LIFE / FIT for REACH

ASSESSING THE ENVIRONMENTAL IMPACTS OF SUBSTITUTION OF HAZARDOUS SUBSTANCES

2020

Assessing the environmental impacts of substitution of hazardous substances

Experiences from the LIFE Fit for REACH project

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1 Introduction

The LIFE Fit for REACH project started in 2015 and ended in December 2020. While many of the project activities that were not directly related to substitution had intangible results and did not directly cause material effects, the changes in use of chemicals has an immediate impact on the pressure on the environment from chemicals.

During the five project years, in total 49 substitution cases were implemented: six companies participated as partners in the project and carried out complex substitutions in their products and processes, and 30 non-partner companies implemented at least one "simple" substitution. The project team supported the companies as necessary and documented their activities, in order to be able to share experiences and learnings. Detailed impact assessments were conducted for the partner company cases.

The current report summarises how the impacts of the project were assessed, presents the environmental and health achievements, and includes a discussion about challenges of the methodology and indicators used.

The report addresses persons who are interested in learning about the achievements of the LIFE Fit for REACH project and/or the evaluation of substitution impacts in general. The target group includes companies assessing alternatives or wanting to measure the impact of their substitutions. Additionally, scientists, consultants and project implementers may find the report inspiring with regard to the results and methods used.

The detailed description of the project activities and overall results are provided on the project website at http://www.fitreach.eu.

2 Substitution in the LIFE Fit for REACH project

In this project "*substitution means the replacement or reduction of hazardous substances in products and processes by less hazardous or non-hazardous substances, or by achieving an equivalent functionality via technological or organisational measures*." [1] Consequently, all cases where companies (with the help of the project team) reduced the use of hazardous chemicals without starting to use a more hazardous one are considered "substitution cases".

Six partner companies phased out the use of 10 hazardous substances (9 cases) and implemented the steps of searching and assessing alternatives, testing and implementation. In addition, the use of one chemical was stopped by switching to another technology and the use of another was significantly reduced by improving quality controls of the process. The necessary investments and external assistance were supported by LIFE funding.

In total, 40 substitution cases were carried out in non-partner companies with the support of the project team and partly using small grants of the LIFE programme. Most of these cases did not require any reformulation or redesign of mixtures and articles. The following figures show the types of companies conducting a substitution and indicate whether the alternative was another chemical (substitution 1:1) or the use of another technology (substitution technology)[2]. Approximately one third of the substitution cases involved the use of a new technology.

[1] Joachim Lohse et al, *Substitution of Hazardous Chemicals in Products and Processes, Final Report*. Report compiled for the Directorate General Environment, Nuclear Safety and Civil Protection of the Commission of the European Communities, Hamburg 2003

[2] In practice the introduction of a new technology sometimes required the use of a new, but less hazardous chemical. In these cases, a substitution was counted as "technology" in the statistics.

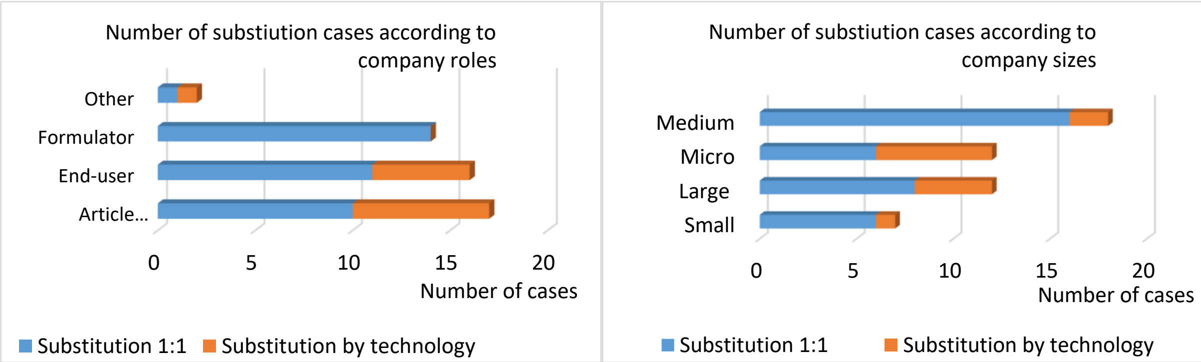

Figure 1 Types of substitution cases according to company role and company size

3 Substitution impacts and how they might be measured

3.1 Chemical risks

The main aim of substitution is to avoid damage to human health (toxicity) and the environment (ecotoxicity). Additionally, the prevention of damage to property (physical-chemical hazards) may play a role in substitution considerations.[3] Consequently, the focus of any impact assessment should be on identifying how a substitution would change the amount and type of potential damage to human health and the environment.

The most hazardous chemicals, which are of the highest priority for substitution, are the so-called substances of very high concern (SVHCs). SVHCs have at least one of the following properties:

- Carcinogenicity, mutagenicity or reprotoxicity (CMR);
- Persistence, bioaccumulation potential and toxicity (PBT) or very high persistence and very high bioaccumulation potential (vPvB);
- Properties giving rise to an equivalent level of concern (EloC), such as endocrine disruption (ED) or respiratory sensitisation.

The potential damage from chemicals is difficult to link to one particular use of one particular substance, amongst others because

- the adverse effects are not substance-specific, i.e., one type of damage may be caused by many different substances as well as by other factors;
- humans and the environment are simultaneously exposed to changing levels/concentrations of many different hazardous substances;
- there may be a (significant) time delay between exposure and damage (e.g., in the case of cancer);
- due to substances partitioning in the environment, damage may occur at different locations than the chemicals use, far from the emission sources.

Figure 2 depicts a simple model of emission and exposure sources of humans and the environment from substances used for the production of a piece of clothing.

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[3] Physical-chemical aspects of substitution are not further discussed here as they involve a different type of decision making, assessment methodology and impact assessment, which were not relevant in this project.

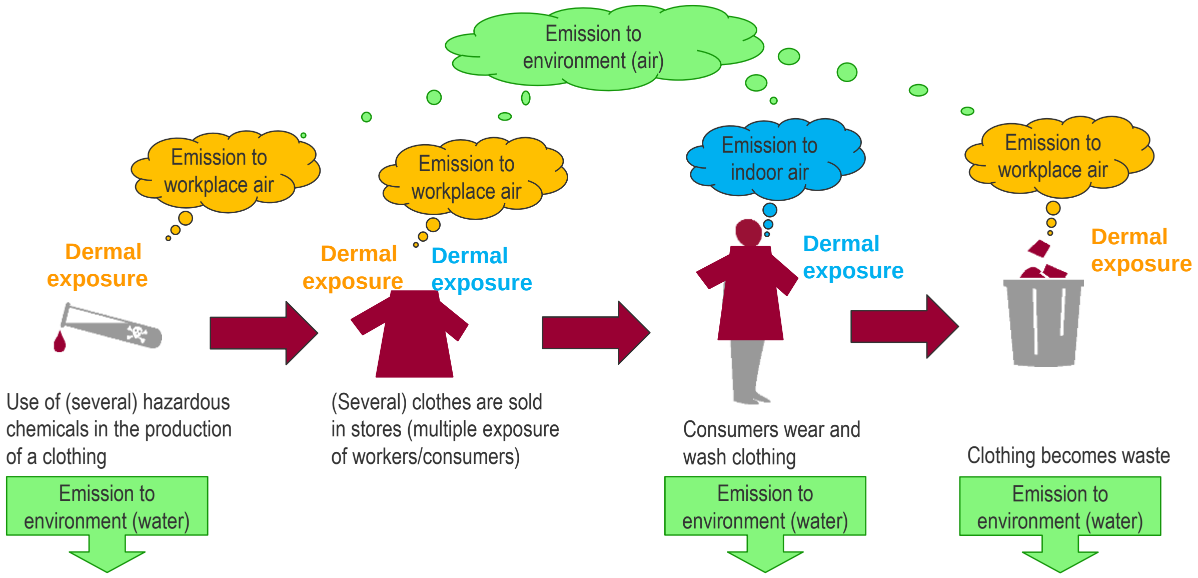
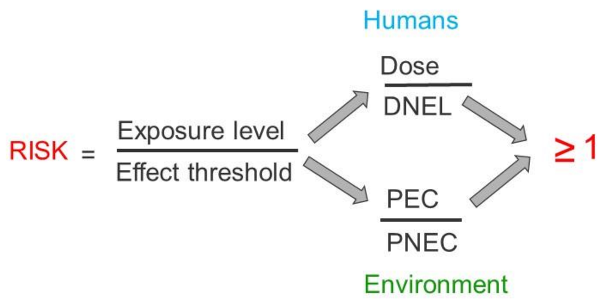


Figure 2 Emission and exposure sources directly linked to the use of chemicals (own illustration)

Since damage should be prevented, chemicals legislation requires assessing chemical risks from the use of substances to determine action needs. A chemical risk is defined as the relation between the concentrations/doses above which damage is expected (effect threshold[4]) and the actual exposure levels. If the risk characterisation ratio (RCR) exceeds 1, a risk exists.



Equation 1: Regulatory definition of chemical risks

The effect threshold is derived from (eco-) toxicity testing results, and the exposure levels are usually modelled based on information on the use and emissions of substances as well as algorithms about the distribution in the environment. The higher the RCR value, the higher the likelihood that adverse effects occur. Substitution aims at using less hazardous substances, i.e. those with less severe effects and higher effect thresholds.

[4] These threshold values are called derived no effect level (DNEL) for humans and predicted no effect concentration (PNEC) for the environment. The exposure level of humans is called "dose" and the concentration in the environment is called PEC (i.e., predicted environmental concentration), as normally these concentrations are also calculated.

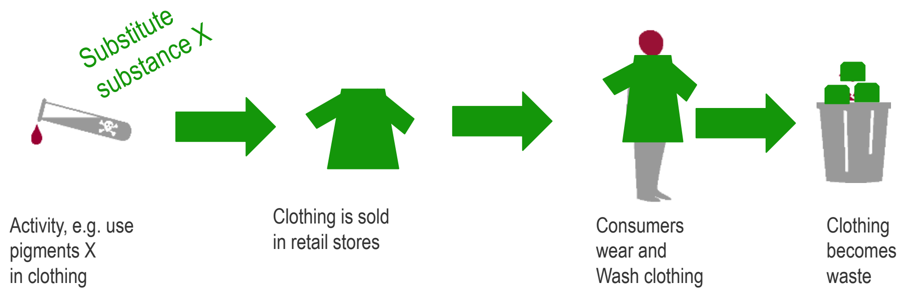


Figure 3 Substitution with a non-hazardous chemical

To measure the changes in human health and environmental risks caused by substitution, the indicator "change in risk characterisation ratio" (ΔRCR) was used.

The ΔRCRs consider

- all relevant lifecycle stages of the production of mixtures, their use by companies for manufacturing or providing services as well as any consumer use of articles or mixture containing a substance;
- all potentially exposed humans, including workers, neighbours of the installation and consumers;
- the aquatic compartment of the environment, representing the environment in total.

The PNECs/DNELs and physical-chemical property data of all hazardous substances involved in a substitution case were extracted from the ECHA's registration database. The exposure levels were calculated using ECETOC TRA, an IT-tool that is also used in the regulatory context. Potential exposure of neighbours was calculated using a distribution model for ambient air, and some consumer exposures were individually assessed. Due to the roughness of the assessment, the results are not considered reflecting any actual level of risk and only the changes in risk characterisation ratios are of relevance for this assessment.

To assess the impacts, the ΔRCRs of all hazardous substances the use (amount) of which changed due to the substitution were calculated individually. For the situation before and after the substitution, the relevant ΔRCRs were summed up per exposure pathway and duration and compared.

3.2 Lifecycle assessment

Substitution may have an effect not only on the (eco-)toxic risks from chemicals use, but also on other environmental problems. For example, if substitution requires process changes, the consumption of water and energy may change, leading to different impacts on emissions and resource depletion, which may show in the LCA results. Substitution may affect the efficiency of the final product, and the type of production process of resources could significantly change the environmental impacts.

In order to measure substitution impacts on the environment, lifecycle assessments (LCA) were conducted. The LCAs were calculated using the software SimaPro 9.1 in combination with the Ecoinvent 3.6 database. The calculation method was ReCiPe 2016 v1.1 midpoint method, Hierarchist version. The LCA results were characterised and normalised using global normalisation factors for the year 2010.

In analogy to the methodology for ΔRCRs and in contrast to the "standard LCA approach", the assessment scope limited to the inputs and outputs which changed due to the substitution (chemicals, water and energy consumption, etc.). Hence, not the absolute impacts of a process or product on the environment were determined, but only those where changes that would have an effect on the environmental impacts occurred.

The LCAs were focused on the company conducting the substitution, unless the use stage of the product was considered significantly influencing the lifecycle impacts. For example, the main emissions of laundry detergents and bleachers take place during the use phase. Therefore, the use stage was taken into account for the cases implemented by the detergent producer. All impact categories that should be considered in LCAs were used in the evaluation of the substitution results.

4 Achievements of the project – impacts on the environment

Of the 49 substitution cases of the project, a detailed impact assessment using the above described methods was applied to the nine cases implemented in the partner companies. The two resource efficiency cases implemented in the partner companies were also assessed. In addition, nine "simpler" cases were qualitatively evaluated and documented but could not be assessed in detail.

Mainly due to a lack of (comparable) data for some or all of the substances involved in the substitutions, it was not possible to measure changes in all RCRs and for all cases. The order of magnitude of the achievements was largely different across the cases (note that the scales in the figures differ!). Not all LCA impact categories are shown in the figures to reduce the information complexity.

All indicators where the data availability and the methodologies allowed a sufficiently reliable derivation are presented in the following sections. The changes in RCRs and LCA impact categories due to substitution are provided as percentage of the initial values. This means that the RCR before a substitution was set to 100% and the change was quantified as a share of this initial value. A reduction is a positive percentage of that 100% and is illustrated by an upward column, while increases are shown as downwards columns (negative values).

4.1 Substitution of Bisphenol A

Bisphenol A is an SVHC (reprotoxic and endocrine disrupting). It was substituted in three input materials to food packages. As a result of the substitution, the company **avoids the use of 300 kg of BPA per year**. The changes in RCR and environmental impact categories show substantial benefits for human health and the environment.

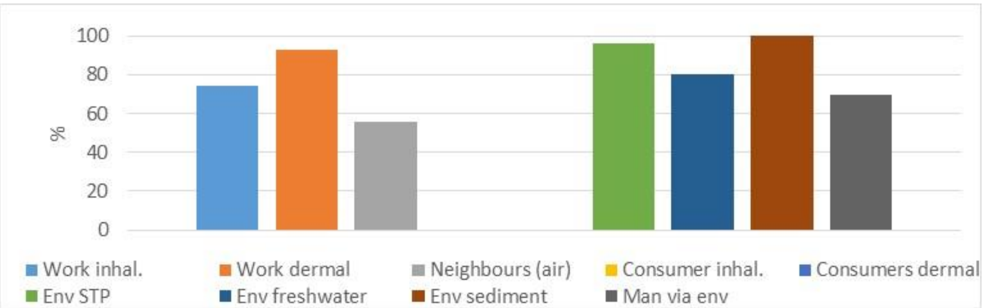


Figure 4: Change in RCR due to substitution of BPA in food packaging

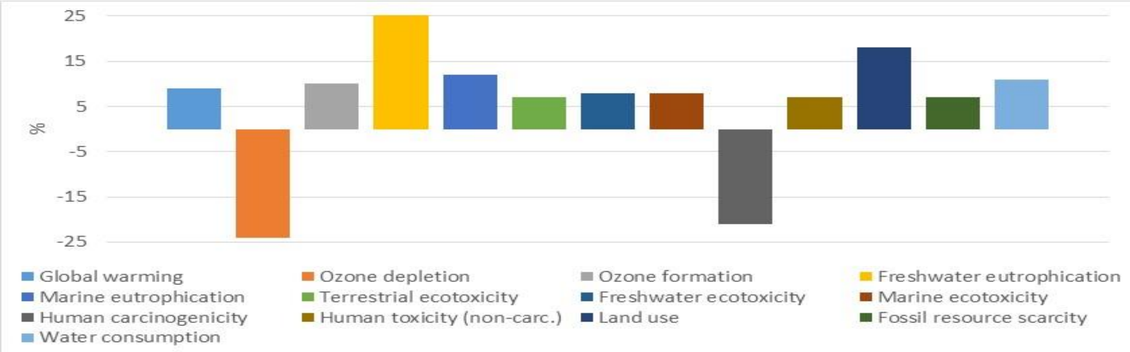


Figure 5: Change in LCA impact categories due to substitution of BPA in food cans

4.2 Substitution of VOCs in a coating system

By replacing the thinner of a coating system, two target substances were substituted: xylene and 2-methoxypropanol (reprotoxic Cat. 1B). Overall, the company aimed at reducing the use of all VOCs, in addition. After the substitution, the company avoids the use of **2-methoxypropanol** (complete **phase-out**) and has **reduced the use of xylene by 920 kg/a**. Overall, the use of VOCs as such was reduced by 500 kg/a.

The worker health risks were significantly reduced while the ΔRCRs for freshwater sediment increased. This result of using less volatile substances is most likely an overestimation associated with the low degree of differentiation between mobility properties of the exposure model (cf. Section 5). The LCA indicators show substantial benefits for all LCA categories, except ozone formation. Overall the substitution decreased the negative impacts of the process.

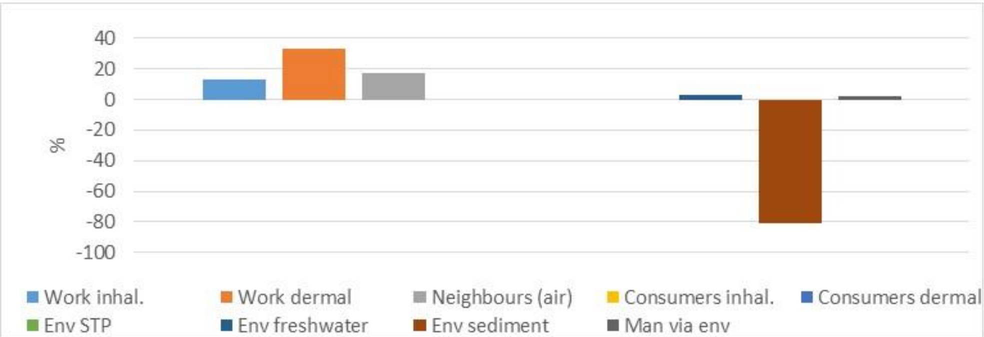


Figure 6: Change in RCR due to substitution of VOCs in a thinner of a coating system

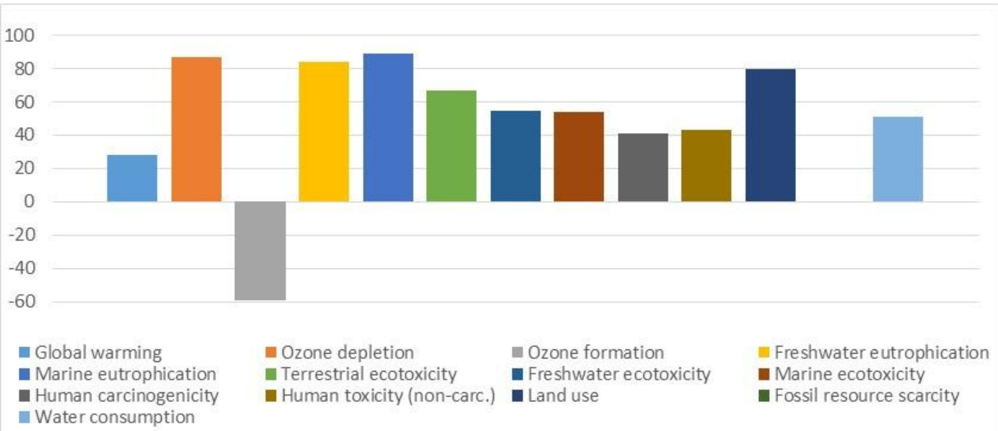


Figure 7: Change in LCA impact categories due to substitution of VOCs in a thinner of a coating system

4.3 Substitution of DINP

DINP was substituted with DINCH in a construction product in order to avoid the use of any phthalate. After the substitution was finalised, new data were available for DINP at the EU level, disproving the initial self-classification as reprotoxicant and significantly increasing the prior published DNELs. Overall, little data are available for DINCH and none on the environmental hazards.

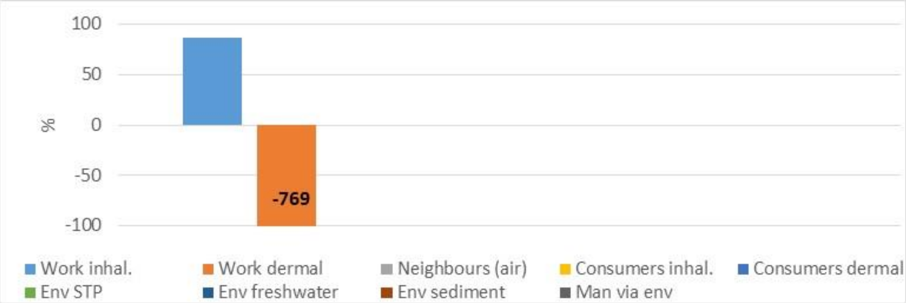


Figure 8: Change in LCA impact categories due to substitution of DINP in a construction product

For workers, the inhalation risk decreased and the dermal risks increased due to the substitution. As the production and use processes in reality give little rise to dermal exposure, the shift in workers risks are considered **positive overall** and the steep increase in dermal risks are attributed partly to an overestimation by the exposure model. The LCA databases did not contain information on either of the two substances; therefore, no LCAs could be performed.

4.4 Substitution of dibutyltin dilaurate by dioctyltin dilaurate

Dibutyltin dilaurate was substituted by dioctyltin dilaurate in a construction product. While the former was an SVHC (mutagenic Cat. 2 and reprotoxic Cat 1B) at the beginning of the substitution, the latter was identified as SVHC after the substitution was completed (reprotoxic Cat 1B). Despite being aware of a potentially similar hazard profile, the company implemented the substitution as an incremental improvement, as dioctyltin dilaurate is not mutagenic. It was not possible to make a detailed RCR-based assessment but the **reduction in mutagenic risk** constitutes a benefit for workers.

The LCA databases did not contain information on either of the two substances; therefore, no LCAs could be performed.

4.5 Substitution of nonylphenol

Nonylphenol is an SVHC (endocrine disruption) and was substituted in a construction product (mixture). The reformulation involved changes in composition and concentrations of its components. After the substitution, the company **avoids the use of 200 kg nonylphenol per year** with increasing trends due to rising sales volumes of the product.

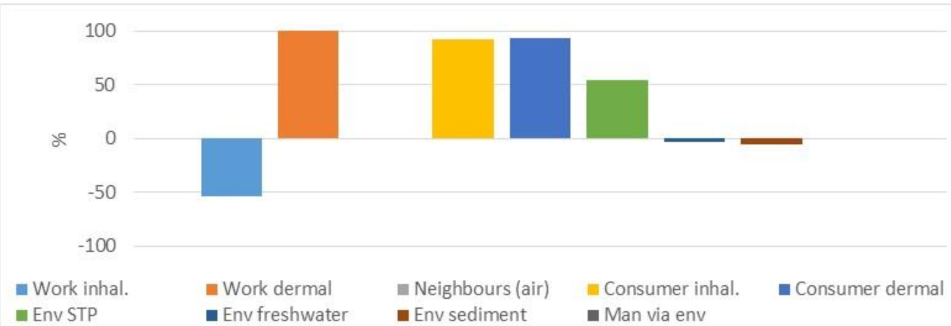


Figure 9: Change in RCR due to substitution of nonylphenol in epoxy flooring

The impacts of the substitution on the environmental risks are relatively small, while an overall decrease of health risks is evident. However, the assessment could not consider the EDC property, which would most likely level out the increased workers risk for inhalation and even further improve the situation for consumers.

For the initial and the final products, information on the composition was available only for a small share of the composition. In addition, for a number of components, no data were available in the Ecoinvent database. As the LCA results are based on incomplete data, it is considered not reliable and therefore not presented here.

4.6 Substitution of benzyl alcohol

Benzyl alcohol is a VOC and classified harmful if swallowed or inhaled. It was substituted in several construction products, resulting in a **use reduction of 6,800 kg/a**.

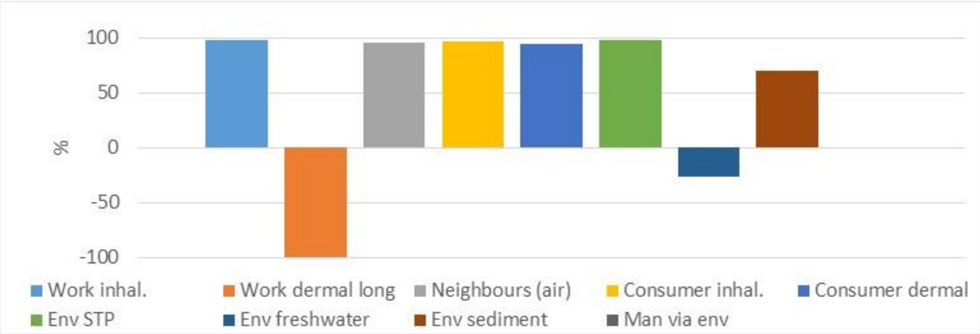


Figure 10: Change in RCR due to substitution of benzyl alcohol in several construction products

The human health and environmental risks decrease due to the substitution, with the exception of the RCRs for workers dermal long-term exposure and for the freshwater environment. The contribution to LCA environmental impact categories shows a decrease except in the category marine eutrophication. Overall, the substitution creates significant health and environmental benefits.

For the initial and the final recipe of the construction products, only a small share of the composition was available for the LCA calculations. In addition, for a number of components of the mixtures, no data were available in the Ecoinvent database. As the LCA results are based on incomplete data, it is considered not reliable and therefore not presented here.

4.7 Substitution of methylene chloride

Methylene chloride is a volatile organic compound and classified as carcinogen, Cat. 2. It was used as a cleaning agent for the production equipment. Due to the phase-out, the company **avoids** the use of approximately **1,600 kg methylene chloride per year**.

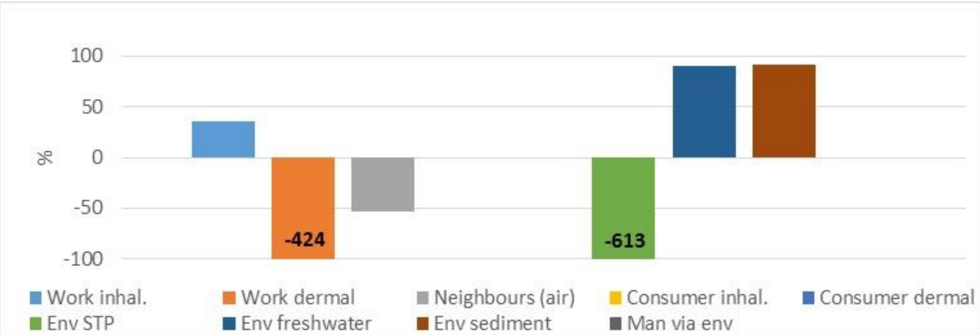


Figure 11: Change in LCA impact categories due to substitution of methylene chloride as a cleaning agent

The health assessments do not reflect the carcinogenicity of methylene chloride because the effect thresholds refer to other health effects. Overall, the increased dermal risks and risks to neighbours are considered to be outweighed by a decrease (not here reflected) in cancer risks for workers and neighbours. The environmental risk is clearly reduced, as the increase at the STP does not affect the ecosystems.

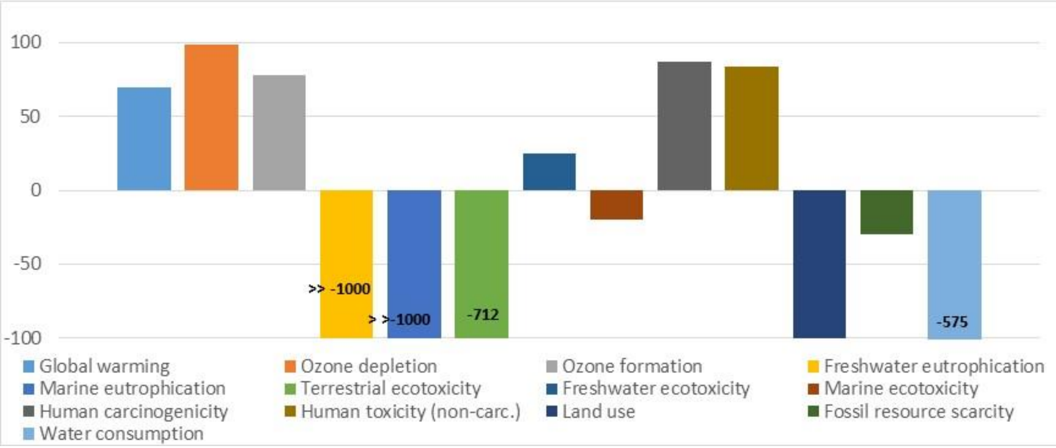


Figure 12: Change in LCA impact categories due to substitution of methylene chloride

The substitution causes mixed changes in environmental impacts, with increased contributions to eutrophication, ecotoxicity and land use and water consumption. The impact assessment gives mixed impressions but overall is evaluated as creating benefits for human health and the environment. The normalised results show the most significant contribution on, and thus the most significant decrease in, impact categories in the field of human carcinogenic and non-carcinogenic toxicity.

4.8 Substitution of sodium perborate

Sodium perborate is an SVHC (reprotoxic 1B) and was used as a component in washing agents. Due to the substitution, the company now **avoids** the use of **11,000 kg per year** in that particular product. As the phase-out took place in all of the companies' products, the overall prevented use is much higher.

As an alternative, enzymes were used. The risks from the toxicity/activity of enzymes could not reasonably be compared to the toxicity of sodium perborate. Therefore, no changes in chemical risks are presented here.

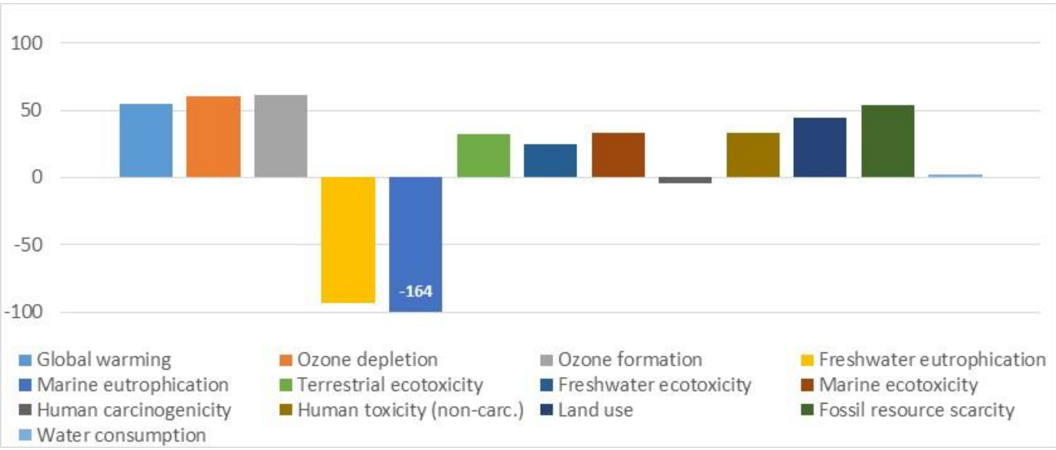


Figure 13: Change in LCA impact categories due to substitution of sodium perborate in washing agents

The LCA indicators show a mixed result, with a significant increase in eutrophication in the aquatic environment as most relevant increase in environmental impacts. The impacts on toxicity decrease according to the LCA, except for the freshwater environment. Overall, the substitution is considered as a significant contribution to an improved state of human health and the environment and a significant contribution to the EU phase-out goal for SVHC.

4.9 Substitution of sodium percarbonate

Sodium percarbonate in washing agents was substituted with enzymes in washing agents, in combination with some other changes to the recipe. Due to the substitution, the company **avoids** the use of **7,500 kg per year** in the example product alone.

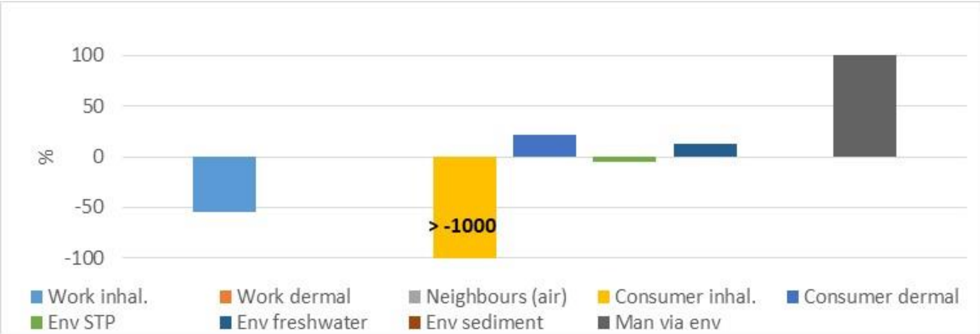


Figure 14: Change in RCR due to substitution of sodium percarbonate in washing agents

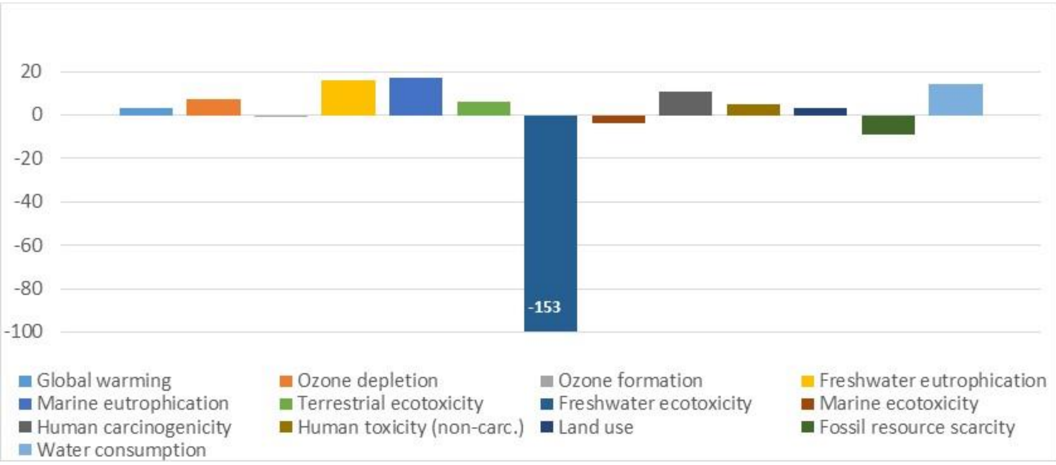


Figure 15: Change in LCA impact categories due to substitution of sodium percarbonate in washing agents

The risks decrease for the environment but increase regarding inhalation for workers and consumers. While worker risks are controlled during the production process in reality, the consumer risk appears overestimated due to the low dusting potential of washing agents (i.e., very little exposure).

The environmental impacts generally decrease, with the exception of freshwater and marine ecotoxicity as well as fossil resource use. Overall, the substitution is difficult to evaluate but is considered creating more benefits than risks.

4.10 Use reduction via improved quality control

The improved quality control in the manufacturing of a construction product reduced the use amounts of several input materials and thereby also reduced the amount of wastes. Amongst others, the company **avoids** the use (and becoming waste) of **more than 1,124 kg *of a*** *substance with a* **high**

chronic aquatic toxicity and more than **2,300 kg of a suspected carcinogen and sensitizer**. As no substitution took place, no RCRs were developed.

As the use reduction was not achieved by changing the process but the quality management, the achieved reduction in environmental impact is similar in all impact categories.

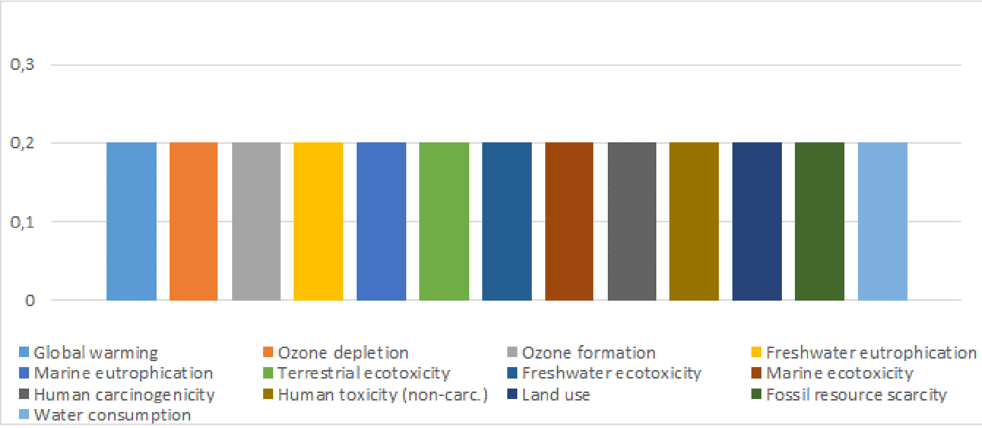


Figure 16: Change in LCA impact categories due to improved quality control resulting in reduced use

The efficiency increase is obviously of benefit for the environment.

4.11 Change of disinfection process

A disinfection process was changed from using hot steam to using an acid-based disinfectant. This decreased the energy consumption. No RCRs were developed as no relevant chemicals were involved. All LCA indicators show an overall improvement due to the lower energy consumption.

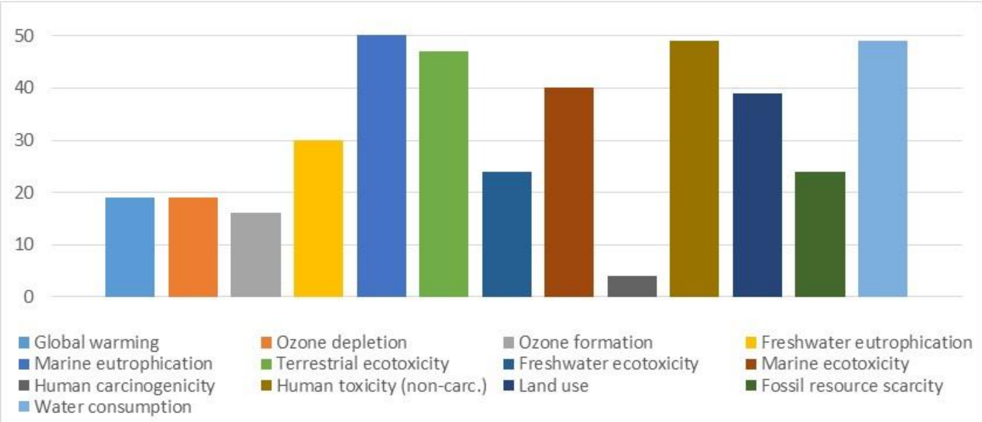


Figure 17: Change in LCA impact categories due to a change in the disinfection technology

4.12 Substitution cases in non-partner companies

Substitution and use reduction cases were assessed in nine non-partner companies at a qualitative level. Table 1 gives a brief overview of the types of cases, the most severe health and environmental hazards of the target substances and the reduction in use amounts achieved.

Table 1: Basic information on non-partner company cases

	Main health hazards	Main env. hazards	Reduced use amount [kg/a]
Substitution of preservatives in detergents			
Buthylphenyl methylpropional	Repro 1B, skin sensitizer	H411	0.23
Butylparaben	EDC		0.004
MIT/CMIT	Skin sens	H410	2.1
Partial substitution of solvent in construction product			
Styrene	Repro 1B		12,500
Substitution of VOC in inorganic product			
Acetone			710
Elimination of lubricant use (technological change) in metal processing			
Boric acid	Repro 1B		10
Use reduction due to efficiency gains in coating use			
BPA	EDC, Repro 1B, sensitizer		500
BPA derivative	Sensitizer	H 411	2,500
Zinc and zinc compounds		H 410	175
Substitution of VOC in construction product			
Xylene			2,557
Isophorene diisocyanate	Sensitizer	H 411	15
m-tolylidine diisocyanate	Carc. 2, sensitizer	H 412	250
diphenylmethanediisocyanate	Carc. 2, sensitizer		175
Substitution of hazardous substances due to changed printing technology			
Toluene	Repro 1B		0.26
Butanone			29
Avoided use of sensitizer in car care products			
Limonene	Sensitizer	H 410	2,268
Avoided use due to increased efficiency in adhesives use in wood processing			
Polymer	Sensitizer	H 412	6,941
Methanol	Carc. 2		42

The changes in hazards of the used substances in the non-partner companies is shown in the following tables, which compare the initial situation (initial) with the situation after substitution (alternative). The criteria are whether or not substances are used that are included in priority lists, if the substances have severe health hazards, are endocrine disrupting or PBTs or have other severe environmental hazards. Red indicates high concern, yellow indicates medium concern and green indicates low concern.

Table 2: Substitution of preservatives in detergents

Compare	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

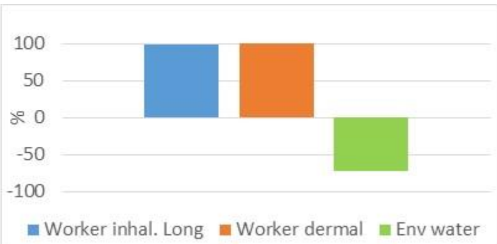
Table 3: Substitution of preservatives in detergents

Compare	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

Table 4: Substitution of preservatives in detergents

Compare	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

Table 5 Substitution of a solvent in construction products



Here, ΔRCRs were developed showing a significant reduction in workers risks and an increase in risks to the environment.

Table 6 Substitution of VOC in inorganic products

Criterion	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

Table 7 Elimination of a lubricant in metal processing

Criterion	Initial product	Use eliminated
Priority list		
Health		
EDC		
PBT		
Env		

Table 8 Reduction due to more efficient coating use

Criterion	Initial product	Use reduced
Priority list		
Health		
EDC		
PBT		
Env		

Table 9 Substitution of VOC in construction products

Criterion	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

Table 10 Substitution of chemicals in printing

Criterion	Initial product	Alternative
Priority list		
Health		
EDC		
PBT		
Env		

Table 11 Avoided use of a sensitizer in car product

Criterion	Initial product	Avoided use
Priority list		
Health		
EDC		
PBT		
Env		

Table 12 More efficient adhesive use

Criterion	Initial product	Use reduced
Priority list		
Health		
EDC		
PBT		
Env		

Overall, the substitution and use reduction work in the non-partner companies resulted in a reduced use of 510 kg/a of SVHCs and a total of 12,918 kg/a of CMRs (mainly Cat. 2). In total, 4,905 kg/a of substances with severe aquatic toxicity are used less. These use reductions are partly counteracted by alternatives with (less severe) hazards but as it can be seen from the profiles above, most alternatives have very few hazards at all.

4.13 Overall assessment of partner cases

Overall, in many cases, a clear reduction of risks could be observed due to the substitution of hazardous substances. In some cases, the alternatives result in a decrease of one risk but an increase of another. Several cases could hardly be assessed because of lacking data. Not all types of risks were relevant for all cases. In particular the consumer risks were not relevant for some cases (product not in consumer applications) as well as the risks to neighbours (substances do not emit to the air).

Similarly, a reduction in environmental impacts due to the substitution or use reduction could be determined for all assessed Lifecycle Impact Categories. However, not for all cases, an LCA could be performed as data on substances were missing in the LCA database.

The **use of several SVHC could be ended** and they were replaced with less hazardous alternatives. Non-SVHC but still hazardous substances and/or those that are VOC could also be reduced.

The substitutions taking place at a smaller scale in the project are not included in the above evaluation. However, in all of these cases, the use of the targeted hazardous substances was phased out. In some cases, no alternative chemical was used, while in other cases substances (or mixtures) with significantly lower hazards were selected as substitutes. Among the cases are some where the use amounts, i.e., the amounts substituted and not used in the future, are above 500 kg/a. This allows the assumption that also the so-called 'light cases' generated significant benefits due to a decrease in RCRs. The types of changes in the LCA impact categories cannot be assumed as they are not correlated to the hazards.

5 Discussion of methodology

The impact assessment methodology included the assessment of changed use and emission amounts as well as changes in (eco-)toxic risks and in contributions to environmental problems, according to LCA impact categories. The changes in RCRs should ensure that the specific aim of the project activities to reduce the (eco-)toxic impacts from the use of chemicals are adequately reflected in the impact measurements. Furthermore, the impact of the behaviour of chemicals in the environment should be reflected in the indicators[5]. The changes in LCA impact categories should ensure that substitution does not involve significant trade-offs in this regard.

The calculation of the above listed indicators proved challenging in all of the assessed cases, mainly due to a lack of suitable data on substance properties and on their lifecycle inventory. As the challenges already arose at the level of individual cases, issues relating to the extrapolation of results are not discussed here.

[5] By including the environmental fate and behaviour and considering the effect thresholds of the substances in the assessment, the indicators are more differentiated than mere "use and emission" by hazard category. In addition, the indicator is more precise in anticipating the actual damage potential by integrating the exposure of humans and the environment.

5.1 Risk characterisation ratios

According to the initial plans, ΔRCRs should have been developed for the following categories, where relevant (for some cases, consumer uses do not occur).

Table 13 Overview of envisaged ΔRCR indicators

Workers	Consumers	Environment
Long-term inhalation	Inhalation	Local, freshwater
Long-term dermal	Dermal	Local, freshwater, sediment
Short-term inhalation	Oral	STP
Short-term dermal		Man via environment

To calculate an RCR, it was planned to:

- identify DNELs and PNECs from the ECHA's database of registered substances; in case no such values were available, these endpoints could not be considered;
- use the ECETOC TRA to calculate RCRs for workers, consumers and the environment;
- aggregate single substances values for all substances that changed due to the substitution, i.e., the phased-out product and the alternative.

The main problem in calculating and comparing the RCRs consisted of a lack of data on substance properties. To calculate environmental RCRs, PNECs were partly missing or inconsistent with the classification. The latter sometimes resulted in an increase in RCR for the freshwater compartment despite a much lower classification, which could not be explained by differences in the environmental fate. The calculation of ΔRCRs for workers and consumers was frequently hindered by a lack of DNELs for at least some of the needed exposure pathways and durations (cf. Table 13). The majority of available DNELs were based on long term toxicity studies, which were usually not the most severe hazards of at least the target substances. Hence, RCRs could be calculated before and after substitution but did not concern the risk that should be reduced or eliminated, such as reprotoxicity or endocrine disruption. Where the points of departure for deriving DNELs differed, e.g., one was based on long term toxicity and another on reprotoxicity, the comparison does not consider the severity of the effect but only the change in risk that the effect with the lowest threshold value occurs. Finally, non-threshold effects by default have no DNEL values, and for these substances, the method does not work, even if information from testing is available.

Challenges with regard to the exposure estimation include the lack of exact information on the concentration of substances in mixtures (ranges in safety data sheets) and the fact that the ECETOC TRA is a rather rough exposure model. Although over- and underestimations of exposure levels are considered levelling out, changes due to e.g. changed mobilities of substances or the options to modify the settings of operational conditions and risk management measures allowed little differentiation in the exposure estimation. Due to a lack of transparency on the calculation of RCRs in the workers module, it is not possible to comprehend the effects this may have on the results. Finally, the ECETOC TRA is not designed for "special cases", such as substances that are active (enzymes).

5.2 LCA impact categories

The aim of LCA indicators was to provide quantitative information on the direction and the extent to which impacts to the environment, human health and resources have changed due to the substitution of hazardous chemicals or implementation of resource efficiency measures during the project.

The methodology for performing LCA involved:

- definition of goal, scope and functional unit;
- collection of inventory data for the initial and alternative situation;
- comparison of input and output data for initial and alternative situation;
- modelling using SimaPro.

It was acknowledged that there are several limitations to this methodology regarding the availability of data as well as possible uncertainties and subjectivities due to the need to make assumptions. The main challenge of implementing the LCA indicators was that a significant number of substances involved in the substitution cases was not contained in the Ecoinvent database, i.e., no lifecycle inventory data were available in the Ecoinvent database. For a few substances, similar compounds were identified in the database and assumed to be similar also in LCA impacts. These were then used in the assessment. In other cases, no information was available at all and, e.g., in the substitution of DINP by DINCH, no assessment could be performed. In other cases, an assessment was performed despite the lack of information. Usually, more than 90% of the composition were known.

5.3 Overall evaluation of the methodology and recommendations

The basic indicators on the use and emissions of hazardous substances can be derived relatively easy and give a clear understanding of what was happening on the target substances at the company level. However, as substitution not only means ending something but also usually marks the start of either the use of a new chemical or a new technology, these indicators only show half of the truth. If the change in the situation should be assessed, the difference in the situations before and after substitution should be assessed.

Here, the two types of indicators used in the project are useful and complement each other in their content and hence give a holistic view of the substitution process. Overall, the results of changes in LCA impact categories relating to human and environmental toxicity were in line with the trends observed in the changes in RCR, with the latter being more differentiated and specific.

When sufficient data are available, the use of the selected indicators is well possible for substances that have an effect threshold. For non-threshold substances, the ΔRCR is not a suitable indicator. The ΔRCR and the changes in LCA impacts allow a more detailed look at the benefits for the environment and a more comprehensive understanding of the situation. While the ΔRCRs give a more realistic and differentiated picture of the changes in risks, the changes in LCA impact categories allow widening the view to the impacts on other environmental challenges, such as climate change, acidification or land use. In addition, the LCA allows assessing cases where the use of chemicals is eliminated or simply reduced, as well as where the change of technologies requires additional considerations to understand the impacts.

The methods could be implemented with reasonable efforts by the project team.

The shortcomings of the approach result from the lack of information to calculate indicators. More information may become available over time but it is likely that there will always be significant data gaps. The roughness of the exposure model and the lack of comparable DNELs for some of the cases revealed challenges in communicating the assessment results regarding RCRs. On the one hand, several cases resulted in a “risk” as defined under legislation, i.e., RCR > 1, which is, with a view to the actual conditions of use, most likely not existing in reality. On the other hand, the uncertainties and the lack of comparable hazard information are difficult to explain to lay persons, including the companies themselves.

A full LCA is too resource-intensive and requires specific knowledge to be practical, while LCA using generic lifecycle inventory data is not always possible due to limited data in LCA databases, especially on chemicals, which are a huge variety.

5.4 Recommendations

It is important for companies and their decision making on substitution that up-to-date, understandable and relevant information on substance hazards is available. Therefore, the **ECHA should continue assessing registration dossiers. The ECHA should monitor** the effect of the new EU regulation[6] on **dossier updating** requirements and, if the data quality does not sufficiently increase, it should initiate further measures in this regard.

It is common that different hazard information is available for different substances, including DNELs and PNECs. The **ECHA and the EU Commission** should **discuss with the stakeholders which data are essential to support the assessment of alternatives and agree on a set of values** covering human health and the environment. They should then analyse **how they could be provided** with reasonable efforts and how their existence could be ensured for all substances. This may involve extending the REACH information requirements for registration, also in the lower volume bands.

The existing alternatives assessment tools are mostly hazard based, partly too difficult to use for the downstream users and usually do not allow the comparison of alternative mixtures. Therefore, **stakeholders** should cooperate **and develop simple approaches and tools to compare alternatives** – which are mixtures – with regard to their hazards and potential risks in order to identify the best alternatives.

The assessment of sustainability of chemicals requires considering environmental impacts of substitution at least at a generic level and in particular where there are several alternatives with similar hazard profiles. Here, LCA considerations could help decision making. As full scale LCAs are not possible due to their large resource needs, **simplified LCA** approaches are needed. These **should be developed by scientists**.

[6] Commission Implementing Regulation (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006

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