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Impact of European chemicals regulation on the industrial use of plasticizers and patterns of substitution in Scandinavia

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ABSTRACT

REACH aims at promoting the safe use of chemicals in Europe, inter alia by identification and regulation of substances of very high concern (SVHCs). Once identified, SVHCs need to be substituted by safer alternatives. However, substitutes are frequently not safer than the substances that they replace but rather show similar hazard profiles, resulting in regrettable substitution. This paper investigates the impact of chemicals regulation on substitution of chemicals by analyzing time trends in the industrial use of chemicals from 2000 to 2014 in Scandinavia. It is shown that the use of ten water-relevant SVHCs decreased by about 90% in the considered period in Sweden as compared to a control group of unregulated substances which decreased by only 20%. A closer inspection of the use of 23 highly used plasticizers revealed that the use of regulated phthalate plasticizers decreased while the use of non-phthalate plasticizers increased. A first comparison of hazardous properties showed that during the 15-years period chemical substitution drastically reduced the chemical hazard burden of plasticizers in Scandinavia for both, the environment and human health. This study shows that regulation and the related discussion on chemicals safety have significantly reduced the chemical hazard burden from plasticizers in Scandinavia since the year 2000. It is assumed that similar trends can be found for the whole European Union. To combat regrettable substitution, mitigation options are suggested, including information-based tools for the identification of safer alternatives and an improved accessibility of information on production volumes and uses of chemicals to allow for an improved assessment of chemical's risk.

1. Introduction

To ensure the safe use of chemicals the EU adapted the REACH Regulation (Registration, Evaluation, Authorization, and Restriction of Chemicals) in 2007. Inter alia REACH aims to replace substances of very high concern by safer substitutes; this practice is called the substitution principle (Öberg, 2013). To find adequate substitutes alternative chemicals need to be identified, compared, and selected on the basis of their hazards, performance, and economic viability (Geiser et al., 2015). When seeking to avoid chemicals of concern, decision makers select alternatives based on ease of substitution, regulatory frameworks, performance and cost of the chemical. If, however, health and safety properties of the substitute are not considered at this stage, it may later turn out to exhibit equal or even more hazardous properties.

Such “regrettable substitution” does not reduce the negative environmental or human health impact but merely shifts the chemical burden. Among the examples of regrettable substitutions is the substitution of trichloroethylene (TCE) for n-hexane (Fantke et al., 2015) i.e. the substitution of a carcinogen by a neurotoxic compound, or the substitution of bisphenol A (BPA) with bisphenol S (BPS), a substance closely related in chemical structure and with a similar hazard profile (Trasande, 2017). The decision to substitute a hazardous substance by an alternative, which turns out to be regrettable, is often taken due to better performance and lower cost of the regrettable substitute compared to a safer alternative. In other cases, lack of awareness or knowledge on the properties of a substitute may lead to regrettable substitution. Tickner et al. (2017) suggest that methods for identifying, evaluating and adopting safer alternatives including cost and performance considerations are insufficient. Additionally, due to a lack of policies requiring more thoughtful review of alternatives, the practice of regrettable substitution has been and still is likely to continue in the future.

For successful substitution, the function of a chemical in a specific product application needs to be considered as the function of a chemical is always related to its product application. According to Tickner et al. (2015) substitution may occur at three different levels, by substituting

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one chemical, by substituting the end-use function or the service function. a) A chemical in a product or process may be replaced by another chemical with no or only minor changes in the production process (so called "drop-in chemical"). This may lead to regrettable substitutions (e.g. BPA for BPS) but can also employ safer alternatives such as the replacement of bis(2-ethylhexyl) phthalate (DEHP) for epoxidized soybean oil (ESBO). b) Substitution efforts based on end-use function will lead to a change in material, product or process (e.g. low-density polyethylene instead of high density polymers requiring plasticizers), making drop-in chemicals redundant. c) Substitution based on a specific service function will lead to a system change (e.g. printing receipts could be substituted by digital receipts), therefore not requiring any substitutes. However, substitution based on end-use or service function does not always find application. In this case, safer "drop-in" chemicals need to be identified. Numerous tools for identifying safer alternatives are available, however there is no universal protocol for the identification, evaluation and comparison of alternatives. Aspects considered in this respect are a chemical's hazard exposure, life cycle impacts, technical and economic feasibility, and an overall decision-making strategy (Tickner et al., 2017).

Chemical substitution efforts supported by regulations such as REACH lead to a shift of chemicals used in industry. To detect patters of substitution (which substance might be substituted by which substitute), it is necessary to group substances according to technical function (i.e. plasticizer, flame retardant, surfactant, solvent, etc.). Such a grouping can be complicated by the fact that some substances have different technical functions depending on the product application (i.e. DEHP which can be used as plasticizer in plastics, but can also be used as a solvent in perfumes (Al-Saleh and Elkhatib, 2016)). Despite other possible product applications, grouping chemicals according to technical function can provide a starting point to detect possible patterns of substitution. For the Scandinavian countries (Sweden, Finland, Norway, and Denmark) chemical substitution patterns can be analyzed quantitatively (tons) according to industrial use data retrieved from the SPIN (Substances in Preparation in Nordic countries) database. SPIN is provided by the Scandinavian chemical agencies and offers time trends on the industrial use of chemicals in Scandinavia for around 28,000 individual substances (as such and in preparations) starting from year 2000 (Scandinavian Environmental Agencies, 2017).

The SPIN database is a useful tool to analyze time trends on individual substances or substance groups, especially for commonly used substances. It should be acknowledged, however, that SPIN can only address drop-in substitution and cannot capture nor quantify functional substitutions based on end-use or service changes.

Time trends of industrial use of chemicals depend on multiple factors, such as market trends including economic fluctuations, the demand of products over time, oil price development, etc. These developments can influence the substitution of individual chemicals. However, as SPIN data shows, general patterns of substitutions can be detected despite of market fluctuations. Quantifying potential substitution efforts could help estimate the extent of regrettable substitution while simultaneously demonstrating safer alternatives. ECHA states that successful substitution often stays unidentified and undocumented, as companies do not have to report substitution choices (European Chemicals Agency, 2016). The identification of functional substitutes, including safer chemical alternatives and the transfer of this knowledge is essential to move towards sustainable chemistry (Fig. 1). As an overarching concept, sustainable chemistry explicitly addresses economic and social questions and aims to support solutions which help to reach the sustainable developments goals (Blum et al., 2017; Friege, 2017).

Regrettable substitution might be detected by analyses of industrial use data at an early stage. For this paper, a list approach was adopted to find safer drop-in alternatives, thus ensuring that the alternatives selected are neither substances that have already been classified as hazardous, nor are structurally relate to any substance already classified as hazardous. Further, a first hazard assessment based on the hazard classifications of the C& L Inventory (classification and labeling) was conducted.

2. Methods

2.1. Temporal development of uses of industrial chemicals

The Scandinavian SPIN database was used to retrieve annual industrial use tonnages of substances. SPIN holds data on substances as such and substances in preparations, thus all plastic articles produced (all plasticizer used) in Scandinavia are accounted for. Substances contained in imported articles, however, do not appear in SPIN. This analysis is based on non-confidential data in SPIN that covered around 80% of all entries of the REACH Candidate list in August 2017. The remaining 20% were confidential, as they were registered by too few companies or in too few products. For non-confidential data however, the industrial use tonnages cover all industrial usage of a substance.

This data was used to analyze time trends of the industrial use of three groups of substances: I) water-relevant substances of very high concern (SVHC) regulated under REACH, II) unregulated polar mobile organic chemicals (PMOCs) as control group and III) a group of 23 highly used plasticizers to analyze potential patterns of substitution. I) Water-relevant substances were defined based on article 16 of the Water Framework Directive (2000/60/EC) as substances that show "evidence regarding the intrinsic hazard of the substance concerned, and its aquatic ecotoxicity and human toxicity via aquatic exposure routes", or show "evidence from monitoring of environmental contamination, and other proven factors which may indicate the possibility of widespread environmental contamination, such as production or use volume of the substance concerned and use patterns" (European Commission, 2016). Water-relevant substances therefore include SVHC already regulated under the Water Framework Directive (2000/60/EC) and substances that are listed as emerging substance in the NORMAN network of emerging pollutants and have been found in water-related environmental matrixes such as surface water or sediments or sewage sludge on the NORMAN EMPODAT database (NORMAN network, 2017). To create the group of water-relevant SVHC, the REACH candidate list (holding 173 SVHC in August 2017) was searched for substances that are also regulated under the Water Framework Directive or are listed by the NORMAN network of emerging pollutants and had end-to-end time trends (2000–2014), without data gaps in the Swedish SPIN database. This search resulted in 16 substances (Table S1). Of those substances, 10 had a use volume > 10 t in the year 2000 in Sweden and were selected for further analysis (Table S2). II) The control group comprised PMOCs that were claimed to be an environmental hazard (Reemtsma et al., 2016). PMOCs were chosen as control group, due to the fact that they are a group of unregulated chemicals as compared to the regulated SVHC (Schulze et al., 2017; Schulze et al., 2018). The PMOCs mentioned in the publication of Schulze et al. were searched for in the Swedish SPIN database, and for all PMOCs registered in SPIN, time trends were retrieved. Of those, PMOCs used in quantities > 10 t in 2000 in Sweden were included (Table S3). To ensure that the selected PMOCs are not regulated under national or other legislation, a policy framework analysis was conducted (Table S4) showing that the PMOCs are widely unregulated, when taking 19 regulative frameworks (S5) into account.

2.2. Pattern of substitution

Potential patterns of substitution were analyzed by looking at the industrial use of 23 highly used plasticizers (> 900 t in all Scandinavian countries from 2000 to 2014) and their time trends in all Scandinavian countries from the SPIN database. All plasticizers were categorized according to their regulation status (REACH authorization list, REACH restriction list) and lists which indicate that substances are likely to be