hydrogen arsenate (7784-40-9) Lead(II) bis(methanesulfonate) (17570-76-2)
(16) Mercury and its compounds (7439-97-6)	PHS Limit values for concentration in soil and sludge for agricultural use	Mercury compounds (no CAS No) are banned for use as antifouling agents of boats and fish farming appliances or equipment, for preservation of wood, and for impregnation of heavy-duty industrial textiles and yarn intended for their manufacture (Annex XVII, 18) Mercury (CAS No 7439-97-6) shall not be placed on the market in fever thermometers or in "other measuring devices intended for sale to the general public", e.g. manometers and barometers (Annex XVII)
(17) Nickel and its compounds (7440-02-0)	PS Limit values for concentration in soil and sludge for agricultural use	Restricted in post assemblies inserted into pierced parts of the body and in articles intended to come into direct and prolonged contact with the skin (Annex XVII)
(18) Nonylphenol (25154-52-3)	PHS	Restricted for use in e.g. textile and leather processing (Annex XVII)
(19) 4-Nonylphenol (104-40-5)	PHS	Restricted for use in e.g. textile and leather processing (Annex XVII)
(20) Octylphenol (1806-26-4); (4-(1,1′,3,3′-tetramethyl-butyl)-phenol) (140-66-9): representative of octylphenol	PS	SVHC on the candidate list (equivalent level of concern having probable serious effects to the environment)
(21) Pentachloro-benzene (608-93-5)	PHS	Restricted for use in aerosol dispensers (Annex XVII)
(22) Benzo(a)pyrene (50-32-8): representative for PAHs	PHS	Restricted in extender oils used for e.g. production of tires (Annex XVII)
Benzo(b)fluoranthene (205-99-2): representative for PAHs	PHS	Restricted in extender oils used for e.g. production of tires (Annex XVII)
Benzo(g,h,i)perylene (191-24-2): representative for PAHs	PHS	–
Benzo(k)fluoranthene (207-08-9): representative for PAHs	PHS	Banned in extender oils used for e.g. production of tires (Annex XVII)
Indeno(1,2,3-cd)pyrene (193-39-5): representative for PAHs	PHS	–
Strong coherence		
(23) Pentabromodiphenylether (32534-81-9)	PHS	Banned in articles (Annex XVII)
(24) Perfluorooctane sulfonic acid (PFOS) (1763-23-1)	Subject to possible inclusion in WFD (Annex III)	Banned in semi-finished products and articles (Annex XVII)

[a] Substances identified as PS should be progressively reduced (WFD, Article 16).
[b] Emissions, discharges and losses of substances identified as PHS should be ceased or phased out by 2015 (WFD, Article 16).
[c] Substances identified as SVHC will gradually be selected to undergo authorization for continuous uses, and suppliers are are obliged to inform professional users about their presence in articles and to provide that same information to consumers within 45 days upon request (REACH Article 33).
[d] SVHCs in Annex XVI need to be authorized for continuous use (REACH, Article 60).

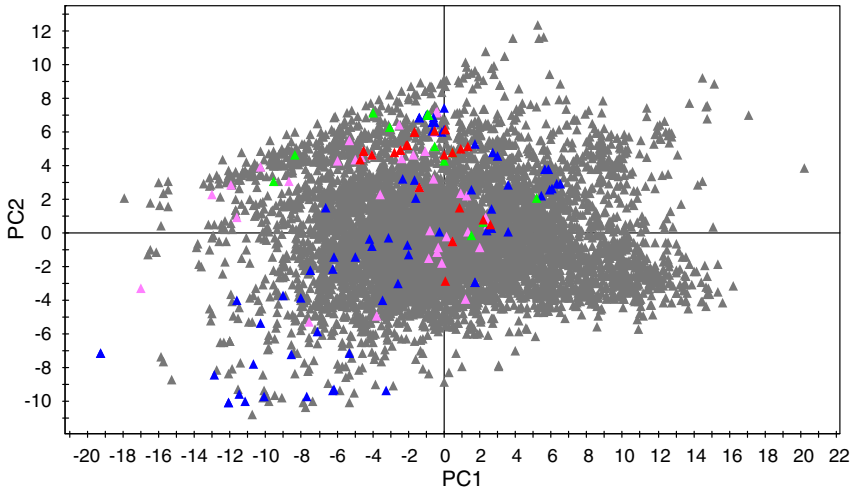

Fig. 1. PCA score scatter plot with the first component PC1 plotted versus the second PC2 explaining 55% of the total chemical variation. Marked with gray triangles are European high and low production chemicals; pink triangles are chemicals prioritized under WFD; blue triangles are REACH-regulated substances; red triangles are POP chemicals listed by UNEP; and green triangles indicate chemicals that are listed both by WFD and REACH.

one chemical and its position reflects its chemistry. The first principal component mainly reflects molecular size with large chemicals having positive PC1 values, whereas the second principal component is mainly hydrophobicity-driven with the most hydrophobic chemicals having highest PC2 values. The SVHC, Annex XVII and WFD chemicals show a large chemical variation covering a major part of the chemical domain of European H/LPVCs (Fig. 1). Clearly, the chemistry of the SVHC, Annex XVII and the WFD chemicals shows little covariance. They could not be separated in the first dimension (PC1), indicating that they show a similar range in molecular size. However, a large share of the WFD chemicals is more hydrophobic, i.e. have higher PC2 values than most REACH-regulated chemicals. Chemicals defined by the Stockholm Convention as POPs were added to the analysis as markers of widely accepted pollutants and indicators of undesired chemical properties. Notably, a large number of the potential or emerging pollutants have chemical properties significantly different from the well recognized legacy pollutants (POPs).

4.2. Coherence of prioritized substances and associated restrictions

Table 2 lists the substances and groups of substances regulated or assessed for inclusion and the associated requirements or restrictions under the WFD and the SSD together with the requirements or restrictions for these substances under REACH when incorporated in articles. The requirements and restrictions for each substance/substance group were identified as being incoherent, limited in coherence or strongly coherent.

Substances/groups of substances not identified as being relevant for use in articles have been excluded. Information made available since the first listing of the PS and PHS in 2001 led the European Commission in their review of the EQS Directive to propose reclassification of two existing PS (DEHP and trifluralin) to PHS (European Commission, 2012a). However, Table 2 shows the PS and PHS as currently listed in the legal act.

As can be read from Table 2, two thirds (16/24) of the WFD substances overlap with REACH substances, i.e. for which there is limited or strong coherence. Four out of seven SSD-regulated substances overlap with REACH substances.

Of those substances that are identified as potentially posing or posing a risk to the environment under the WFD and/or the SSD, 8 of 24 substances are not regulated at all in articles by REACH, e.g. BPA and zinc (see Section 4.3.1). In only two cases the restrictions are strongly coherent between the legislations, i.e. for pentabrominated diphenyl ether (pentaBDE) and perfluorooctane sulfonic acid (PFOS) (see Section 4.3.3). These substances are both prioritized (identified PHS and recommended to be included as a PHS, respectively) to ultimately be phased out in the water environment and being restricted for use in practically all articles on the market. However, for the majority of the substances there are limited coherencies in restrictions and requirements (14/24), e.g. for nonylphenol and octylphenol (see Section 4.3.2).

There are no noticeable differences in coherence between different groups of substances with regard to their hazardous properties (i.e. CMR, PBT, vPvB and substances of "equivalent level of concern") or their identification as SVHCs, Annex XVII-restricted substances, PS or PHS. There are six SVHCs[2] (3 with CMR properties, 2 with PBT/vPvB properties, and one due to equivalent level of concern) among the Table 2 substances, and four of them overlap with PS and two with PHS in the WFD. A few more of the overlapping substances are restricted for use in articles under Annex XVII, and among these there are four PS and eight PHS (including PFOS and counting the PAHs as one) according to the WFD.

4.3. Case studies

The case study chemicals, identified under the WFD or the SSD for posing a potential risk to or via the environment, are listed in Table 3 with their hazardous properties, examples of uses and functions in articles. See Sections 4.3.1 to 4.3.3 for the case studies. The case studies are summarized in Table 4.

4.3.1. Incoherence: zinc and bisphenol A

Zinc (CAS no. 7440-66-6) has been identified as a substance potentially posing a risk to and via both the aquatic environment and agricultural soils. Zinc is very toxic to aquatic organisms and may cause long-term adverse effects in the aquatic environment (European Commission, 2008c). Several national EQSs have been set for zinc, e.g. in the UK (Comber et al., 2008). The review of the EQS Directive stated that more monitoring data are needed for estimating the bioavailability in order for a better assessment of the risk posed by zinc across surface waters in the EU (European Commission, 2011b). However, it has been stated that a harmonization of the national EQSs for zinc would be

[2] The lead compounds (classified as toxic to reproduction and/or carcinogenic) on the Candidate list are here counted as one SVHC.

Table 3
Summary of the case study chemicals' hazardous properties, uses and functions in articles.

Chemical	Hazardous properties	Use in articles	Function
Zinc	Very toxic to aquatic life; very toxic to aquatic life with long lasting effects (European Commission, 2008c).	Car tires, rubber shoe soles (European Commission, 2008e).	Zinc oxide is used as a catalyst in the manufacture of rubber, and widely used as an additive in different materials and products, e.g. as a coloring pigment (European Commission, 2008e).
BPA	Suspected of damaging fertility; may cause an allergic skin reaction; causes serious eye damage; may cause respiratory irritation (European Commission, 2008c).	Food and drink containers, electrical/electronic equipment, thermal papers and medical equipment (European Commission, 2010b).	A monomer that is polymerized to form polycarbonate plastic, and for the production of epoxy resins (European Commission, 2010b)
NP	Harmful if swallowed; causes severe skin burn and eye damage; suspected of damaging fertility and suspected of damaging the unborn child; very toxic to aquatic life; very toxic to aquatic life with long lasting effects (European Commission, 2008c).	For production of nonylphenol ethoxylates, and for plastic and stabilizer resins (European Commission, 2002)	Nonylphenol ethoxylate is a detergent used e.g. in the manufacturing process of textiles and leather (European Commission, 2002).
OP	Causes skin irritation; causes serious eye damage; very toxic to aquatic life; very toxic to aquatic life with long lasting effects (European Commission, 2008c). Hormone disrupting properties of equivalent level of concern as compared to CMR, PBT, vPvB (ECHA, 2012a).	May be present in plastic and rubber articles (Swedish Chemicals Agency, 2012).	"4-(1,1,3,3-Tetramethylbutyl)phenol is mainly used in the manufacture of polymer preparations and of ethoxylate surfactants. It is further used as a component in adhesives, coatings, inks and rubber articles." (ECHA, 2011a)
PentaBDE	May cause harm to breast-fed children; may cause damage to organs through prolonged or repeated exposure; very toxic to aquatic life; very toxic to aquatic life with long lasting effects (European Commission, 2008c). Listed in the Stockholm Convention on POPs (UNEP, 2009)	PentaBDE was used in a vast number of materials and products, including electronics, building materials, furnishings, plastics and textiles (Darnerud, 2003; European Commission, 2001).	A flame retardant (European Commission, 2001)
PFOS	Harmful if swallowed or inhaled; suspected of causing cancer; may damage the unborn child; may cause harm to breast-fed children; causes damage to organs through prolonged or repeated exposure; toxic to aquatic life with long lasting effects (European Commission, 2008c) Listed in the Stockholm Convention on POPs (UNEP, 2009)	PFOS was e.g. used as an impregnation agent for textiles, paper, and leather (Brooke et al., 2004). Due to exemptions from the article restriction under REACH Annex XVII and listed accepted purposes in the Stockholm Convention, it is e.g. still used in hydraulic fluids for aviation.	A surfactant (Brooke et al., 2004)

desirable (Clayton and Rodriguez Romero, 2011). Zinc is also one of the metals for which the SSD lays down concentration limits. With regard to zinc, the SSD states that EU member states must "seek to ensure that there is no resulting hazard to human health or the environment and in particular to ground water" (Annex 1A). Long-term accumulation of zinc in the soil environment is of concern because it can reduce plant growth and negatively affect soil microbial processes if concentration limits are exceeded (Smith, 2009).

Bisphenol A (BPA) (CAS no. 80-05-7) has been identified as being of concern for the aquatic environment due to its hormone-disrupting properties (European Commission, 2008c). BPA has therefore been subject to review for possible inclusion as a PS under the WFD. However, the review of the WFD and the EQS Directive concluded that there is currently not enough evidence showing that BPA poses a risk to the aquatic environment. This statement was mainly based on the 2008 update of the EU risk assessment of BPA which concluded that there was no risk to the aquatic environment from the use of BPA. However, due to conflicting data regarding BPA's effects on snails, the existing evidence will be reviewed again (European Commission, 2012a; European Commission, 2010b). Although BPA is not regulated by the SSD, it has been identified as a potential emerging contaminant in biosolids (e.g. Clark and Smith, 2011).

Both zinc and BPA are present in numerous articles, including consumer articles. Zinc in the form of zinc oxide is not only used as a catalyst in the manufacture of rubber, but is also widely used as an additive in different materials and products, e.g. as a coloring pigment (European Commission, 2008e). High concentrations of zinc were e.g. identified in shoe sole leachates in a study testing the ecotoxicity of three different shoe soles made of different types of rubber (Ingre-Khans et al., 2010). In the same study, zinc was suggested to constitute the main explanation for the toxic effects reported for the aquatic test organisms exposed to the shoe sole leachates (Ingre-Khans et al., 2010).

The largest use of BPA is for polycarbonate plastic production. Epoxy resin production, comprised of can coatings and ethoxylated BPA, accounts for the second largest use of BPA (European Commission, 2010b). BPA is found in widely used consumer products such as food and drink containers, electrical and electronic equipment, and thermal papers, as well as in medical equipment, and coatings of e.g. concrete, steel tanks and pipes (European Commission, 2010b; Sharma et al., 2009).

The use of zinc and BPA in articles is unrestricted under REACH. There are, however, certain targeted use restrictions under product-specific directives for both zinc and BPA. Zinc is regulated in toys by the Toys Safety Directive, which lays down migration limits for zinc that must not be exceeded in the toy, or components of the toy (European Council, 2009). The use of BPA recently became restricted for the manufacturing of infant feeding bottles through Directive 2011/8/EU (European Commission, 2011c).

Keeping zinc levels below the regulatory concentration limit in sewage sludge is important for sustainable recycling of nutrients via agricultural application. The very limited restriction of the use of zinc and BPA in articles (i.e. in toys and infant feeding bottles, respectively) is potentially an obstacle for meeting soil and water concentration limits, as well as conflicting with the precautionary principle as emphasized in the EU environmental policy.

4.3.2. Limited coherence: nonylphenol and octylphenol

Nonylphenol (NP)[3] (included here are CAS no. 25154-52-3 (nonylphenol) and 104-40-5 (4-nonylphenol)) and octylphenol (OP) (CAS no. 1806-26-4 (octylphenol) and 140-66-9 (1,1′,3,3′-tetramethylbutyl)-phenol)) are both priority substances in the WFD. NP has been

[3] NP released into the environment is primarily technical nonylphenol, which is a mixture of more than 100 isomers that differ in structure and position of the alkyl moiety attached to the phenol ring (Ieda et al., 2005).

Table 4
Summary of regulatory requirements and concluded coherence of the case-study chemicals.

Chemical	Restriction(s) in articles under REACH	Restriction(s) under SSD and WFD	Restriction(s) in articles under other directives	Coherence
Zinc	No	Restricted in sludge, proposed specific pollutant under WFD	Concentration limit in toys (Toys Directive)	Incoherence
BPA	No	Subject to review for possible inclusion in the WFD	Banned for use in the manufacturing of polycarbonate infant feeding bottles (Directive 2011/8/EU)	Incoherence
NP	Restricted use in articles produced within the EU (Annex XVII)	PS under the WFD	No	Limited coherence
OP	SVHC on the Candidate list	PS under the WFD	No	Limited coherence
PentaBDE	Banned for use in articles (Annex XVII)	PHS under the WFD	Banned for use in EEE under the RoHS Directive Restriction on production and use under the Stockholm Convention	Strong coherence
PFOS	Banned for use in semi-finished products or articles (Annex XVII)	Recommended for inclusion in the WFD	Restriction on production and use under the Stockholm Convention	Strong coherence

identified as a PHS and should therefore be phased out completely by 2015, while OP is currently listed as a PS meaning that is should be progressively reduced (European Commission, 2000).

NP and OP are degradation products of nonylphenol ethoxylates (NPEs) and octylphenol ethoxylates (OPEs), respectively, which are commonly used in the formulation of different types of detergents, paints, lubricants, resins and pesticides (European Commission, 2002; Van Miller and Staples, 2005). OP is mainly used as an intermediate for the production of phenolic resins and lacquers, while much of NP is used as a precursor for the production of ethoxylates used as surfactants (Van Miller and Staples, 2005). Neither NPEs nor OPEs are persistent in the environment but via e.g. microbial processes they break down to NP and OP, respectively, which are more persistent, bioaccumulative and toxic than their parent compounds (Giger et al., 1984; Sharma et al., 2009; Soares et al., 2008).

NP is listed in Annex XVII to REACH, according to which NP is not allowed to be used e.g. in textile and leather processing (European Commission, 2006). However, the ban does not cover NP or NPEs when contained in finished articles. It may therefore be present in and released to the environment via e.g. textile articles sold on the European market that are imported from countries outside the EU. The use of NP has decreased within Europe during the last decade due to both regulatory restrictions and voluntary initiatives (Soares et al., 2008). Similarly, between 2006 and 2010 the export of textiles and clothing from the EU declined. However, there has been an increase in the import of such articles during these years (Eurostat, 2010) and NP still constitutes an environmental problem. Source screenings conducted for NP and OP under the WFD states that discharges in sewage effluents or storm water as a result of households, including domestic cleaning and use of consumer products containing NP/NPE or OP/OPE, constitute a source that may result in or contribute to potential failure of WFD objectives (European Commission, 2004a, 2004b).

OP is listed as a SVHC, which means that its presence in an article has to be recognized as part of the information disseminated in the supply chain, and also to consumers if such information is requested. In time, OP will be selected to undergo authorization for continuous uses showing that the risks associated with the identified uses are adequately controlled (European Commission, 2006).

Although NP and OP have been identified as "emerging" pollutants in sludge (e.g. Nordic Council of Ministers, 2011) there are currently no restrictions or requirements concerning these substances under the SSD.

4.3.3. Strong coherence: pentaBDE and PFOS

Pentabrominated diphenyl ether (pentaBDE)[4] (CAS no. 32534-81-9) and perfluorooctane sulfonic acid (PFOS) (CAS no. 1763-23-1) are prioritized for restriction under both the WFD and REACH and they are listed as persistent organic pollutants (POPs) by the Stockholm Convention (UNEP, 2009). Inclusion in the Stockholm Convention means that there is a restriction on production and use with the goal of ultimate phase out of the substance (UNEP, 2009). Thus, they constitute examples of how chemical legislations can work together with the aim of phasing out certain hazardous chemicals.

PentaBDE was primarily used as a flame retardant in a vast number of materials and products, including electronics, building materials, furnishings, plastics and textiles (Darnerud, 2003). Mixtures including pentaBDE generally produce toxic effects at the lowest doses compared to other PBDE mixtures. The critical effects seen in animal toxicity studies of pentaBDE are developmental toxicity and, at somewhat higher doses, altered thyroid hormone levels (Darnerud, 2003). PentaBDE has been classified as hazardous to health as well as very toxic to the aquatic environment (European Commission, 2008c). Due to their high persistence and bioaccumulative potential, PBDEs are still widespread environmental contaminants (Darnerud, 2003), although most of their uses are prohibited.

PentaBDE is prohibited for use in articles, or in flame-retarded parts thereof, in over 0.1% by weight, according to Annex XVII to REACH. Annex XVII states that this restriction shall not apply to electrical and electronic equipment which are within the scope of the RoHS Directive (2002/95/EC). The RoHS Directive restricts the use of two whole classes of flame retardants, polybrominated diphenyl ethers (PBDEs) and polybrominated biphenyls (PBBs), in electric and electronic devices. Its Annex provides a maximum tolerable concentration of 0.1% by weight for these substances in homogenous materials (European Council, 2003a; European Union, 2011).

PFOS has been used as a grease, oil and water repellant in textiles, carpets, paper and general coatings. It was previously also used in fire-fighting foams in considerable quantities. As pentaBDE, PFOS is also a persistent, bioaccumulative and toxic (PBT) substance. Besides its potential to cause effects on growth, reproduction and mortality in standard toxicity tests, toxicity data also indicate that PFOS has the potential to induce adverse effects on the endocrine system of animals, including rats and fish (European Commission, 2011d).

The use of PFOS has significantly been reduced in the EU due to both the voluntary phase out of PFOS beginning in 2000 by the global PFOS-producing company 3M, and to legislative use restrictions (Brooke et al., 2004). According to REACH, PFOS is not to be used and placed on the market in "semi-finished products or articles, or parts thereof" in concentrations equal to or exceeding 0.1%. Some uses are, however, exempted where the risk is considered low or where there are no suitable alternatives available, including photolithography, photographic coatings, mist suppressants and wetting agents in electroplating (European Commission, 2006).

5. Missing links in EU chemical management

The present analysis has identified that there is, to a great extent, incoherence or limited coherence in which hazardous chemicals are

[4] Commercially available pentaBDE is not a pure substance but a mixture of diphenyl ethers with varying degree of bromination, where pentabromodiphenyl ether is the main component (European Commission, 2001).

regulated in articles under REACH and for which chemical concentration limits and phase-out goals are set in the environment by the SSD or the WFD. This is not in line with the intentions of the EU environmental policy and the WFD.

Hence, the main EU chemical legislation REACH does not constitute an effective tool for controlling this emission source. As is illustrated in Fig. 1, only a minority of the HPVCs in use on the European market is regulated under REACH when incorporated into articles. Notable is also that these chemicals show a large chemical variation, in contrast to legacy POPs, and possibly classical prioritization tools may not be capable to identify potential emerging pollutants in use in consumer articles.

The identification of SVHCs and their inclusion on the candidate list is a key process under REACH for evaluating and regulating risks associated with chemicals in articles. In order to increase the coherence between REACH and the SSD and the WFD, substances identified as environmental pollutants by the latter legislations should be prioritized for consideration in the process of identifying new SVHCs. Furthermore, a problematic aspect with regard to the authorization process is that imported articles containing a SVHC fall outside the authorization requirement. If REACH would target also SVHCs present in imported articles, it would strengthen the measures at the source of the potential problem.

Since only a small share of the substances registered under REACH will undergo a full substance evaluation, there will be a criteria-based prioritization among the registered substances (ECHA, 2011b). These criteria include PBT substances, substances with endocrine disruptors and/or with widespread use, which are all of relevance to the WFD substances. Thus, the prioritization should preferably cover the substances already identified as priority substances with regard to posing risks to or via the environment.

As has been recognized, there is a strong bias in monitoring substances in the environment towards already regulated substances (European Commission, 2011a). Since the prioritization of substances to be included in the WFD to a great extent is based on exposure estimates, what monitoring data is available for this process is crucial. It would therefore also be reasonable to consider substances widely used in articles in the process of identifying "emerging" environmental contaminants. The REACH registration database, where information on identified uses of a substance should be available, could be a helpful tool for this identification. This requires, however, that the gathered data is transparent and easily accessible to all actors involved in the field of "chemicals, health and the environment". A more straight-forward process for tracing environmental pollutants to their uses in articles would be to require a declaration of the chemical content in articles.

Although the coherence analysis and the case studies revealed that several environmental pollutants that are present in articles are not regulated by REACH, it is important to recognize that there are product-specific and other regional and international legally binding instruments in place controlling the use of a few of these chemicals in articles, e.g. for PeCB which is listed as a POP according to the Stockholm Convention and forbidden in the EU since 2002 (UNEP, 2009). However, many consumer articles, such as textiles and construction products, are only regulated by REACH.

One goal of the EU environmental policy is to turn EU into a "recycling society" (European Commission, 2005). This goal may be difficult to reach in a sustainable way against the background of the limited coherence identified between what substances are prioritized for regulation in articles under REACH and what substances are regulated in the environment under the WFD and the SSD. The recycling society is sought to be achieved by avoiding the generation of waste and by using waste as a resource as far as possible (European Commission, 2008b). To use waste as a resource without harming the environment, Member States should encourage the separation of hazardous compounds from waste streams (European Commission, 2008b). An illustrative example of this is that consumer articles ultimately end up as household waste, which is commonly incinerated in Europe. There is an emerging use of ash produced from incineration in e.g. constructions, concrete and unpaved roads, in accordance with the principle of regarding waste as a resource. However, as metals from waste will concentrate in the final ash, it may become unusable and will instead be regarded as hazardous waste that needs to be disposed of (Ribbing, 2007). Analogous to this, contamination of sewage sludge by metals, but also organic substances emitted from consumer articles, hampers its use as a resource. Hence, for a sustainable use of chemicals within EU, we argue that hazardous substances should be regulated at an earlier life cycle stage. Measures that manage the source of the problems are needed; problematic substances in articles and waste should be avoided already during development and production. This is what is often referred to as Green Chemistry, and would be in line with the EU environmental policy.

We believe that a more stringent control of the use of toxic substances in articles will help reaching the EU environmental policy goals, to which also the WFD refers. This will require actions on many levels, from research and development to improved information systems and regulations. One, in our view, important action is to consider what substances have been identified as priority environmental contaminants already at the design and manufacturing phases.

5.1. Conclusions and recommendations

The present analysis has identified missing links in EU chemical management. The missing links include (1) the incoherence between the REACH rules regulating chemical emissions during the articles' life cycle and maximum environmental concentration limits, set for sludge and soil under the SSD and for surface water under the WFD, and (2) the incoherence between the regulation of chemicals in articles during use (and the waste phase) and the environmental and waste goals as outlined in the EU environmental policy.

The insufficient restriction of hazardous chemicals in articles and the differences identified in substance priority and level of restriction between REACH and the SSD and WFD environmental rules are (1) a possible obstacle towards reaching a good chemical status of European surface waters and for reaching a sustainable sludge management, (2) incoherent with the precautionary principle and that actions to prevent pollution should be taken, and (3) that REACH currently does not seem to contain enough mechanisms sufficient to achieve the objectives of the WFD.

In order to better manage risks posed by chemicals in articles to or via the environment, we recommend that:

- 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.
- 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.
- The authorization requirement under REACH also targets SVHCs in imported articles.

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