Study for the strategy for a non-toxic environment of the 7th Environment Action Programme

Final Report

Written by Milieu Ltd, Ökopol, Risk & Policy Analysts (RPA) and RIVM
August 2017

EUROPEAN COMMISSION

Directorate-General for Environment
Directorate B — Circular Economy & Green Growth
Unit B.2 — Sustainable Chemicals

European Commission
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Sustainable Chemicals

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ABSTRACT

The 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council, mandates the European Commission, inter alia, to develop by 2018 "*a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions*". This study supports the Commission with its development of the strategy by providing a comprehensive overview of the state of play and by identifying gaps and deficits in the current EU chemicals policy and legislative framework in relation to the following aspects:

- Substitution, including grouping of chemicals & measures to support substitution;
- Chemicals in products (articles) and non-toxic material cycles;
- The improved protection of children and vulnerable groups from harmful exposure to chemicals;
- Very persistent chemicals;
- Policy means, innovation and competitiveness;
- Programme on the development on new, non/less toxic substances;
- Early warning systems for examining chemical threats to human health and the environment.

Each of the above-mentioned topics is the subject of a sub-study under the overall study which identifies improvement opportunities in relation to all seven sub-study areas with the ultimate goal of creating and maintaining a non-toxic environment that is free of exposures to minimise and eliminate all exposures to hazardous substances.

EXECUTIVE SUMMARY

The 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council, mandates the European Commission, inter alia, to develop by 2018 *"a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions"*.

The chemicals-related objectives of the 7th EAP are not isolated but are embedded in global policy initiatives, first and foremost the goal to achieve the safe management of chemicals throughout their life-cycle, as agreed during the 2002 World Summit on Sustainable Development in Johannesburg (WSSD) and as further elaborated through the Strategic Approach to International Chemicals Management (SAICM) process. In order to achieve these international chemicals-related commitments, the European Union needs to set out a clear, longer term strategy – one that complements, guides and frames its current laws and policies in relation to chemicals.

The EU's current legislative framework is anchored by the 2006 REACH Regulation and CLP, a major milestone in the effort to establish a regulatory framework able to keep abreast of the challenges of ensuring a high level of protection of human health and the environment, whilst promoting the free circulation of substances on the internal market and enhancing innovation and competitiveness. Under the European Commission's better regulation programme (REFIT), all EU chemicals legislation except REACH is undergoing a comprehensive fitness check, expected to be finalised in 2017, and a REFIT evaluation of REACH is nearly completed. The preliminary results of this stocktaking of EU chemicals legislation to date indicate that the current instruments are basically still fit for purpose. However, some gaps have been identified, e.g., a lack of controls over substances in articles, including imported articles. Separate Commission processes are also considering other problem areas, namely combination effects, nanomaterials and endocrine disruptors.

The gaps and problem areas mentioned above are strongly interconnected and closely linked with the current chemicals *acquis.* In particular, some type of process or mechanism that acts horizontally across the various pieces of EU legislation that deal with chemical risks and pollution appears to be needed, in order to ensure a coherent approach to achieving the EU's longer-term objectives and goals as well as to meet its international commitments with regard to the protection of human health and the environment.

This study complements all of the Commission processes mentioned above. It provides support for the development of the non-toxic environment strategy by examining the possible building blocks of the strategy. It focusses on the following topic areas selected by the Commission:

- Substitution, including grouping of chemicals & measures to support substitution (sub-study a);
- Chemicals in products (articles) and non-toxic material cycles (sub-study b);
- The improved protection of children and vulnerable groups from harmful exposure to chemicals (sub-study c);
- Very persistent chemicals (sub-study d);
- Policy means, innovation and competitiveness (sub-study e);
- Programme on the development on new, non/less toxic substances (sub-study f);
- Early warning systems for examining chemical threats to human health and the environment (sub-study g).

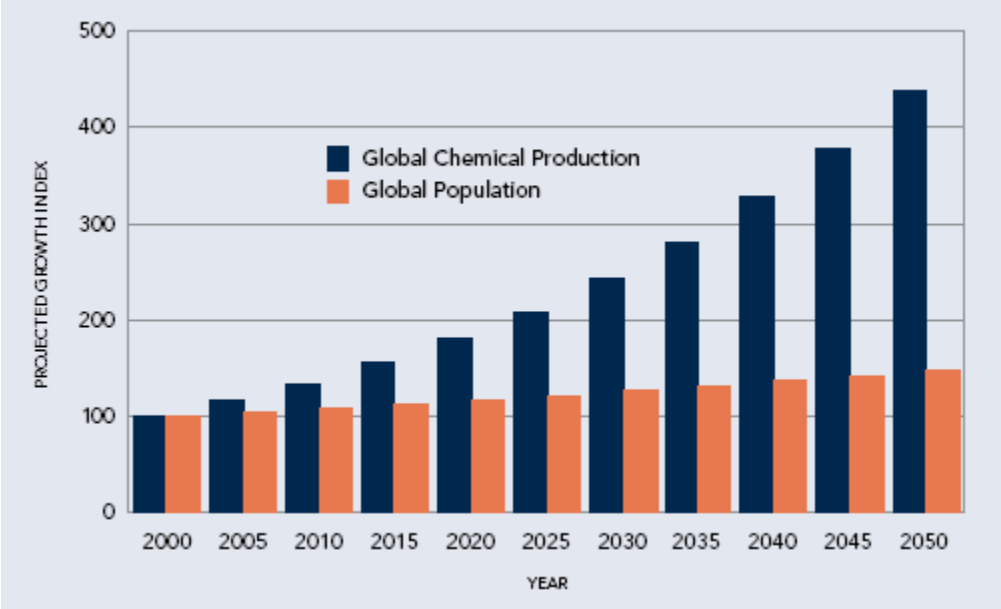
Sub-studies b, c and d present assessments of the information available concerning the scale of the problem, as well as analyses of gaps, deficits and improvement opportunities in their respective areas. Sub-studies a, e, f and g explore possible ways forward. This final report summarises key findings.

The role of chemicals in modern society and the regulatory challenge

The chemical industry shapes a range of other economic activities, from agriculture, construction and textiles to high tech industries such as aerospace, automotive, health care and electronics, more than any other manufacturing sector. Due to its role in the value chain, i.e. transforming raw materials and feedstock into tailor made solutions for downstream industries, it serves all sectors of the economy and contributes to our well-being.

The use and production of chemicals within the EU and around the globe is ever increasing. Global chemicals sales more than doubled between 2004 and 2014 (from €1,458 billion to €3,232 billion) and the total value of EU sales increased by 80% in the same period. Growth is expected to continue by 4% every year by 2020. The figure below shows how the rate of growth of the global chemicals production has already outpaced, and is expected to keep outpacing, global population growth rates over the next decades.

Figure 1: Projected growth in chemicals production in comparison to growth in global population



Source: Green Chemistry: Cornerstone to a Sustainable California (2008).

These increases in chemical production translate into more chemicals used in products and more exposures of humans, animals and environmental media such as air and water. Exposure to a chemical with an intrinsic hazard, such as the CMRs (carcinogens, mutagens, reproductive toxins), can lead to harm. But of the over 100,000 chemicals present on the EU market today, only a small fraction has been thoroughly evaluated by authorities regarding their health and environmental properties and impacts, and even fewer are actually regulated, e.g. REACH partially restricts or bans some 60 individual chemicals and some groups of chemicals with similar properties, such as carcinogens, mutagens and repro-toxic substances (CMRs).

Chemicals regulation depends on a hazard identification and a risk assessment procedure to estimate the extent of the exposure and on that basis the probability of harm as well as its possible severity. On the basis of such assessments, measures can be set in place to manage the known risks so that they are at levels considered acceptable (safe) to humans and the environment. But controlling the risk of harm is a moving target, given that quantities of chemicals and subsequent exposures are likely to increase dramatically. Moreover, risk assessments, usually carried out by a chemical's proponents (e.g., the producer), often underestimate the risk of harm. Additional scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment.

Chemicals in products (articles) and non-toxic material cycles (sub-study b)

An estimated 35,000 chemicals are on the EU market in volumes above 1 tonne per year, and over 60% (by tonnage) of these are hazardous to human health and/or the environment. These are not just 'chemical products' (paint, glue, detergents, solvents, pharmaceuticals); they are virtually all materials (metals, plastics, paper, glass). The millions of articles used every day consist of chemicals, are manufactured using chemicals and are treated with chemicals (e.g., coatings, preservatives).

Hazardous chemicals are known to be used in a vast array of consumer articles, from clothing/textiles, furniture, buildings and infrastructure, electronics and vehicles to tinned food linings, medical devices and toys. Without labelling or laboratory analysis, it is not possible to know which products contain which chemicals -- a challenge made more difficult by the volumes of products produced in other countries and imported into the EU. The difficulty of figuring out how and when people are exposed to which hazardous chemicals risks is compounded because of the complexity of possible exposure situations, the combination (or so-called 'cocktail') effects of exposure to multiple chemicals, and the impacts of cumulative exposures from multiple sources over time.

Some of the costs of chemicals-related damages known to date

- Health care costs and lost earnings linked to exposure to endocrine disrupting chemicals comes to an estimated €157 billion each year. Impacts on the unborn child, young children and women of fertile age are of particular concern.
- Chemical-related damage to the environment can also be costly. Use of tributyltin as anti-fouling marine coatings caused population declines in shellfish, with an associated economic loss estimated in €22 million per year to the UK shellfish industry alone.
- Decontamination of buildings, infrastructure, land and water is very expensive, e.g, cleaning up contamination just from PCBs is estimated to have cost the EU more than €15 billion between 1971 and 2018.

A recent Swedish market survey illustrates by analogy the variety, number and complexity of products containing hazardous substances. It searched for articles treated with biocides, a group of substances by definition more or less toxic. The survey found a wide range of treated articles marketed with a claim such as "antibacterial", including sanitary products, electronic products, kitchen utensils, textiles, leisure equipment, home products, baby products, pet accessories etc. Much more difficult to identify were articles which made no biocidal claim but yet contained a biocide such as a preservative in order to protect the content, e.g., leather, from microbial and algal development. The survey found many more biocide-treated products than were identified as such and concluded that the numbers of treated goods on the consumer market is huge.

Scientific evidence is mounting that the exposures from everyday products, including articles, are exposing modern society to multiple hazardous chemicals, and that these chemicals, even at low dose levels, can give rise to subtle but long-term health effects such as reduced fertility, lower birth weights and neurodevelopmental diseases. Pathways of exposure to chemicals in products involve indoor air as well as household dust. And, since many of the chemicals involved are persistent and long-lived, once they are out into the environment and into our food chains they can continue to cause problems for many decades or even centuries.

The presence of hazardous substances in articles and subsequent material cycles could also undermine the EU's goal of a circular economy. Chemical contamination will make recycling more difficult and present new, unexpected exposure situations, e.g. if contaminated recycled materials get used in products not originally foreseen. Brominated flame retardants used in plastics being recycled have already been found in thermos cups and plastic tableware. Other well-known examples of problematic substances found in material flows include PCBs, lead, cadmium, and some highly fluorinated substances.

Current EU legislation does not adequately regulate the chemicals in articles and material cycles. The

REACH requirements for providing information on the content of SVHCs in articles (REACH Article 7 and 33) are insufficient, poorly complied with and rarely enforced. Gaps exist in other critical EU policy areas – products, waste -- and the interfaces between them. The very few restrictions relating to the use of chemicals in articles are scattered in different legislation, lack a systematic basis and do not take the overall and combined exposures to chemicals in articles sufficiently into account. Furthermore, the authorisation process under REACH does not cover SVHCs in articles from non-EU manufacturers and imported into the EU. Even if hazardous substances are restricted and phased out, they will continue to appear in waste streams and hence also in recycled materials, in particular from articles like buildings and infrastructure with a long lifespan of decades or more.

The scale of the problem with respect to chemicals in articles

- As global production of chemicals increases, so does the production and international trade of articles made from these chemicals. The yearly import of manufactured goods to the European Union has almost tripled between 2000 and 2015, including from countries with insufficient regulatory controls over chemicals. In 2016, 3.4 tonnes of products (2.1 raw, 0.4 semi-finished and 0.9 finished products) per capita were imported in the EU. About 20% of these were imported from China (value of €344.7 billion).
- According to Eurostat data, in 2015, products worth more than 3 trillion EUR have been produced and sold within the EU market while during that same period products worth more than 1,7 trillion EUR have been imported into the EU-28 from third countries. A high share of these products are articles in terms of REACH.
- When Member States find articles on the market that are dangerous and not in compliance with EU legislation, they circulate notifications through the EU rapid alert and information exchange system (RAPEX) so that other Member States can withdraw those products from the market also. Of 2044 notifications in 2016, 23% were related to chemicals, including in consumer products and toys. Because RAPEX notifications are mainly limited to acutely toxic chemicals, they are considered just the tip of an iceberg.
- Human biomonitoring studies in the EU point to a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers, flame retardants, etc.

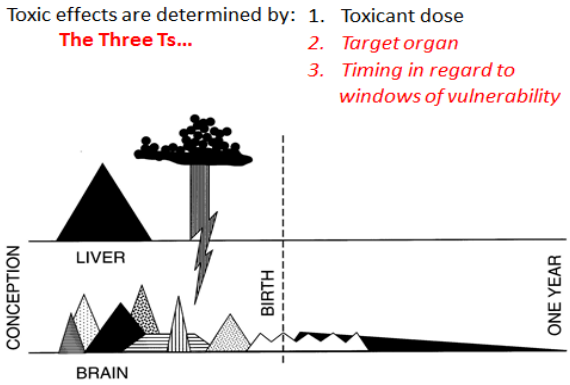
The lack of quantitative and qualitative knowledge regarding the actual content of hazardous chemicals in articles and resulting exposures provides little incentive for substitution and development of less toxic products. This knowledge base needs to be strengthened. Further, access to this information needs to be improved throughout the supply chain, including at waste and recycling stages, where this could prevent contamination of waste streams or initiate a targeted decontamination. The need for further policy development runs across chemicals, product and waste policy, and is particularly important in the light of the objectives of a circular economy.

The sub-study concludes that three approaches are necessary with regards to achieving non-toxic articles and material cycles. First, the transparency about the occurrence of toxic substances in articles needs to be increased in the supply chains and for the authorities (market overview). Secondly, strategies and implementation instruments that prevent toxic substances from entering articles and materials cycles will avoid risks to human health and to the environment throughout the substances' lifecycles. Third, strategies and implementation instruments that motivate and enable the waste treatment sector to decontaminate waste streams from toxic substances are needed, as long as toxic substances continue to enter the waste stage from articles. Complementary activities are needed to ensure that all of the actors understand, implement, and benefit from the use of less toxic substances in articles and materials.

The improved protection of children and other vulnerable groups from harmful exposure to chemicals (sub-study c)

The full impact on modern society due to continuous exposure to a range of chemicals is not yet known. But alarms are being raised, particularly with respect to certain groups of the population – such as children, pregnant women, the elderly, some categories of workers and groups of low

socioeconomic status. These groups are known to be especially vulnerable to the risks stemming from chemical exposure, and, as such, have a higher probability of developing adverse health effects throughout their life. This increased vulnerability depends on a variety of reasons, spanning from increased sensitivity to chemicals, specific biophysical characteristics, health status, constant exposure to highly hazardous chemicals, specific behaviours, reduced ability to protect oneself from exposure, and social factors, e.g. where a person lives or works or spends the majority of his/her time. In light of their higher vulnerability, these groups need special protection from chemical exposure.



Source: Grandjean, 2017

The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents – of which more than 200 have been identified, with many more suspected to exist - can cause functional deficits and life-long adverse health effects at low levels of exposure that would have little or no adverse effect in an adult. Early-life epigenetic changes are also known to affect subsequent gene expression in the brain. The figure above illustrates how the timing of an exposure to a toxic chemical helps to determine the effect of that dose during critical windows of vulnerability during development of a foetus and then infant.

The scale of the problem with respect to vulnerable groups

- Over 200 synthetic chemicals have been detected in umbilical cord blood, including pesticides, ingredients in consumer products, food packaging, and chemical by-products from burning coal and flame retardants.
- A 2010 study of British children aged 0-6 years showed that children, on average, consumed 1.6-3 times more food packaged in plastic than adults, implying a proportionally higher exposure to substances leaching from plastic food contact materials for children than adults.
- Certain hazardous substances can contribute to neuropsychiatric disorders in children, with disorders of neurobehavioral development affecting 10–15% of all births, and prevalence rates of autism spectrum disorder and ADHD appeared to have spread worldwide.
- The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually. Europe-wide epidemiological evidence indicates that diphenyldichloroethene (DDE)-attributable fibroids and phthalate-attributable endometriosis affects some 56,700 and 145,000 women, respectively. This costs the EU €163 million (for attributable fibroids) and €1.25 billion (for endometriosis) per year.
- The percentage of U.S. women having difficulty in achieving and maintaining pregnancy increased between 1982 to 2002. The sharpest increase in reported infertility between 1982 and 2002 was among younger women.

Though many policy and legislative measures are now in place at EU level, the protection of vulnerable groups from harmful exposure to chemicals remains sporadic. For instance, although the EU Toys Directive provides standards to protect children as a vulnerable group, other products aimed at children such as clothing and bedding are not covered. Other EU legislation aimed at protecting

citizens from ingesting contaminants, such as the 1998 Drinking Water Directive, need to be updated to reflect the most recent scientific evidence and lack specific measures which could strengthen the protection of vulnerable groups. Parameters for 12 of the 17 types of food contact materials listed in the 2004 Food Contact Materials Regulation are still not regulated at EU level, though some may contain substances that could migrate into food, resulting in exposures associated with adverse health effects on children.
EU risk assessments have traditionally focused on single substances and not taken into account combined or cumulative exposures to toxic chemicals. But recent studies indicate that combined exposure to several substances, including substances in articles, can have greater impacts than exposure to a single substance. Combined prenatal exposure to several chemicals led to reduced foetal growth and lower birth rates for children, just as low doses (below no observed adverse effect levels, or NOAELs) of several pesticides in combination resulted in decreased birth weights in rats. This indicates the need for a greater safety margin for exposures, in particular for foetuses and neonates.

Moreover, the scientific community has tended to study the same substances, e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc. Additional substances and new areas, such as the health impacts of nanomaterials and chemical mixtures on certain categories of the population, need to be studied. Chemical risk assessment needs to consider any particular impacts for vulnerable groups, whose consumption patterns and exposure levels may differ significantly according to age group, geographical location, and lifestyle factors. Finally, with respect to certain industrial chemicals known to have neurotoxic properties, it may be necessary to apply precautionary measures in order to provide vulnerable groups such as foetuses and children with sufficient protection.

Very persistent chemicals (sub-study d)
The use and dispersal in the environment of very persistent (vP) chemicals represents another significant threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. However, concentrations of chemicals with a high degree of persistence will tend to build up and eventually reach levels where harmful effects to human health and natural resources may occur.

With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, certain toxic effects (e.g. chronic or occurring at low concentrations) may take many years to identify and may not become evident until long after exposure, even for chemicals where laboratory tests did not indicate any considerable toxicity. By the time evidence is gathered about a chemical's propensity for harm, accumulations may have already occurred. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they are at a global scale and affecting a vital earth system process.

The scale of the problem with respect to very persistent chemicals

- Only 220 chemicals out of a set of 95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives; data on bio-concentration is available for just 1,000 (UNEP).
- The Stockholm Convention covers 26 substances and groups of substances and another three are under consideration for future inclusion. Yet as many as 1,200 of the 100,000 substances on the market today could be potential POPs, i.e., meeting all criteria for persistence, bioaccumulability, toxicity and long-range transport.
- The number of substances meeting only the POPs criteria for persistence alone is certainly much higher. More than 3,000 different PFAS (a group of highly fluorinated and extremely persistent chemicals) are known to be on the market today. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, and textiles, and are used in pesticide formulations, oil production and mining.
- A 2017 study carried out by consumer groups in Belgium, Italy, Denmark, Spain and Portugal found that a third of the 65 samples of fast food packaging tested contained high levels of PFAS.
- Some 3.5 million sites around Europe are already contaminated by hazardous substances,

including vPs. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Concern is especially mounting with regard to the highly fluorinated chemicals known as PFAS (per- and polyfluorinated alkyl substances). PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea. The thousands of new short-chain PFAS marketed by producers as "safer" than the long-chain PFOS and PFOA are also extremely persistent, and evidence of their toxicity and presence in the environment is increasing.

The use of PFAS-based fire-fighting foams in training exercises at major airports and other industrial uses has led to widespread contamination of water resources throughout the USA. When the USEPA established lifetime health advisory limits for PFOS and PFOA in 2016 and compared them to levels of PFAS found in drinking water, over six million US residents learned they were being supplied with water exceeding those limits. PFAS has also been found in drinking water in Sweden, Germany, the UK, the Netherlands and Italy, but because no EU-wide monitoring for PFAS contamination has been carried out to date, how many EU citizens also drink water contaminated by PFAS is not known.

Current EU policies and legislation do not provide an adequate way to control substances on the basis of their persistent properties. The lack of a common framework for screening substances for persistence combined with inadequate requirements for persistence testing have contributed to major knowledge gaps. As a consequence, the fate of a substance released during a product's use or at the end of product life is seldom fully evaluated. Moreover, in those EU acts that consider persistence as a property of concern, persistence is regulated only if bioaccumulability is also present. Failure to take persistence into account risks build-ups of vP substances, which could lead to increases in exposure similar to those occurring due to bioaccumulation including in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.

From the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and proactive approach and to prevent and/or minimise releases of vP chemicals in the future. One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. Other important measures identified include development of better methods for screening and testing chemicals for persistence, along with systems for recovery and destruction of persistent chemicals in production wastes and during end-of-product life recycling and disposal.

Substitution, including grouping of chemicals & measures to support substitution (sub-study a)

The traditional approach in chemicals legislation has been substance by substance regulation, which is time-consuming and not adequate to handle the range of chemicals known to be problematic. For example, several hundred individual substances meet the criteria for being considered substances of very high concern (SVHC). The criteria for carcinogenicity, mutagenicity or toxic for reproduction (CMR) alone apply to about 600 different substances, and as many as 1,200 of the 100,000 substances

on the market today could be potential POPs. In the meantime, the use of large quantities of hazardous substances in products, including consumer products, is exposing humans and the environment during manufacturing, product life, waste management and recycling as well as their likely presence in recycled materials.

To address this problem, REACH and other EU legislation have provisions to require/encourage substitution, i.e., the replacement of a hazardous substance with a less toxic substance. Indeed, studies have shown that reducing exposure to hazardous substances is cost-effective. For instance, benefits to women's and men's reproductive capability due to reduced exposure to phthalates between 1996 and 2008 is estimated at €7 billion and €6.7 billion. Further, the application of binding and indicative occupational exposure limits resulted in an avoidance of 1.4 million premature deaths across Europe. However, substitution towards less toxic/safer substances is proceeding very slowly. Moreover, resources for assessment and control being limited, manufacturers tend to focus on chemical-by-chemical substitution. In many cases they have used a structurally similar substance with similar properties, and posing similar hazards to human health and the environment, but less well-studied and regulated. This has been termed 'regrettable substitution'.

As some groups of structurally related substances and often sharing similar harmful properties are quite large, the likelihood of regrettable substitution could continue for a long time. Of particular concern are the several hundred Substances of Very High Concern (SVHC), including some 600 chemicals classified as CMR. Some of these count hundreds of congeners within each group. On the other hand, strategies grouping chemicals of similar properties or use ('grouping strategies') could help accelerating beneficial substitution and increasing the efficiency and effectiveness of the legislation.

So what is stalling progress with substitution? Some shortcomings in current EU chemicals policy include:

- Low quality, insufficient and not updated information on substances in e.g. REACH registration dossiers, including on their properties and uses,
- Lack of information on chemicals used in articles, and of their risks during such uses, including during their service life and waste stages,
- Insufficient incentives for substitution, e.g., inadequate resources for enforcement of chemical policy, lack of regulatory signals encouraging investments in innovation,
- Lack of information on alternatives, including non-chemical solutions, along with insufficiently developed tools for assessment of alternatives.

To counter the issue of regrettable substitution and to increase regulatory efficiency and effectiveness, the use of grouping strategies for assessing chemicals with structural similarities needs to be scaled up. Other measures to consider include: streamlining legislation to provide more incentives for substitution; active support and training on substitution; promotion of functional substitution; more research on grouping strategies for regulatory purposes, focusing on the systematic analysis of the structural similarities of substances and trends in (Q)SAR predictions. Measures for a transition to a non-toxic environment could also rely on economic instruments, better enforcement of current legislation and the enhancement of monitoring programmes.

Policy means, innovation and competitiveness (sub-study e)
A stable and predictable regulatory environment is a key requirement for the competitiveness of the European industry and for its ability to innovate. Regulation has the potential for both negative and positive impacts on these two aspects: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring a level playing field for all the actors involved.

While on the one hand the EU environmental legislation, and in particular the legislation of the chemical industry, is one of the most ambitious in the world and may constitute an additional burden to EU industry against extra-EU chemical companies, the legislation does ensure the internalisation of the externalities of the industry, enforcing the "polluter pays" principle and delivering benefits to the whole society in terms of human health and the environment on the other. An assessment by the UK DEFRA shows that for every €1 of cost incurred by industry and government authorities in implementing EU chemical legislation, €19 of health and environmental benefits accrue to society as a whole. Stricter environmental requirements can also stimulate innovation towards sustainability, providing first move competitive advantages to the more pro-active companies.

Conversely, the lack of environmental requirements can also have negative consequences on the innovation capacities of SMEs. For example, the lack of information on the uses and presence of hazardous chemicals in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purposes of substitution by downstream users. Gaps in information may also result in imperfect synergies between the different chemical legislative acts. Chemicals regulated by REACH may leak from products during their life cycle or during the waste stage, contaminating water resources regulated by the Water Framework Directive. The lack of upstream measures, such as a restriction, may lead to a need for downstream remediation, the costs of which will be covered by the water and wastewater sectors and ultimately by taxpayers/society, reducing the incentives for the producers and users of the chemicals upstream to pursue less toxic innovations.

In addition to these regulatory considerations, the potential for innovation is limited by lack of funding for supporting transformative technologies with strong innovative potential and added value. EU support is scattered over a large range of calls for proposals and topics research, and the funding available does not meet the ambition of industrial scale projects. More support or encouragement for co-operation within and/or between sectors could be helpful, as well as measures to attract foreign investment to enable innovation.

Programme on the development of new, non/less toxic substances (sub-study f)

A non-toxic environment implies that hazardous substances are replaced with safer alternatives including non-chemical solutions. The use of hazardous substances can however only be phased-out if suitable alternatives are available. With some 60% by tonnage of the chemicals on the market considered hazardous for health and the environment, a potential demand for non-toxic or at least less toxic substances of a large scale is expected, if a non-toxic environment should be achieved. Barriers to the development of new, non/less-toxic substances currently result from various challenges in the supply chain. These include:

- an overall hesitation to using new (non/less-toxic) substances because of fears about (hidden) costs and a lock-in in the current production situation (the possible need to change the overall choice of material or design of a chemical product or an article as well as processing equipment);
- the potential need to break existing supplier-customer relationships in combination with the need to identify new suppliers with whom they take the risks of developing a new substance;
- a lack of communication and collaboration opportunities and capacities, which are necessary for substitution, particularly where the alternatives do not exist yet;
- an overall lack of awareness of the benefits of using new, non/less-toxic substances;
- overall economic uncertainties as to the future performance of products, the development of markets, potential profits and stability of supply, if new, non/less-toxic substances are used

No national programmes that focus on the use of new, non/less-toxic substances were identified. However, a number of activities on green chemistry are under way in the USA, interconnected via an overall mission of the US EPA. Moreover, some Member States conduct activities related to the development and use of green or sustainable chemicals, including support for tools for substance design, hazard prediction, risks and alternatives assessment, stakeholder platforms, stakeholder dialogues and awareness raising about the needs and opportunities presented by substitution.

Several provisions exist in the EU regulatory framework and scientific programmes to support the development and use of new (non/less-toxic) substances. However, overall guidance and market signals, e.g. from the authorisation decisions under REACH, are mixed. Whilst stricter legislation may better promote the development of new, non/less-toxic substances, overall awareness on the benefits of using such substances is low and sufficient emphasis on the issue across all relevant policies is still missing.

At EU level, the Research and Innovation Programmes cover a wide range of different scientific, economic and societal challenges. Whilst no specific theme addresses the development of new, non-toxic substances, some themes -- notably LEIT-NMPB (Leadership in Enabling and Industrial Technologies, Nanotechnologies, advanced Materials, advanced manufacturing and Processing and Biotechnology) – could fund activities relevant to a non-toxic environment. One example of action is the Horizon 2020's €3 million prize for clean air, for which challengers must develop innovative, design-driven material solutions that will reduce the concentration of particulate matter in the air.
However, the overall perception is that the EU funding instruments direct their resources towards other societal challenges than the toxicity of substances, such as to climate change, resource efficiency or health sciences. Therefore, an EU programme specifically supporting research and development of new, non/less-toxic substances could be an integral part of the strategy for a non-toxic environment and could support the provision of alternatives to toxic substances as well as enhancing the design of new, benign materials at a smaller scale, thereby complementing the existing funding programmes. A programme to enhance the development of new, non/less-toxic substances should also include activities aimed at improving the overall business environment and readiness to innovate, e.g. by providing guidance at the policy level, raising awareness, improving education and supporting networking of the relevant actors.

Early warning systems for examining chemical threats to human health and the environment (sub-study g)
The EU chemicals regulatory framework provides for predicting hazardous properties and taking risk management measures that limit human and environment exposure. Despite this legislation, numerous cases have been documented of extensive damages to health and environment caused by the production and use of chemicals. It can take societal institutions a long time before warning signals are picked up and even longer for them to react, which jeopardizes any prospect of preventing or minimising damages.

For example, 10 of the 15 *Late Lessons from Early Warnings* identified by the European Environment Agency are directly linked to chemicals with hazardous properties (i.e. benzene, asbestos, PCBs, halocarbons, DES, antimicrobials, MTBE, PFAS, TBT, EDCs). Half of those cases highlighted issues caused by the persistent nature of chemicals (i.e. PCBs, halocarbons, MTBE, PFAS and TBT), several emphasized the additional risks induced by the cumulative effect of hazardous substances (i.e. PCBs, halocarbons, MTBE, TBT, EDCs), and two underlined the impacts of late lessons on vulnerable groups (i.e. PCBs, EDCs). This report highlighted instances in which years or decades spanned before regulatory intervention.

Early identification of new and/or emerging risks (NERCs) to human health and to the environment is of great importance in taking timely measures to reduce or eliminate the risk of hazardous compounds. Rather than an alternative instrument replacing current legislation, the development of such fast identification and response system is critical and must be considered as a complementary action.

At the moment, several approaches are used to pick up signals, such as online media monitoring and expert consultation, or registration systems for the collection, evaluation and systematic monitoring of spontaneous reports of undesirable events. Current systems depend heavily on observed and documented signals relating to occurrence of effects and potential exposure, the so-called 'effect-based' or 'disease first' systems. By contrast, other systems contain elements that can be used to

proactively identify possible NERCs, based on a proper risk assessment, the so-called 'exposure first' method.

Screening and filtering signals are essential for early identification. However, it is labour intensive and requires input from experts at the national level, which is currently not organised or coordinated at the EU or an international level. A related issue is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread before it is detected. There is often a lack of information, due to the absence of relevant hazard data and the absence of details on exposure and use.

These issues highlight a general need for more cooperation and exchange of information on NERCs at EU level, including a supra-national platform for coordination. At the national and international levels, various existing initiatives in the area of early identification and management of chemical threats could provide the basic opportunities for more comprehensive and coordinated work. However, an overall approach covering the different steps needed for the identification and management of risks at the EU level is necessary. An essential step would be to generate an overview of existing data sources, their availability, accessibility, and their usefulness, and to make this data accessible through a central database. Investigation of appropriate risk management options, communication of the risks identified, and identification of measures to propose would be important to managing the risks observed.

Overall findings

After identifying the most significant gaps and deficits in the current situation, each sub-study concluded with lists of identified responses to those gaps and deficits. Some of the major knowledge gaps and deficits in policies and legislation identified across the different focus areas include:

- Remaining gaps in knowledge on health and environment hazardous properties of chemical substances;
- Slow progress in identification of Substances of Very High Concern, and in substitution of hazardous chemicals in industrial processes and products
- Lack of information concerning chemicals in articles, including imported articles, and the resulting exposure
- Insufficient attention to hazardous chemicals in material flows important for a Circular Economy
- Deficits in the framework for protection of children and other vulnerable groups, e.g. from chemicals in products such as e.g. textiles, electronics and other consumer products
- The still insufficient management of a number of aspects related to exposure and toxicity (sometimes termed 'emerging issues'), such as combination effects, cumulative, low dose and long-term exposure, endocrine disruptors, neurotoxicity, protection of children and vulnerable groups, and chemicals in articles including in waste, materials recycling and the circular economy.
- Insufficient knowledge of the occurrence of chemical substances in the environment and technosphere, as well as the societal costs of the resulting exposure.
- Insufficient means to address risks posed by chemicals on the basis of persistence alone
- Lack of monitoring of environmental compartments concerning possible build-ups of chemical contamination and health and environmental risks thereof, in particular with respect to sources of water intended for human consumption
- Need for better incentives for development of new, non-toxic substances as well as non-chemical solutions
- Need for more comprehensive compilation of monitoring data at EU level and establishment of an early warning system.

The gaps and deficits indicated the need for an additional, overarching framework for protection of human health and the environment from harm due to hazardous chemicals, i.e., a framework additional to REACH that has the overall objective of minimising human and environmental exposures to

hazardous chemicals. A broad outline of the types of measures that could be considered as relevant for a strategy for a non-toxic environment has been emerging in the course of the project. In particular, it could include the following building blocks:

Improve knowledge on chemicals

- Commit long-term to develop chemical knowledge bases (hazardous properties, uses, presence of chemicals in articles, monitoring data);
- Develop and implement an early warning system for identifying new chemical threats;
- Move from the current chemical-by-chemical to groupings of chemicals approaches in risk assessment and risk management.

Promote innovation, development of non/less-toxic chemicals and non-chemical solutions, and substitution

- Promote innovation in material and product design aimed at non-chemical and non/less-toxic chemical solutions;
- Promote circularity: promote chemical re-use solutions and facilitate non/less-toxic material cycles by, e.g. enabling dismantling and separation;
- Support substitution: increase access to knowledge crucial for those who can substitute and support substitution activities.

Reduce chemical exposures and promote circular economy

- Address very persistent chemicals;
- Establish a system of tracking chemicals in products (articles) and promotion of the development and use of non-toxic materials and articles;
- Improve protection of children and other vulnerable groups.

A strategy for a non-toxic environment could be translated into the overall principle that hazardous substances of particular concern (e.g substances corresponding with the criteria of SVHC in REACH and equivalent) should as far as possible be phased out in uses which are not sufficiently well contained/controlled during their life cycle. Further, there should be a constant striving towards minimising the exposure to all hazardous substances, including those of lower concern. This would include a range of different activities such as avoiding uses that are not essential, development of non or low toxic chemicals and non-chemical solutions, product and material design, reducing volumes used, avoiding uses involving large exposure, improving information and different protective measures. Choice of substances, design of products etc. should also meet the needs of reuse and recycling and aim to as far as possible achieve non-toxic material cycles.

In connection to this a type of **hierarchy in chemicals policy and management**, similar to that which guides EU waste management policy, is envisioned. Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

ABBREVIATIONS USED

BPR	Regulation (EU) 528/2012 concerning the placing on the market and use of biocidal products
CEL	Critical Exposure Levels
CEPA	Canadian Environmental Protection Act
CLP	Classification, labelling and packaging or Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures
CMR	Carcinogenic, mutagenic and toxic for reproduction
CO2	Carbon Dioxide
CSA	Chemical Safety Assessment
CSR	Chemical Safety Report
DNELs	Derived No-Effect Levels
EAP	Environment Action Programme
ECHA	European Chemicals Agency
EDC	Endocrine Disrupting Chemical/s
EEA	European Economic Area countries
EFSA	European Food Safety Authority
EMAS	Eco-Management and Audit Scheme
EU	European Union
EWS	Early Warning System
FAO	Food and Agriculture Organisation
GHG	Greenhouse gas
GHS	Globally Harmonized System of Classification and Labelling of Chemicals
HFC	Highly Fluorinated Chemical
ICCM	International Conference on Chemicals Management
JPOI	Johannesburg Plan of Implementation
KEMI	Swedish Chemicals Agency
KET	Key Enabling Technology
MS	Member State
MSCA	Member State Competent Authority
NERCs	New and/or Emerging Risks
NGO	Non-Governmental Organisation
NTE	Non-toxic environment
OECD	Organisation for Economic Co-operation and Development
OELs	Occupational exposure limit values
OSH	Occupational Health and Safety
PBT	Persistent, Bioaccumulative and Toxic
PCBs	Polychlorinated biphenyls
PFAS	Polyfluorinated Alkyl Substances
PFOA	Perfluorooctanoic Acid
PFOS	Perfluorooctanesulfonic Acid
PIC	Prior Informed Consent
PM	Particulate matter
POPs	Persistent Organic Pollutants
PPPR	Regulation (EC) No 1107/2009 concerning the placing on the market of plant protection products on the market
PXDD	brominated-chlorinated dioxins
PXDF	brominated-chlorinated furans
RAPEX	European Rapid Alert System
REACH	Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
REFIT	Regulatory Fitness and Performance Programme of the European Commission
RMM	Risk management measure

R&D	Research and Development
SAICM	Strategic Approach to International Chemicals Management
SCENHIR	Scientific Committee on Emerging and Newly- Identified Health Risks
SDG	UN Sustainable Development Goals
SiA	Substances in articles
SMEs	Small and Medium Enterprises
SVHC	Substances of very high concern
TSCA	US Toxic Substances Control Act
UNEP	United Nations Environment Programme
USEPA	United States Environmental Protection Agency
VOC	Volatile Organic Compounds
vP	Very persistent
vPvB	Very persistent, very bio-accumulative
WHO	World Health Organisation
WSSD	World Summit of Sustainable Development in Johannesburg

1 INTRODUCTION

Chemicals and their uses are essential elements of modern society. They are used as processing aids or as integral parts in the production of the articles and mixtures that people use in their daily lives and which help to ensure a high level of quality for these products. Moreover, the chemical manufacturing industry is the third largest EU industry. It is a significant contributor to the EU economy and its growth over the next ten years is projected to be robust.

However, of the over 100,000 chemicals estimated to be on the EU market today over 60% by tonnage are considered hazardous to human health and/or to the environment. The risks may be present at various points throughout a substance's life cycle: during production, when they are transported and when the mixtures and articles in which the substances are contained are used and then discarded. Given the importance of chemicals to the EU strategy for jobs and growth, it is crucial to manage these substances sustainably.

The European Union has adopted comprehensive chemicals legislation to protect both human health and the environment from these risks. The main pillars of this legislation are the REACH[1] and CLP[2] Regulations, complemented by legislation that addresses chemicals with specific functions, such as biocides, plant protection products, fertilisers and detergents. In addition, chemicals are addressed in some specific product-related legislation, such as the Toys Directive or the Medical Devices Directive, in order to prevent harm from product service lives where human exposure is of particular concern. Occupational health and safety legislation (OSH) forms another important element of the overall framework.

The knowledge and access to information on health and environment properties of chemicals has improved considerably as a result of REACH and CLP. However, chemicals legislation including the testing, assessment and risk management of chemicals is still dominated by substance-by-substance approaches and is mostly not designed to assess exposure to mixtures of chemicals, exposures from multiple sources and over long periods of time or the risks associated with this. Moreover, it is difficult for regulators to keep abreast of new developments, such as the increasing use of nanomaterials.

Many of the emerging issues related to the growing presence of chemicals in everyday life are recognised in the 7th Environment Action Programme (7th EAP), adopted in 2013 by the European Parliament and the Council. As a response, the 7th EAP commits to the development of a Non-Toxic Environment strategy in paragraph 54 under Priority objective 3: "*To safeguard the Union's citizens from environment-related pressures and risks to health and well-being by 2020*". The 7th EAP notes that to meet this objective the Commission will, inter alia, develop by 2018:

> *"a Union strategy for a non-toxic environment that is conducive to innovation and the development of sustainable substitutes including non-chemical solutions".*

In parallel, the European Commission presented an EU action plan for the Circular Economy in December 2015. The action plan refers to the transition to a more circular economy, where the value of products, materials and resources is maintained in the economy for as long as possible and in which the generation of waste is minimised. In the action plan set out in the Circular Economy package, the Commission commits to analysing and proposing options about the interface between chemicals,

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals.
[2] Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures.

products and waste legislation, and this work is destined to feed into the future non-toxic environment strategy too.

Moreover, some aspects of the EU legislative framework concerning chemicals are evaluated as part of the ongoing 'Fitness check of chemicals legislation except REACH' and the 'REACH review'. The development of the future non-toxic environment strategy should complement these processes.

To support the European Commission in examining the possibilities of such a strategy, Milieu Ltd (Milieu), together with Risk & Policy Analysts (RPA), Ökopol, and the Institute for Public Health and the Environment of the Netherlands (RIVM), was awarded a study contract by DG Environment for '[Study for] The strategy for a non-toxic environment of the 7th Environment Action Programme (EAP)' (ENV.A.3/ETU/2015/0027). The contract entered into force on 1 December 2015.

This Report summarises the results obtained from the research carried out during the course of the project. It is based on the seven sub-studies required as per the Technical Specifications:

a. Substitution, including grouping of chemicals & measures to support substitution (RPA);
b. Chemicals in products (articles) and non-toxic material cycles (Ökopol);
c. The improved protection of children and vulnerable groups from harmful exposure to chemicals (Milieu);
d. Very persistent chemicals (Milieu);
e. Policy means, innovation and competitiveness (RPA);
f. Programme on new, non-/less toxic substances(Ökopol);
g. Early warning systems for examining chemical threats to human health and the environment (RIVM).

The draft final reports for each of the seven sub-studies are included as annexes to this report. Additional input includes the results from a general literature review, from a workshop held in June 2016 and based on comments received about the interim reports. Further details are provided in Section 2 on the study's objectives and methodology.

2 STUDY OBJECTIVES AND METHODOLOGY

2.1 OBJECTIVES

This study focuses on some of the chemicals policy gaps identified in the 7th Environment Action Programme. Many of these, such as combination effects, endocrine disruptors, and chemicals in articles, cut across a range of policy areas and are already well known and long established. Seven sub-studies, on topics stipulated in the Technical Specifications from the Commission, were carried out as part of this project to strengthen the evidence base where information was lacking. The seven sub-studies (and the responsible project partner) are:

Sub-study	Subject	Author
A	Substitution, including grouping of chemicals & measures to support substitution	RPA
B	Chemicals in products (articles) and non-toxic material cycles	Ökopol
C	The improved protection of children and vulnerable groups from harmful exposure to chemicals	Milieu
D	Very persistent chemicals	Milieu
E	Policy means, innovation and competitiveness	RPA
F	Programme on new, non-/less toxic substances	Ökopol
G	Early warning systems for examining chemical threats to human health and the environment	RIVM

On the basis of the Tender Specifications, and instructions provided by the Commission throughout the course of the project, the overall objectives of the study can be summarised as follows:

- Present a comprehensive assessment of available information, i.e., the state of play, to be used as a base of evidence for the development of a non-toxic environment strategy;
- Provide an overall analysis of the current approaches for reducing health and environmental burdens in connection with the focus areas selected for analysis, including gaps and deficits and improvement possibilities presented in connection to these;
- Present an overview of the improvement opportunities and related policy instruments across the sub-study areas and identify synergies[3].

These objectives took into consideration the broader body of work that the Commission is currently undertaking in this area, including the comprehensive fitness check of all chemicals legislation being carried out by the Commission under its better regulation programme (REFIT) (see Section 4.1 on the EU regulatory framework). Several of these other studies are also likely to provide significant input to the Commission's planning on the strategy for a non-toxic environment, as they are among other things assessing the performance of current legislation and policy, including policy gaps. Hence, it was important to continuously consider the work carried out in these studies (to the extent the Commission made the (interim) results available to the contractor), and as far as possible to avoid overlaps and follow their progress.

A key difference between the fitness check/REACH review and the strategy for a non-toxic environment should be noted. Whereas the REFIT process is intended to consider how current legislation addresses the present situation, the strategy for a non-toxic environment process is more forward-looking and aims to consider chemicals policy in the long term. The study in support of the

[3] The tender specifications set out the following (p.18): "*Present a simplified impact assessment or analysis of costs and benefits for the policy options presented. This will most likely be qualitative, but possibly some elements can be quantified or illustrated through monetised examples*." This task was changed upon request of the Steering Committee after submission of the Inception Report.

strategy for a non-toxic environment was carried out from this wider perspective, in parallel to the REFIT studies and related policy processes.
The fact-gathering and inventory of improvement possibilities are meant to serve as a solid basis for the development of the non-toxic environment strategy, to enable the Commission to meet the 2018 deadline, as laid down in the 7th Environment Action Programme. The results of the work, thus, do not provide the actual 'strategy for a non-toxic environment', but instead represent a gathering of existing information that can feed into the development of the strategy, along with the results of the other studies mentioned above.

2.2 METHODOLOGY

The initial desk research, including a literature review and stakeholder consultation, focused on the respective sub-study themes. This research was supported by a general literature review, which has provided an evidence base for an analysis of the policy gaps and deficits per sub-study area. It has also informed the identification of improvement opportunities to address these gaps and deficits.

The desk research was complemented by a workshop entitled "Strategy for a Non-toxic Environment of the 7th Environment Action Programme (EAP)", organised by the Commission with the support of Milieu and held on 8-9 June 2016 in Brussels. The workshop had two central objectives: (i) to inform stakeholders from a wide range of organisations and institutions about the ongoing study and its different sub-studies and (ii) to obtain feedback from these stakeholders about the gaps and barriers identified during the course of the study and preliminary recommendations on how to address them. In total, 118 participants (excluding speakers and study team) registered and were confirmed as participants of the workshop. They represented public authorities, industry, NGOs, academia, trade unions and consultancies.

In order to foster fruitful discussions during the workshop, participants received in advance summaries ('workshop materials') of the different sub-studies' findings to date, including gaps/deficits identified and related improvement opportunities. This material was kept short, with a view to allowing participants to read the materials provided under all of the sub-studies. Tailored feedback forms were used to facilitate valuable feedback from participants beyond the discussions held at the workshop, which was then gathered by the study-team and fed into the draft sub-studies at the interim report stage; this was submitted at the end of August 2016.

This Report incorporates the additional work carried out in response to comments received from the Commission on the interim report, including the seven draft sub-studies. The seven sub-studies are annexed to this report.

Each sub-study contains a section containing the literature review (some in a separate appendix), a section on gaps and deficits and one on improvement opportunities which are relevant for the sub-study area. The improvement opportunities include short-, mid- and long-term options and cover a range of measures from soft measures, such as awareness-raising programmes, to legally binding measures. Each improvement measure identified is described qualitatively in a table at the end of each sub-study.

Section 7 of this Report comprises a horizontal overview of the gaps and deficits identified for each of the focal areas and the suggested improvement opportunities. Section 7.2 below presents the categorisation of the gaps and deficits identified in the sub-studies by type of gaps. It then draws parallels between the past and present experiences with policy instruments in the chemicals area (Section 7.3) and the identified responses, describing qualitatively the pros and cons of implementing a certain type of policy instrument to address a specific gap/deficit and comparing these with softer or harder approaches.

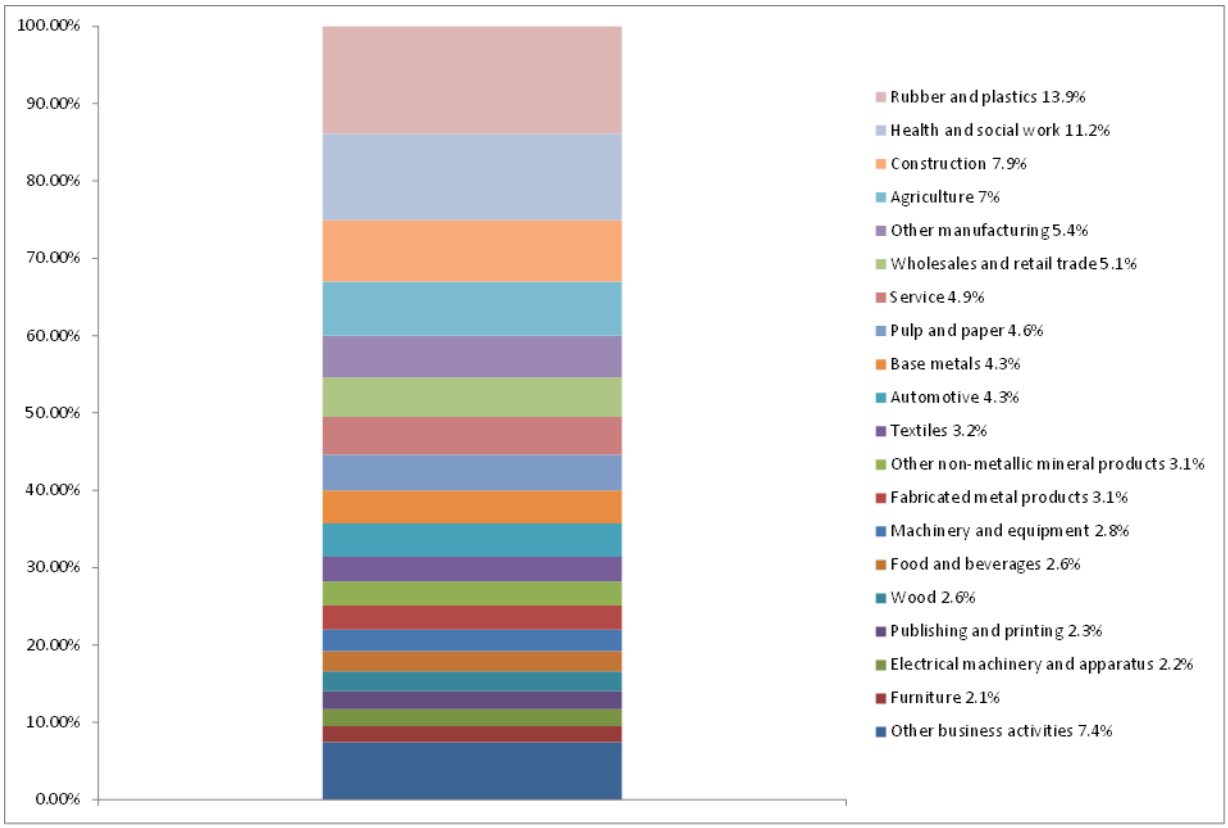
3 THE ROLE OF CHEMICALS IN MODERN SOCIETY AND INDUSTRY

This section has been drawn from the draft final report for sub-study e on *Policy means, innovation and competitiveness* drafted by RPA. More details are included in the sub-study.

The chemical industry shapes other economic activities, from agriculture, construction and textiles to high tech industries such as aerospace, automotive, health care and electronics, more than any other manufacturing sector. Due to its role in the value chain, i.e. transforming raw materials and feedstock into tailor made solutions for downstream industries, it serves all sectors of the economy (see the figure below) and contributes to our well-being.

Chemicals are not just 'chemical products' (paint, glue, detergents, solvents, pharmaceuticals); they are virtually all materials (metals, plastics, paper, glass). The millions of articles used every day (electronics, toys, clothing, vehicles, buildings) are manufactured using chemicals or consist of chemicals, treated with chemicals (e.g., coatings, preservatives) and/or manufactured using chemicals. In the EU, the biggest downstream users of chemicals are the plastics and rubber industry, construction, the pulp and paper industry and automotive manufacturing. In total, two thirds of EU chemicals sales go to the manufacturing sector and one third to agriculture, services and other industries.

Figure 2: Percentage of output consumed by customer sector



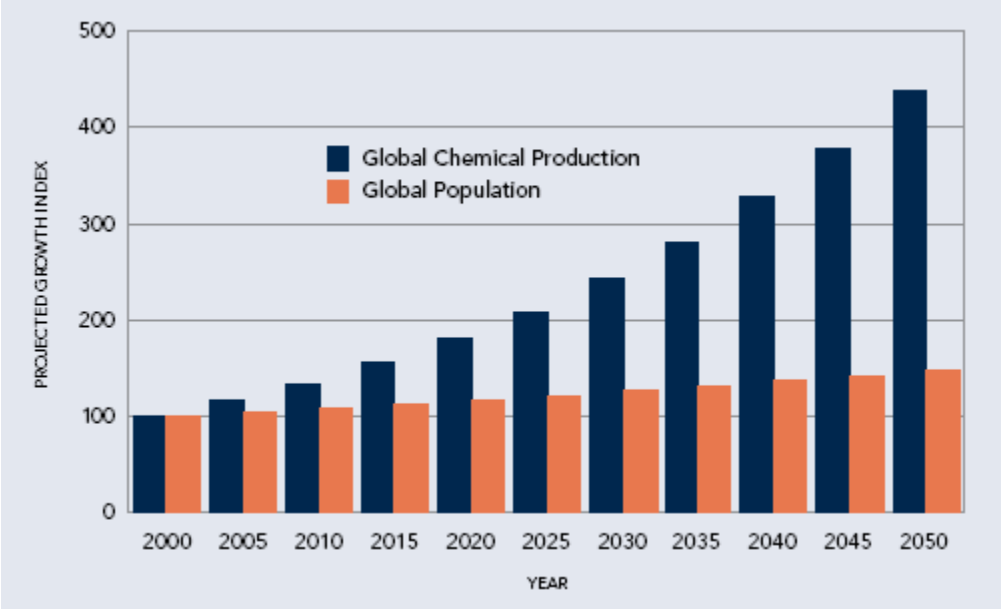
Source: Cefic, 2014

The chemical manufacturing industry is the third largest in the EU, accounting for 7% of the EU's industrial production. It directly employs around 1.2 million people and generates nearly 3.6 million indirect jobs. In terms of chemicals sales, the EU chemical industry represents 17% of the global

market, behind China (34%) but before NAFTA countries[4] (16%) (Cefic, 2014).

The use of chemicals is ever increasing. From 1950 until 2000, chemicals production expanded 60-fold by tonnage. Global chemicals sales more than doubled between 2004 and 2014 (from €1,458 billion to €3,232 billion) and the total value of EU sales increased by 80% in the same period. Growth is expected to continue by 4% every year by 2020, and by 2035 global revenues are expected to have doubled compared to 2015 (Roland Berger, 2015). The figure below shows how the rate of growth of the global chemicals production has already outpaced, and is expected to keep outpacing, global population growth rates over the next decades.

Figure 3: Projected growth in chemicals production in comparison to growth in global population[5]



Source: Green Chemistry: Cornerstone to a Sustainable California (2008).

Over 100,000 chemicals are present on the EU market today, with some 35,000 chemicals marketed in volumes above 1 tonne per year. Moreover, the number of known chemicals continues to grow. The CAS Registry, which already lists over 129 million unique organic and inorganic chemical substances, is reportedly updated with another 15,000 substances every day[6].

The chemical industry produces thousands of different products that are utilized for a broad range of end-use applications. It underpins many different sectors within the economy, which results in a strong correlation between economic growth in the region and the growth of the chemical industry. However, the expansion of global chemicals sales is primarily driven by emerging economies such as China, India, Korea and Brazil, where over 80% of new production capacities are being developed. Growth in these countries is expected to benefit European producers via increased exports and local investments, but it is vital for the European industry to retain its manufacturing and innovation capacity, not only of high added-value chemicals (e.g. specialty chemicals) but also of basic chemicals, which provides the raw materials for the high added-value sectors. This is because the proximity and close interconnection of the chemical industry with its client industries is one of the major strengths and innovation motors of the EU manufacturing industry as a whole (High Level Group on the Competitiveness of the European Chemicals Industry, 2009).

[4] Canada, Mexico and the US.
[5] http://coeh.berkeley.edu/docs/news/green_chem_brief.pdf (accessed 20.07.2017).
[6] https://www.cas.org/content/chemical-substances#how (accessed 30.03.2017).

EU chemicals sales cover three broad areas: base chemicals (petrochemical, polymers and basic inorganics), specialty chemicals and consumer chemicals. In 2014, base chemicals represented around 60% of total EU chemical sales, specialty chemicals (which include paints, dyes, inks and pigments) accounted for around 30% and consumer chemicals (e.g. soaps, detergents, perfumes, cosmetics, etc.) made up around 10%.

The competitiveness of the manufacture of basic chemicals is mainly driven by price and availability of energy and feedstock. The EU has a strong disadvantage on these factors against the US and the Middle East countries. The European Union has also high labour and capital costs compared to China. Despite an increase in fuel and power consumption efficiency (Cefic, 2016), unlike other regions, the EU chemicals industry is unable to base its growth on inexpensive resources and labour. Moreover, future opportunities of further decreasing fuel consumption in the sector appear limited unless major shifts toward recycling and bio-based chemicals will occur.

The main competitive advantage of the EU chemical industry is the high level of technological development, skilled workforce and strong research base. The chemicals industry is one of the most R&D intensive manufacturing sectors within advanced economies (behind US and China only).

One of the challenges faced by European chemicals companies is to find new ways to meet customer demands and increase market share, e.g. by continually improving products, technologies and processes.

Another challenge concerns the many chemicals that can cause harm to health and the environment. Over 60% by tonnage of the chemicals on the EU market are hazardous to human health or the environment. Diseases linked to exposure to hazardous substances include cancers, neurological disorders, allergies and other acute and chronic health effects, resulting in socioeconomic costs for the EU. As an illustrative example, exposure to endocrine disrupting chemicals has been estimated to cause €157 billion in annual health care costs and lost earnings (Trasande et al, 2015). There is a particular concern for the unborn child, young children and women in the fertile age.

Damage to biodiversity and ecosystems is also a concern. The use of tributyltin as anti-fouling marine coatings caused the decline of the population of shellfish, with an associated economic loss estimated in €22 million per year to the UK shellfish industry alone (Giacomello et al, 2006).

Environmental contamination reduces the value of fish stocks used as food or feed, contaminates drinking water and soils, and can reduce crop production by adversely affecting pollinators. Substantial costs arise from decontamination and remediation of buildings, infrastructure, land and water, e.g. the estimated EU environmental (remediation) costs just for cleaning up PCBs are estimated to be more than €15 billion between 1971 and 2018 (Von Bahr, 2004).

Only a small fraction of the many chemicals currently on the market have been thoroughly evaluated regarding their health and environmental properties and impacts, and even fewer are actually regulated, e.g. REACH partially restricts or bans some 60 individual chemicals and some groups of chemicals with similar properties, such as carcinogens, mutagens and repro-toxic substances (CMRs).

Scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment. This implies that initial scientific assessments of a substance often underestimate the risk of harm (Grandjean, 2017). Section 7.2 of this Final Report summarises a number of the knowledge gaps relating to chemical substances and their uses, including:

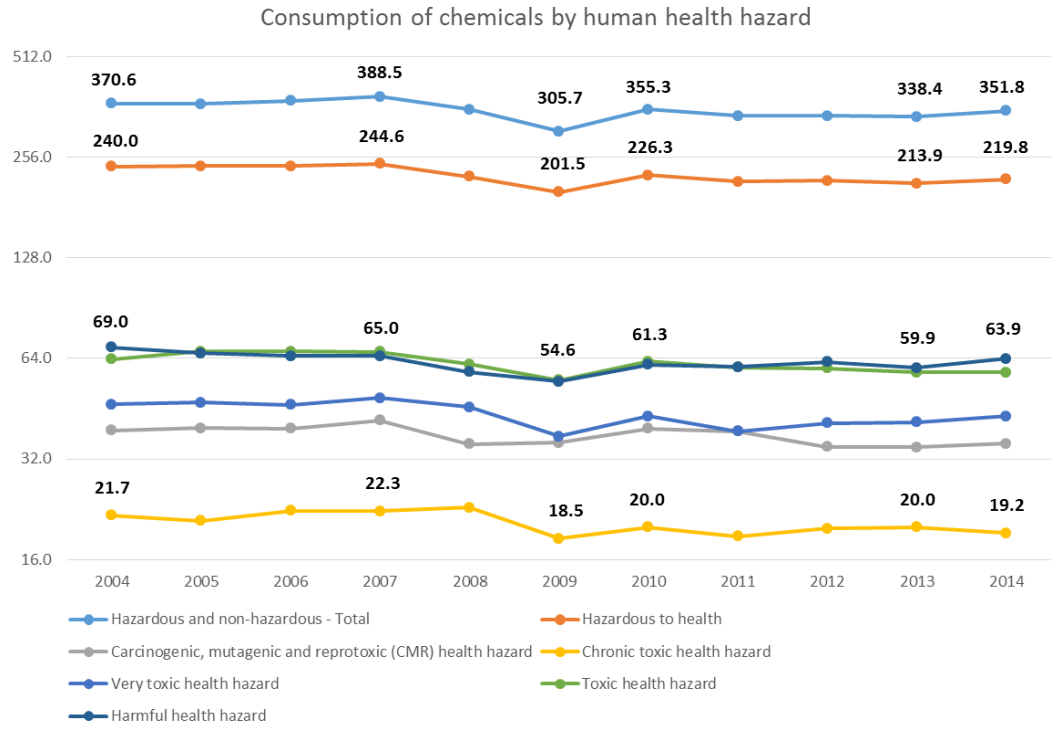
- Remaining gaps in knowledge on health and environment properties of chemical substances;
- Lack of information on the use of chemicals in articles and the resulting exposure;
- Continued usage of some substances of very high concern (SVHCs) in ways not well

controlled/contained and hence involving exposure;

- The still insufficient management of a number of aspects related to exposure (sometimes termed 'emerging issues'), such as combination effects, cumulative, low dose and long term exposure, endocrine disruptors, neurotoxicity, protection of children and vulnerable groups, and chemicals in articles including in waste, materials recycling and the circular economy.
- Insufficient knowledge of the occurrence of chemical substances in the environment and technosphere, as well as the societal costs of the resulting exposure.

There is some evidence that the EU chemical industry may be tending towards the development of safer chemicals: between 2013 and 2014, while total chemical production increased, the production of CMR substances went down. Figure 4 on the following page indicate that while the consumption of hazardous substances has increased, the increase is proportionally less than the total consumption of chemicals. It should be noted that the indicators on production and consumption of hazardous substances maintained by Eurostat are only an imperfect proxy for exposure, as this depends upon a number of other factors[7], such as how a substance is used, any safety measures in place to control emissions and exposures during the substance's life cycle, and any imports of substances, including articles containing them.

Figure 4: **Consumption of chemicals by human health hazard**



As an input provider for other industries, the chemical industry is considered to be at the forefront of innovation and a solution provider for many societal and environmental challenges, with chemical technological breakthroughs spilling over its downstream sectors. Patterns of innovation towards more sustainable solutions therefore not only have a profound effect on the industry itself but also on the wider economy. The question is whether the direction of this innovation is toward more sustainable and more benign chemicals in terms of protection of human health and the environment, and whether the rate of innovation needs to be speeded up to meet societal goals and needs.

[7] http://www.eea.europa.eu/airs/2016/environment-and-health/production-of-hazardous-chemicals.

A close co-operation between the chemical industry and the downstream sectors is therefore fundamental for the competitiveness and innovative capacity of the EU economy as a whole, but also for achieving the 2020 goal of sound chemicals management globally, set by the World Summit of Sustainable Development (WSSD) 2020 chemicals goal and the United Nations' Strategic Approach to International Chemicals Management (SAICM). The Overall Orientation and Guidance document adopted during the fourth International Conference on Chemicals Management held in Geneva in 2015 recognises the "need for stronger engagement and increased assumption of responsibility by downstream entities, in particular industries, to address the distribution and use of chemicals in the manufacture of products and throughout their lifecycle, and for a more extensive approach to stewardship"[8].

Moreover, companies in downstream sectors are closer to consumer demands for safer and greener products and have different perspectives on how to develop and implement safer chemical and non-chemical alternatives. Hence the challenge for Europe today is how to ensure steady progress towards sustainability with respect to the production, use, materials reuse, and safe recycling and disposal of synthetic chemical substances in combination with retained competitiveness.

[8] http://www.saicm.org/Portals/12/Documents/OOG%20document%20English.pdf (accessed 30.03.2017), p. 5.

4 CHEMICAL REGULATION IN THE EU AND GLOBALLY

4.1 THE EU REGULATORY FRAMEWORK FOR CHEMICALS

The European Union has put together a comprehensive regulatory framework, aiming to ensure a high level of protection of human health and the environment whilst preventing barriers to trade. EU chemicals legislation applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals that they place on the market. The legislation put in place consists of rules governing the marketing and use of chemical products, major accidents and exports of dangerous substances, as well as restrictions on the placing on the market of specific hazardous substances (European Parliament, 2016). This legislation can be considered to be the most advanced and comprehensive legal framework regulating chemicals in the world.

Substantial progress in the management of chemical substances has been achieved in Europe since 2006, when the EU adopted its flagship regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)[9]. As more than 100,000 substances were on the EU market but knowledge on their potentially hazardous properties was insufficient, the EU legislator decided that this knowledge would have to be generated and that the burden should be shifted from governments to the industry. To comply with the Regulation, companies must identify and manage the risks linked to the substances that they manufacture and market in the EU. They must demonstrate how the substance can be used safely and they must communicate the risk management measures to downstream users.

If the risks cannot be managed effectively, then authorities can restrict the use of substances in different ways. In the long run, the most hazardous substances should be substituted with less dangerous ones (ECHA, na). As of 12 January 2017, 173 substances have been identified as substances of very high concern (SVHC) (ECHA, 2017) and are, hence, potentially subject to the authorisation requirement and eventual phase-out or to restriction. One of the challenges in implementing REACH is how to speed up the process of identifying all substances meeting the Article 57 criteria for SVHCs as well as other substances of equivalent concern that may meet endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.

REACH also aims to enhance the communication on chemicals up and down the supply chain. Downstream users must communicate uses to suppliers and must know and disclose (in case of consumers, on request) if their product contains an SVHC to recipients. In reality, however, the number of notifications of SVHCs in articles is very small, raising concerns that this provision is poorly implemented and not functioning as intended by the legislation.

The complementary Regulation on the classification, labelling and packaging of substances and mixtures (CLP Regulation[10]) aims to ensure that the hazards presented by chemicals are clearly identified and communicated to workers and consumers in the European Union through the classification and labelling of hazardous chemicals. In addition to the overarching rules of REACH and CLP, specific pieces of legislation address particular groups of chemicals, such as biocides, pesticides, fertilisers, detergents, pharmaceuticals or cosmetics.

Most pieces of chemicals legislation have been subject to an impact assessment, prior to their adoption, and some of them have undergone further reporting and review during the course of their implementation. Under the European Commission's better regulation programme (REFIT), all EU

[9] REACH Regulation (EC) No. 1907/2006.
[10] CLP Regulation (EC) No. 1272/2008.

chemicals legislation except REACH has undergone a comprehensive fitness check, and a REFIT evaluation of REACH is nearly completed.

The goal of the fitness check is to assess the relevance, coherence, effectiveness, efficiency and added value of the legislative framework for the risk management of chemicals; it also aims to identify excessive administrative burdens, overlaps, gaps, inconsistencies and/or obsolete measures (European Commission, 2017). The Commission's Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs and the Directorate-General for the Environment share the responsibility for this fitness check (European Commission, 2017).

The Study on the regulatory fitness of the legislative framework governing the risk management of chemicals (excluding REACH), in particular the CLP Regulation and related legislation, was launched in 2015 to identify and to evaluate issues arising out of the implementation of CLP, as well as the interplay between different pieces of chemical legislation (excluding REACH) and provisions relating to chemicals management in other pieces of legislation (European Commission, 2017). Issues negatively impacting upon effectiveness include, according to the study, the lack of assessment for combination effects and multiple routes of exposure, delays in determining appropriate criteria for endocrine disrupting chemicals under some legislation and the variations in willingness of Member States to support harmonised classification dossiers under the Biocidal Products Regulation and the Plant Protection Products Regulation. The study also highlights a need for the increased use of more innovative tools to supplement current labelling requirements to increase the quality of the information being communicated. It acknowledges that the reliance on CLP, as the basis for classification across almost all other legislation, has increased the efficiency of the legislative framework. However, the study also points to some coherence issues, including the identification of allergens under different pieces of legislation and the prohibition of animal testing under the Cosmetic Products Regulation[11]. The study finds that, generally, the objectives of the chemicals legislative framework continue to be relevant and provide added value at the EU level.

Among other supporting studies, the ones particularly relevant for the development of the Strategy for the Development of a Non-toxic Environment include the following:

- Study to develop EU enforcement indicators for REACH and CLP (published in April 2015) (European Commission, 2015);
- Study on the impact of REACH on innovation, competitiveness and SMEs (published December 2015) (European Commission, 2015);
- Study on impacts of REACH and corresponding legislation in 3rd countries on the international competitiveness of the EU chemicals industry and selected downstream user (draft final report published in February 2016) (ECSIP Consortium, draft);
- Calculation of the indicators of benefits of chemical legislation on human health and the environment (published in 2016) (European Commission, 2016);
- Study on the cumulative health and environmental benefits of chemical legislation, highlighting the benefits of existing legislation and areas where there is still significant damage (for completion by early 2017) (European Commission, 2017);
- Evaluation of the Practical Implementation of the EU Occupational Safety and Health (OSH) Directives in EU Member States (not yet published);
- Supporting studies for the Fitness check for the construction sector (published in October 2016) (European Commission, 2017).

The stocktaking of chemicals legislation is expected to provide a comprehensive assessment of current chemicals legislation, preparing the ground to identify any possible additional actions needed in the

[11] Ingredients that are used in cosmetic products may still require data from animal testing derunder REACH, the BPR, the PPPR or other legislation.

area of chemicals. Thereby, they will also contribute to the factual basis for the non-toxic environment strategy.

In parallel, as part of the Circular Economy Package, the Commission has committed, by 2017, to identify ways to reduce the presence and improve the tracking of chemicals of concern in products[12].

In December 2015, the European Commission presented an EU action plan for the Circular Economy. The action plan refers to the transition to a more circular economy, where the value of products, materials and resources are maintained in the economy for as long as possible and in which the generation of waste is minimised. The plan refers to several aspects related to chemicals policy. These include the facilitation of substitution of chemicals of concern and supporting SME access to innovative technologies (p.5), the promotion of non-toxic material cycles and better tracking of chemicals of concern in products (p.12-13, Annex p.3). Furthermore, the Commission commits to analysing and proposing options on the interface between chemicals, products and waste legislation, and this work is destined to feed into the future non-toxic environment strategy.

The development of the non-toxic environment strategy should complement these processes. Horizontal Commission processes already exist for certain aspects of some problem areas; namely, combination effects, nanomaterials and endocrine disruptors. To date, in the area of substances in articles, no focused horizontal work has been carried out by the Commission. It is useful to consider them from a general level through a comprehensive strategy, given that these issues are strongly interconnected and closely linked with the current chemicals *acquis*.

4.2 OVERALL GLOBAL POLICY INITIATIVES

The production of chemicals is expected to continue growing in the near future and there are geographical shifts in production from Europe and North America to Asia and developing countries elsewhere. This causes new challenges in tackling the issue of exposure to toxics. For example, the phasing out of emissions of long-chain polyfluorinated alkyl substances (PFASs) by US and European manufacturers has been offset by a geographical shift of their manufacture and use to countries in Asia. This means that when developing a strategy for a non-toxic environment in Europe, it is important to consider the international aspects of chemicals both relating to the impact of chemicals on the environment and health and the global policy processes that attempt to govern them.

The magnitude of chemicals-related health problems around the world is difficult to estimate. On the basis of data available for 2004, the World Health Organization (WHO) found that 4.9 million deaths (8.3% of the total that year) and 86 million disability-adjusted life years (DALYs) (5.7% of total) were attributable to exposure to selected chemicals[13]. Critical chemicals not able to be included in the analysis due to lack of data included mercury, dioxins, organic chlorinated solvents, PCBs, and chronic pesticide exposures as well as health impacts from exposure to local toxic waste sites, which are estimated to affect more than 56 million people worldwide.

Of special note was the finding that children under age 15 years were especially vulnerable and bore 54% of the global burden, including 80% of that imposed by lead and 19% of acute accidental poisonings. The WHO noted the limitations in the data available, and stressed that these were underestimates of the real global burden attributable to chemicals.

[12] European Commission, Closing the loop – An EU action plan for the Circular Economy, COM(2015) 614 final, available at: http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52015DC0614.
[13] http://www.unep.org/chemicalsandwaste/sites/unep.org.chemicalsandwaste/files/publications/GCO_web.pdf. DALYs, or disability- adjusted life years, reflect a blend of death and disease impacts.

In light of this global dimension, the EU has made the commitment to help achieve the United Nations' **2030 Agenda for Sustainable Development** including the Sustainable Development Goals (SDG) (UN, 2015). Goal 12.4 requires to:

> "[*by*]*2020, achieve the environmentally sound management of chemicals and all wastes throughout their life cycle, in accordance with agreed international frameworks, and significantly reduce their release to air, water and soil in order to minimize their adverse impacts on human health and the environment*".

The participants at the **World Summit of Sustainable Development in Johannesburg (WSSD)**, including the European Union (EU) (European Parliament and Council, 2002) and its Member States, made a commitment to the sound management of chemicals throughout their life cycle in 2002, the 'WSSD 2020 goal'. It was expanded upon in paragraph 23 of the Johannesburg Plan of Implementation (JPOI) (UN, 2002). In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals.

The box below lists the international processes under way aimed at better global chemicals management. A second box provides a brief overview of the international conventions relevant to chemicals regulation.

International processes aimed at better global chemicals management

- The activities on substances in articles in the framework of the Strategic Approach to Global Chemicals Management (**SAICM**), managed by the United Nations Environment Program (UNEP) - a global policy framework to promote safe chemicals management with the explicit aim of implementing the World Summit on Sustainable Development 2020 Goal on chemicals. SAICM aims to provide a policy framework to foster the sound management of chemicals; however, it is important to note that it is a voluntary instrument and is not a legally binding agreement;
- The international activities on **endocrine disrupting chemicals (EDC)** related to several processes and organisations, e.g. SAICM, studies and reporting by UNEP and the World Health Organisation (WHO), as well as the work of the Organisation for Economic Co-operation and Development (OECD);
- The **OECD's work on combination effects of chemicals/mixture toxicity**, mainly on test methods and guidance for risk assessment;
- Work on the **safety of nanomaterials in the framework of SAICM and by the OECD**, including e.g. a programme aiming at pooling technical knowledge on testing, hazards, risk and the risk management of nanomaterials across the OECD countries and making it systematically available.

Overview of international conventions relevant for chemicals regulation

The **Rotterdam Convention's** objective is to promote shared responsibility and cooperative efforts among parties in international trade of certain hazardous chemicals in order to protect human health and the environment from harm. The Convention creates legally binding obligations for the implementation of the Prior Informed Consent (PIC) procedure, building on voluntary PIC procedure, initiated by UNEP and FAO.

The overarching objective of the **Basel Convention** is to protect human health and the environment against the adverse effects of hazardous wastes. Its scope of application covers a wide range of wastes defined as "hazardous wastes" based on their origin and/or composition and their characteristics, as well as two types of wastes defined as "other wastes" - household waste and incinerator ash.

The **Stockholm Convention** is a global treaty to protect human health and the environment from chemicals that remain intact in the environment for long periods, become widely distributed geographically, accumulate in the fatty tissue of humans and wildlife and have adverse effects to human health or to the environment. Parties are required to take measures to eliminate or reduce the release of POPs into the environment.

Overview of international conventions relevant for chemicals regulation

The **Minamata Convention** is the first global policy aimed at limiting anthropogenic releases of an inorganic substance –mercury and its compounds. The Convention seeks to reduce emissions to the atmosphere, soil and water from a number of sources. Under the treaty, new mercury mines are banned and existing mines are to be phased out, the use of mercury in a number of products and processes is to be reduced and/or eliminated, and measures set in place to control emissions to air as well as releases to land and water. The European Union is current working on a ratification package for the Minamata Convention for implementation.

The **Globally Harmonized System of Classification and Labelling of Chemicals** (GHS) addresses the classification of chemicals by types of hazard and proposes harmonised hazard communication elements, including labels and safety data sheets, ensuring that information on physical hazards and toxicity from chemicals be available during the handling, transport and use of these chemicals. The GHS also provides a basis for the harmonisation of rules and regulations on chemicals at national, regional and worldwide levels, another important factor for trade facilitation.

The **OSPAR Convention** (Convention for the Protection of the Marine Environment of the North-East Atlantic). It combines and up-dates the 1972 Oslo Convention on dumping waste at sea and the 1974 Paris Convention on land-based sources of marine pollution. It adopted a 'Strategy with regard to Hazardous Substances' which aims at the cessation of discharges, emissions and losses of hazardous substances by 2020 in order to achieve 'close to zero' concentrations in the marine environment.

These international agreements form the backbone of international policy relating to the sound management of chemicals. The EU has historically played a central role in developing and implementing these agreements. While developing a strategy for a non-toxic environment, it is relevant to consider both the EU's role in the development current and future international agreements, as well as links between this strategy and international chemical management policy. See also Section 7.1.

4.3 NATIONAL INITIATIVES OUTSIDE OF THE EU – EXAMPLES FROM THE USA AND CANADA

In June 2016, the **USA** adopted a new chemicals act—the Frank R. Lautenberg Chemical Safety for the 21st Century Act—which updates the 1976 US Toxic Substances Control Act (TSCA) (US EPA, 2016). The 1976 act had been widely acknowledged as an insufficient instrument for management of risks of the many chemicals in US commerce. The US Environmental Protection Agency (USEPA) had struggled to gather information about the hazard characteristics of the chemicals in commerce. As of 2015, it had tested only 250 of the more than 84,000 'existing' chemicals on the US market (Center for Effective Government, 2015). Because of the vacuum left by an ineffective TSCA, many states set in place their own more stringent state-level laws, resulting in a patch-work of requirements that created difficulties for the chemical industry to achieve compliance across the nation.

The 2016 amendment includes several much-needed improvements on the previous regime, such as increased public transparency for chemical data and a mandatory requirement for USEPA to evaluate existing chemicals, as well as a consistent source of funding so that it can carry out those responsibilities. However, in comparison to REACH, it is not very ambitious. Though the USEPA now has more authority to request data on high priority chemicals, US industry is not required to provide a minimum data set concerning any hazards inherent in the chemicals that they produce. In fact, the 2016 act explicitly prohibits USEPA from requiring minimum data sets with a common set of endpoints.

The work programme set forth for evaluating high priority substances has a long time frame, compared to the timelines of REACH. USEPA plans to carry out safety assessments for 20 substances over the next 3+ years, most of which have already been regulated under REACH.

Moreover, in contrast to REACH, where the burden is on industry to prove that any risks involved with use of the chemical can be sufficiently controlled, the USEPA still has the burden of proof of showing that certain substances pose 'unreasonable risks'. Additionally, the new act does not support downstream users and consumers with information concerning whether a product contains high priority substances. Note that actual implementation of the new act and its policies depends on the USEPA, which is currently experiencing rollbacks in funding under the Trump administration. Thus, the future of this work programme is uncertain.

For these and other reasons, those who are familiar with the history of chemicals regulation in Europe are comparing the amended TSCA as equivalent to the EU's 1993 Regulation on Existing Substances (793/93), which 15 years later was replaced by REACH.

Another national effort is **Canada**'s effort to introduce a systematic, outcome-oriented approach to chemicals management, with substances prioritized for assessment on the basis of risk. A 1999 revision of the *Canadian Environmental Protection Act* (CEPA) established a deadline of 2006 to complete a systematic sorting of the 23,000 substances on their list of 'existing' substances to determine which ones were either inherently toxic to humans or non-human organisms, and either persistent or bioaccumulative, or had the greatest potential for subjecting people in Canada to exposure to the substances. Canada's Chemicals Management Plan (CMP) was launched to implement the 1999 CEPA's sections on toxic substances, followed by a second phase in 2011. A major focus of the Plan was to launch calls for any data held by the chemicals industry and other actors on specific priority substances so that the substances could be evaluated, using powers provided under the 1999 CEPA.

A third phase of the Plan was launched in 2016 (running from 2016 to 2021), aimed at addressing the remaining 1550 priority substances out of a total of 4300 chemicals that have been identified as requiring health and ecological assessment. Under Canada's approach, the burden of data gathering has shifted from falling solely on government to a shared responsibility with industry. However, substance assessment still rests with Environment Canada and Health Canada, which means that Canada's authorities still shoulder a considerable burden of assessment and monitoring.

5 THE STATE OF PLAY, INCLUDING NEW AND EMERGING HEALTH AND ENVIRONMENTAL CONCERNS

5.1 IMPLEMENTATION OF THE CURRENT POLICY

5.1.1 Evaluation of substances

The REACH Regulation requires the registration of substances manufactured or imported in quantities of more than 1 tonne per year (per manufacturer or importer), by the provision of information on the physicochemical and (eco)toxicological properties of the substances put on the EU market. As of January 2017, around 48,000 dossiers, referring to over 10,000 unique substances, have been submitted.

Although the Regulation has brought a significant improvement of the information on chemical substances and their uses, additional efforts are necessary to ensure the protection of human health and the environment. ECHA and the Member States evaluate the information submitted by companies to examine the quality of the registration dossiers and the testing proposals and to clarify if a given substance constitutes a risk to human health or the environment. The compliance check of the dossiers submitted by the registrants has found that the information provided is of poorer quality than originally expected. As a result, substances are being used by EU citizens based on non-compliant data and the identification of needs for regulatory risk management by authorities is being hampered.

The possibility of recurring to category and read across approaches to fulfil the test data requirements for the registration process has been widely misused, with registrants not providing proper justification and grouping substances erroneously.

Registrants are also required to update their dossiers with any relevant new information (Article 22) but, despite the fact that many suppliers have certainly encountered one or more changes in the circumstances listed by the Article, two thirds of the dossiers have never been updated.

Moreover, substances which are manufactured or imported in low quantities have no or limited information requirements and the scope of the Regulation does not adequately cover nanomaterials. These substances may prove to be a good pool of potential alternatives and the lack of information considerably limits the possibility of carrying out robust comparative risk analyses.

5.1.2 Progress in substitution

This section presents some of the key findings from the sub-study a final report on "Substitution, including the grouping of chemicals & measures to support substitution" prepared by RPA.

The problem

A large number of hazardous chemicals, including substances of very high concern, are used in industrial processes as well as industrial and consumer products. These are sometimes associated with human and environmental exposure, and their presence in products may also cause problems in relation to waste management and recycling once the products become waste, e.g. by contaminating recycled materials.

Through the REACH registration process, information on the (eco)toxicological properties of the substances available on the market is being generated. However, the information provided in the registration dossiers already submitted appears to be inadequate to perform a comprehensive hazard and risk assessment for many of the registered substances. Moreover, substances manufactured or imported in low quantities (1-10 tonne per year per producer or importer) have no, or reduced, information requirements.

The lack of this information on the uses and presence of hazardous substances in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purpose of substitution by downstream users. Although REACH is enhancing the communication of information throughout the supply chain, and although there are several initiatives aiming to provide information about the content of hazardous chemicals in articles to the public, these initiatives are patchy and may benefit from some form of harmonisation.

Very few resources are currently dedicated to substitution initiatives among Member States, ECHA and the Commission. This may be linked to the budgetary limitation at both national and EU level and has already been identified as an issue, for example, with regard to the effective fulfilling of European Agencies' mandates. At Member State level, the engagement in substitution initiatives is not homogeneous, with some Member States very active and others, even those with a sizeable chemical industry, focusing mainly on traditional risk management activities and dedicating scarce resources to substitution initiatives or to supporting green chemistry solutions.

Key findings on substitution

The problem

- The prevailing use of hazardous substances including substances of very high concern and equivalent in industrial processes and industrial and consumer products may lead to human and environmental exposure.
- The presence of hazardous substances in products may cause problems through exposure of humans and the environment during the service life as well as in relation to waste management and recycling once the products become waste.

Gaps and inconsistencies in current policy

- Information on the (eco)toxicological, bioaccumulation and environmental degradation properties of the substances provided in the registration dossiers already submitted appears to be inadequate and is not kept up-to-date in 69 % of the dossers the were subject to compliance check in 2014.
- Substances manufactured or imported in low quantities have no or reduced information requirements.
- There is a lack of information on the uses and presence of hazardous substances in articles, in particular in imported articles.
- Risk assessment methodologies for the article service life and waste stage are not sufficiently developed to assist all actors.
- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution.
- There is scarcity of information on alternatives.
- The REACH authorisation does not cover imported articles and NGOs and some Member States complain about the lack of speed and ambition of the authorisation process.
- Companies complain about the regulatory uncertainty on available alternatives, the insufficient time to identify and develop suitable alternatives, the excessive lengthening of the time to market for products containing alternatives and, more in general, of the high administrative burden, in particular for SMEs.
- Synergies between chemical policies are still unsatisfactory.
- There are insufficient regulatory signals to investments in innovation.
- Resources dedicated to the enforcement of chemical policy are inadequate.
- There is a lack of resources dedicated to substitution initiatives among Member States, ECHA and the Commission.

For about half of the 31 substances currently in Annex XIV of REACH (the authorisation list), no applications for authorisation have been received, and around half of the applications are so-called "bridging authorisations", meaning that the applicants are working on phasing out the substance from their processes/products but need more time to fully develop an alternative. In addition, the inclusion of substances in the Public Activities Coordination Tool (PACT), in the Community Rolling Action Plan (CoRAP) , in the candidate list and ultimately in Annex XIV, has led to significant levels of activity as regards substitution, withdrawal and replacement. The regulatory banning of substances,

and even the anticipation f regulation itself, are strong drivers for the substitution of hazardous substances. Once initiated, regulatory processes send signals to the market and act as an incentive for innovation and substitution throughout the supply chain.
Member States' competent authorities consider that the costs of preparing proposals for restrictions under REACH have risen considerably, due to the information required from ECHA's Risk Assessment Committee (RAC) and Socio-Economic Assessment Committee (SEAC) in order to form an opinion. This has resulted in fewer restriction proposals being submitted, thus slowing down the substitution of hazardous chemicals. There is also concern that the authorisation process can become cumbersome and labour intensive, subsequently increasing ECHA's workload.

In addition, some NGOs have criticised the slow pace of including substances on the candidate list.

Beyond REACH, a number of legislative acts aim to promote substitution, directly or indirectly. A non-comprehensive list of examples from environmental, product safety and health and safety legislation is presented below:

- Directive 2011/65/EU (RoHS 2) on the *restriction of the use* of certain hazardous substances in electrical and electronic equipment (EEE) restricts the use of lead, mercury, cadmium, hexavalent chromium, polybrominated biphenyls (PBB) and polybrominated diphenyl ethers (PBDE) in EEE when substitution is possible from the scientific and technical point of view. Moreover, it requires the list of restricted substances to be updated as soon as new scientific evidence is available on more environmentally friendly alternatives;
- Directive 2012/19/EU on waste electrical and electronic equipment (WEEE) is built around the "*producer responsibility*" principle and, indirectly, promotes the substitution of hazardous chemicals in EEE by making producers responsible for the collection and management of waste and hazardous waste;
- Both Directive 2000/60/EC establishing a framework for Community action in the field of water policy (WFD) and Directive 2010/75/EU on industrial emissions (IED) recall the *polluter pays principle* (Article 191 of the Treaty on European Union) and indirectly promote substitution by promoting the internalisation of the externalities due to the use and release into the environment of hazardous chemicals;
- Regulation (EC) No 1223/2009 on cosmetic products (CPR) *prohibits and restricts the use* of some hazardous chemicals, in particular carcinogens, mutagens and substances toxic for reproduction (CMR) and these are listed on annex II of the Regulation;
- Both Regulation (EU) No 528/2012 (concerning the making available on the market and use of biocidal products) and Regulation (EC) No 1107/2009 (concerning the placing of plant protection products on the market) require active substances meeting certain criteria for hazardousness to be considered as candidates for *substitution*;
- Directive 2009/48/EC on the safety of toys *restricts the use* of substances with certain hazardous properties and encourages the *replacement* of dangerous substances and materials used in toys with less dangerous substances or technologies, where suitable economically and technically feasible alternatives are available;
- Directive 2004/37/EC on the protection of workers from the risks related to exposure to carcinogens or mutagens at work (CMD) requires employers to *replace*, where technically possible, carcinogens and mutagens at the place of work with substances, preparations or processes which pose a lower level of risk. Council Directive 98/24/EC on the protection of the health and safety of workers from the risks related to chemical agents at work (CAD) requires that *substitution* should be undertaken, preferably with chemical agent or process, which under its condition of use is not hazardous (or less hazardous) to workers' safety and health.

Along with regulatory measures, other initiatives such as economic and information-based instruments are deployed to support companies in pursuing the substitution of hazardous chemicals form their processes and products. Scandinavian countries have successfully used taxes to reduce the consumption of pesticides and to steer farmers towards the application of fertilisers with a lower

cadmium content. Chemical action plans at local level are being used to include the objective of reducing the use of hazardous substances in public procurement strategies. Moreover, public authorities grant environmental subsidies in the form of funds for research and development, in particular to SMEs. At European level, funds for research and development into chemical substitution are awarded mainly through:

- **Horizon 2020** is the main EU funding programme for research and innovation, running from 2014 to 2020 with an €80 billion budget. The instrument provides full-cycle business innovation support from business idea conception and planning to execution, demonstration and commercialisation.
- **The environment and climate action programme (LIFE)** is the EU financial instrument for the environment and climate action. For the period 2014-2020, LIFE has a budget of €3.4 billion to co-finance projects aiming to contribute to the Europe 2020 Strategy, 7th EAP and other relevant EU environment and climate strategies and plans.
- **The new cohesion policy**, with a budget of up to €351.8 billion to invest in Europe in order to achieve the goals of smart, sustainable and inclusive economic growth by 2020.

Pressure towards the substitution of hazardous substances does not come only from public authorities, but also from NGOs and downstream users. Large enterprises and global players have developed standards to ensure quality in the supply chain. These standards are perceived as quasi-legislative and can be stricter and more detailed. They are enforced by the power of the market and so can be even more demanding than conventional enforcement of legal requirements. NGOs developed a non-regulatory list of substances to be considered priorities for substitution in order to influence the public and big product manufacturers and retailers.

Conclusions

Identified responses span from actions to streamline the existing legislation and strengthen its enforcement (e.g. increase information requirements for low production volume substances; co-ordinate substitution initiatives across member states around prioritised chemicals of concern; extend the use of grouping strategies to avoid regrettable substitution; dedicate more resources to enforcement) to the use of economic instruments (e.g. tax the use of hazardous substances; enhance government green procurement programmes, considering the functional substitution of hazardous chemicals) and to initiatives that support companies in their substitution efforts (e.g. develop tools to track hazardous chemicals in articles; fund further research into alternative assessment methodologies; scale-up research on grouping strategies based on similarity of chemical structures and trends in (Q)SAR predictions).

Other important measures that could contribute to promote substitution are chemical monitoring programmes. These can be periodic surveys of concentrations of certain substances in human, animal and plant samples (biomonitoring) or monitoring programmes of emissions of chemicals in environmental media, but also initiatives such as chemical footprint, aiming at measuring and benchmarking the progress of companies to safer chemicals.

5.1.3 Grouping approaches

This section presents some of the key findings from the sub-study a final report on "Substitution, including grouping of chemicals & measures to support substitution" prepared by RPA.

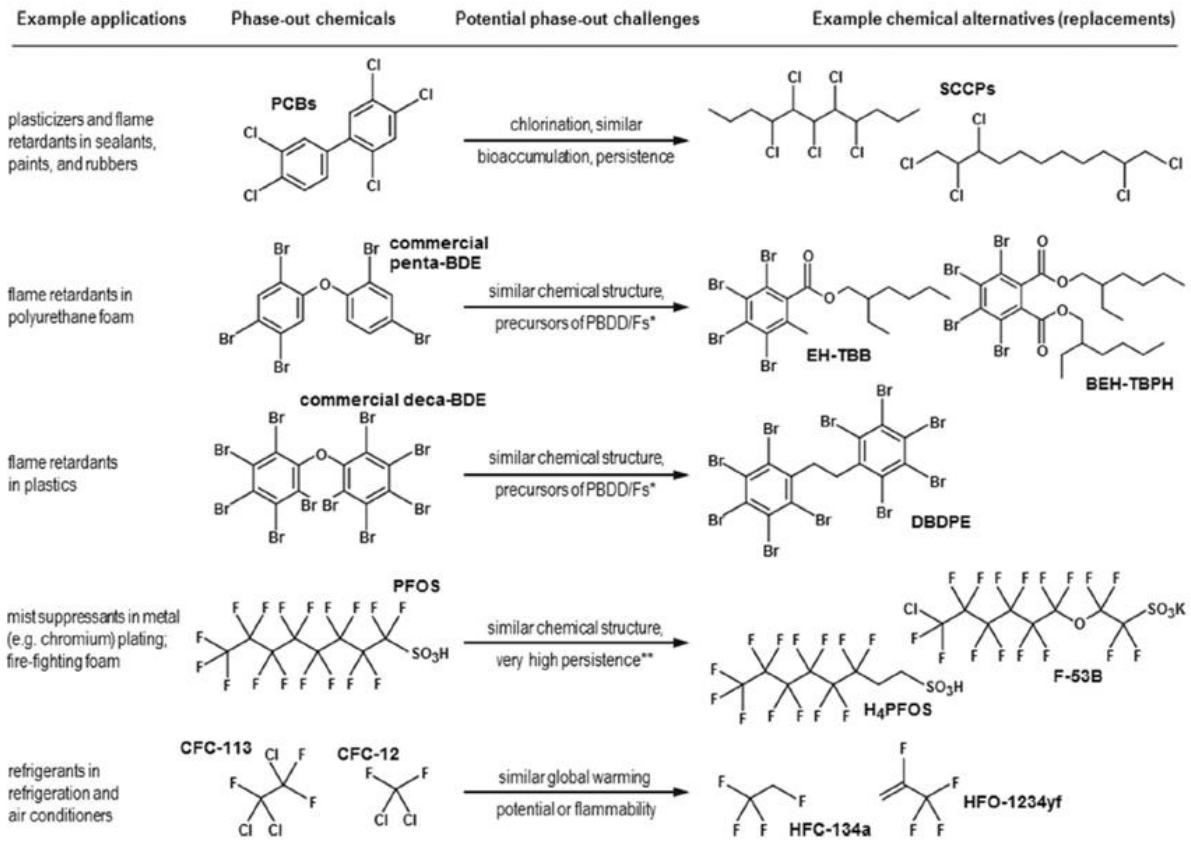
The problem

There are groups of chemical substances that have raised particular concerns and that count hundreds of congeners within each group (for example, phthalates, bisphenols, brominated flame retardants and highly fluorinated substances). Resources for assessment and control are limited. Moreover, different pieces of legislation create incentives to substitute hazardous chemicals in processes and products by restricting the use of certain substances in certain applications, resulting in companies applying

alternative assessment methodologies to find less hazardous alternatives. The available tools typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution. This often leads to cases of regrettable substitution, i.e. the replacement of hazardous substances with structurally similar substances which exhibit similar hazardous properties. In some cases, the substitution occurs with substances for which the information on (eco)toxicological properties is limited.

While intended to promote sustainability and reduce negative impacts on human health and the environment, the application of the substitution principle in policymaking may lead to this type of unintended consequences. There are numerous examples of situations in which the restriction of certain hazardous substances did not result in their substitution with safer alternatives. Figure 5 presents some well-studied examples.

Figure 5: Archetypal cases of incremental substitution for selected phase-out chemicals used in large applications in consumer products



Source: Fantke et al, 2015

Applying the substitution principle without the appropriate comparative risk analysis may result in the premature replacement of existing chemicals with those that may be just as hazardous, or may be less toxic but carry a greater potential for release and exposure. Robust comparative risk analyses need a high level of information and can be resource and time intensive. However, research is ongoing on user-friendly approaches to develop, evaluate and interpret multiple chemical-product-application scenarios for human exposure that would enable to quantitatively assess exposure in a more rapid and efficient way.

Examples abound of regrettable substitutions within groups of chemicals with similar structures and similar hazard properties. Fantke et al described in 2015 these as cases of incremental rather than fundamental change in the structure of hazardous substances that hampers their successful phase-out and propose the use of the term "lock-in" problem. The authors suggest that several challenges and

obstacles are present in the phasing out process of hazardous chemicals: phase-out agreements are often voluntary and do not cover all relevant manufacturers or have a wide range of exemptions. It is also problematic to find a suitable alternative achieving the same performances in the applications, without altering other functions, properties or processes. There are also methodological challenges, related to the different assessment criteria applied by the different alternatives' assessment tools available and that may result in inconsistency in the results. Most tools also neglect life-cycle aspects, which are essential for identifying trade-offs and avoid burden shifting. When life-cycle impacts are considered, the available information may not be sufficient for a proper assessment.

Key findings on grouping approaches – Sub-study a

The problem

- Some groups of chemical substances (e.g. phthalates, bisphenols, brominated flame retardants, highly fluorinated substances) count hundreds of congeners, with more or less similar chemical as well as health and environmental properties, constituting major regulatory challenges as resources for assessment and controls are limited.
- The practice of adopting structurally-similar alternatives (incremental rather than fundamental substitution) often leads to cases of regrettable substitution.

Gaps and inconsistencies in current policy

- The available tools for the assessment of alternatives typically combine hazard and risk assessment with economic and technical feasibility, focusing on chemical-by-chemical substitution which is not effective or even feasible for some groups of chemicals.
- Additional efforts are required in the research of grouping strategies for regulatory purposes, focusing on the systematic analysis of the structural similarities of substances and trends in e.g. (Q)SAR predictions and other methods supporting such approaches.

The grouping of chemicals may be an effective way to enhance the efficiency and effectiveness of the regulatory initiative in promoting substitution to less-hazardous chemicals. Grouping strategies have been proposed by different stakeholders (SIEFs and registration consortia, regulators, NGOs, retailers, etc.) and carried out by different criteria (chemical structure, functional group, mode of action, particle size, etc.) for different purposes (to minimise animal testing, to manage the risks associated with chemicals with the same health and environmental effects, etc.). Various pieces of legislation make use of grouping approaches to different extents. However, further research is needed on the association between chemical structures and trends in (Q)SAR predictions, so to scale up their adoption and move from the current incremental substitution practice to a more effective substitution of hazardous substances.

In REACH, grouping of chemicals is actively promoted in the registration process and registrants are invited to use QSARs or read across methods, when possible and suitable.

With regard to the authorisation and restriction mechanisms, while in the authorisation list there are currently two groups of chemicals only, around half of the entries in the restriction list refer to groups of chemicals. It should be noted that the authorisation list includes different entries referring to chemicals that could be grouped, as chromates and dichromates, although not all chromates and dichromates have been listed. The same applies to low molecular weight phthalates DEHP, BBP, DBP and DIBP, although these have been restricted in toys and childcare products with some high molecular weight phthalates (DINP, DIDP and DNOP).

The same degree of flexibility in using grouping strategies is present in the CoRAP list and PACT table of substances. In order to maximise efficiency of substance evaluation, some substances for which there is an indication of structural similarity (e.g. o-xylene, p-xylene and m-xylene) may be jointly evaluated; other substances that could be grouped by functional group (e.g. diisocyanates) are evaluated by different Member States and in different years.

Hazard classification and use categories have also been applied to group chemicals. For example, Directive 2004/37/EC regulates the protection of workers from the risks related to exposure to carcinogens or mutagens at work. Use categories are used to regulate broad groups of substances, such as pesticides, biocides or cosmetics. Within these groups, more categories can be identified in combination with other criteria (e.g. in pesticides: fungicides, herbicides, insecticides, etc. grouped by target; these can be further categorised by chemical type, e.g. for insecticides: chlorinated hydrocarbons, organophosphorus, nicotinoids, etc.; in biocides, disinfectants, preservatives, pest control, other biocidal products; these can be further categorised by product-type: human hygiene, veterinary hygiene, food and feed area, etc.; in cosmetics, cosmetic ingredients can be grouped by function: preservatives, UV-filters, colorants, etc.).

Another criterion currently used to group chemicals for optimal risk management measures is particle size. All particles of insoluble materials, even if these materials are not classifiable as dangerous to health, are hazardous, and in many Member States there are general limit values for dust based on respirable or inhalable size criteria. Particle size is also the determinant of a new branch of technology, nanotechnology, which makes deliberate use of materials with dimensions in the order of nanometres. Nanomaterials may show novel physicochemical properties compared to the bulk form of their parent substances, and can be used to enhance the performance of materials across several different fields and in a wide range of applications. The same special properties that occur at the nanoscale, and can enhance the performance of materials, could, however, result in "hazard profiles" that may also be different from that of the bulk form. The nature and extent of these hazards are difficult to predict, and therefore need to be assessed on a case-by-case basis. This, however, would require a considerable amount of resources and, therefore, many stakeholders are working on grouping strategies of nanomaterials, using criteria such as biopersistence and high-aspect ratio.

Conclusions

In order to increase the efficiency and effectiveness of the legislation, the extent to which grouping strategies are adopted may need to be scaled up. ECHA is currently studying the possibility of a systematic analysis of the structural similarities of substances in connection with the prioritisation of such substances prior to the substance evaluation stage. Further research on grouping strategies is ongoing at national level too. The Danish EPA explored the possibility to group brominated flame-retardants that were found in a survey of consumer products in 2014. Sixty-seven brominated flame-retardants were grouped according to their chemical structures and trends in (Q)SAR predictions for a number of environmental and health effects, resulting in 15 preliminary structural groups and 7 single substances exhibiting peculiar chemical structures and (Q)SAR trends so that they could not be grouped.

In addition, Fantke et al (2015) propose to have binding phase-out agreements on groups of substances, which would push all stakeholders to design more sustainable substances or find non-chemical solutions. The design process, however, should be aligned to the principles of Green Chemistry and should consider life-cycle aspects in a wider context of the chemicals' applications in consumer products. Moreover, the focus in the alternatives assessment should be on the functions delivered by the substance (functional substitution). This should ensure that entirely new chemical structures, and even non-chemical solutions such as new materials or processes, are considered in the assessment. When alternatives can only be found in the same structurally similar chemical group, two options are suggested: the first option is that, in the absence of comprehensive information on (eco)toxicological properties and environmental fate of the alternatives, it should be assumed that they exhibit the same hazardous properties of the substance(s) to be substituted, based on the similarity in chemical structure. The second option is that the manufacturers of the alternatives generate the information required. The latter is already mandate by the REACH Regulation but, as already noted, the information provided in the registration dossiers appears to be inadequate to perform a comprehensive hazard and risk assessment for many substances registered.

5.1.4 Innovation challenges

This section presents some of the key findings from the sub-study e on *Policy means, innovation and competitiveness* prepared by RPA.

The problem

A stable and predictable regulatory environment is a key requirement for the competitiveness of the European industry and for its ability to innovate.

Regulation has the potential for both negative and positive impacts on these two aspects: negative impacts can occur when the cumulative costs of the environmental legislation on the industry add to other adverse global trends; positive impacts can be achieved by regulation through the promotion of green innovation and by ensuring an even playing field for all of the actors involved.

While on the one hand the EU environmental legislation, and in particular the legislation of the chemical industry, is one of the most ambitious in the world and may constitute an additional burden to EU industry against extra-EU chemical companies (Cefic, 2015 and Cefic, 2016, p.27), the legislation does ensure the internalisation of the externalities of the industry, enforcing the "polluter pays" principle and delivering benefits to the whole society in terms of human health and the environment on the other. Moreover, stricter environmental legislative requirements can stimulate innovation towards sustainability (Porter and van der Linde 1995, WWF, 2003, CIEL 2013, OECD, 2014) and may provide first mover competitive advantages to the EU industry, where the environment is recognised as a megatrend for the short, medium and long terms.

Key findings on innovation – Sub-study e

The problem

- The chemical policy may constitute an administrative burden that, in a context of adverse global trends, may have negative effects on the competitiveness and innovation capacity of European companies, in particular SMEs, against extra-EU companies.
- However, stricter environmental requirements can also stimulate innovation towards sustainability, providing first move competitive advantages to the more pro-active companies.

Gaps and inconsistencies in current policy

- The use of EU funding in supporting transformative technologies with strong innovative potential and added value for manufactured products and services is inadequate.
- The funding available for innovation projects does not meet the ambition of industrial scale projects, mainly due to scattering of support over calls and topics across a large range.
- There is a lack of support or encouragement for co-operation within and/or between sectors (e.g. between large businesses and SMEs; between industry and academia).
- There is an insufficient capacity to attract foreign investment to enable innovation.
- Regulatory signals to investments in innovation are lacking.

If, from one side, environmental legislation poses an administrative burden that, in particular for SMEs, may have as unintended consequences the diversion of resources from research and development activities, the lack of environmental requirements can also have negative consequences on the innovation capacities of SMEs.

For example, the lack of information on the uses and presence of hazardous chemicals in articles prevents informed choices and affects the efficiency of any prioritisation strategy for the purposes of substitution by downstream users.

Gaps in information may also result in imperfect synergies between the different chemical legislative acts, with the ultimate effect of a limited or inefficient internalisation of human health and environmental costs by the chemical or product manufacturers. For example, the emissions into water basins of substances designated as Priority and Priority Hazardous Substances by the Water

Framework Directive need to be brought under very strict Environmental Quality Standards that often can be comply with by investing heavily in tertiary treatments. Sometimes, tertiary treatments are not even sufficient. The costs of these investments are sustained by water companies and, ultimately, by companies and consumers rather than the substances manufacturers and users. Their emissions could be brought under control more effectively by implementing restrictions (through REACH) on certain uses and applications.

The lack of a legislative framework that clearly rewards the substitution of hazardous chemicals, and that at the same time penalise the continued use of hazardous substances may undermine the confidence of industry stakeholders to invest in green innovation. During the workshop, some stakeholders indicated that the granting of authorisation for the uses of substances in applications, for which safer alternatives were available, is a regulatory signal that may stifle, rather than reward, innovation. Others pointed to the inability of regulation in dealing with cases of regrettable substitution, where substances are substituted with other substances with similar hazardous properties or of equal concern.

The European framework to support innovation may benefit from enhanced co-operation between geographical areas and sectors. Many downstream users would like to manufacture and put safer products, which do not contain hazardous substances, on the market, but they face two major problems:

- Lack of communication with their chemical providers; and
- Lack of adequate expertise and the inability to find alternative providers of sustainable alternatives.

Moreover, SMEs willing to engage in green innovation may lack the adequate market power to require safer substances to their chemical providers or may lack the resources to find and switch to an alternative provider.

Trade agreements are essential for maintaining the competitiveness of the European industry. However, human health and environmental protection principles should not be seen as part of the negotiable elements for getting a good deal.

Conclusions

Responses to the identified gaps and deficits suggested in the literature and by the consulted stakeholders mainly focus on reducing the administrative burden on companies, when possible, while supporting innovation through economic instruments (e.g. VAT reduction on products with safer alternatives, promoting taxation of hazardous substances among Member States, enhancing government green procurement programmes) and support and capacity building (e.g. funding further research into chemical product life cycle risk assessment; raising awareness on the benefits of – and stimulating market demand for - safer alternatives; enhancing supply chain collaboration and engagement through shared performance testing and the creation of demonstration sites; facilitating public-private investment partnerships to support research).

5.1.5 A programme on new, non-/less toxic substances

This section presents key findings from the sub-study f final report on a *programme on new, non-/less toxic substances* prepared by Ökopol.

The problem

The use of toxic substances can only be phased-out if suitable alternatives are available. Alternatives could be selected from among existing substances or from non-chemical solutions. In addition, new, non-toxic substances could be developed that fulfil the technical needs of a particular use, have a low or no (eco-)toxicity and do not cause negative impacts on waste treatment and recycled materials. New

substances may be developed because (i) existing alternatives are not available at all, (ii) are of an insufficient (technical) quality or (iii) if even higher performance levels, additional (innovative) functions or a significantly decreased (eco-)toxicity are expected from the new substances. Finally, new substance development may occur in a larger innovation context, i.e. to develop new materials with new or significantly enhanced functionalities.

This section discusses how the development of new, non-toxic substances[14] could be enhanced through different activities and approaches at the EU level.

Key findings on new, non-toxic substances development

The problem

- A non-toxic environment implies that toxic substances are replaced with safer alternatives. Existing substances and non-chemical solutions are not always suitable alternatives and new solutions may be required;
- Barriers to the development of new, non-toxic substances include fears of costs, a lock-in in the current production situation, the potential need to establish new relationships with suppliers/customers, a lack of experience in cooperating on issues of substitution and substance development and uncertainty about the outcome of the development process and the future market opportunities for the new, non-toxic substances;
- Contextual factors that hamper the development of new, non-toxic substances include a lack of clear development goals at policy level (i.e. definition of non-toxic substances), missing inter and transdisciplinary cooperation in science and at the corporate level, a generally hesitant business environment regarding "green chemistry" and a lack of awareness and education;
- Research and innovation programmes exist which integrate the development of new, non-toxic substances as an option to achieve larger solutions to societal problems at the Member State and EU level. However, specific programmes addressing small scale innovation, without a large impact on society, are largely unavailable.

Gaps and inconsistencies in current policy

- The need to develop new, non-toxic substances is not integrated as horizontal issue in all EU policies and research programmes;
- Although substitution of hazardous substances is discussed since a long time, little emphasis has been placed on supporting the related development of new, non-toxic substances and creating a favourable business environment, e.g. with view to replace restricted substances;
- A strategy, implementation instruments and networks to raise awareness about the benefits of using non-toxic substances and building related capacities in companies, academia and the general education system should be considered; Such measures are still lacking at EU level (including providing support to Member States).

The Current Policy Framework and Research Context

Two contexts for the development of new, non-toxic substances can be distinguished in the following manner:

- The development of new or significantly improved functionalities of substances or materials; these activities are frequently embedded in larger material and product development processes aiming to create qualitatively new solutions to technical or societal problems. The development of nanomaterials and nano-enabled materials is one of the relevant research areas in this regard;
- The development of new alternatives, for use as substitutes for toxic substances, to achieve an existing functionality at least at the same level of performance, but with a significantly reduced toxicity level. One example is the phthalate DINCH (EC-431-890-2), which was developed as an alternative to hazardous phthalates.

[14] While the concept of sustainability is increasingly guiding company decision-making, and is defining requirements for solutions to societal challenges, an emphasis is being placed on the aspect of (eco-)toxicity of substances in the context of the non-toxic environment.

It is not possible to quantify the present demand for new, non-toxic substances for either of the two cases, *a fortiori* neither is it possible to quantify the demand that will arise in the future. This is due to a lack of knowledge about the extent of the requirement for substitution and the availability of already existing and suitable solutions. The following main factors determine the demand for new, non-toxic substances:

- The guidance from the policy level on substance properties to be avoided, and to strive for, as well as overall priorities for related innovations at the large and smaller scales;
- The regulatory and market pressure to phase-out toxic substances, regulatory burdens of and incentives for the development of new (non-toxic) substances;
- the need, and innovative potential in the scientific and business communities, to develop fundamentally new solutions to existing problems;
- the availability of alternatives from the existing substance portfolio or other types of substitutes;
- the openness of supply chains to accept and take the risk of developing and using new, non-toxic substances; opportunities of chemicals suppliers and users to make contacts and overall awareness of the opportunities "green chemistry" as such;
- the costs and expected prices, as well as profit margins and overall economic opportunities, for a new, non-toxic substance;
- the research funding and the availability of substance design and hazard prediction tools.

The consulted stakeholders emphasised the need to define the term "non-toxic" and give overall guidance on the envisaged phase-out and replacement process at a high level. This would include disambiguation at policy level and the integration of the "toxic issue" across policies and Commission Directorates as well as in research and innovation programmes.

The implementation of REACH - the restriction and authorization process as well as the listing of substances of very high concern in particular - increases the regulatory pressure for substitution and give overall guidance as to which substances should be avoided and eventually phased-out. However, the number of restrictions are low and they cover only specific applications, thus not promising large markets and, therefore, incentivising the development of new substances only to a lesser extent. According to some stakeholders, the regulatory clarity and substitution incentives from the authorisation process are weakened by the, partly inconsistent, authorisation decisions.

Little specific information is available about the extent to which requirements to register new substances and to provide information on their toxic properties actually hinder the development of new, non-toxic substances. Literature analyses and stakeholder comments give the overall impression that these burdens are comparatively low and are outweighed, by far, by the fact that the registration under REACH created a level playing field for new and existing substances (Engler, 2016) (Fennelly, 2015) (Green Chemistry & Commerce Council, 2015).

While options to provide regulatory incentives, such as requiring less registration information or lowering (registration) fees for non-toxic substances, do exist, the impetus they might have on new, non-toxic substances cannot be deduced from the information available. The main incentive from regulation is the pressure to substitute toxic substances as such.

The existing potential alternatives to toxic substances is difficult to assess, due to a lack of information on the current uses of (toxic) substances, their functions and functionalities in materials and articles and the other options for their substitution. This lack of information is also a barrier to new substance development, given that economic actors cannot easily estimate the market potential for an alternative and the actual needs of the market are not transparent.

The potentially largest barriers to the development and use of new, non-toxic substances result from

the challenges in the supply chain. These are, among others:

- an overall hesitation to using new (non-toxic) substances because of fears about (hidden) costs and a lock-in in the current production situation (the possible need to change the overall choice of material or design of a chemical product or an article as well as processing equipment);
- the potential need to break existing supplier-customer relationships in combination with the need to identify new suppliers with whom they take the risks of developing a new substance;
- a lack of communication and collaboration opportunities and capacities, which are necessary for substitution, particularly where the alternatives do not exist yet;
- an overall lack of awareness of the benefits of using new, non-toxic substances;
- overall economic uncertainties as to the future performance of products, the development of markets, potential profits and stability of supply, if new, non-toxic substances are used

All these challenges also exist for substitution with existing solutions, but the risks are (perceived as) higher, given that the development phase of a substance involves more uncertainty and resources for identifying an alternative than searching for one in the existing substance portfolio.
In the field of new materials innovations, these barriers have less weight, as the process is normally integrated into larger networks of actors dedicated to reach a common goal and to cooperate. Nevertheless, the challenges mentioned also apply in this area.

The availability of substance design and hazard prediction tools impact on the resources needed to develop a new substance and, therefore, modify other factors. Similarly, the availability of research funding either for developing new, benign materials in the context of larger innovation activities or for targeted research on specific alternatives might decrease the resource input needed from stakeholders into the R&D activities, which might lower the related barriers.

Gaps identified and inconsistencies in current policy/legislation
The current regulatory framework creates a level playing field for "new" and "existing" substances, with regards to the registration and assessment of hazardous properties. Several provisions exist in the EU regulatory framework and scientific programmes to support the development and use of new (non-toxic) substances, such as exemptions for process and product oriented research and development as well as lower data and authorisation requirements for low risk substances under biocides legislation.

Overall guidance and market signals, e.g. from the authorisation decisions under REACH are, however, mixed. According to literature and stakeholder comments, stricter legislation may better promote the development of new, non-toxic substances, while overall (policy) guidance is stated to be insufficient, despite the availability of the SVHC criteria of REACH Article 57. Furthermore, the overall awareness on (the benefits of using) non-toxic substances is low and an integration of, and sufficient emphasis on, the issue across all relevant policies is still missing.

No national programmes that focus on the use of new, non-toxic substances could be identified during the project research. However, a number of activities on green chemistry, which are interrelated and connected via an overall mission of the Environmental Protection Agency, do exist in the United States. Furthermore, some Member States conduct activities related to the development and use of green or sustainable chemicals. These include research and innovation funding and the development of tools for substance design, hazard prediction, risks and alternatives assessment. Furthermore, they support stakeholder platforms, stakeholder dialogues and awareness raising about the needs and opportunities presented by substitution.

At EU level, the Research and Innovation Programmes cover a wide range of domains addressing different scientific, economic and societal challenges. There is no specific theme on the development of new, non-toxic substances, but this issue is covered by projects funded under different themes; notably LEIT-NMPB (Leadership in Enabling and Industrial Technologies, Nanotechnologies, advanced Materials, advanced manufacturing and Processing and Biotechnology). Activities address

the whole innovation chain with technology readiness levels spanning the crucial range from medium levels to high levels preceding mass production. They are based on research and innovation agendas defined by industry and business, together with the research community, and have a strong focus on leveraging private sector investment. One example of action is the Horizon 2020's €3 million prize for clean air, for which challengers must develop innovative, design-driven material solutions that will reduce the concentration of particulate matter in the air.

Conclusions

Most aspects identified as barriers or potential incentives along the supply chain are out of direct reach of the EU Commission but can be (better) addressed by the Member States, the market actors themselves or by other stakeholders, such as NGOs or trade associations. These concern, among others, the integration of concepts and methods from green chemistry into the education and training systems, general awareness and creating a positive attitude to the use of non-toxic substances and the related benefits and providing opportunities for information and experience exchange as well as general networking of business and scientific actors.

Nevertheless, activities at EU level may have an important impact on these actions. These could involve the development and implementation of legislation (market demand for new, non-toxic substances), awareness raising campaigns (acceptance of new solutions, communicating good practice and benefits of substitution) and support activities e.g. on the networking of actors (facilitating contacts and experience exchange) or education and training of researchers. Here the EU Commission, and its agencies, could provide financing and infrastructure as well as capacities and competences from their staff.

While research and development funding is available, and in principle allows for and invites substance and material innovations, opportunities for smaller scale and less innovative applications to new, non-toxic substances appear to be lacking.

The extent to which current and past EU research projects foster the development of new substances, and if these constitute improvements with respect to their (low) toxicity and eco-toxicity, cannot be determined from the available evaluation reports on those projects. However, it is an overall perception observed from the consulted stakeholders that the funding instruments direct their resources towards other societal challenges than the toxicity of substances, such as to climate change, resource efficiency or health sciences. Therefore, an EU programme specifically supporting research and development of new, non-toxic substances could be an integral part of the strategy for a non-toxic environment and could support the provision of alternatives to toxic substances as well as enhancing the design of new, benign materials at a smaller scale, thereby complementing the existing funding programmes, such as Horizon 2020.

An overall programme that enhances the development of new, non-toxic substances should not stop at research funding but should include additional activities, such as of improving the overall business environment and readiness to innovate, e.g. by providing guidance at the policy level, raising awareness, improving education and supporting the related networking of the relevant actors.

5.1.6 Early warning systems[15]

Through predicting hazardous properties of substances and by requiring risk management measures that limit human and environmental exposure, the EU chemicals regulatory framework aims for the safe use of chemicals as well as protecting the population and the environment. Despite the various

[15] This section has been drawn from the draft final report for sub-study g on *Early warning systems for examining chemical threats to human health and the environment* drafted by RIVM. More details are included in the sub-study.

kinds of legislation, numerous well-documented cases exist of extensive damages to health and environment caused by the production and use of chemicals. Furthermore, it often takes a long time before these warning signals are picked up by societal institutions and even longer for these to react. Therefore, the early identification of chemical threats to human health and to the environment is of great importance in taking timely measures to reduce or eliminate the risk of hazardous compounds. Developing a fast response system for detecting and tackling approaching chemical threats to health and environment should be considered as a complementary action, and not as an alternative instrument to replace current legislation.

A variety of tools, methods and activities have been drawn up, developed or initiated for the early identification of new or upcoming chemical threats. These tools and methods are commonly known as early warning systems (EWS). The aim of early warning systems is to identify the chemicals that might potentially be hazardous and cause adverse effects as early as possible, as well as identifying situations in which exposures to substances could lead to harm coming to humans or to the environment. Early identification allows for the appropriate actions to protect man and the environment to be undertaken earlier and can provide great value in achieving a high level of public safety and environmental protection. Early identification allows more time for further investigation or taking the right measures to control issues of concern. In this way, an EWS could facilitate progress towards a non-toxic environment. A systematic approach for the early identification of chemical threats could also contribute to identifying gaps in existing legislation, as well as in data and knowledge, and could also support enforcement authorities.

Apart from early detection, early warning systems should also aim to provide insight in the appropriate risk management options for the chemical risks identified and communicating this information to the authorities concerned. This includes providing additional evidence, examining appropriate risk management measures, and providing options to communicate the information to the stakeholder concerned.

Early warning systems considered

Important aspects to consider when establishing an early warning system includes the definition of new and/or emerging risks (NERCs) and the system's specific aim. This pre-defines what the system will be able to do and sets the boundaries to the kind of information to use and which output to generate.

A variety of terms and definitions have been used, such as new risk, emerging risk, emerging issue, emerging pollutant, emerging substance, and contaminant of emerging concern. These can be grouped into three main categories: (i) newly created risk; (ii) newly identified risk; or (iii) increasing risk becoming widely known or established. Combined and cumulative exposure to chemicals and low dose and long term effects caused by chemicals, which are considered to represent major additional challenges, could be qualified as newly identified or, to some extent, as increasing risk becoming widely known or established.

A review of currently available methodologies and systems identified various components that will be required in order to develop an operational warning system for the EU aimed at proactively identifying new and emerging risks of chemicals. In general, the phases presented in **Error! Reference source ot found.** have been identified. An EU early-warning system should first be able to filter signals from media, scientific literature, and experts and to evaluate those signals. This could also include the screening of data. The second step should be to check if the signal has been identified previously, and if actions or regulatory measures have already been implemented. A third step, based on target-specific criteria, would involve the gathering of additional exposure, hazard, and policy data regarding these risks, for discussion by experts. Subsequently, the data could be translated into a risk score, thereby prioritizing newly identified risks from chemicals and, finally, defining the risk management options (RMO) required and/or the identification of the most suitable actor to address the risk.

Figure 6: Components and Steps involved in an EWS

In-depth analysis of existing systems

In general, two basic methods to analyse existing systems can be distinguished. The proactive "exposure first" method would aim to identify possible new and emerging chemical risks (NERCs) based on physical, chemical, and toxicological properties of a substance and/or the (altered) exposure resulting from the use of a substance, taking technological and societal developments into account. The second method is the 'disease first method' (or 'effect first method'). This method is a reactive method that tries to identify the environmental and health effects of NERCs as soon as possible. The 'disease first' method is complementary to the 'exposure first method'.

Environment

Only two operational systems have been identified that aim both at the identification and management of new or emerging risks of chemicals (NERCS) for the environment – the NORMAN network (2016) and the NERC system operated by the RIVM. Both non-institutionalised systems are currently operational in the EU and are discussed in greater detail below. In addition, a more general approach on the identification and prioritisation of emerging issues is presented.

NORMAN is a network of reference laboratories, research centres, and related organisations responsible for the monitoring of emerging substances. It systematically collects monitoring data and information about the effects and the hazardous properties of substances. The substances are assigned to priority action categories based on this information. A set of criteria is used for the allocation of emerging substances to these clearly pre-defined categories and their subsequent prioritisation. The ultimate result could be that substances are selected to be put on the Watch list of the Water Framework Directive 2000/60/EC. The list of substances to be considered for prioritisation is established through expert consultation and through chemical analytical methods such as non-target screening; a method aiming at a broad detection and identification of chemicals that is not directed to a specific set of chemicals. Action is taken when clear evidence on actual environmental effects emerges. The method could, therefore, be characterised as 'effects first'.

The system operated by the RIVM uses online media monitoring, expert consultation, and non-target screening for the identification of new or emerging risks. A hazard- and exposure-based approach is used to provide further evidence about the possible risk and to derive a risk score in order to prioritise them. A variety of information sources are used to provide information about the possible exposure and hazardous properties of the identified potential, new or emerging chemicals.

Highly prioritised chemicals can then be proposed for a risk management option analysis under REACH. Based on this analysis, the most suitable risk management measure within REACH or other legislation are determined. This method allows for substances to be identified and to undertake action before an effect occurs, based on the hazardous properties identified for instance, as well as to identify substances with clear environmental effects, based on the effects observed or in the exceeding of quality standards, resulting from the evaluation of monitoring data. This system uses the 'disease first' method, which is complementary to the 'exposure first method'.

The work done by the Scientific Committee on Emerging and Newly-Identified Health Risks (SCENIHR) is largely based on expert consultation. Two parallel and complementary approaches may be used to identify emerging issues: (i) a proactive approach that requires 'brain storming' sessions to identify the emerging issues of principal concern, followed by the introduction of procedures to detect and characterise their development; (ii) and a more reactive approach based on the identification of indicators of change, and the monitoring thereof, to detect emerging issues.

SCENHIR proposes a decision tree approach (algorithm) for the identification and prioritisation of NERCS, based on qualitative criteria such as uniqueness, soundness, and scale of severity.

Workers

In relation to chemicals at the workplace, proactive 'exposure first' methods aim to identify possible NERCs, based on a proper risk assessment. However, the necessary information to use deductive reasoning is lacking for most substances. This holds especially true for toxicological information regarding the routes of exposure that are important for workers, i.e. inhalation and dermal exposure (the most available toxicological information is for oral exposure). Therefore, an inductive way of reasoning is needed to identify and handle those substances that have a negative impact on worker's health; i.e. 'the disease first' method. This inductive way of reasoning works from observations (cases of diseased workers) and moves toward generalisations and theories. The 'disease first' method is used in pharmacovigilance, for instance. Drugs are tested thoroughly prior to their introduction onto the market, but the identification and evaluation of negative health effects reported after their introduction onto the market remains necessary.

Considering the disease first method, there are systems based on expert forecasts. One review consists of an overview of more than 40 (potential) NERCs for workers reported over the last few decades using several data sources. A method for the prioritisation of these NERCs is presented in Palmen and Verbist (2015). As part of the current sub-study, a survey was carried out among European countries to get an overview of existing early warning systems for workers. This revealed three different methods within the 'disease first method' category:

- '*clinical watch system*' for the collection of spontaneous cases reported throughout Europe;
- *databases* that may be used for epidemiological research on possible relationships between occupation and/or exposure to substances and health effects (e.g. occupational cancer);
- *biomarkers* for exposure and/or *biomarkers* for biological effects that can be used to detect NERCs.

One limitation of such a system can be the long response time between exposure and observed effects. This can be addressed partly by detecting the more sensitive effects or end-points by using biomarkers, for instance.

No typical system using the 'exposure first' method has been identified for workers.

Consumers

Several systems or organizations dealing with new and emerging risks of chemicals in food or consumer products (toys, cosmetics and household cleaning products) were found to be of potential use for the possible layout of a future EU-wide, sector-specific early warning system for consumer protection.

The systems that exist at present highly depend on observed and documented signals relating to occurrence of effects and potential exposure. Cosmetovigilance systems such as the European Cosmetovigilance and the Dutch Consumer Exposure Skin Effects and Surveillance, and the national poison centres all provide valuable information about the epidemiology of adverse effects, intoxications, and poisoning incidents that can be used to pick up on a signal and to take measures.

The EU-wide Rapid Alert System for dangerous non-food products (RAPEX) enables the rapid exchange of information about the dangerous products found. The reports in RAPEX deal mainly with failure of compliance with regulations and, therefore, with regulated products and chemicals primarily. This system is pro-active, in a sense, given that it aims to prevent harmful effects resulting from product failure or non-compliant products.

The European Food Safety Authority (EFSA) seems, so far, to possess the most advanced early warning system regarding food related consumer exposure. This EWS aims to proactively identify a given (re)emerging hazard and to, consequently, prevent the presence of this hazard from giving rise to a risk by taking preventive measures. The key characteristic of this system is that it is anticipatory rather than responsive. It is different from rapid alert systems, such as the Rapid Alert System for Food and Feed (RASFF) where notifications are triggered by controls or by consumer complaints.

Conclusions

Several approaches have been used to pick up signals, such as online media monitoring and expert consultation or registration systems for the collection, evaluation, and systematic monitoring of spontaneous reports of undesirable events. The systems that exist at present depend highly upon effects observed, the so-called 'effect based' or 'disease first' systems. Some systems contain elements that can be used to proactively identify possible NERCs, based on a proper risk assessment, the so-called 'exposure first' methods.

Many data sources that can be used to provide further evidence for the selection or prioritisation of potential new or emerging risks related to chemical substances are already available. The selection of suitable approaches for picking up signals and prioritisation should be based on effectiveness and efficiency. Generating an overview on existing data sources, their availability, accessibility, and their usefulness would be essential in establishing an EWS. Subsequently, the data would have to be made accessible through a central database. A quantitative risk based procedure, based on hazard assessment and exposure assessment, is common in the field of risk assessment of chemicals for human health and the environment. An alternative way to identify or prioritise new or emerging risks, such as the manner proposed by SCENIHR, is based on identifying possible NERCs, based on qualitative criteria.

Investigating appropriate risk management options, the communication of the risks identified, and the identification of the measures to be proposed are essential to managing the risks observed. It appears that the component that covers risk-communication is not always well covered in existing systems, meaning that there is limited or no information on a communication plan directed at decision-makers and enforcement authorities or to defining the actions about how to communicate the results obtained. The need to develop a communication plan (where and how to do so) should, therefore, be addressed in the development of an early warning system in particular. Building an overview of the current environmental legislation and the risk management options they provide, including the competent authorities, is a first step in formulating a communication plan.

Due to the many differences that exist between the fields of environmental, consumer, and worker protection and between and within Member States about how signals on new and emerging risks are collected, processed, and interpreted, it may not be feasible at this point in time to create a single system that covers these three fields. The overall advice given, therefore, would be to utilise existing systems as much as possible and to try to make interconnections and facilitate communication at the Member State and European levels. The basic building blocks and steps from **Error! Reference ource not found.** can be used as a starting point to establish a European early warning system for identifying chemical threats to human health and to the environment.

There are several reasons why existing approaches are insufficient and greater effort at the European Union level is needed, based on the analysis of existing national and European tools and methods developed and in operation for the early identification of new or upcoming chemical threats, developed or initiated.

The continuous effort of screening and filtering signals is essential for early identification, but a labour-intensive process needs input from experts at the national level that is organised and coordinated at an international level.

Furthermore, it will always be hard to establish a causal link between exposure to chemicals and, for example, diseases. One issue relating to this is the limitations of epidemiology, meaning that a harmful effect must often be rather drastic and widespread before it is detectable. There is often a lack of information, due to the absence of relevant hazard data and the absence of exposure and use information. Therefore, it is important to identify all of the useful sources of information and databases that are available, to centralise this information, as much as possible, and to come to an effective and efficient procedure for the evaluation of the signals collected that allow the identification of new or emerging risks from exposure to a certain chemical.

An international platform, working on the identification of chemical threats, is lacking. There is a general need for greater cooperation and exchange of information at the EU level about NERCs. At the national and international levels, there are various initiatives in the area of the early identification of chemical threats that could possibly be linked to each other. An overall approach that covers the different steps needed for the identification and management at the EU level seems to be lacking to some degree.

5.1.7 Enforcement

The 7th Environment Action Programme highlights the importance of law enforcement in maximising the benefits of Union environment legislation[16].

The issue of the enforcement of chemicals legislation within the EU was also highlighted by numerous stakeholders consulted during the desk research and at the workshop held in Brussels on 8 and 9 June 2016 ('the workshop'). It has been referred to in relation to all seven sub-study topics and, hence, merits close attention, even though the Commission has limited means to impact enforcement activities of the Member States.

The focus in this context is on substances in articles (SiA), imported articles in particular, and on the non-compliance with the relevant provisions under REACH; namely, Article 33 and Annex XVII. The concern that there is a compliance issue, in relation to the obligations for companies to identify, report and to communicate on the presence and safe use conditions of the SVHCs contained or imported in articles, is also reflected in the ECHA Report on the Operation of REACH and CLP 2016. The report stresses the importance of these obligations "*for ensuring the safe use of chemicals, to facilitate*

[16] Paragraph 65 of the 7th EAP.

substitution and to support the realisation of a circular economy" (ECHA, 2016), and hence, the obligations highly relevant for this study. It states that 359 notifications of the presence of Candidate List substances in articles for a total of 38 Candidate List substances had been submitted to ECHA by the end of 2015; it also holds that the low figure is "*likely to illustrate a low level of compliance*" (ECHA, 2016).

The report also refers to a press release by the Commission according to which the European Rapid Alert System (RAPEX) reported 'chemical risk' as the most frequently notified risk in 2015 with toys (27%) and clothing, textiles and fashion items (17%) being the two main product categories for which corrective action had to be taken (ECHA, 2016).

The ECHA report reproaches that the "*activities of Member States Competent Authorities (MSCAs) […] to enforce the SiA-related objectives and legal obligations of REACH have been modest*" and that *"[t]his was confirmed by a survey launched by ECHA among MSCAs in 2013 on their plans and willingness to cooperate with ECHA in this field*" (ECHA, 2016).

The report found a lack of enforcement, which undercuts impetus for substitution, in relation to the substitution of hazardous chemicals by less or non-hazardous substances. The Commission has highlighted that enforcement of the substitution of substances classified as C1, C2, M1 or M2 under the Carcinogens and Mutagens Directive was a particularly poorly enforced area and, as a result, substitution is infrequent (European Commission, 2012).

Another Commission study highlights the importance of harmonisation in the implementation of REACH at Member State level, in terms of market surveillance and enforcement, as a critical success factor in the operation of a harmonised single market (European Commission, 2015). According to the study, "*MS authorities identified the following as the key areas to address to increase harmonisation:*

- *Issues surrounding languages (e.g. translations of SDS/ Exposure Scenarios);*
- *Lack of resources for staff, staff training and retention;*
- *Collaboration between different government bodies;*
- *The supply of test laboratories (costs and time to get a response);*
- *The lack of knowledge as regards REACH among firms*." (European Commission, 2015)

Companies interviewed as part of the above-mentioned study indicated that mainly the following factors cause problems regarding surveillance and enforcement (European Commission, 2015):

- "*Different penalties for non-compliance in different Member States;*
- *Different OSH (Occupational Safety and Health) legislation in Member States, also different Binding Occupational Exposure Limit Values (BOELV);*
- *Lack of enforcement as regards imported articles;*
- *Lack of valid test methods for SVHC contents in articles;*
- *Products entering from non-EU/ EEA countries (polymers, cosmetics, biocides and chemical articles); […]*
- *Re-imports of chemicals into the EU;*
- *Nanomaterials (amendments to REACH Annexes are not implemented yet);*
- *Varying inspection requirements between and within Member States;*
- *Knowledge levels of inspectors as regards complex technical matters*."

The Commission published a study on enforcement indicators for REACH and CLP in April 2015 (European Commission, 2015). The study proposed a set of 50 enforcement indicators at the MS level, EU level and in relation to the Forum for Exchange of Information on Enforcement ('Forum') with the aim to measure enforcement at these different levels. The idea is to help to enhance the knowledge of the state-of-play of the implementation and enforcement of REACH and CLP and to try to streamline enforcement activities in the EU.

In relation to the work carried out by the Forum, ECHA recommends that all Member States should take part in all REACH-EN-FORCE (REF) projects (ECHA, 2016). These are carried out by inspectors based in the national authorities in the participating Member States and focus on different subjects related to the compliance of registrants with REACH, CLP and the PIC regulations.

Several examples of best practices in relation to enforcement activities were identified during the desk research carried out for this study and by stakeholders who also came up with additional ideas to tackle the issue.

The **Swedish Government** passed a bill establishing a non-toxic environment as one of its overall goals (KEMI, 2015). The national Chemicals Inspectorate (**KEMI**) implements the strategy via action plans. The action plan from 2015 to 2020 includes, amongst other things, the enhanced enforcement of banned or restricted substances in articles. In 2016, KEMI adopted a strategy for the enforcement of chemicals in articles (KEMI, 2016). The strategy focusses on toys and childcare articles, clothing, shoes and accessories, electrical products, building material and furnishing and hobby and sports equipment. It includes inspections of those companies that put relevant products on the Swedish market, including via e-commerce. KEMI carries out chemical analyses of those products and cooperates with other authorities in Sweden and throughout the EU. In addition, the strategy foresees the development of a work model that combines enforcement with other activities, such as "*education for companies, information to the general public and further development of legislation*".

KEMI has also dedicated a specific enforcement action on (soft) plastic articles used by consumers (KEMI, 2015). The substances targeted in the analyses were phthalates (plasticisers), short chain chlorinated paraffins (plasticisers and flame retardant), lead, cadmium and dimethylformamide/methylacetamide. Almost 10% of the articles sampled contained restricted substances in levels that exceeded the limit values, with short chain chlorinated paraffins being the most frequently found substance. KEMI prohibited sales in instances in which companies did not stop selling the products. KEMI reported 20 companies to the environmental prosecutor and reported articles that contained high levels of short chained chlorinated paraffins and cadmium to RAPEX.

In 2013, the **Danish government** agreed with all parliamentary parties to launch a new chemicals initiative between 2014 to 2017 to protect humans and the environment from chemical risks (Ministry of Environment and Food of Denmark, 2016). A budget of DKK 184.8 mill. (around €25M) has been allocated for this period. Around €10M will be spent on the programme on 'Non-toxic products', which includes an inspection and enforcement initiative to ensure compliance of consumer products for the children and young people. Specifically, the Central Customs and Tax Administration (SKAT) and the Danish Safety Technology Authority are involved.

Participants in the June 2016 workshop, organised in the context of the Non-Toxic Environment study, referred to the US approach concerning toys. Under the **US Consumer Product Safety Improvement Act** (CPSIA), all toys intended for use by children 12 years of age and under, must be third party tested and certified in a Children's Product Certificate as compliant to the federal toy safety standard, and to other applicable requirements as well[17].

In 2013, ECHA proposed the launching of a common action plan for SiA-related activities, which was not supported by the MSCAs (ECHA, 2016). However, the **Forum for Exchange of Information on Enforcement** will run a pilot project on this topic in 2017.

The ECHA report notes that the possibility for consumers to require information about the presence of SVHCs in articles under Article 33(2) of REACH "is not generally known and therefore only sparsely

[17] Section 15 CPSA.

used" (ECHA, 2016). In this context, initiatives in Denmark and Germany should be mentioned, that encourage consumers to use their right to request the information by using online tools[18]. The German online tool is provided by the NGO BUND. The idea that NGOs could help to strengthen the implementation of legal requirements, even though they do not have a "formal role", was presented by participants at the workshop. Participants reported that models that support civil society groups in the screening of products on sale for the presence of SVHC were very effective in the US.

5.2 CHEMICALS IN ARTICLES AND THE CIRCULAR ECONOMY

This section presents key findings from the sub-study b final report on *non-toxic articles and material cycles*, prepared by Ökopol.

The overall aim of achievingnon-toxic articles and material cycles is to prevent their related risks for human health, for the environment, and to improve resource efficiency through the recycling of article wastes. Combining the goal of a non-toxic environment and a circular economy requires:

- improving article design and as far as possible preventing the inclusion of toxic substances in articles with the aim of reducing the exposure throughout the life cycle, increasing recyclability of the articles or the materials of which they are composed, and;
- collecting and separating wastes that contain toxic substances with the aim of decontaminating material streams and ensuring high quality recycled materials generated from article wastes.

The issue of non-toxic articles and material cycles is complex because three different but interconnected regulatory areas are relevant i.e. chemicals legislation, article-related legislation, and waste legislation. Furthermore, a large number of different types of actors are involved in article production and in waste treatment. Finally, numerous types of articles and waste streams, which have complex compositions, need to be considered.

Key findings on chemicals and articles and the circular economy

The problem

- Toxic substances are included in articles and may be released at any lifecycle stage, resulting in exposures and potential risks for humans and for the environment. This is true for new/currently produced articles, as well as for articles already present in society.
- The scale of the problem is significant. The following examples involves two substances from problematic substance groups widely used in articles. The annual amount of DEHP (a phthalate used as plasticiser in PVC, now listed in REACH Annex XIV as a SVHC substance subject to authorisation) included in articles on the EU market (produced in the EU or imported), which is estimated to 210,000 t/y (KEMI, 2015). Further, 7 t/y of BDE (a flame retardant listed as a POP) included in plastics waste from WEEE in the Netherlands, and 22% of this is estimated to be recycled and used in new products (RIVM).
- Linking the incidence of the health and environmental damage observed to exposures to single articles or article categories is challenging due to the complex exposure situation and a lack of basic exposure data. Furthermore, the extent of risks varies with the type of substance, type of article, and its actual use situation. However, there is evidence that many substances, including such with known toxic effects, are released from articlesand are present in the human body and the natural environment.
- Toxic substances contained in end-of-life articles eventually reach the waste stage and may contaminate recycled material streams, enter into a second service life, and potentially occur in unsafe uses, as has been demonstrated e.g. for brominated flame retardants from recycled plastics

[18] Tjek Kemien website (initiated by Danish EPA and Danish Consumer Council), available at: https://www.docdroid.net/ER4DMta/tjek-kemien-information-to-companies-2016-eng-version.pdf.html (last accessed on 18 July 2016); BUND website, available at: http://www.bund.net/themen_und_projekte/chemie/stell_die_giftfrage/anfrage_generator/ (last accessed on 18 July 2016).

Key findings on chemicals and articles and the circular economy

used in thermos cups (Samsoneka, 2013).

- Information about the content of toxic substances in articles is largely missing, both for specific articles and at a general level. This lack of data renders it extremely difficult for:
  - Regulators to carry out overall risks assessment, determine the scale of risks, and to choose regulatory risk management measures;
  - Economic operatorsand consumers to make informed choices about how to avoid toxic substances in articles;
  - Waste treatment operators to separate and treat end-of-life articles in a manner that prevents contamination of recycled materials.

Gaps and inconsistencies in current policy

- The methodology of current regulatory risk assessment under REACH and other chemicals legislation does not ensure that risks relevant for articles can be identified, because:
  - Information on relevant substance properties is partly not available or considered on a routine basis (e.g. PBT/vPvB if registered in low volumes, endocrine disruption or neurotoxicity as not sufficiently covered by information requirements under REACH, nanomaterials as testing regimes is not adapted to them);
  - Long-term and low-dose effects, cumulative and combined exposures as well as combination effects are not sufficiently well addressed;
  - The exposure assessment is generic and requires information on substance uses and releases from articles, which are frequently not available.
- Legislation preventing the presence of toxic substances in articles (where possible) is scattered, neither systematic nor consistent and applies only to very few substances, articles and uses, often with many exemptions.
- Legal information requirements on toxic substances in articles are vague and cover only a few substances (of very high concern) under certain conditions, hence rarely resulting in useful information. If information on toxic substances does exist it is frequently insufficient to support:
  - Article producers in gaining full knowledge about the presence of toxic substances in the complex objects they assemble and place on the market. Consequently, they can hardly ensure material compliance, improve product design regarding the reduction of toxic substances or provide information to their customers;
  - Waste treatment operators in separating waste streams or components thereof that include toxic substances from other waste streams that are not contaminated.
- Legislation and current practices in the waste sector were generally designed to safely treat and dispose wastes containing toxic substances rather than decontaminate waste streams in a manner intended to generate recycled materials free from toxic substances.

5.2.1 Challenges for non-toxic articles

The substance related composition of articles is complex

Most articles consist of a number of different materials which themselves include a large number of chemicals that constitute their matrices, such as polymers or metals. Chemicals may also be included as additives to provide a particular functionality to a material, such as flame retardance or general stability. They may also be present as contaminations from the production process. The possible combinations of chemicals in articles and complex objects are infinite.

It is not possible to easily deduce the substance contents of articles from their material composition or their functionalities, because frequently, the latter could be achieved using different combinations of chemicals or applying different production methods.

The possibilities to deduce a level of risk from "substance in articles" are even more limited, because even if information on the content were available, the release potential of a substance from the product matrix and the article itself would have to be estimated, including with a view to the particular use situation and the user behaviour.

Finally, situations mayoccur where the chemicals present in an article at the waste stage are not the

same as those added to the article during production. Reasons for changes could be for example chemical reactions with other substances (intended or unintended), weathering or aging (contact with oxygen or sunlight) or modifications during the use-phase (e.g. renovation or repainting of buildings).

The volume of (toxic) substances included in articles is large and increasing

The production volume of chemicals, of which a large share has toxic properties (Eurostat, 2015), and of articles are increasing in the EU and at global level (European Commission, 1992) (European Commission, 2001). However, information on the actual amounts of toxic substances used in articles ismissing due to a lack of respective statistics[19]. Therefore, some examples of information from recent studies limited to a few substances and materials is provided in the following.

Kemi has estimated the amount of hazardous substances placed on the market in specific construction products (flooring, carpets, and panel materials) (KEMI, 2016). They have concluded that, among others, 36,000 t/y of DINP are placed on the Swedish market in flooring and 22,000 tonnes of phenols in wooden panels. In addition, via flooring materials, e.g. styrene (2,6000 t/y) and bisphenol A (2,000 t/y) are placed on the Swedish market.

Kemi has also estimated the supply of phthalates in a number of article categories for the Swedish and the EU markets (KEMI, 2015). In summary, they conclude that the falling EU production volumes of DEHP indicates a use reduction following the introduction of more extensive regulation. They estimate that approximately 120,000 t/y of DEHP are used in the production of articles in the EU and 210,000 t/y are included in articles on the EU market (including imports).

The RIVM Institute for Environmental Studies analysed pentaBDE and octaBDE (POP-BDE) flows in waste plastics from WEEE and ELV wastes as well as recycled plastics in the Netherlands (Leslie, 2013). Their mass flow analysis shows that approx. 7 t/a of POP-BDE reach the waste stage in plastics from WEEE and approximately 0.2 t/a from ELV. The IVM estimated that 22% of the POP-BDE from WEEE end up in recycled plastics whereas 14% from the ELV end up in recycled plastics. The POP-BDE detected in new products, made of recycled plastics originated, in non-EU countries primarily.

The majority of supply chains are complex and dynamic

The supply chains of articles are complex and frequently include economic actors from all parts of the world. Furthermore, supply chains are not static over time, but change dynamically depending on prices and product availability. The management of, and communication about, the content of toxic substances in articles along those supply chains are hindered by a lack of harmonised communication tools and language barriers. Additionally, communication is addressed differently (or not at all) by legal requirements across the globe.

Different requirements for EU- and non-EU articles

A large share of articles on the EU-market are imported from non-EU countries. Imported articles may include substances that require authorisation in the EU and may no longer be allowed for use, if no authorisations were granted. This creates an uneven playing field for EU enterprises and generates a need for differentiation between imported and EU-produced articles by economic actors and enforcement authorities in compliance checking and material compliance management.

Imported articles may also include substances unknown to EU regulators if these are not registered under REACH or notified to the CLP inventory.

Risks from hazardous substances in articles do occur

There is evidence from several sources that exposure to hazardous substances in articles does occur and may cause risks to human health or the environment. In current and past restriction processes

[19] Production and trade statistics mostly relate to trade values rather than volumes; furthermore, information on the composition of articles, which could be linked to volume information, is not available.

under REACH, acute and long-term risks from the use of toxic substances in articles were, and have been, identified, e.g. for PBT/vPvBs or sensitisers (Annex XVII, e.g. nickel in jewellery, current proposal on PFOA, and precursors in several article categories). According to the RAPEX database, approximately 25% of all product warnings made by the enforcement authorities are due to the content of toxic substances. Most, but not all of these relate to articles (European Commission, 2016).
Articles contribute to a continuous, long-term, and low-level exposure to a mixture of different hazardous chemicals, which cause or enhance the adverse effects on human health and the environment. For example, several studies have analysed the content of toxic substances in household dust and identified, among others, considerable amounts of phthalates and brominated flame retardants, which give rise to various concerns (Mitro, 2016). These substances are likely to have emitted from articles, because they are not allowed for use in consumer mixtures and are not likely to have accumulated from other sources. The occurrence of a mixtures of various substances in the environment can be deduced from monitoring data and is demonstrated in studies on mixture toxicity in the environment.

Chemical analyses are costly
Due to the large number, and sheer variety, of chemicals that could be present in various articles, identifying the content of toxic substances via chemical testing is cumbersome and costly. Therefore, companies and enforcement authorities can use chemical analyses only to verify a suspicion, but not as a standard routine to assure the quality of the input material.

Supply chain communication is hampered by confidentiality
The (innovative) use of substances in materials and articles may form part of the specific know-how of article producers and their suppliers. Therefore, they communicate only the minimum amount of information needed to comply with restrictions and communication requirements to their customers. This information may not be sufficient for chemicals users and article producers to assess workers' risks, to check notification obligations under Art. 7(2), and to identify options to improve their product design and assess substitution options.

Overview data on the content of toxic substances in articles is missing
General information on the use (amounts) of toxic substances in articles is missing, due to the limited scope of legal provisions regarding information about hazardous substances included in various articles. Therefore, the overall assessment of the scale of risks from toxic substances is not possible nor is targeted decision making on potential risk management measures.

5.2.2 Challenges for waste management and non-toxic materials

Articles with varying composition enter the waste stage
Articles entering the waste stage are diverse, with regards to their composition and content of toxic substances. This is obvious for different article types, but the content of toxic substances may differ significantly even for the same types of articles made from similar base materials (polymers, metals, etc.). The sheer variety of articles causes challenges for sorting and separate treatment.

There are two mains reasons for the variations in the composition of articles:

- Article producers implement different design and production principles for their articles, thereby choosing different materials and technical solutions for their products. These choices also include where materials are sourced from, which may have implications on the product composition;
- Dynamic regulation and increasing numbers of restrictions, as well as pressure to substitute, as exerted e.g. by the REACH candidate list, push article producers to change their product design and to substitute restricted substances. The overall substance-related composition may change to a greater extent, given that this is normally not a 1:1 replacement.

Few waste-driven limitations exist for toxic substances atthe waste stage

A systematic regime preventing (certain) toxic substances, which may cause technical or (eco)toxic problems, from entering waste streams does not exist. From the waste treatment perspective, only very few requirements have been defined for specific (listed) substances in specific articles; e.g. some heavy metals, flame retardants, and phthalates are regulated in vehicles and electrical and electronic equipment as well as in batteries. Overall, the legislation of articles also does not provide for such systematic restrictions, as has been examined above.

Toxic substances in articles may contaminate material streams

Post-consumer wastes are heterogeneous, unlike production wastes, despite increasing trends for separation that exist already in households and in public waste collection schemes. Waste treatment that aims to close material cycles either involves the recovery and reuse of entire articles (complex articles) or their components[20] or, much more often, the separation of materials, their homogenisation, and the potential further processing thereof to obtain secondary raw materials. In the recycling processes, articles (and the materials they consist of) that contain toxic substances contaminate the respective waste streams and are diluted in materials that do not contain toxic substances. These substances will continue circulating for as long as toxic substances in articles are included in waste streams that enter recycling processes. According to modelling studies, it may take centuries to decontaminate a recycled waste stream, even if preventive measures are implemented, such as restrictions that would end the input of those substances to articles placed on the market after the restriction enters into force (Pivnenko, 2016).

Information on toxic substances in end-of-life articles and material streams is missing

There are only a few legal and practical mechanisms in place to create an information flow about the substance content of end-of-life products from article producers to the waste sector. The respective requirements are specified as part of the "extended producer responsibility" only in the case of electrical and electronic devices and vehicles. The knowledge gap on the toxic substances content in end-of-life articles is carried over to the recycled materials, in the case of packaging wastes for example.

Information on certain hazardous substances, such as PBT/vPvB and POPs, are systematically not communicated in the waste chain

Within the waste sector, actors communicate about the hazardousness of wastes via the waste codes, which are defined in the EU List of Waste. The List of Waste categorises wastes according to their origin. A waste's hazardousness is identified via the HP criteria, setting out different hazard properties of wastes. The substance categories PBT/vPvB and POPs, which may be particularly relevant for risks from articles and article wastes as well as "persistence in material cycles", are not specifically considered.

Toxic substances in recycled materials may contaminate articles

The quality of virgin and secondary materials used for the production of articles should be the same, but related legal requirements do not exist. Therefore, it appears that the content of toxic substances in recycled materials is only controlled systematically if it is used in products with critical exposures, e.g. for toys or food contact materials. Consequently, toxic substances in recycled materials are currently included in newly produced articles and may cause risks during production and article service life. When these articles become waste, the toxic substances continue circulating in the material streams. This leads to a continuous dilution of toxic substances in articles and materials over time. A widespread presence of SVHC's and substances corresponding with the criteria for identification of SVHC's but not yet listed on the REACH candidate list or substances of equivalent concern is problematic because it disables efficient risk management, while potentially being acceptable for substances with a low toxicity.

[20] The reuse of articles may be prohibited if toxic substances in the reused article have been restricted. It is, however, possible that there are exemptions from the restriction for reused articles. The issue of reuse is not further discussed in this sub-study report.

Waste management practices are not designed to systematically decontaminate waste streams
The EU regulatory framework for waste management was not developed with a view to implementing a circular economy and targeted decontaminating waste streams. Although the Waste Framework Directive generally requires the "depollution of waste streams", this is concretised only for end-of-life vehicles, electrical and electronic wastes and batteries by additional legislation (sometimes referred to as the "waste stream directives"). What depollution means and how it should be implemented remains vague and unclear for all other waste streams.
The precondition for generating non-toxic recycling material streams is the implementation of the following:

- article waste streams, and the components therein, that contain toxic substances can be distinguished from those that do not contain toxic substances;
- article waste streams, and the components therein, can be sorted according to their recycling potential/substance content and directed towards specific treatment options;
- waste managers have criteria and information to select the optimal treatment option for a particular article waste stream with a view to maximising recycling and minimising the presence of toxic substances;
- contaminated waste materials can be decontaminated from toxic substances during a recycling process;
- the waste treatment company has sufficient information to inform their customers about the secondary raw materials' quality and the content of toxic substances.

The existing legislation and infrastructure is not sufficiently well developed to support these tasks to the extent necessary. Separate collection and treatment, as well as decontamination technologies which can be operated at reasonable costs, currently do not exist.

Costs for producing recycled materials that do not contain any toxic substances, where contaminated wastes are thoroughly sorted and only the purest fractions are recycled, tend to be higher than the benefits that can be achieved on the market. It is more likely that the production costs of lower quality recycled materials can be commercially justified. In addition, due to the high level of uncertainty about the content of toxic substances in secondary raw materials, many article producers hesitate using recycled materials.

5.2.3 The Current Policy and Legislative Framework

The issue of non-toxic articles and material cycles relates to, and is influenced by, three regulatory areas; namely, chemicals legislation, articles related legislation, and waste legislation. All of these legal areas consist of overarching legislation, i.e. REACH and the CLP regulation (chemicals), the General Product Safety Directive (articles), and the Waste Framework Directive (waste) and specific legislation such as the Biocides Regulation (chemicals), the Toy Safety Directive or the RoHS Directive (articles) or the End-of-Life Vehicles Directive (waste).

Each legislative area contributes to a framework that, among others, aims at the production of non-toxic articles and for the generation of material cycles as free from toxic substances as is possible. The following description depicts the general approaches of legislation, but does not include the individual requirements. The main gaps and deficits, i.e. where legislation does not (sufficiently) fulfil the needed function to ensure production of non-toxic articles and maintaining waste streams clean, are outlined in the following section.

Chemicals legislation ensures that:

- the **hazardous** properties of substances potentially contained in articles **are identified and that this information is available** to all market actors (registration/active substances approval, substance evaluation, SVHC identification and candidate listing, notification of classification, and

labelling);

- **unsafe uses** of toxic substances in articles **are identified** via generic risk assessments **and prevented** via the limitations of their use[21] (chemical safety assessment and discouraged uses, biocide product approval for use in articles, communication of binding conditions of use through safety data sheet or article labels, restrictions and authorization procedure);
- substances and mixtures recovered from waste are the same as the substances registered as part of the virgin materials or alternatively are the recovered materials registered and safety assessed according to the same requirements as a new mixture;
- **information** about the content of **SVHC and biocides in articles is available** to all actors handling, using, and regulating articles (REACH Article 33 and Article 7 as well as labelling of treated articles under biocides legislation). The information should be sufficient to enable:
  - economic actors to comply with legal requirements, protect their workers from potential risks during processing, and to consider chemicals related risks in their product design processes;
  - consumers to make informed choices and to potentially avoid articles containing SVHC
  - regulators to assess and identify risks from SVHC in articles at an aggregated level and to implement risk management measures, if necessary.

Articles related legislation ensures that:

- **all articles** placed **on the market are safe for human health** during normal and in reasonably foreseeable use (General Product Safety Directive);
- **the content of substances** that are **of particular concern** in articles with sensitive exposure potentials or with regards to the treatment of waste **are restricted** (specific restrictions, e.g. Toy Safety Directive, RoHS or positive lists (food contact materials));
- information on the **content of certain substances** (e.g. sensitisers in toys and heavy metals in batteries) and on **how to dispose an article** properly to ensure that it enters the correct waste treatment stream (e.g. electronic devices) **is communicated** to the consumers.

This also ensures a level playing field, with regards to the content of the restricted toxic substances, given that articles legislation applies to imported and EU-produced articles alike.

Waste legislation ensures that:

- incentives are set to **prevent hazardous wastes** (waste treatment hierarchy, extended producer responsibility, ELV, and WEEE) and to increase recycling of materials (collection and recycling targets);
- **infrastructure and management routines exist to** collect, sort, and **treat large volumes of wastes** in an efficient way, including recycled materials as much as technically and economically feasible (Waste Framework Directive);
- **hazardous wastes** are identified and related information is used to decide on the treatment technology and that stricter management and documentation requirements apply (waste classification and related requirements) for hazardous wastes;
- **toxic substances** are separated from the waste streams and are either finally disposed of by incineration or landfilling or are extracted from a material stream through specific decontamination and treatment technologies, where such are available and feasible.

Use restrictions, to prevent toxic substances from entering articles, could originate from chemicals, articles, and waste legislation. Chemicals legislation generally takes a top-down perspective that integrates workers, consumer, and environmental concerns in generic risk assessment and management approaches that cover the entire lifecycle. In contrast, articles legislation focuses on

[21] There may be options to limit exposure by article-integrated risk management measures, but it is unlikely that a registrant will identify this as a risk management measure and will communicate it along the supply chain.

consumer health issues and the use phase of articles. Existing restrictions of sertain toxic substances in waste stream directives such as the ELV and WEEE Directives, consider problems encountered during waste treatment and recycling that may relate to environmental and health risks or problems in waste material management and contamination.

Specific requirements to decontaminate waste streams exist only in the ELV and the WEEE Directives. In addition, the end-of-waste criteria indirectly imply these provisions because the quality of the input and output materials are defined for recycled materials that become a product. However, these criteria exist only for very few materials. Chemicals legislation may require decontamination during recycling, given that substance bans and use restrictions (e.g. REACH authorisation, POPs regulation) apply to secondary materials as well.

5.2.4 Gaps and deficits in policies and legislation

The assessment of risks from toxic substances in articles, respective risk management measures, as well as communication on the content of toxic substances in articles are partly addressed by different pieces of the EU legal framework. However, a number of significant gaps and weaknesses have been identified with a view to producing non-toxic articles and maintaining non-toxic material cycles.

Identification of risks from toxic substances in articles
Several pieces of legislation, REACH in particular, include safety/risk assessment procedures, which may result in uses advised against/restrictions or (binding) recommendations for risk management measures. These assessment approaches do not sufficiently cover some important aspects on hazards and exposures, for instance:

- Some hazardous properties are not identified systematically or are not sufficiently well characterized for safety assessment, such as endocrine disruption, neurotoxicants or very high persistence;
- Nanomaterials are partly not identified specifically, characterized with regards to their (eco)toxic properties and potentially existing specific effects (including e.g. carrier effects and ability to cross biological membranes);
- Accumulated exposures to one chemical from multiple sources (including articles) have not been sufficiently considered;
- Rules to include combined effects from exposures to several different chemicals (including from articles) remain missing;
- Long-term and low-dose exposures are not particularly addressed.

The risk assessment practice defines an unacceptable risk as an exposure level exceeding the concentration above which adverse effects are expected (i.e. a risk characterization ratio (RCR) > 1). For articles, demonstration of an RCR > 1 is hardly possible, where the factors listed above are not taken into account in the assessment. As this is currently not sufficiently implemented, specific restrictions of toxic substances in individual article types are not very frequent.

Use restrictions and information on substances in articles

- Current chemicals and articles-related legislation, including use restrictions, are generally not precautionary but require the demonstration of a specific risk before it is possible to take action. This may lead to unnecessary damage, due to the lag time between risk assessment and measures triggered by regulatory risk management, if legal action is taken at all;
- Restrictions have been developed on case-by-case basis. They, therefore, concern only a few

substances in a few specific articles and are partly inconsistent across legislation[22].

- Aggregated information about the content of toxic substances in articles is largely missing. Therefore, neither the actual scale of exposures or risks from toxic substances in articles can be derived, nor can targeted risk management be implemented.
- The General Product Safety Directive does not consider environmental safety and human exposure via the environment, while generally applied only in simple and obvious cases of non-compliance and direct acute risks.
- The REACH authorisation scheme does not cover imported articles. This creates an uneven playing field for EU article producers and, given that these substances are SVHC, may cause risks for human health and the environment as well as prolong the lifetime of these substances in material cycles.
- There are only a few obligations that require toxic substances in articles to be communicated, in addition to REACH Article 33. This lack of specific information requirements on toxic substances in articles (except on SVHC) is a problem, because:
  - Actors in the article supply chain lack information for product design and potential phase out of toxic substances, other than SVHC; they lack information about SVHC below 0.1%
  - Article producers, who want to conduct a thorough safety assessment for their articles, lack data on the chemical composition and potential release of hazardous substances
  - Consumers wanting to avoid toxic substances in their products lack information for their purchasing decisions and have no rights to request it
  - The lack of information reduces the potential for market forces to enhance phase-out and substitution, given that this cannot be a purchasing criterion.

Prevention measures and decontamination of material streams

Similarly to the regulation of articles, waste legislation does not systematically define requirements on the content of toxic substances in (end-of-life) articles. Collection and recycling targets focus on increasing the amounts of recycled materials, not on their quality regarding the absence of toxic substances. No quality standards for recycled materials (as well as virgin materials) exist, except for the end-of-waste criteria, which exist only for a few material streams. Hence, legislation does not incentivise activities to decontaminate waste/recycled materials. The existing waste treatment infrastructure (collection, decontamination, and treatment, including recycling) appear to technically and economically limit the potential for high quality recycling.

Information about the content of toxic substances in end-of-life articles is the essential basis for the implementation of a material management system in the waste sector that includes processes that separate toxic substances from material cycles and/or destroy them. Key issues in this regard that need to be addressed are:

- Structured information about the content of toxic substances in article wastes is not generally available to the waste sector. Legal communication requirements are missing for the majority of article wastes;
- The waste sectors' efforts, necessary to accessing information on toxic substances in end-of-life articles, are generally too high in relation to the comparatively small profit margins. Time-consuming research, e.g. in safety data sheets or databases or in the separation of individual end-of-life products rarely pay-off;
- Waste management operations are often mass volume operations, i.e. the entirety of large containers with various articles having different compositions is treated, rather than individual end-of-life products. The identification of articles that contain toxic substances in theses waste

[22] An overarching, consistent, and horizontal approach could consist of restricting substances with certain hazard categories in article groups with particular exposure patterns. This would also ensure that future substance uses are covered and that resources for the development of restriction proposals are preserved. It would also enable regulatory action for substances to be predicted in a better manner.

streams is time- and resource-intensive.

- There are no legal consequences triggered by information about the content of toxic substances in wastes. For example, if the waste treatment operator knows of the presence of beryllium in electrical products' contact points, they would not separate them from the other waste materials, because they are not legally required to do so, and it is not considered economically profitable.

5.2.5 Conclusions

The goals of a non-toxic environment, and of the circular economy, are in conflict as long as toxic substances are used for the creation of technical materials and contained in articles and recycling material streams. The goals converge if toxic substances are either phased out from articles or if a gapless tracing of toxic substances is implemented, followed by waste separation based on the toxic substances content and a respective recycling or reuse (if possible and desirable) of the material or articles.

At present, the opinions on how to manage the problem of toxic substances in articles and wastes differ. Some actors prefer an increase in recycling volumes and deprioritise the need to decontaminate recycling material streams. Other actors prefer implementing a non-toxic environment and would at least temporarily reduce recycling rates in favour of finally disposing of toxic substances, thereby removing them from material cycles. A political decision on the hierarchy of goals and an analysis of the best combination of measures to achieve them is both urgent and necessary.

Two approaches are necessary with regards to non-toxic articles and material cycles. First, strategies and implementation instruments that prevent toxic substances from entering articles and materials cycles will avoid risks to human health and to the environment throughout the substances' lifecycles. Second, strategies and implementation instruments that motivate and enable the waste treatment sector to decontaminate waste streams from toxic substances are needed, as long as toxic substances continue to enter the waste stage from (long-lived and imported) articles. These strategies will also help with the extraction of those substances from waste streams in the future which, at present, are not yet known to cause problems.

A systematic and fundamental approach to restrict substances is useful in order to manage the complexity of articles, article supply chains, functionalised technical materials, and substance combinations used to produce articles. The restriction approach should complement the top-down risk management approach under REACH and consider all of the relevant hazards, should integrate long-term, low-level multiple exposures as well as related combination effects. Furthermore, it should integrate the needs from waste treatment practices. In addition, modern article design principles should be amended to include the goals of a non-toxic environment and of the circular economy. Requirements and mechanisms to communicate information on toxic substances in functionalised technical materials and articles along the supply chain, which are sufficient for informed decision making on article design and substitution, would increase incentives for the (voluntary) phase-out of toxic substances.

Legal requirements regarding the decontamination of material streams appear to be indispensable for the waste sector, given that the related economic incentives are low. Furthermore, instruments like extended producer responsibility could be amended to also cover the waste stage until the final secondary materials. This could enable the triggering of preventive approaches in article design that consider the needs of the waste sector. Requirements and tools that ensure that the necessary information to separate contaminated from non-contaminated wastes, as a fundamental step to keeping material streams clean, are urgently needed.

The prioritisation of substances, articles, and material streams, with regards to preventive measures, as well as decontamination requires more elaborated risk assessment approaches than are currently in place. Article-specific emission characteristics and exposure situations (long-term, low-level, multiple

exposures, and combined effects) need to be assessed and taken into account, as well as a thorough approach for the evaluation of risks from the waste stage, including for recycled materials is needed.

To enable the closure of material cycles, the legal interfaces between chemicals and waste legislation should be better interlinked, so that the status of a material is clear (waste or product). In addition, a situation in which the (information) basis for compliance under either legislation is not structurally available or is insufficient, it should be avoided.

Apart from improving the legal framework in relation to the content of, and information about, toxic substances in articles, complementary activities are necessary to ensure that all of the actors understand, implement, and benefit from the use of less toxic substances in articles and materials. This includes economic incentives, information campaigns, and training as well as funding and supporting research on technological developments and substitution options.

5.3 PERSISTENCE

This section presents key findings from the sub-study d final report on *very persistent chemicals*, prepared by Milieu. The full sub-study is annexed to this Final Report.

The problem

The use and dispersal in the environment of very persistent (vP) chemicals represents a (potential) threat to health, the environment and natural resources. Due to technical/functionality reasons, such chemicals are widely used in a broad range of applications. Chemicals with a high degree of persistence will remain in the environment for a long time, and lead to exposure of humans and the environment, including a.o. vulnerable population groups, wildlife and environmental media. This may involve previously overlooked or unpredictable negative effects even for chemicals where laboratory tests did not indicate any considerable toxicity, e.g. if the effects are chronic or appear at low concentration levels.

Key findings on very persistent substances

The problem

- A range of very persistent substances, including several groups of halogenated organic compounds, are widely used in different applications, often due to the functionality of the substance.
- Very persistent (vP) substances may accumulate in the environment and man-made materials to levels harmful to human health and natural resources.
- Certain toxic effects (e.g. chronic or occurring at low concentrations) may take many years to identify, by which time rising concentrations/levels could have already occurred and prove irreversible.
- Highly fluorinated chemicals such as PFAS are extremely persistent and will remain in the environment for hundreds of years. They are highly mobile and have been found in groundwater used for drinking water across Europe as well as in remote areas such as the polar region and the deep sea.
- The thousands of new short-chain PFAS marketed by producers as "safer" than the long-chain PFOS and PFOA are also extremely persistent. Evidence of their toxicity and of their presence in the environment is mounting. Known technologies are not able to remove short-chain PFAS from drinking water.
- An estimated 3.5 million sites around Europe are contaminated by hazardous including vP substances. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to removal of natural resources such as drinking water, land, soils and fish stocks from productive use.

Gaps and inconsistencies in current policy

- Current EU legislation does not provide an adequate way to systematically control substances on the basis of their persistent properties.
- Major gaps in knowledge concerning vP substances are due to lack of a common framework for screening substances for persistence and inadequate requirements for persistence testing and for

further testing of health and environment properties if a substance is found to be persistent.

- Evaluation of risks from exposure to vP chemicals during the use phase of products is insufficient, and almost entirely missing in the case of imported products, with a few exceptions covering a limited number of substances in certain product groups such as toys. Product regulations also seldom take account of a substance's fate at end of product life, which risks build-ups of vP substances in recycled material waste streams. Strict controls over releases of any vP substances during manufacturing, product use or end of product life may be needed to prevent build-ups in the technosphere as well as the environment.
- Criteria for maximum allowable levels of vP substances in food, drinking waterand groundwater are needed to ensure that accumulations of vP pollutants in water and soil resources are given sufficient attention.

Concentrations of a vP chemical will tend to build up and eventually reach levels where harmful effects to health and natural resources may occur. Damage from exposure to vP chemicals is poorly reversible or even irreversible and may entail considerable cost to society. With the current high levels of production and widespread use of vP substances, cases of such damages are highly likely to appear or may even be unavoidable. Moreover, some health effects may not become evident until long after exposure.

Some scientists argue that persistence is in fact the most important single factor affecting chemical exposure and risk from the environment, because build-ups of a vP chemical could lead to the same type of continuous exposure as occurs with bioaccumulation (Stephenson, 1977) (Cousins G. B., 2016). Because of uncertainty about chemical properties, a situation could arise where accumulations have already occurred by the time evidence is gathered about a chemical's propensity for harm. As already experienced in the case of persistent ozone-depleting chemicals, the disruptive effects may not be discovered until they occur on a global scale and are affecting a vital earth system process.

Exposure to the well-studied persistent organic pollutants (POPs) has been linked to a number of serious health effects including certain cancers, birth defects, dysfunctional immune and reproductive systems, greater susceptibility to disease and damages to the central and peripheral nervous system. Further, presence of POPs in the environment is associated with severe effects such as impaired reproduction in birds and mammals.

Once a vP substance is released into the environment, its breakdown or transformation products may raise new concerns. In the case of PCBs, for example, it took considerable time for scientists to discover that the process of bioaccumulation resulted in concentrations of the more toxic congeners than were found in the commercial products. DDT is another example in that the compound itself is considered to have low toxicity for humans, but when released into the environment its transformation products include the more toxic DDE (U.S. Department of Health and Human Services, 2002).

The problems related to vP chemicals are particularly challenging in view of a **circular economy** that strives to close the loops by e.g. increasing reuse and recycling of material. If the material is recycled and used again, vP substances may accumulate in recycled materials, leading to increasing concentrations of contaminants in recycled materials, along with increased long term dispersal and presence of vP chemicals in the technosphere as well as the natural environment.

Testing and identification of persistence in substances. A common misconception is that environmental persistence is an inherent property of the substance that can be readily measured. However, assessing the persistence of chemical substances in the environment is not straightforward. It entails an assortment of supporting information and the need to address gaps and uncertainties (Boethling, 2009).

Moreover, current requirements for testing and test methods to screen and test chemicals for persistence are insufficient (Scheringer, 2012). According to UNEP, only 220 chemicals out of a set of

95,000 industrial chemicals have been evaluated fully in relation to their biodegradation half-lives and only 1,000 have data on bio-concentration (UNEP & WHO, 2013).

A major challenge is that testing for multimedia half-lives is time consuming and costly. While chemicals might be screened for persistence potential based on chemical structures and characteristics, no common framework for doing this has been adopted or accepted. As a result, knowledge and/or information available about the persistence of chemicals produced and used as well as about actual quantities and uses of many vP substances is poor.

To be included in the Stockholm Convention on persistent organic pollutants (POPs), a substance must meet the POPs screening criteria for persistence, bioaccumulation, long-range transport potential and toxicity. At this point only 26 substances and groups of substances are covered under the POPs Convention, with another three under consideration for future inclusion. Yet as many as 1,200 of the 90,000+ substances on the market today could be potential POPs (Scheringer, 2012). The number of substances meeting the POPs criteria for persistence alone is surely much higher.

In the regulatory context, persistence is defined by single-media half-life criteria. REACH provides, for example, that a chemical is persistent (P) if its half-life in soil exceeds 120 days or its half-life in water is more than 60 days. It is considered very persistent (vP) when the half-life in water is higher than 60 days, or when the half-life in soil or in water sediment is higher than 180 days.

The highly-fluorinated chemicals – especially the per- and polyfluorinated alkyl substances known collectively as PFASs – are very stable and durable, which makes them useful for a broad range of applications. However, scientific tests to determine their degradation half-lives have found almost no degradation during the testing period, meaning they will persist in the environment for hundreds or even thousands of years (Russell, 2008) (Washington, 2009).

In the 1950s, when highly fluorinated compounds were first commercialised, the focus was on long-chain PFASs -- the so-called C-8 substances used in the manufacture of Teflon-coated cookware, water- and stain-resistant textiles, and fire-fighting foams. In the 1980s and 1990s, evidence emerged of the toxicity and bioaccumulability of the long-chain PFAS, such as PFOS and PFOA. Human epidemiological studies have found positive associations between exposure to PFASs and hepatocellular damage affecting liver function in adults, obesogenic effects in females, liver and kidney cancer, and, low birthweight and reduced length of gestation. Exposures to low levels of highly fluorinated chemicals have also been linked to reduced immune response to routine childhood immunizations (Grandjean, P., et al., 2015).

Regulatory pressure has led to phase-out of the manufacture and use of long-chain PFAS in Europe and the USA. As a result, many manufacturers have replaced the C-8s with short-chain homologues -- the C-6s and C-4s. PFAS producers argue that the short-chain PFAS are "safer" in that they are not as bioaccumulative as the long-chain PFAS. However, they are just as persistent, and evidence is emerging that the short-chain alternatives are also problematic in terms of risks to health (Lerner, 2016).

Today, more than 3,000 different types of PFAS are estimated to be on the market. They are found in cosmetics, food contact materials, inks, medical devices, mobile phones, pharmaceuticals and textiles, and they are used in pesticide formulations, oil production and mining. They are capable of long-range transport and are found even in remote locations. A major source has been the use or spillage of PFAS-containing aqueous film firefighting foam (AFFF); in the EU, PFAS-contaminated waters have so far been documented in the Netherlands, UK, Germany, and Sweden. However, the problem is likely to affect most Member States. Discharges from industrial production processes, wastewater treatment and landfill leachate are also important sources.

Other groupings of highly persistent substances. **Highly chlorinated substances** form another

grouping of chemical compounds that tend to be very persistent and therefore problematic. Many of them are known to be toxic for health and environment. For example, the manufacture and use of polychlorinated biphenyls (PCBs) was banned by the EU and most other industrialised countries some 30 years ago, because of concerns about their extreme environmental persistence, ability to bioaccumulate and their association with adverse human health and environmental effects. While concentrations in air, soil, sediment and biota declined rapidly during the first decade of the ban, since then they have remained stubbornly at the same levels and are now ubiquitous in food from terrestrial and aquatic sources. Types of highly chlorinated substances also of concern include chlorinated paraffins, and unintentionally formed POPs such as dioxins and furans. Other groups of highly persistent substances discussed in the study include **highly brominated substances**, **siloxanes** (D4 & D5), and **organometallics**, e.g., organotin compounds, methyl mercury and tetraethyl lead.

Contamination from vP substances has already had a significant impact on Europe's natural resource base. The use of hazardous substances in industrial production processes over the years has led to some 3.5 million potentially contaminated sites across Europe, with 0.5 million of these considered highly contaminated and needing remediation. Though it is not possible to estimate how many of these sites are contaminated by vP substances, overviews showing contamination of media by specific vPs, including PCDD/Fs (Weber, 2008), HCHs (Vijgen, 2006) and PFASs (Rumsby, 2009) (Cousins I. V., 2016) do indicate a widespread problem.

In addition to local sources, contamination from vP substances has also been documented in soils away from point sources, e.g. highly fluorinated chemicals (HFCs) have been found at high altitudes due to tendency for long-range transport. Recently, contamination of waters by highly fluorinated chemicals (HFCs) has drawn attention in the USA, where drinking water supplies for 6 million residents were found to exceed national lifetime health advisory limits (70 ng/L) for PFOS and PFOA. While activated charcoal can remove the long-chain HFCs from drinking water, currently available technologies cannot remove the short-chain HFCs. The same type of activities that contaminated groundwater in the USA have also been carried out in the EU, e.g., releases from industrial sites and use of aqueous film firefighting foams at major airports and military bases. But because no EU-wide monitoring for HFCs in water has occurred, it is not known how many similarly contaminated drinking water supplies are to be found around the EU.

The presence of vPs in recycled products will be a particular challenge for the EU's action plan on a Circular Economy aimed at maximizing the use of, and minimizing the waste of, material resources in the economy. These substances by their nature can persist and therefore accumulate in recycling streams for long periods, including through now-restricted products made before regulations were applied. The potential for contamination of the 'technosphere' is a serious concern because of the long-term implications for human and ecosystem health.

The Current Policy and Legislative Framework

A number of EU acts consider persistence as a property of concern. However, in almost all cases, persistence is regulated only if bioaccumulability is also present. For example, the **REACH Regulation** sets criteria for identifying if a substance is PBT or vPvB. A PBT or vPvB substance may then be identified as a Substance of Very High Concern (SVHC) under Article 57 and added to the Candidate List for eventual inclusion in Annex XIV as subject to authorisation. Alternately, the substance may be restricted under Annex XVII.

In theory, REACH Article 57(f) might be invoked if evidence can be presented that a vP substance gives rise to an equivalent level of concern as a substance meeting the criteria for PBT/vPvB. In addition, REACH Annex I mentions the possibility of assessing particular effects such as ozone depletion, strong odour or tainting, which could in theory also include the particular effect of persistence. However, to date, neither of these provisions has been applied to a substance solely on the basis of persistence.

In addition to being persistent, the substances controlled under the 1996 **PCBs Directive**, the 2004 **POPs Regulation** implementing the Stockholm Convention, and the 2008 **Mercury Regulation** are also bioaccumulative and toxic. Similarly, the cut-off criteria for active substances set forth in the 2009 **Plant Protection Products Regulation** (PPPR) and the 2012 **Biocidal Products Regulation** (BPR) also require findings of BT and vB in addition to P or vP.

The **Detergents Regulation** is an exception in that it requires surfactants used in detergents to meet biodegradability standards.

The 2011 (recast) **RoHS Directive** is one of the few pieces of legislation dedicated to controlling the use of hazardous substances in articles in order to reduce downstream impacts of the substance at the end of the product's life. By banning the use of the hazardous substance, the RoHS Directive prevents it from entering the material waste stream, i.e., the technosphere. The Directive targets four metals and two toxic and persistent flame retardants. However, the other persistent flame retardants now used extensively in plastic casings of electronic goods are not covered. These other substances are an instance of "regrettable substitution") in that plastics with added flame retardants may not be recyclable and in any case the flame retardants should be kept out of recycled material flows. The substance-specific provisions in the other "waste stream directives", e.g. end-of-life vehicles, batteries and packaging materials, play similar (albeit incomplete) roles in keeping problematic substances out of the technosphere.

The 2010 **Industrial Emissions Directive** (IED) is aimed at achieving best overall reduction of polluting emissions. This does not take into account the intrinsic quality of persistence which may require measures to prevent any releases of vP substances in order to avoid build-ups in the environment, e.g., the emission limit values (concentration levels) set in integrated permits would not prevent such releases. A vP substance not meeting the additional criteria for BT and vB would not be included in the controls over the industrial facility's emissions.

Systematic environmental monitoring and surveillance of vP substances is also needed in order to track their presence in the environment, including any build-ups, e.g., as part of an early warning system. The so-called WATCH List under the 2000 **Water Framework Directive** is an example of an instrument that could be adapted for such a purpose, though additional analytical methods may be needed to detect the range of vP substances of concern.

An additional gap in the EU regulatory regime is the lack of standards in the **Drinking Water Directive** for PFAS and the other vP substances now showing up in Europe's waters. PFAS have already been found in water resources used for drinking water in Germany, the Netherlands, and Sweden. Without limit values for PFAS in drinking water and EU-wide monitoring for the presence of PFAS in water, the number of other EU residents with drinking water supplies contaminated by PFAS and other chemical substances cannot be known. EU legislation for food contact materials and for contaminants in food stuffs is also in need of revision to include health-based limit values for e.g. PFAS and brominated flame retardants.

Identified gaps and inconsistencies in current policy/legislation

The current EU regulatory framework is insufficient for protecting human health, environment and natural resources from risks of exposure due to accumulations of very persistent substances. Four types of gaps were identified:

1. **Gaps in identifying and regulating vP substances.** Testing of chemicals to determine their half-lives is time consuming and costly, and no common framework for comprehensive screening of substances for persistence has been agreed on EU level. REACH does not require data on persistence for low volume substances. Moreover, the role of vP substances in combination effects and cumulative exposures is not adequately considered.

2. **Gaps in regimes to protect the ecosphere from releases of vPs.** Controls over releases of pollutants during manufacturing or production are usually in the form of emission limit values (concentration levels). In the case of vP pollutants, strict controls over any releases may be needed to prevent substances from building up in the environment. Related to this is the lack of controls over vP substances used in certain products, such as in cosmetics or textiles, which will end up being released into the natural environment via wastewater discharges.
3. **Deficits in controlling vP substances in the technosphere.** In general, product regulations often do not evaluate the risk of a vP during a product's entire life cycle – just the risk associated with the exposure to the chemical during the use phase. Failure to take account of the substance's fate at end of product life risks build-ups of vP substances in waste materials recycled as part of the circular economy and which could form reservoirs for future exposure.
4. **Deficits in protecting human health and in addressing vP build-ups in the ecosphere**. Systematic monitoring is not carried out to spot the presence and/or build-up of vP chemicals in environmental media and biota, including humans. For example, the Groundwater and Drinking Water Directives do not set criteria for maximum allowable levels of vP substances, so build-ups of vP pollutants in water resources are not given sufficient attention. EU food safety legislation also lacks monitoring requirements and limit values for a number of vP substances.

Conclusions

The traditional approach in chemicals legislation has been substance by substance regulation, which is too time-consuming and not adequate to handle the range of chemicals known to be very persistent. The risk is that by the time action covering all of the problematic chemicals is taken, concentration levels in the environment will have reached levels where health or environmental impacts occur, and reversibility of contamination would take a very long time (depending on the nature of the chemicals involved) and be very costly to society, or may no longer be possible.

Very persistent chemicals released into the environment can render resources such as soil and water unusable far into the future as well as damaging ecosystem services. In the context of an increasingly resource-constrained world, preserving the usefulness of these essential resources appears important. Related to this, limiting the presence of persistent chemicals in products is an important consideration of the circular economy package, in order to avoid its goals being undermined by the accumulation of persistent chemicals in material recycling streams.

For these reasons, from the standpoint of public health, environmental protection and economic growth, it appears desirable to take a more precautionary and proactive approach and to prevent and/or minimize releases of vP chemicals in the future.

One possibility could be to make it a principle to avoid the production and use of very persistent chemicals where persistence is not required and where release into the environment is likely to take place, e.g. for use in cosmetics or consumer textiles. If persistence is needed for a specific use, manufacturers and down-stream users could be required to justify this. There may also be a need for some type of very strict authorisation requirement –something that would allow only so-called essential uses where persistence was required, and where manufacture and use was carried out in closed systems. Systems for recovery and destruction of the persistent chemical would also need to be in place, for production wastes and to ensure end-of-product life disposal.

5.4 THE PROTECTION OF VULNERABLE GROUPS

This section presents key findings from the sub-study c final report on *protection of children and vulnerable groups from harmful exposure to chemicals*, prepared by Milieu.

The problem

Certain groups of the population – such as children, pregnant women, the elderly, and certain categories of workers – are particularly vulnerable to the risks stemming from chemical exposure, and, as such, have a higher probability of developing adverse health effects throughout their life. This increased vulnerability depends on a variety of reasons, spanning from specific behaviours, increased sensitivity to chemicals, specific biophysical characteristics, health status, constant exposure to highly hazardous chemicals, lower ability ability to protect themselves from exposure, and social factors (e.g. where a person lives or works or spends the majority of his/her time). In light of their higher vulnerability, these categories of the population need special protection from potential adverse health effects.

Key Findings

The problem

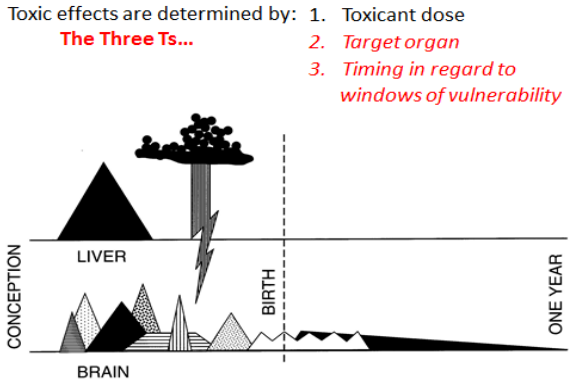
- Children, pregnant women, workers, and the elderly are particularly vulnerable to risks arising from chemical exposure, and have higher probabilities of adverse health symptoms or diseases throughout their lives.
- The developing human brain is particularly vulnerable to chemical exposures, with major windows of developmental vulnerability occurring in utero, during infancy and early childhood. During these sensitive life stages, exposure to EDCs and neurotoxins such as lead, arsenic, mercury, PCBs, pesticides, and solvents can cause lifelong neurological damage.
- Chemicals can enter the body through ingestion, inhalation, skin contact, and injection. Everyday sources of exposure include consumer products, household dust and drinking water. Toddlers, who often play or crawl on floors and carpets, are especially vulnerable because of hand to mouth behaviour.
- Lack of attention to the vulnerabilities of specific populations has led to only sporadic protective measures in the relevant pieces of legislation.

Gaps and inconsistencies

- Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.
- Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered.
- Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.
- Certain EU legislation, e.g. the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which could strengthen the protection of vulnerable groups.
- EU risk assessments focus on single substances and do not protect children and other vulnerable groups from combined or cumulative exposures to toxic chemicals.
- Knowledge is lacking on the toxic effects that certain categories of chemicals (e.g. Non-intentionally added substances [NIASs] and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

Vulnerable groups

The **foetus** is particularly vulnerable to chemical exposure due to developmental mechanisms which increase both exposure and risks. These include: cellular differentiation and specialisation, rapid cell reproduction rates, the sensitive periods of development for different organ systems, the immature liver and kidney enzyme systems to metabolise, conjugate and eliminate toxicants, as well as the undeveloped blood brain barrier which does not shield the developing brain from transport of toxic chemicals. Over 200 synthetic chemicals have been detected in umbilical cord blood, including pesticides, ingredients in consumer products, food packaging, and chemical by-products from burning coal and flame retardants (EWG, 2005).



Children also have increased susceptibility to chemicals in the environment. Firstly, children have greater exposures to toxic chemicals in proportion to their bodyweight. They are constantly growing and they breathe more air, consume more food, and drink more water relative to adults. A 2011 study of British children aged 0-6 years showed that children, on average, consumed 1.6-3 times more food packaged in plastic than adults, implying a proportionally higher exposure to substances leaching from plastic food contact materials for children than adults (Muncke J, 2011). Secondly, children's ability to metabolise toxic chemicals is weaker than adults, making more difficult for them to process and eliminate residual toxic substances. Thirdly, children's early developmental processes are sensitive and vulnerable to chemicals. At certain early stages of postnatal development, exposure to environmental toxicants can lead to irreversible damage. Fourthly, children exposed to chemicals related hazards will have more time than adults to develop chronic diseases during their lifetime. Fifthly, children's behavioural patterns can exposure them to increased levels of toxic substances compared to adults, (e.g. playing closer to the ground may lead them to be exposed to toxic chemicals in household dust). Certain hazardous substances can contribute to neuropsychiatric disorders in children, with disorders of neurobehavioral development affecting 10–15% of all births, and prevalence rates of autism spectrum disorder and ADHD appeared to have spread worldwide (Landrigan PJ, et al., 2012.)

Pregnant women are vulnerable to due to the numerous physiological changes occurring during pregnancy, such as weight gain and increases in blood and plasma volume, both of which can affect concentrations of chemicals and thus lead to a greater absorption of toxins. Pregnant women, and the developing foetus, also potentially suffer major exposure to chemicals contained in personal care products, such as sunscreens, fragrances, shower gels and hairsprays, as well as to some medicine which may lead to adverse health outcomes. The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually. Europe-wide epidemiological evidence indicates that diphenyldichloroethene (DDE)-attributable fibroids and phthalate-attributable endometriosis affects some 56,700 and 145,000 women, respectively. This costs the EU €163 million (for attributable fibroids) and €1.25 billion (for endometriosis) per year (Hunt PA, et al., 2016).

The elderly are also vulnerable due to the ageing process, which imposes both physiological and metabolic limitations. Declines in the structure and function of the nervous system limit their ability to respond to, or compensate for, toxic effects. Furthermore, decreased liver and kidney function increases the likelihood of not being able to metabolise or excreate toxic substances. Concentrations of certain toxic chemicals – lead, palladium, cadmium and mercury - appear to increase with age ((Croes, 2014); (Alimonti, 2011); (Lee, 2011)). Further, elderly also tend to suffer from certain medical conditions where chemicals exposure might aggravate the symptoms. An example of this is cadmium exposure aggravating osteoporosis. In addition, the elderly often spend the majority of their time indoors, so that their main source of exposure to pollutants comes from household products. Inadequate ventilation in elderly care centres further increases the risk of absorption of toxic substances.

Certain categories of **workers** might be more vulnerable to chemical exposure than the general population due to: constant exposure to hazardous chemicals in certain occupations, language barriers which may hamper access to safety and health information, poor working conditions which increase the likelihood to be exposed to toxic chemicals, lack of training on safety standards, lack of access to preventative services, as well as working at client premises with changing or unregulated conditions. Migrant workers, young workers, pregnant workers and those with certain medical conditions are particularly vulnerable. Other workers may also be vulnerable at certain times, e.g. when conducting high risk, non-routine work activity such as maintenance work involving chemicals.

Lower socio-economic groups (e.g., low income, minority andcertain indigenous groups) bear multiple sources of chemical exposure and disease burdens associated with where they live, work, or play which can increase their risk of adverse health outcomes. For instance, some studies have found that low-income, or indigenous populations often live in areas where the concentration of pollution is higher (e.g., high-traffic roadways, industrial sites, hazardous waste sites or in housing with higher exposure to hazardous chemicals) than the average population, which increases their risk of chemicals exposure. It is also worth noting that people with low incomes may not have the same level of education, language competence or access to health care as those in higher socioeconomic groups, which in turn might contribute to higher exposure as well as the adverse outcomes of this.

People with **medical conditions** or with a **disability** may also have particular susceptibilities to chemical exposure. For instance, atopic people are more likely to develop respiratory symptoms as a result of inhaling irritant or sensitising materials. People suffering from cardiovascular diseases are more vulnerable to particles and persons suffering from asthma and other respiratory diseases are more susceptible to several air pollutants. Likewise, decreased liver metabolism or kidney function, as may occur in the elderly, may also be prevalent in younger people with medical conditions that impair their metabolic or excretion capacities.

Routes of exposure

Exposure is defined as the contact of an individual with a chemical substance for specific durations of time. It can be described in terms of intensity, frequency, and duration (WHO, Summary of Principles for Evaluationg Health Risks in Children Assocaited with Exposure to Chemicals, 2011). A chemical can make contact with or enter the body and constitute a risk to a person's health through four major routes: ingestion, inhalation (breathing), skin contact and injection. Exposures also occur through the placenta and breast milk. The route of exposure is important to consider as it often predicts which organ system or part of the body will be affected directly or later in life.

Ingestion can involve swallowing contaminated mucus expelled from the lungs, or eating and drinking contaminated food. Food and drink are frequently contaminated by contact with unwashed hands, gloves or clothing, or by being left exposed in the workplace. Children and the elderly are more susceptible to the ingestion of chemicals products because of their behaviour and differences in some physiological parameters.

Inhalation of contaminated air is one of the most common ways of chemicals entering the body. Chemical vapours, gases and mists, which reach the alveoli in the lungs, pass into the blood stream and are distributed around the body where they may cause a wide range of adverse effects on human health. Inhalation exposure can involve indoor as well as outdoor pollutants.

I**ndoor air pollution** is responsible for 2 million deaths per year globally (WHO, Air Pollution, n.d.) where the major sources are combustion for heating and cooking purposes as well as sources in the outdoor environment. Groups particularly susceptible to indoor air pollution include children, pregnant women, the elderly, and people suffering from respiratory and cardiovascular diseases. Genetic traits, nutritional status and lifestyle factors may also contribute in making certain population groups more

vulnerable. A particular area of concern is **indoor dust**, which can harbour a cocktail of toxic chemicals linked to increased risk of a range of adverse health hazards, including endocrine disruption, cognitive and behavioural impairment, cancer, asthma, and immune dysfunction.

Outdoor air pollution is a significant and increasing consequence of the inefficient combustion of fuels for transport, power generation and other human activities like home heating and cooking. According to the World Health Organisation (WHO), urban air pollution causes significant health problems throughout Europe, reducing the life expectancy of residents of more polluted areas by over one year. The six main outdoor pollutants of concern are: ozone (O3), particulate matter (PM10 and PM2.5), lead, sulphur dioxide (SO2), carbon monoxide (CO) and nitrogen oxide (NO2). The most vulnerable people to the effects of outdoor pollution are children and elderly.

Chemicals can also enter the body through **skin contact**. Organic and caustic (alkaline) chemicals can soften the keratin cells in the skin and pass through this layer to the dermis, where they are able to enter the veins and hence the blood stream. Areas of the body such as the forearms, which may be particularly hairy, are more easily penetrated by chemicals since they can enter the small duct containing the hair shaft. Chemicals can also enter through cuts, punctures or scrapes of the skin since these are breaks in the protective layer. In some instances, chemicals may enter by accidental injection through the skin. Once in the blood stream, the chemicals can be transported to any site or organ of the body where they may exert their effects. Female adolescents, pregnant women, children and workers are particularly vulnerable to chemical absorption through the skin.

Particular routes of exposure

The **placenta** is a key organ for the growth and development of the embryo and foetus during pregnancy. While originally the placenta was thought to shield the cord blood and the developing foetus from most chemicals and pollutants in the environment, this has now proved to be untrue. Any toxic substances that the mother is exposed to might be transported to the foetus. In particular, the placental transport can in fact be either a passive diffusion for smaller molecules that are lipid soluble or an active transport for substances that are larger and/or electrically charged. Moreover, since the foetus has an immature metabolism and it is thus unable to detoxify substances efficiently, the role played by the placenta is crucial insofar it determines the substance exchanged between the mother and the foetus. Lead, ethanol (alcohol), and compounds in cigarette smoke are all examples of substances that are likely to be transferred through the placenta.

Breast milk provides a range of benefits for the growth, immunity, and development of the infant. It contains powerful immune factors that help infants fight infections, as well as growth factors that appear to influence brain development and increase resistance to chronic diseases such as asthma, allergies, and diabetes. However, breast milk can be also a source of chemical exposure. Since the 1950s, scientists are aware of the widespread contamination of human breast milk, as a consequence of decades of inadequately controlled pollution of the environment by toxic chemicals. Polychlorinated biphenyls, perfluorinated compounds, dioxins, dibenzofurans, polybrominated diphenyl ethers, and bisphenol A (BPA) are among the toxic chemicals most often found in breast milk. The level of risk to infants and children of exposure to chemical residues in human milk depends on the food consumption patterns of the mother, the nature and levels of chemical residues in her milk, and the toxicological potency of those chemicals.

The EU policy and legislative framework

The **7th Environmental Action Programme** (7th EAP) stresses the need to "*develop a comprehensive approach to minimising exposure to hazardous substances, in particular for vulnerable groups, including children and pregnant women*". The EU is equipped with a comprehensive regulatory framework to protect human health and the environment from the risks associated with chemical exposure, including **REACH** and **CLP Regulations** and specific pieces of legislation regulating particular groups of chemicals, such as biocides, pesticides, pharmaceuticals or cosmetics.

However, the EU chemicals regulatory framework is fragmented as far as the protection of vulnerable groups from chemical hazards is concerned. A range of provisions, spread across different legal acts, refer to the importance of protecting vulnerable people from chemical exposure. Most of these provisions stress the need to protect vulnerable groups in a general way, such as recital 12 of the REACH Regulation, or recital 8 of the Plant Protection Products Regulation. Other provisions are more specific, and require concrete actions to be taken, such as Article 33 of the CLP Regulation which establishes that '*packaging containing a hazardous substance or a mixture supplied to the general public shall not have either a shape or design likely to attract or arouse the active curiosity of children*'[23], or article 6 of Council Directive 92/85/EEC on the introduction of measures to encourage improvements in the safety and health at work of pregnant workers and workers who have recently given birth or are breastfeeding, which prevents pregnant and breastfeeding workers to be obliged to perform duties for which the assessment has revealed a risk of exposure of toxic chemicals.

The EU legislation does not have a comprehensive definition of the groups in society that require specific attention and/or protection from the risks stemming from chemical exposure. The only two EU Regulations which define vulnerable groups are the Plant Protection Products Regulation (Art. 3) and the Biocidal Products Regulation (Art. 3). Yet, while these definitions offer a strong basis for describing population groups that are particularly vulnerable to chemical exposure, they do not cover all groups identified in the study and they only apply as far as pesticides and biocides are concerned.

The EU legal framework also features legislation that, despite dealing with chemicals and having the protection of human health as a general objective, nonetheless does not contain any direct references to vulnerable groups. Among these are the Drinking Water Directive, and the Food Contact Materials Regulation. The **Drinking Water Directive**'s Annex I, part B (chemical parameters) only contains 25 chemicals of concern for both general and vulnerable populations - such as arsenic, cadmium, chromium, lead and mercury. But other chemicals of concern, such as the highly fluorinated substances, are not included in the list.
The **Food Contact Materials Regulation** also has gaps with specific EU rules set for only 5 of the 17 types of food contact materials. Such rules usually involve more specific requirements for safety assessment and limits for the maximum migration of chemicals into the food, important for the protection of vulnerable groups.

EU risk assessment
Chemicals regulation depends on a hazard identification and a risk assessment procedure to estimate the extent of the exposure and on that basis the probability of harm as well as its possible severity. On the basis of such assessments, measures can be set in place to manage the known risks so that they are at levels considered acceptable (safe) to humans and the environment. But controlling the risk of harm is a moving target, given that quantities of chemicals and subsequent exposures are likely to increase dramatically. Moreover, risk assessments, usually carried out by a chemical's proponents (e.g., the producer), often underestimate the risk of harm. Additional scientific research into the possible hazards posed by chemicals almost always leads to increased (and seldom to lessened) concern over risks to human health and the environment.

Moreover, recent studies have pinpointed the detrimental effects caused by combined exposure to certain chemicals on the foetus which can ultimately lead to persistent pathological diseases later in life (Govarts E., *et al*., 2016). As such, these studies stressed that risk assessment based on single substances alone is not to sufficient to interpret the effects that combined exposure may cause on human health, and thus urged policymakers to develop a cumulative risk assessment which could take into account all chemicals, spanning from pesticides, to industrial chemicals, and environmental contaminants (e.g. food, cosmetics, dust, and other sources) (Hass U., *et al*, 2017).

[23] CLP Regulation (EC) N0 1272/2008.

Identified gaps and inconsistencies

Despite the policy and legislative measures and other activities put in place, the protection of vulnerable groups is insufficient. The following major gaps were identified:

1. Lack of provisions in EU legislation defining which vulnerable groups should be ensured special protection, especially for those pieces of legislation that are of particular relevance to the protection of certain groups in society from chemical exposure.
2. Although the EU Toys Directive provides standards to protect children as a vulnerable group, other consumer products aimed at children such as clothing and bedding are not covered.
3. Certain EU legislation, e.g. the Drinking Water Directive and Food Contact Materials Framework Regulation, are not updated with the most relevant scientific evidence and lack specific measures which can strengthen the protection of vulnerable groups.
4. EU risk assessments typically focus on single substances and do not consider the risks to children and other vulnerable groups from combined exposure to toxic chemicals. Therefore, a regulatory approach for cumulative risk assessment needs to be developed.
5. Chemicals having developmental neurotoxic (DNT) properties should be further regulated in order to ensure an adequate level of protection for the foetus and children.
6. Knowledge is lacking on the toxic effects that certain categories of chemicals (e.g. non-intentionally added substances(NIASs) and nanomaterials) can have on vulnerable groups. More research is also needed on how chemicals interfere with brain development.

Conclusions

Despite the many policy and legislative measures now in place at EU level, the protection of vulnerable groups from harmful exposure to chemicals remains sporadic and a wider approach is required. For instance, the EU legislation covering food contact materials has gaps; it does not regulate 12 of the 17 types of food contact materials listed in the Regulation, some with substances that may migrate into food and result in exposures associated with adverse health effects on children. Challenges also exist with respect to chemical risk assessment for vulnerable groups, whose consumption patterns and exposure levels may differ significantly according to age group, geographical location, and lifestyle factors, and who may be exposed to multiple chemicals over time.
The review of scientific and grey literature revealed a wealth of information and data collected in recent decades on these topics. However, the scientific community has tended to focus on the same substances (e.g. copper, lead, zinc, cadmium, iron, nickel, chromium, etc.). There is a need to study additional substances and new areas, such as the health impacts of nanomaterials and chemical mixtures on certain categories of the population. With respect to certain industrial chemicals known to have neurotoxic properties, it may be necessary to apply the precautionary principle in order to sufficiently protect vulnerable groups such as foetuses and children.

Finally, the general public, producers and politicians need to become more aware of the importance of protecting certain groups in society from harmful chemical exposure. This is particularly important in respect of people's daily chemical exposure in their everyday environment, including schools, playgrounds, offices, hospitals and care facilities. Improving labelling and packaging of consumer products would also help to raise awareness of the potential harmful effects of exposure to certain ingredients or compounds. For instance, there is room for the EU to develop innovative measures and advice to further reduce exposures to neurotoxic chemicals (e.g. arsenic), in particular in pregnant women and small children.

5.5 OTHER EXISTING AND EMERGING HEALTH CONCERNS

The sections below describe other specific existing and emerging health concerns related to particular classes of chemicals, their unique properties or their specific effects.

5.5.1 Combination toxicity

Scientific evidence is mounting that the exposures from everyday products, including articles, are exposing modern society to multiple hazardous chemicals, and that these chemicals, even at low dose levels, can give rise to subtle but long-term health effects such as reduced fertility, lower birth weights and neurodevelopmental diseases. Chemicals with common modes of action may act jointly to produce toxic combination effects that are larger than the effects of each of the mixture components applied separately.

However, EU current risk assessments (RA) of chemicals focus on exposure to individual chemicals and do not provide a comprehensive and integrated assessment of cumulative effects of different chemicals, taking into account different sources and routes of exposure. The 2012 Commission Communication on Combination effects of Chemicals (Chemical mixtures) acknowledged the current limitations of assessing compounds individually and proposed a path forward to ensure that risks associated with chemical mixtures are properly understood and assessed. The new Commission approach draws heavily on the 2012 opinion on "Toxicity and Assessment of Chemical Mixtures", issued by the scientific committees SCHER, SCENIHR and SCCS. The report notes that the number of potential combinations of the toxic substances currently in commerce is astronomical and suggests that risk assessors focus on those situations where the potential for negative impacts is highest. This would require an initial filter to allow a focus on mixtures of potential concern. Though extensive gaps regarding knowledge and data (mainly related to the mode of action and exposure data) limit the extent to which mixtures can be properly assessed, the information being collected in the context of the REACH Regulation will contribute to reducing current uncertainties.

Other frameworks for the assessment of chemical mixtures have been developed by international bodies in recent years. For instance, a WHO/IPCS workshop resulted in a widely-accepted approach or framework for risk assessment of combined exposure to multiple chemicals that could be adapted to the needs of specific users. However, its use is often hampered by large data gaps on exposure as well as hazard information.

Although methodologies for assessing the combination effects of chemicals are being developed and applied by scientists and regulators in specific circumstances (Meek, 2011); (Price, 2012)), a systematic, comprehensive and integrated approach across different pieces of legislation is still not in place. While frameworks such as the ones described above may provide high-level guidance as well as tiered approaches for screening-level assessments and further refinements, their application for performing higher tier assessments are limited due to lack of data (Kienzler, 2016)

5.5.2 Endocrine-disrupting chemicals

Endocrine-disrupting chemicals (EDCs) represent a unique kind of toxicity. They are referred to by WHO as "*…exogenous substances or mixtures that alter function(s) of the endocrine system and consequently causes adverse health effects in an intact organism, or its progeny, or (sub) populations*" (WHO-IPCS, 2002). The chemical disrupts hormone action, and can do so in three different ways:

- Mimic or partly mimic naturally occurring hormones in the body like oestrogens, androgens, and thyroid hormones, potentially producing overstimulation.
- Bind to a receptor within a cell and block the endogenous hormone from binding. The normal signal then fails to occur and the body fails to respond properly.
- Interfere or block the way natural hormones or their receptors are made or controlled, for example, by altering their metabolism in the liver or by acting directly on the proteins that control the delivery of a hormone to its normal target cell or tissue.

Most of the research conducted studying the impacts of endocrine disruptors have so far focused predominantly on the interaction of EDCs with the reproduction and thyroid hormone systems. A

growing number of studies, however, indicate that endocrine disruptors can also affect other systems, such as neural and reproductive systems. Associations with weight gain, insulin sensitivity and glucose tolerance indicate a potentially important role for endocrine disruptors in immune, digestive, and cardiovascular systems, and a possible role in the development of obesity, type 2 Diabetes and metabolic syndromes, all conditions associated with major public health impacts and socioeconomic costs.

Examples of EDCs are industrial lubricants and solvents and their by-products: polychlorinated biphenyls (PCB), polybrominated diphenyl ethers (PBDE) and dioxins such as 2,3,7,8-tetrachlorodibenzo-p-dioxin (TCDD); plastics components: bisphenol A (BPA) and bisphenol S (BPS); plasticisers: phthalates; pesticides: atrazine, cypermethrin, dichlorodiphenyltrichloroethane, dieldrin, methoxychlor (MXC) and vinclozolin (VCZ); and drugs: diethylstilbestrol (DES) and ethinyl oestradiol (EE), as well as non-steroidal anti-inflammatory drugs (NSAID) and acetaminophen. Natural chemicals such as genistein, a phytoestrogen and heavy metals can also have endocrine-disruptive effects (Marques-Pinto & Carvalho, 2013). EDCs have diverse applications and thus come from a variety of sources, such as flame retardants, plasticizers, pesticides, preservatives, pharmaceuticals, clothing, and food contact materials, cosmetics and personal care products (shampoos and other hair products, toothpaste, soaps, lotions). Importantly, humans are not only exposed to EDCs through direct usages or consumptions. Such chemicals might also be dispersed during production, use and disposal and hence lead to human exposure via the environment.

The Commission adopted its first Strategy on Endocrine Disruptors in 1999. While EU legislation does take account of endocrine disruptors via the authorisation of chemical substances used in plant protection products, biocidal products, Annex XIV of REACH, and cosmetics, formal criteria for identifying substances with endocrine-disrupting properties have not yet been established, internationally or at EU level. For this reason, on 15 June 2016, the EC issued two draft legal acts – one under the Biocidal Products legislation, the other under the Plant Protection Products legislation – which set out the criteria to identify endocrine disruptors. The two draft legal acts are currently being reviewed by the Parliament and the Council under the relevant procedures for the adoption.

5.5.3 Nanomaterials

Nanomaterials are chemical substances or materials at a very small scale (some 10,000 times smaller than the diameter of a human hair). Some manufactured nanomaterials are developed to exhibit novel characteristics (such as increased strength, chemical reactivity or conductivity) compared to the same material without nanoscale features. The special properties of nanomaterials have led to their use in many applications, including medical and technical ones. However, while nanomaterials have the potential to improve the quality of life and to boost industrial competitiveness, they may also pose risks to the human health and the environment.

At EU-level today, nanomaterials are regulated only through specific measures spread in different pieces of legislation (e.g. Novel Food Regulation, Food Contact Materials Regulation, Cosmetic Regulation, etc.). Other than the European Commission Recommendation on the definition of a nanomaterial, no overarching nanotechnology-specific legislation is in place.

Due to their special properties, nanoparticles are able to enter the human body through several routes, and, consequently, they can damage human health in a range of different ways ((Niwa, 2007); (Oberdorster, 2005);. However, there is scientific uncertainty about the exact health risks associated with exposure to nanomaterials. There is also debate about whether standard procedures of risk assessment need to be modified in light of the special features of nanomaterials. Some argue that, given their special properties, together with the fact nanomaterials share no common characteristics besides the nano-scale size, the safety assessment of nanomaterials should be carried out on a case-by-case basis (Rock, 2008). There is also a lack of analytical methods for the detection of nanomaterials

in products as well as in biota and the environment.

While the literature search carried out for this project did not find studies looking at the effects of nanomaterials on specific vulnerable groups, nonetheless, certain groups have been identified as being particularly vulnerable to the effects of nanomaterials, in particular when inhaled as fine dusts. Among these groups are:

- People with pre-existing diseases (such as asthma, diabetes, among others), who may be more prone to toxic effects of nanoparticles;
- Children, as nanomaterials may interact with them in ways that differ from adults;
- Workers, especially those working in nanotechnology related industries as well as in waste management and recycling, who may be exposed at (much) higher levels than the general public and on a more consistent basis.

It is not known how many nanomaterials are being assessed for risk. REACH in fact does not explicitly require registrants to provide separate dossiers for a bulk substance and its nanoform(s) and it also does not set specific information requirements for the nanoforms of bulk substances in registration dossiers. In practice, very few registration dossiers include references to the nanoform of bulk substances, and the only supporting information from testing and risk assessment are those applying to the bulk substance, despite the potentially different characteristics of the nanoform. The current revision of the REACH Annexes is attempting to address the issue of inadequate identification and/or characterisation of nanomaterials. However, even if nanomaterials do become required to be registered under REACH, registrants will experience difficulties in providing adequate information. While many of the REACH testing strategies and standard test guidelines are in principle applicable to nanomaterials, the current natural science understanding of the environmental fate of nanomaterials is limited. Without further guidance on nanomaterials specific testing issues, assessment of their environmental and health risks will have gaps (Ricardo, 2016).

It is important to keep in mind that assumptions about how chemical substances behave once they have been used in the final product do not necessarily apply to nanomaterials. For example, even fundamental properties, such as magnetism in nanoparticles made of materials that are non-magnetic in bulk form, are still being discovered. Therefore, despite the availability of a wide range of scientific studies, more research is needed before we can fully understand the health risks that nanomaterials – nowadays used in hundreds of products world-wide - may pose to human health. As a recent study concluded: "*until we understand what realistic environmental concentrations [of nanomaterials] are likely to be, we don't really know what the impacts are*" (Garner, 2015).

5.6 EMERGING ENVIRONMENTAL CONCERNS

5.6.1 The concept of planetary boundaries

The concept of planetary boundaries developed by the Stockholm Resilience Centre stresses the need for humanity to live within the boundaries of our planet[24]. The initial work defined nine (9) areas as planetary boundaries to avoid "unacceptable global change" and to secure "a safe operating space for humanity". Five of the nine planetary boundaries identified involve chemical agents: ozone depletion (halocarbons), climate change (CO_2, CH_4 and other agents with global warming potential), the nitrogen and phosphorus cycles, ocean acidification (CO_2) and chemical pollution. The other planetary boundaries are atmospheric aerosol loading, freshwater use, land use change and biodiversity loss.

The 2009 study that introduced the concept proposed thresholds for seven of the parameters beyond

[24] Rockström J., *et al.* 2009.

which non-linear, abrupt environmental change could occur on a planetary scale. Several of these boundaries have been far exceeded, e.g., climate change, biodiversity and phosphorus cycles. The study was not able to determine boundary levels for chemical pollution. In an updating of the planetary boundary concept, the term '**chemical pollution'** has been renamed as '**introduction of novel entities'**, to include other potential human-driven global risks such as the release of radioactive materials, nanomaterials and plastics. The Stockholm Resilience Centre website notes (Steffen, 2015):

> "*These compounds can have potentially irreversible effects on living organisms and on the physical environment (by affecting atmospheric processes and climate). Even when the uptake and bioaccumulation of chemical pollution is at sub-lethal levels for organisms, the effects of reduced fertility and the potential of permanent genetic damage can have severe effects on ecosystems far removed from the source of the pollution. For example, persistent organic compounds have caused dramatic reductions in bird populations and impaired reproduction and development in marine mammals.*"

The problem of ignorance is an important factor, in that the disruptive effects are not discovered until they already occur on a global scale and are affecting a vital earth system process. The depletion of the stratospheric ozone layer because of the production and release of halocarbons is cited as a clear example of a global-scale environmental impact that no one foresaw at first. This argues for a regulatory approach based on hazard rather than risk, including the PBT and vPvB classifications, and the Stockholm Convention's definition of a POP (PBT and subject to long-range transport), with a focus on persistence (Persson, 2013).

The work to quantify chemical pollution boundaries, or thresholds, has been difficult to progress, given the vast number of commercial chemicals and the complex linkages between emissions, environmental concentrations, exposures and adverse effects to species and ecosystems. The critical point is that the assimilative capacity of the earth in terms of being able to degrade or immobilise human-released chemicals is limited at the global level, even for biodegradable chemicals. Based on this, studies have emphasised the need for a preventative approach (Diamond, 2015; MacLeod, 2013).

5.6.2 The contribution of chemical pollution to a loss of biodiversity, contamination of natural resources, and resilience of ecosystems

The 2005 Millennium Ecosystem Assessment provided a framework that acknowledges biodiversity as one key factor for ensuring the continuous supply of ecosystem services and facilitating ecosystem stability, such as formation and retention of agricultural soils for food cultivation and purification and detoxification of water resources. Biodiversity and ecosystem services that may be adversely affected by chemical pollutants include the pollination of crops and natural pest control carried out by insects and other animals. For example, pesticides and their use in intensive farming systems have long been linked to biodiversity loss, mainly due to loss in regional diversity of invertebrates. Analysis shows that pesticides currently used in Europe and Australia may cause the decline of up to 42% of stream invertebrate species (Beketov, M.A. et al., 2013). Other studies have suggested a link between POPs and immune system deficiencies of Arctic mammals and reproductive effects of TBT (AMAP, 2004). The top predators that help to maintain balance and biological diversity in ecosystems, as well as provide value for recreation and ecotourism, are particularly vulnerable to chemical pollution due to their position in the food chain (European Commission, 2017).

Trace metals and heavy metals such as cadmium, mercury and lead can harm aquatic organisms through lethal and sub-lethal effects, and can reduce or eliminate species in ecosystems through increased susceptibility to disease and mortality, and decreased fecundity. Lead in ammunition is a useful example of how a specific use of lead can result in significant annual deposits in the environment, where it contaminates soils and waterways, and may be bio-accumulated by soil-based organisms, putting vegetation, invertebrates and other organisms at risk.

Organic contaminants such as pharmaceuticals, insecticides, surfactants, and endocrine disruptors (including hormones) in wastewater being released in surface water – even if present only at trace levels – can cause widespread contamination of freshwater supplies. The case of increasing concentrations of highly fluorinated chemicals in groundwater illustrates the inability of a natural resource to recover when the contamination is in the form of very persistent chemicals.

The resilience of an ecosystem is its capacity to respond to a perturbation, disruption or disturbance by resisting damage and recovering quickly. This is a particularly important concept for examining the potentially disruptive role chemicals can play and whether ecosystems can resist damage or recover and in what time frame. Note that the ability of an ecosystem to recover depends on how persistent the chemical is in the environment or ecosystem.

An important example of the complexity in the provision of ecosystem services is the case of pollinating insects or birds nesting within the vegetation of agrarian habitats which provide important pest control in agricultural fields. Herbicides drifting to off-target areas may affect sensitive non-target plants and thereby the vital ecosystem services of various species, and eventually affect the entire food web through complex mechanisms and interlinking systems. Along these same lines, systemic insecticides, thought to have less toxic properties to humans, affect decomposition, nutrient cycles, soil respiration and invertebrate populations valued by humans. Invertebrates, particularly earthworms that are important for soil processes, wild and domestic insect pollinators, and several freshwater taxa which are involved in aquatic nutrient cycles, were all found to be highly susceptible to lethal and sub-lethal effects of neonicotinoids and/or fipronil at environmentally relevant concentrations (Chagnon, 2015) .

The ecosystem services concept is increasingly being used in policy development processes, for example, the EU Biodiversity Strategy, "Our life insurance, our natural capital", with its headline target of halting biodiversity loss and the degradation of ecosystem services. However, much of the research conducted so far has focused on a nature conservation perspective. Development of effective approaches for assessing and managing chemical risks to ecosystems services will require more systems thinking and an ability to recognise and address the complex interrelationships among single and multiple stressors across different spatial scales (global, regional and local).

5.6.3 Chemical pollution and climate change

The Intergovernmental Panel on Climate Change (IPCC) has noted a number of impacts related to chemical pollutants and climate change. Positive impacts related to synergies with measures to mitigate greenhouse gas pollution include improved energy efficiency and cleaner energy sources, leading to reduced emissions of heath damaging, climate-altering air pollutants (IPCC, 2014). However, climate change is expected to reduce the quality of freshwater resources, due to increased pollutant loadings from heavy rainfall and increased concentrations of pollutants during droughts. This will pose risks to drinking water quality even with conventional treatment (*medium evidence, high agreement*), including increases in sediment, nutrient and pollutant loadings due to heavy rainfall, reduced dilution of pollutants during droughts, and disruption of treatment facilities during floods. Among other deleterious effects, terrestrial, fresh water and marine ecosystems are predicted to face increased extinction risks, especially as climate change interacts with other stressors such as inter alia over-exploitation and e.g. chemicals pollution.

A 2009 workshop organized by the Society of Environmental Toxicology and Chemistry (SETAC) concluded that the fate, transport and sources of chemical substances of concern are expected to change considerably (Balbus et al., 2013), albeit by different magnitudes, affecting the contamination of air, water supplies and food resources. An overall increase in exposure to chemicals is predicted, which will have important repercussions on human health and the environment.

POPs. The fate and behaviour of persistent organic pollutants (POPs) are highly impacted by climate change (Macdonald et al., 2003). A UNEP report stresses that efforts to reduce the release of POPs into the environment can be undermined by climate change, e.g. higher temperatures will affect the transport, fate and behaviour of POPs (UNEP, 2011). The degradation of POPs will increase, but this will probably go hand in hand with the formation of new transformation products. The long-range availability of POPs will increase as a result of various atmospheric processes and changes in climate will also alter exposure of humans and wildlife to POPs. Concentrations in aquatic environments might decrease, resulting in higher concentrations in the atmosphere. In addition, higher temperatures will result in melting of permafrost and ice caps, in turn triggering release of previously contained POPs in these natural reservoirs (Noyes et al., 2009). In sum, the risk assessments done originally may no longer hold up to scrutiny.

Pesticides. Agriculture contributes to climate change and climate change will directly affect agricultural practice. Increased volatility and faster degradation could reduce pesticide concentrations in soil and aquatic environments, which might result in higher dosages and/or more frequent use of pesticides (Delcour et al., 2015). Additionally, extreme weather events like flooding and storms might increase contamination of water and soil due to increased pesticide run off. Climate change will also impact pest populations as well as location and types of crops, which might necessitate a wider geographical application of pesticides, exposing areas that have been previously unaffected by pollutants.

Air Pollution. Several studies suggest that toxicity of ground-level ozone and particulate matter will increase due to climate change and potentially endanger human health, especially for vulnerable populations like elderly and children. For example, higher levels of ozone were recorded during the 2003 heatwaves in Europe. Extreme weather events resulting from climate change are similarly expected to increase pollution levels in urban areas. For example, wild fires resulting from increased temperatures and dry periods will also affect air quality. Indoor air quality will also be affected, since increases in outdoor concentrations of ozone and other pollutants is likely to result in higher concentrations indoors.

Heavy Metals. Climate change is also expected to affect the long-range transport potential of heavy metals. For one, the deposition of mercury to the Arctic is predicted to decrease with a warmer climate (Hansen et al., 2015). In parallel, effective measures aiming to mitigate climate change will further reduce mercury in the atmosphere, resulting in lower depositions. However, interactions of climate change with other factors might also influence these processes, such as release of mercury from melting glaciers which could potentially increase concentrations of this toxic chemical in the environment. In addition, temperature variability may increase sensitivity to toxicants such as cadmium (Kimberly, 2014).

Indirect Impacts. Climate change is expected to have more subtle, secondary impacts on how pollutants interact with environment in general and human populations. It should be considered not only as a trigger but also an intensifier of risks from stressors and pollutants. In some cases, changes in climate might alter the tolerance levels of an organism for toxic pollutants (climate induced toxicant sensitivity), while in other cases exposure to toxic chemicals might alter the tolerance of an organism for stressors related to climate change (toxicity induced climate sensitivity). Since exposure to toxic chemicals can suppress immune system functions, this could reduce resilience in the face of climate induced changes to stressors like vector borne diseases. In addition, higher temperatures are likely to increase vulnerability for cardiovascular respiratory disease linked to air pollutants.

Extreme weather events related to climate change, such as heavy precipitation and flooding, may also result in increased exposure to chemical pollution. Several studies mention risks related to damage to infrastructure from extreme events, which could trigger release of pollutants from landfills,

contaminated sites, sewage systems and water recycling facilities.

A Swedish Chemicals Agency report calls the complex relationship between climate and pollutants both conflicting and synergistic (KEMI, 2010). Initiatives aiming at reducing GHG emissions will have additional positive effects on reducing concentrations of toxic pollutants, e.g. increased energy efficiency and alternative energy systems will decrease the release of mercury into the environment from fossil fuel combustion. At the same time, biofuels -- seen as an alternative to fossil fuels in the efforts to contain climate change – could lead to increased use of pesticides due to intensive cultivation of such fuels. Also, though energy efficiency is crucial, the production of the rare-earth materials incorporated into efficient energy systems such as photovoltaic cells, batteries and light bulbs is associated with toxic pollutants like mercury and cadmium.

The 2015 Lancet Commission on Health and Climate formed in 2015 to provide an overview of the impacts of climate change and the policy responses necessary to tackle these impacts stressed the many co-benefits to be obtained from the efforts to fight climate change. It predicted that ground level ozone and particulate air pollutants are the elements that will be greatly affected by climate change, especially due to higher temperatures and it noted that regional variations will be significant.

The EU's current risk assessment processes for hazardous chemicals do not yet pay sufficient attention to the complex relations between the changing climate and the impact of such changes on risks posed by chemical substances. For example, higher indoor and outdoor temperatures may result in higher concentration levels of some substances and hence higher degrees of exposure, including new combined and cumulative exposure scenarios. Higher temperatures may also increase biological sensitivity to certain substances. The unpredictable nature of extreme weather events will also require a rethinking of basic notions of risk assessment and public health protection. Climate change and chemical exposure might also interact to increase the overall stress on ecosystems and biodiversity.

Attempts to mitigate and adapt to climate change will present a number of chemicals-related challenges, such as how to include risks from chemicals in assessments of new technologies, in order to avoid creating new problems. The potentially conflicting relations mentioned above will require a critical lifecycle assessment of new technologies, if policies targeting climate change mitigation and adaptation, are to be beneficial overall and not compromised by unintended negative side effects.

6 WORKSHOP PARTICIPANTS' VIEWS ON STATUS QUO AND IMPROVEMENT OPPORTUNITIES

This section intends to summarize the points of views of stakeholders in the fields covered by the different sub-studies. Their perspectives were collected during the workshop held in June 2016 and from their subsequent written feedbacks.

6.1 SUBSTITUTION, INCLUDING GROUPING OF CHEMICALS AND MEASURES TO SUPPORT SUBSTITUTION (SUB-STUDY A)

Criteria for defining sustainable substitution **-** The workshop participants felt that the definition of "sustainable substitution" and "safer substitutes" is mainly a political decision on how to weigh hazard, risk and socioeconomic arguments. The definition of what is meant with "non-toxic" environment would be already a considerable step towards the development of the strategy. The different perspectives of businesses and society may lead to different criteria. The question is therefore: how to reconcile these different perspectives to ensure the protection of the human health and the environment without hindering innovation and competitiveness of the EU industry. In the weighing process, groups vulnerable to chemicals' exposure should be carefully considered. It was also deemed that the clear definition of the function of the chemicals used in the processes/products would be a good starting point of a step by step process. Indeed, a recurrent discussion theme has been that the first important question is whether the chemical substance is needed to achieve the desired functionality. Once this has been established, the assessment could take into account not only hazards and risks during the production of the chemicals and their use in the processes/products but also life cycle impacts and other aspects, such as impact on energy consumption. These types of assessments, however, are resource and time intensive and require good quality data that, despite the implementation of the REACH Regulation, are not yet available for most of the chemicals of concern. It is however emphasised that introducing additional layers of data demands in a situation where health and environment data is still insufficient for assessments in chemicals policy might not be realistic. Transparency in the assumptions used to overcome these information gaps but also in the weighing process is of vital importance while more efforts are put on the development of the assessment methodologies and in filling the data gaps.

Assessment and data **-** Workshop participants agreed that there is a trade-off between the quality and the quantity of data needed for the assessment of chemicals and their potential substitutes. While some participants believed that life cycle impacts should be considered not only in the assessment but also in the designing of the chemicals, others considered that methodologies should be kept as simple as possible, possibly trying to enhance the available tools and not to develop new ones. Some participants expressed the opinion that a better and more inclusive stakeholders' consultation in the gathering of data and in the decision-making process of the Scientific Committees would be beneficial too, but others pointed out that in the formation of scientific evidence, stakeholders' consultation should be avoided. All data gaps should be made transparent and highlighted so that downstream users can avoid untested materials and put pressure on suppliers to fill in data gaps.

Co-ordination **-** There was a wide consensus that enhancing the co-ordination of the different initiatives on substitution and the sharing of information among scientists, industry and regulators would be very beneficial for the promotion of the substitution of hazardous chemicals and the development of safer alternatives. In this regard, participants agreed that co-ordination at EU level would be beneficial to avoid the multiplication of efforts and initiatives at national and local level, often sharing the same objectives but not the resources to achieve them. Harmonisation of the guidance documents referring to different pieces of legislation may also help in identify remaining gaps and increase awareness. The creation of a platform at European level may also be an option to

achieve this enhancement, possibly in combination with databases searchable for functionalities, hazardous properties, upcoming/current regulations of the substances, and assessment of safer alternatives. In that respect, the databases maintained by ECHA are a good starting point but are still not sufficient for substitution purposes. Collaboration across the supply chain was also seen as very important, in terms of traceability of hazardous substances along the supply chain (and in imported articles) but also for the development of safer alternatives targeted to the needs of the articles manufacturers and users. The development of best practices on the basis of successful collaborations across the supply chain (e.g. Italian glass sector, IKEA)[25] is another important tool.

Incentives **-** As highlighted in the discussion on co-ordination, information support instruments play a vital role to promote substitution. Moreover, a "shared knowledge" between chemists and toxicologists should be facilitated through the formation of university courses on green chemistry and sustainable substitution. Factual information on the hazardousness and impacts of the chemicals contained in articles should be provided to the public, avoiding the "greenwashing" phenomena and the multiplication of ecolabels. Additionally, green public procurement, but also green private procurement by large corporations with sustainability strategies, has an important role to play in rewarding innovators and thus incentivise the development of safer chemicals, shaping market demand and raising public awareness. Engaging the directors' boards of large enterprises, to change their mind sets and to commit them on green chemistry may be an important part of the strategy. Technological support should be offered to SMEs, but also incubators (see DexLeChem's experience in Berlin[26]) and easier entry to markets to innovative start-ups dedicated to green chemistry. Taxation on the production or use of hazardous chemicals also gives a clear signal to stakeholders and incentivises substitution (see Scandinavian experiences on taxation of pesticides and solvents).

Grouping strategies **-** Workshop participants recognised the importance that grouping strategies may play in avoiding regrettable substitution. Some participants suggested that, before considering grouping strategies, it should be ensured whether the use of a chemical product is necessary and its functionality not delivered by non-chemical means. As a first step, the definition of the groups is challenging and enough flexibility should be left for dealing with different situations as, in some cases, it may not be possible to obtain the same functionality from a substance not pertaining the use of chemicals from the same structural group as the substance to be substituted. Different strategies was proposed by the participants, e.g. grouping of substances of concern for certain vulnerable groups (pregnant women, children), by intrinsic properties (persistence), by effect type or mode of action (also referring to combined exposure) or by functionality/application. Some participants suggested following a tiered approach, others suggested leaving the possibility to prove that a substance from the same group is safer or requiring more information on toxicity and exposure if the substitute is from the same problematic group as the substance to be substituted. An example of a different approach is the German evaluation procedure for volatile organic compounds (VOC) from building products. All emissions must be identified and assessed according to a list of 180 chemicals with threshold values. Sometimes the industry substitutes chemicals on the list with other compounds for which no threshold values are derived. To avoid surprises (not knowing the toxicological potential of these new compounds) the authorities set a criterion to limit the emissions of unknown chemicals or chemicals without threshold values. However, industry can apply for the derogation from threshold values for this new compound. They then have to provide the German authorities with the toxicological data.

In any case, the transparency of the criteria used to define the groups as well as the objectives of the grouping strategy was deemed very important. The promotion of a public debate on which groups of

[25] The glassmakers of Murano (a Venetian island in Italy), in collaboration with the research institute of the local chamber of commerce and thanks to the funding of the Italian government, found two suitable alternatives to arsenic trioxide, a carcinogenic substance used in glassmaking that was included in the Authorisation list.
IKEA strives to ensure that its products do not contain substances included in the REACH Candidate list. In order to achieve this objective, it needs to maintain close collaboration with all its suppliers.

[26] http://www.dexlechem.com/home_en.html

chemicals should be considered for regulatory purposes may ensure more transparency in the decision-making process. At the same time, some participants suggested that downstream leading companies are already applying grouping strategies to avoid classes of hazardous substances, hinting that legislative measures are not the only way to proceed but that information based instruments and raising public awareness may be as important.

Suggestions – Based on the discussions, a range of ideas were extracted from the views of a majority of the workshop participants to be (potentially) further explored:

- Clear signals should be provided to the market. These can be in the form of economic instruments such as taxation on the use of hazardous chemicals or through the creation of a market demand for safer alternatives, using green public procurement and raising awareness along the supply chain of chemical products, starting with the directors' boards of large companies;
- A flexible approach should be followed in developing grouping strategies for regulatory purposes and research and legislative action should be prioritised on those chemical groups that raise the highest concern, because of their presence in consumer products or because of the exposure of vulnerable population groups;
- More and better co-ordination is needed at European level to increase the efficiency and effectiveness of the multiple initiatives on substitution currently ongoing at international, national and local level, across different sectors and under different legislative frameworks;
- The networking of SMEs should be promoted and market access of innovative SMEs in green chemistry should be facilitated through the provision of funds and administrative burden ease;
- Most of the workshop participants felt that the current legislative framework provides sufficient incentives to substitute hazardous substances and argued that there is no need for new legislation but there is a strong need for a better enforcement, in particular on imported articles. Some suggested that lessons can be learned from the enforcement of legislation regulating the electronics sector.

6.2 CHEMICALS IN PRODUCTS AND NON-TOXIC MATERIAL CYCLES (SUB-STUDY B)

Information flow & gaps - In general, all stakeholders agreed on the fact that the information flow on toxic substances in articles is crucial for implementing any related risk management activities and directing waste streams in a circular economy. One of the identified gaps is that the information flow with articles is limited to SVHC contained in concentrations above 0.1%. Although this information at the point of purchase is needed for consumers to exert their market power, they would appreciate information on other substances. In general, it was underlined that supply chain communication does not function well. This is particularly problematic in the waste sector, because waste treatment operators lack information to decide on treatment options, including recycling. While more research is required on the assessment methodologies and on the chemicals life cycles impacts, transparency should be ensured in the decision-making process, from the assumptions used to overcome information gaps to the criteria used in grouping strategies.

Legislative framework - Besides stakeholders pointing out that overarching and consistent legislation restricting the use of chemicals in articles is missing. This was assessed to contribute to an insufficient level of protection of humans and the environment. Furthermore, the waste sector would miss legislation requiring depollution and setting qualitative (substance-related) targets for recycled materials. Corresponding to this gap analysis, stakeholders recommended, among others to:

- develop overarching, consistent legislation on the content of and communication on toxic substances in articles along the supply chain and to consumers,
- include imported articles in all approaches limiting the content of toxic substances in articles; i.e. in particular the REACH authorization scheme,
- (support) the development of approaches to globally standardize communication on substances in

articles that may extend beyond SVHC but should not require full disclosure of content information,
- establish methods and processes to communicate information on toxic substances in articles to the waste sector that are easy to use, fit to every day practices and do not require extensive resources,
- support implementation of a circular economy by implementing qualitative recycling targets, creating markets for secondary raw materials and ensuring economic feasibility of separate waste collection and treatment approaches, including decontamination technologies, where needed,
- identify options to use the principle of extended producer responsibility to enhance the reduction of use and communication on toxic substances in articles throughout the supply chain including the waste sector,
- clarify the legal interlinks between waste legislation and chemicals /products legislation to reduce uncertainty about the applicable requirements,
- increase resources and capacities for the enforcement of provisions on toxic substances in articles and wastes, including analytical methods for compliance checking,
- implement awareness raising, education and training campaigns to support the phase-out of toxic substances and create an understanding of chemical safety in general in supply chains also outside the EU and in the public.

6.3 THE IMPROVED PROTECTION OF CHILDREN AND VULNERABLE GROUPS FROM HARMFUL EXPOSURE TO CHEMICALS (SUB-STUDY C)

Risk assessment & testing methods **-** Participants discussed whether risk assessment methods and overall risk management should be harmonized across legislation and areas, or whether specific assessments depending on the vulnerable group are more appropriate. An integrated approach for screening and testing chemicals that is low cost and yet able to review a large number of chemicals and that takes account attention of the vulnerabilities of certain populations, was discussed. A consensus could not be reached, but overall people agreed that we need to refine current approaches. Participants also underlined that there is a need to translate the scientific evidence into effective tools in order to improve the risk assessment system.

Research **-** Participants agreed that more research is not always the solution. While scientific gaps most certainly still exist, a wealth of information has already been brought together. A problem mentioned in this context was that a large share of the studies tend to focus on a rather limited number of well-known and long-studied chemicals, while studies on chemicals with more recent histories are largely missing. The scientific agenda needs to be rationalised and scientific efforts need to be channelled towards: i) the available evidence; ii) specific vulnerable groups. For that last item, there is a need to perform (more) biomonitoring studies as they are useful tools for understanding the chemical exposure levels, particularly for the foetus and breastfed child. However, it was stressed that such studies do not explain routes of exposure and sources. One of the speakers also pointed out that it would be wiser to focus on human studies, rather than animal studies. In general communication between scientists, regulators and the wider public should be strengthened (see further points on awareness raising).

Legislative framework **-** The participants agreed that the provisions of the EU legislation addressing the issue of vulnerable groups are often vague and/or not binding. The issue is addressed horizontally, leaving room for manoeuvre and failing to provide solid protection of vulnerable groups, particularly children. The majority agreed on the need to ensure more coherence between the legislation. Some participants identified specific pieces of EU legislation that need to be amended (e.g. the food contact materials and the water contact materials legislations). However, participants agreed that in the short perspective, the situation does not require an amendment of all the legislation relevant to vulnerable groups, as this solution will require time, lead to wide legal uncertainty and is politically too sensitive. Participants stressed that for most products, a proper legal framework protecting certain vulnerable

consumer groups does not exist (e.g. products for children, textile, furniture, etc.). Some participants underlined that the precautionary principle should be underpin all the legislation in this matter.

Policies & awareness raising **-** There was a consensus on the necessity of having better information about the routes of exposure, and in particular the need to raise awareness among the general public. However, it was stressed that raising awareness among the public should not result in a shift of responsibilities from politicians to consumers. It is key to involve politicians in awareness raising and prevention initiatives; they will facilitate a better targeting of certain vulnerable groups (e.g. schools, childcare centres, elderly care facilities, etc.). Specific, targeted information (campaigns) should be developed for the vulnerable groups, presented in a constructive way.

6.4 SUB-STRATEGY FOR VERY PERSISTENT CHEMICALS (SUB-STUDY D)

Criteria and evidence **–** Participants agreed that the evidence needed to identify very persistent (vP) chemicals is complex. Established degradation tests e.g. "ready test" and "inherent test" can show which chemicals are not vP. Estimation methods like the USA BIOWIN tool can be useful as training and test sets to predict persistence or screen chemicals. More realistic half-life tests, such as simulation tests of environmental compartments, are time and labour intensive, and costly. Participants highlighted the challenge of testing for persistence in very or extremely persistent chemicals i.e. using a 90-day test of biodegradability and extrapolating test data to determine how long these substances will remain in the environment, because extrapolation is associated with a degree of uncertainty. There were two main views on this challenge, on the one hand participants indicated that there is enough information available: the pursuit of better information or evidence should not impair our ability to take action or regulate. On the other hand, participants noted that we do not have enough information to assess how persistent chemicals actually are, and that in the case of extremely persistent substances there is a need to develop new screening procedures and test protocols, this was highlighted as homework for the scientific/academic community. Participants agreed that, as a first step, it would be useful to take a very pragmatic approach, and suggested that one possible first step would be to develop a list of very persistent chemicals or candidates for this list within the remit of the ECHA.

Regulation and management **-** There was consensus amongst the participants that the current regulatory framework is not adequate for regulating and managing vP substances. There is currently no regulatory paradigm to prevent poorly reversible chemical exposures and regulation is often retrospective i.e. regulation is first put in place after enough evidence is gathered on the environment and health impacts. In addition, the current criteria for persistent, bioaccumulative and toxic (PBT) and very persistent, very bioaccumulative (vPvB) are not particularly useful in predicting planetary boundary threats. For this reason, reliable methods for predicting hazards and risk management are needed. Participants suggested that a few improvements could be made within the current regulatory framework, such as including criteria for P and vP under the Classification, Labelling and Packaging (CLP) legislation; and consideration of vP under Art. 57 (f)[27] as having level of equivalent concern. Workshop participants also pointed out that there is always some leakage during the manufacturing of vPs or manufacturing processes using vPs and suggested creating a system for environmental permits for vP substances as one way to effectively reduce releases into the environment. At the same time, participants suggested that providing incentives for downstream users to avoid vP substances would be effective in reducing release of vP chemicals in combination with environmental permits.

Global perspectives **-** Persistent chemicals are a global problem because of their long-range transport

[27] This article under reach specifies that substances — such as those having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points under article 58 in REAC for which there is scientific evidence of probable serious effects to human health or the environment which give rise to an *equivalent level of concern*.

potential. In practice this means that persistent chemicals have the ability to be transported and in some cases, accumulate in areas far from their point of release into the environment. Participants stressed the importance of maintaining a global perspective, when discussing regulation and management of vP substances. Restricting vP substances in Europe alone, would likely lead to production being moved to other parts of the world e.g. the current case where PFOS production has moved to China following legal action in the EU. Because of vPs long-range transport potential, restricting vPs in Europe alone will also not necessarily reduce exposure. Most the participants agreed, that the starting point should be the Stockholm Convention, but that its coverage of regulated chemicals (i.e. 23 substances) is limited. Participants also discussed what the chain of responsibility should be, and in this respect highlighted several ideas for improvements in global management and governance. There was general agreement that identification of vP substances in imported products was an important first step. Currently it is virtually impossible to know what substances or chemicals are involved or used in manufacturing of imported products. Along the same line, participants suggested that certification schemes could be used to promote higher product standards in articles and promote transparency in supply chains. Naming and shaming was mentioned, but there was broader acceptance for developing a global hub to communicate success stories, including voluntary efforts by industry. The OECD's current work in this area was highlighted as a positive model for communicating success stories and that a logical first step would be to expand upon this model. Finally, participants stressed that it was important to find solutions that benefit multiple targets i.e. providing information and incentives that facilitate downstream users to move away from "high performance" chemicals.

6.5 POLICY MEANS, INNOVATION & COMPETITIVENESS (SUB-STUDY E)

The participants agreed that well-designed **regulation** can promote innovation (Porter and Van der Linde paradigm) but held diverging views on whether the current legislative framework is posing a high administrative burden on SMEs and therefore diverting resources from research and development, ultimately hindering innovation.

An important point is that well-designed regulation needs to be properly enforced: poor **enforcement** is an issue, in particular on imported articles. The work of the Enforcement Forum is a good starting point, but more resources should be dedicated to the co-ordination of enforcement across member states.

The **availability of information** on safer alternatives is an issue: actors along the supply chain willing to engage on the substitution of hazardous chemicals need to be aware of the availability of possible solutions. In this regard, distributors have a potential role in bringing together demand and offer of safer alternatives. Another measure that could foster innovation is the creation of a marketplace for safer alternatives (e.g. the web-based solution currently being developed by Chemsec).

The participants agreed that there are plenty of initiatives trying to promote innovation at European, national and local level, providing funds, knowledge sharing, incubators for start-ups or other networking platforms. However, it would be good to have a better **co-ordination** of these initiatives, which e.g. could be under the OECD umbrella. Moreover, some participants questioned whether it is the responsibility of the public authorities to provide funding to scale up production of innovative solutions, arguing that their role should be limited to facilitate innovation.

In this regard, **economic instruments** such as taxation, public procurement and fee waivers can definitely play a role in providing the market with clear signals towards the changes that are needed to achieve a non-toxic environment. Moreover, innovation should not be seen as the substitution of hazardous chemicals with chemical alternatives only, but product design should start from the question on whether chemicals are necessary to achieve the functionalities required.

Industry stakeholders were of the opinion that free and open markets boost the development of the global economy for industrial and developing countries alike and ensure worldwide availability of products based on the most efficient processes and therefore strongly encourage governments to engage in free trade negotiations with all major trading partners. Importantly, Free Trade Agreements or other (international) agreements must include provisions on **intellectual property rights (IPR) protection**. Industry needs transparency and predictability with regard to IPR protection because of the duration and complexity of innovation processes. A stable regulatory environment allows the long-term planning that is needed to innovate. Furthermore, international agreements should define adequate IPR enforcement rules, as the value of IPRs is strongly linked to their effective enforcement.

6.6 PROGRAMME ON NEW, NON-/LESS TOXIC SUBSTANCES (SUB-STUDY F)

Feedback from stakeholders on issues related to the development of new, non-toxic substances was collected from direct interviews with stakeholders, during the discussions at the stakeholder workshop and from written feedback received after the workshop.

Overall, stakeholders stressed that there is a need for new, non-toxic substances development and that related activities should also take other aspects of sustainability into account. It was emphasised that, with a view to the increasingly complex market of substances and materials, orientation on the term "non-toxic" is of high importance, i.e. explanation would be needed on what are the properties to avoid and the protection goals and how to measure if new substances fulfil the related requirements.

Stakeholders at the workshop agreed that non-toxic substances should satisfy societal needs, be safe in their uses and be "gone" after their use. Achieving these goals would require considering the hazardous properties and the behaviour during the use as well as the waste stage (recyclability) early in the design phase of substances, at least in parallel to the assessment of technical performance criteria.

Stakeholders pointed out the following main barriers to the development of new, non-toxic substances:

- need to change production facilities and equipment potentially requiring large investments;
- making contacts between suppliers (researchers) and users of new, non-toxic substances and overcoming traditionalized supply chain structures;
- fear from change-over costs, in particular if existing (commodity) substances should be replaced
- lack of education and training and (transdisciplinary) cooperation experience;
- low profile and priority of the issue of non-toxic substances in R&D.

The stakeholders proposed, among others, the following activities to respond to these challenges:

- increase legal pressure for substitution (of substance groups) in general;
- make the topic "non-toxic substances" an integral part of all funded research;
- raise awareness and promote non-toxic substance development in ongoing change processes in companies;
- enable basic research for substance innovation and development.

The feedback on the need for targeted research and for better substance design tools was unclear and cannot be interpreted unambiguously.

6.7 EARLY WARNING SYSTEM FOR EMERGING CHEMICAL RISKS (SUB-STUDY G)

The participants to the workshop discussed the creation of an early warning system (EWS), the expectations of its functioning and ability. Stakeholders stressed that an EWS should be flexible and

build on existing experience to avoid duplication of work and should involve the appropriate stakeholders. Furthermore, an EWS should support informed decision making. The expectations were that an EWS should be able to: forecast; prevent; facilitate safe products (use/design); connect data; identify new end-points; be flexible; include vulnerable groups (children, workers); have a multiple compartment (air, water and soil) focus; include post-marketing surveillance; function on proper methods and procedures for signal identification; include measuring strategies such as analytical chemistry; connect to circular economy; facilitate follow-up choosing the best risk management measure or policy options; involve industry and public; include ranking/scoring systems based on for instance (Q)SARs; identify substances with PBT-properties; facilitate informed-decision making; use input from enforcement authorities/inspectors; give for instance a high priority to situations with signals but with little information and consider how to address the situation (e.g., through targeted information gathering); include alternative or new end-points such as neurotoxicity, immunotoxicity, biodiversity loss or ecosystem risk for prioritisation.

Meeting all these expectations is likely to be challenging and going through a procedure capable of achieving all these goals might take too long to address emerging risks. It is essential to find the right balance between timely action and gathering data for building a case. In that sense, the real needs of information should be defined. Overall it should be clear what the aim of the system is, and what it aims to protect. Regarding target audiences, traditionally, the focus is on authorities and policy makers, neglecting other audiences. Examining existing systems that are lacking some of the functionality and purposes of an EWS (e.g. RAPEX) would also be useful. Different methodologies should be identified for each step of the EWS.

6.8 COMMON POINTS

The perspectives shared by the stakeholders during the workshop, through their written feedback, or during interviews were enlightening. Although diverging views exist on the shortcomings of the current legislative and policy frameworks and on the next priorities, it seems clear from the opinions of all represented groups that the current system falls short from providing a holistic framework that ensures the health and well-being of EU citizens. The feedback overwhelmingly underlined that supplementary action is desirable and improvements achievable. The next sections of this report explore those elements for a future strategy of a non-toxic environment.

7 ELEMENTS FOR THE NTE STRATEGY: REDUCING EXPOSURE WHILE MAINTAINING COMPETITIVENESS

7.1 THE NON-TOXIC ENVIRONMENT IN THE GLOBAL POLICY CONTEXT AND IN THE 7TH EAP

Section 5 provides snapshots of the state of play with respect to several key topics related to chemicals and their impact on modern life. On the one hand, these snapshots affirm the importance of the strong foundation in place via current EU regulatory policy on chemicals. On the other hand, they highlight a number of existing and emerging concerns related to exposures to chemicals which are not yet covered or are insufficiently covered by the existing framework of controls, including areas where such exposures carry the potential for harm to human health and the environment. Many of these issues are already identified in the 7th Environment Action Programme (EAP), which commits to developing by 2018 a European Union strategy for a non-toxic environment.

7.1.1 Global policy context

As mentioned in Section 4.2, the chemicals-related objectives of the 7th EAP are not isolated but are embedded in global policy initiatives, first and foremost the WSSD 2020 goal to achieve the safe management of chemicals throughout their life-cycle, as agreed during the World Summit of Sustainable Development in Johannesburg (WSSD). In 2006, governments and stakeholders agreed on the Strategic Approach to International Chemicals Management (SAICM) (UNEP, 2006), a global policy framework to promote safe chemicals management with the explicit aim of implementing the WSSD 2020 Goal on chemicals. The fourth session of the International Conference on Chemicals Management in 2015 endorsed an 'Overall orientation and guidance for achieving the 2020 goal of sound management of chemicals' which takes stock of the progress made towards achieving the 2020 goal[28]. The conference identified the following emerging policy issues: lead in paint, chemicals in products, nanotechnologies and manufactured nanomaterials, hazardous substances within the life cycle of electrical and electronic products, and endocrine-disrupting chemicals. In addition, perfluorinated chemicals and the transition to safer alternatives were identified as an area of concern.

The 7th Environment Action Programme includes a number of specific targets for chemicals up until 2020, and reiterates the EU commitment to meeting the WSSD 2020 Goal specifically [29].

In 2013, the Commission published a report assessing the progress made by the EU towards achieving the WSSD 2020 Goal from the baseline year of 2002 until the end of 2012 (European Commission, 2013)[30]. It identified gaps and developed recommendations to address specific gaps. The gaps were identified against a set of indicators categorised into five different topics, namely:

1. Knowledge, information and infrastructure;
2. Risk reduction;
3. Governance;
4. Illegal traffic in hazardous chemicals, products and waste; and
5. Technical assistance and capacity building.

The report identifies a number of gaps relevant to this study and its sub-study areas, including:

[28] SAICM Document 29 June 2015, available at: http://old.saicm.org/images/saicm_documents/OOG%20document%20English.pdf.
[29] 7th EAP, priority objectives no.3 and 9.
[30] https://publications.europa.eu/en/publication-detail/-/publication/e636b772-1164-4a91-b024-069000bf5626/language-en

Information on chemical substances and their risks

- Lack of consideration of the combination effect of exposure to multiple chemicals, both in chemical risk assessment and horizontally across legislation;
- Gaps in the assessment of environmental impacts for medicinal products;
- Adaptation of risk assessment tools to the special case of nanomaterials needed;
- Low public recognition and understanding of the new CLP hazard symbols, which calls for targeted awareness raising activities.

Chemicals in articles and the Circular Economy

- Lack of transparency concerning research on chemicals;
- Need to significantly decouple production of hazardous chemicals in the EU from overall chemicals production;
- Low awareness of the Eco-label and low overall penetration of the Eco-Label in products and EMAS in activities of companies/governments/other actors.

Vulnerable populations

- Need for further action to protect children from chemicals in products, i.e. heavy metals in toys, textiles including a review of potential risks associated with nanomaterials in products;
- Failure to address the critical window of exposure of pregnant women to reprotoxic substances prior to a declaration of pregnancy;
- Need to revise EU-wide occupational exposure limit values (OELs) on lead, under the Chemical Agents Directive, and to clarify the relationship between OELs and Derived No-Effect Levels (DNELs);
- Gaps in addressing the specific risks to workers from exposure to EDCs and to nanomaterials.

Early warning systems and very persistent substances

- Lack of data on trends in occupational health and disease at EU level to inform policy making;
- Need for more comprehensive and detailed compilation of comparable monitoring data at the EU level;
- Lack of databases on hazardous waste, contaminated sites and the health risks thereof;
- Need for a common information system.

The last two suggestions were in relation to the implementation of the Stockholm Convention and Aarhus Protocol on persistent organic pollutants (POPs), but they are also relevant for other international obligations and to address many of the gaps identified in the sub-studies. And, last but not least, the report finds that even though the precautionary principle is enshrined in EU legislation and influences the design of legislation on chemicals, its application has been compromised by strong vested interests in the EU.

7.1.2 Chemicals under the 7th Environment Action Programme

The sound management of chemical risks is relevant to at least five of the nine high-level objectives of the 7th EAP:

- To safeguard the Union's citizens from environment-related pressures and risks to health and well-being.
- To protect, conserve and enhance the Union's natural capital.
- To turn the Union into a resource-efficient, green and competitive low-carbon economy.
- To improve the knowledge and evidence base for Union environment policy.
- To improve environmental integration and policy coherence.

The non-toxic environment is discussed in paragraph 54 under Priority objective 3 of the 7th EAP: "*To safeguard the Union's citizens from environment-related pressures and risks to health and well-being*". However, toxics-related topics are also mentioned in other places. The box below lists the various mentions of toxics and toxics-related topics. Since the same or similar topics are mentioned in several places, a topic may have more than one reference.

Chemicals-related topics mentioned in the 7th EAP	
Non-toxic material cycles	Par. 40, 43(viii), 54
Continued development of chemicals legislation: REACH, CLP, biocide and PPP regulations (combination effects, nanomaterial, endocrine disruptors)	Par. 50
Expanding the candidate list of REACH	Par. 50
Global goal (WSSD 2020 Chemicals Goal, Rio +20, SAICM)	Par. 50, 100
Hazard based criteria for endocrine disruptors – all relevant legislation	Par. 50, 54(d)
Comprehensive approach to minimising exposure of hazardous substances – chemicals in products	Par. 50, 54(d)
Nanomaterials and similar particles – definition	Par. 50
Risks to particularly children associated with use of hazardous substances incl. substances in products assessed and minimised	Par. 54(d)
Continuing to implement REACH	Par. 54(iv)
Developing by 2018 a union strategy for a non-toxic environment: ■ Innovation and development of sustainable substitutes, ■ Nanomaterials; ■ Endocrine disruptors; ■ Combination effects; ■ Chemicals in products including i.e. imported ■ Non-toxic material cycles, ■ Reducing indoor exposure to harmful substances	Par. 54(iv)
Filling knowledge gaps, accelerating decision making and enable development of chemicals-related acquis regarding relating to EDCs, combination effects, chemicals in products and nanomaterials	Par. 71.3
Considering a Union-wide database on nanomaterials	Par. 71.3
Human bio-monitoring regarding exposure and pollutants, in particular relevant for sensitive population groups, e.g. children	Par. 71.3
In order to develop a comprehensive approach to minimising exposure of vulnerable groups (children, pregnant women…), a chemical exposure and toxicity knowledge base will be established. This, together with development of guidance documentation on test methods and risk assessment methodologies accelerate efficient and appropriate decision-making, which is conducive to innovation and the development of sustainable substitutes including non-chemical solutions	Par. 71.4
Developing a comprehensive chemical exposure and toxicity knowledge base which draws on data generated without animal testing where possible. Continuing the Union's coordinated approach to human and environmental biomonitoring including, where appropriate, standardisation of research protocols and assessment criteria;	Par. 73 (iv)
Global goals (WSSD 2020 Chemicals Goal, Rio +20, SAICM)	Par.100

A number of these topics are already being addressed in other EU initiatives, e.g., the Commission proposal for the criteria to identify endocrine disruptors and the 2012 Communication from the Commission on Combination Effects of Chemicals[31]. The importance of continuing to implement REACH is also stressed by the 7th EAP. Finally, paragraph 54 recognises several additional areas of legislation and policy relevant to "*long term actions with a view to reaching the objective of a non-toxic environment*" important for safeguarding citizens from environment-related pressures and risks

[31] http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:52012DC0252.

to health and well-being, including indoor and outdoor air pollution; safe drinking and bathing water; the use of plant protection products; nanomaterials; and climate change.
By linking these areas with the goal of the non-toxic environment, the 7th EAP highlights the need for horizontal actions that take into account the interactions present between the many different issues and areas of legislation involved, e.g., ambient air quality, water quality, pesticides, biocides, waste management, and product standards such as for food contact materials. Each of these areas, and the associated environmental and health risks, will need to be part of an integrated and coherent framework for managing chemical pollution.

7.1.3 The objective of a non-toxic environment

The term 'non-toxic environment' has not been defined in the 7th EAP. However, 'environment' should be considered in its broadest terms to include the natural environment, as well as the human, hence including the 'technosphere', i.e. workplaces, indoor environments, cities etc.

A non-toxic environment should be understood as an environment that is free of chemical pollution and of exposures to hazardous chemicals at levels that are harmful to human health and to the environment. This target would take into consideration the need to provide vulnerable groups with as much protection as possible, to take account of potential delays between exposure and disease expression, to prevent accumulations of very persistent substances, and to ensure the quality of the material flows foreseen as part of the Circular Economy.

With these points in mind, the project team has focused on identifying gaps and deficits in the current EU policy for protecting humans and the environment from risks due to chemical exposure, and on possible responses that could form building blocks for a strategy for a non-toxic environment.

7.2 GAPS AND DEFICITS IDENTIFIED IN THE SEVEN SUB-TOPICS

7.2.1 Introduction

On the basis of the 7th EAP, the Commission identified seven areas crucial for the development of the strategy for a non-toxic environment. These are:

a. Substitution, including grouping of chemicals and measures to support substitution;
b. Chemicals in products articles and non-toxic material cycles;
c. The improved protection of children and vulnerable groups from harmful exposure to chemicals;
d. Sub-strategy for extremely persistent chemicals;
e. Policy means, innovation and competitiveness;
f. A programme on the development of new, non/less-toxic substances; and
g. The creation of a joint early warning system for approaching chemical threats to health and the environment.

The project team carried out sub-studies for each focus area to identify gaps and deficits proposed in the literature as well as during the two-day workshop held in Brussels in June 2016. This section prepared by RPA aims to provide a horizontal analysis of the gaps and deficits identified across the focus areas so as to categorise and harmonise the findings.

A first step has been the identification of common categories across the gaps and deficits identified. The analysis allowed defining the following broad categories:

1. Information on hazard, risk and fate of the substance at different stages of the product life cycle;

2. Information on uses/applications of substances and potential alternatives;
3. Analytical tools;
4. Communication and awareness;
5. Resources, guidance and training;
6. Functioning of the market;
7. Functioning of the legislation; and
8. Enforcement.

Tables listing the identified gaps and deficits per sub-study categorised by broad category (Table A) and the identified responses by broad category (Table B) are presented in the annex to this report.

The second step has been the identification of the most problematic areas within each sub-study area:

- For sub-study a (substitution and grouping), sub-study b (chemicals in products and non-toxic circles) and sub-study d (very persistent chemicals): gaps and deficits in the current legislation are the most discussed by literature and by stakeholders.
- For sub-study d, gaps in information on hazard, risk and product life-cycle and deficits in analytical tools have also been frequently indicated.
- For sub-study f (development of new, non/less toxic substances) and sub-study g (early warning system), gaps in communication and awareness and deficits in the provision of resources, guidance and training are the most frequent in the problem discussion.

The analysis also allowed highlighting those broad categories of gaps and deficits that raise less concern within each focus area.

Furthermore, the analysis enabled to identify those broad categories of gaps and deficits that are more common across the different focus areas (horizontal analysis). The aspects that were most discussed across the sub-studies were:

- Deficits in the functioning of the legislation
- Gaps in information on hazard, risk and product life cycle.

It should be noted that the legislation is often considered by stakeholders as the most effective way to require the generation and communication of the information missing. Resources, guidance and training (other category of deficits very common across focus areas) can then be offered to support and improve the functioning of the legislation.

The figure below presents the frequency of gaps and deficits by broad category per sub-study. The colours indicate the level of frequency, blue indicating the lowest, red the highest frequency. Frequency is calculated dividing the number of gaps and deficits in each category by the total number of gaps and deficits per each sub-study. Because some of the identified gaps ticked more than one category the percentages for each sub-study's row do not add up to 100%.

Table 1: Frequency of gaps and deficits by broad category in each sub-study

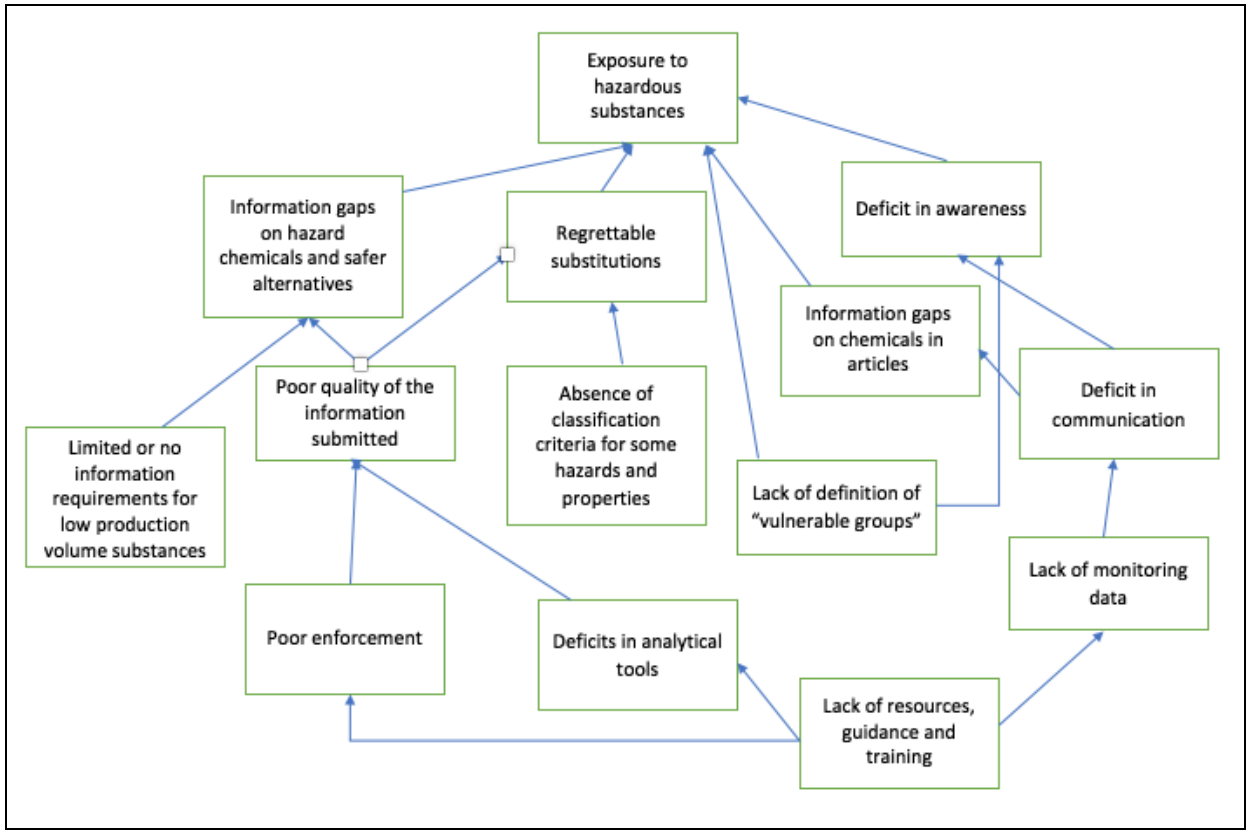
	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	13%	7%	7%	13%	7%	0%	60%	7%
Sub-study b: Chemicals in products	33%	29%	19%	24%	24%	14%	67%	10%

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
(articles) and non-toxic material cycles								
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	41%	0%	0%	22%	4%	0%	33%	0%
Sub-study d: Sub-strategy for very persistent chemicals	56%	48%	52%	12%	16%	12%	64%	4%
Sub-study e: Policy means, innovation and competitiveness	13%	13%	0%	13%	38%	0%	50%	0%
Sub-study f: Programme on new, non-/less toxic substances	13%	13%	0%	73%	60%	20%	13%	0%
Sub-study g: Early warning systems for examining chemical threats to human health and the environment	22%	22%	33%	33%	56%	0%	33%	0%

The third step has been to check the identified responses against the broad categories of gaps and deficits defined, in order to verify whether the range of measures proposed in the literature and by stakeholders during the workshop cover all issues highlighted per sub-study area and to enable the project team to identify potential synergies between the identified responses across the sub-study areas. This step is discussed further in section 7.3 below.

All the gaps and deficits identified are interrelated, confounding each other, ultimately contributing to the ongoing exposure to hazardous chemicals. The figure below presents the "gaps and deficits tree", showing the hierarchical relations among them.

Figure 7: Gaps and deficits tree



The following subsections presents the gaps and deficits identified by broad category.

7.2.2 Information on hazard, risk and fate of the substance at different stages of the product life cycle

All sub-studies have identified gaps in the information on hazard, risk and fate of the substance at different stages of the product life cycle. These gaps result from:

- Insufficient legislative requirements (further discussed in Section 7.2.8);
- Poor compliance with the legislation (further discussed in Section 7.2.9);
- Insufficient resourcing and guidance (further discussed in Section 7.2.6); and
- Inadequate analytical tools to generate the information in the first place (further discussed in Section 7.2.4).

With the entry into force of the REACH Regulation, manufacturers and importers have been required to generate and submit physicochemical and (eco)toxicological information of the substances put on the EU market. Information requirements have been differentiated according to the quantities introduced on the market and, therefore, substances which are manufactured or imported in low quantities have no or limited information requirements. The quality of the information submitted so far has been found to be poorer than expected and around two thirds of the registration dossiers have never been updated with new information. Hazard prediction methods alternative to in vivo testing (QSARs, read across) are not sufficiently developed or have been misused by registrants.

The scope of the REACH Regulation does not adequately cover nanomaterials and the lack of classification criteria for some hazards and properties of substances (endocrine disrupting properties, neuro-toxicological effects, PBT/vPvB properties) in the CLP Regulation and the lack of a definition for extremely persistent chemicals hampers the functioning of the chemical legislative framework.

Moreover, persistence is regulated only if bioaccumulability is also present[32] and there is no common framework for a comprehensive screening of substances for persistence.

The information gaps on chemicals in articles (discussed in Section 7.2.3) mean that the legislation does not consider sufficiently the aggregated and multiple exposures to chemicals contained and leaking from articles during the product life cycle and the waste stage, resulting in partial risk assessment and management procedures. The assessment methodologies are still not able to fully capture and measure the combination effects of chemical mixtures and the environmentally induced epigenetic toxicity.

The effects of bioaccumulation of chemicals over long periods are poorly understood and adult onset effects triggered by early life exposures may go undetected. This is of particular concern with regard to vulnerable populations, whose exposure levels may differ significantly from the typical exposure patterns assumed in current risk methodologies. Human biomonitoring (HBM) can be carried out for a limited number of chemicals and can only indirectly support the identification of exposure sources. At the moment, only few EU countries have implemented HBM programmes for monitoring chemical exposure of different groups of the population over time.

Finally, information on the scale of the effects of chemicals on biodiversity and ecosystem services is missing.

7.2.3 Information on uses/applications of substances and potential alternatives

Information gaps on the applications of hazardous substances and on potential safer alternatives derive from:

- Deficits in the information on hazardous properties of the substances (discussed in the previous subsection);
- Inadequate analytical tools to generate the information in the first place (further discussed in the following subsection);
- Deficits in communication and thus awareness on hazards and risks of chemical substances (further discussed in Section 7.2.5);
- Insufficient legislative requirements (further discussed in Section 7.2.8); and
- Poor enforcement of the legislation (further discussed in Section 7.2.9).

In addition to establishing rules for chemical substances and mixtures, REACH also addresses the use of chemicals in articles by setting out requirements for registration and notification of substances in articles, as well as communication requirements for certain substances to the supply chain (Article 33) and consumers (Article 33(2)). Moreover, hazardous substances may be subject to a ban or to certain restrictions regarding their presence in articles, established in REACH or relevant product-specific legislation (e.g. electrical and electronic equipment and cars), restrictions triggered by considerations on recyclability and minimisation of exposure. Under the framework of the Strategic Approach to International Chemicals Management (SAICM), chemicals in products have been identified as a priority policy issue, and the aim has been set to improve the exchange of information on chemicals contained in products and to propose cooperative actions to address gaps in the current levels of information access. To this end, SAICM has set up a "Chemicals in products" programme, which aims at developing practical solutions for information transfer on the presence of chemicals in products for the priority product categories of electronics, toys, building products and textiles.

However, ensuring compliance to these various requirements by obtaining and managing information

[32] With the only exception of the Detergents Regulation, which requires surfactants used in detergents to meet biodegradability standards.

on the presence (and absence) of hazardous substances in articles poses a considerable logistical challenge for actors in the supply chain, especially in the case of complex products made from a multitude of materials and components. In the case of articles, there is no legally prescribed format for the provision of the required information (as e.g. the safety data sheet used for substances and mixtures) and guidance and tools for the chemical safety assessment of articles during their use lives and during the waste stage are not sufficiently developed. Importers of articles produced outside the EU report problems of obtaining the relevant information from their suppliers, in particular in the case of complex supply chains. A multitude of tools and systems to trace substances in articles and handle the information flow along supply chains have been developed by companies, industry sector associations, authorities and international bodies in order to comply with the various requirements under different EU and international legislations, but the systematic use of these tools is still limited to pro-active actors and not widespread across different supply chains. Enforcement of the existing legislative requirements is not harmonized across the European Union and not sufficient to ensure a level playing field between compliant and non-compliant actors. Consumers do not have systematic access to information on toxic substances in articles and thus cannot exercise optimal purchasing decisions.

Public databases of substances searchable by technical functionalities in materials and articles that would enable an easy comparison of the characteristics (including the (eco)toxicological properties) of the chemicals are missing. In particular, this would be of value for very persistent substances, for which information on their uses is lacking, therefore hampering any regulatory effort or substitution initiative.

7.2.4 Analytical tools

Deficits in analytical tools derive from:

- Information gaps on hazard, risk, fate and applications of chemical substances (discussed in the previous two subsections); and
- Insufficient resources, guidance and training (further discussed in Section 7.2.6).

One important factor in the regulation of chemicals is the availability of methods to identify and assess the hazardous properties of chemical substances. To ensure that test methods are internationally and mutually accepted, a test guideline development programme (TGP) has been established under the auspices of the OECD. Despite the progress achieved on the development and validation of test guidelines, there are still some gaps and weaknesses in the current test methods, in particular on:

- The effects of endocrine disruptors (additional hormonal pathways, animal models, assessment of later life stage effects induced by exposure during foetal or pubertal development, appropriate tests for environmental species);
- Chemical exposure from article service life and waste stage, failing to acknowledge cumulative and multiple exposure to chemicals (in particular of very persistent chemicals);
- Combination effects of chemical mixtures and environmentally induced epigenetic toxicity;
- Expensive, time consuming and in some cases/for some categories of chemicals unreliable or insufficient tests on persistence of chemicals (measurement of the half-lives of substances in different environmental compartments).

A recent review of the food contact materials regulation carried out by the JRC has also found a lack of methods to review and follow up on enforcement and compliance, which makes it difficult to demonstrate that national laws ensure safety[33].

[33] https://ec.europa.eu/jrc/en/publication/eur-scientific-and-technical-research-reports/non-harmonised-food-contact-materials-eu-regulatory-and-market-situation-baseline-study.

Additional efforts are also required in further developing biological measures of body burden of chemicals. Human biomonitoring is the most reliable indicator of actual human exposure (WHO, 2000), but biomonitoring survey are resource-intensive and expensive. Moreover, only a limited number of chemicals can currently be assessed by biomonitoring[34] and comparability of data from different laboratories and years is problematic. There are also issues in the interpretation of such data, due to the limited availability of epidemiological data and differences and changes in dietary habits across the EU, which can have a higher influence than legislation on exposures than changes in the concentration of specific chemicals in human tissues. The European Human Biomonitoring Initiative (HBM4EU), launched in December 2016, is a joint effort of 26 countries and the European Commission aimed at providing better evidence of the actual exposure of citizens across Europe and any associated health effects[35].

7.2.5 Communication and awareness

Deficits in communication and awareness derive from:

- Information gaps on hazard, risk, fate and applications of chemical substances (discussed in Sections 7.2.2 and 7.2.3);
- Insufficient legislative requirements (further discussed in Section 7.2.8); and
- Poor compliance with the legislation (further discussed in Section 7.2.9).

Article 33 of the REACH Regulation establishes rules for articles containing Substances of Very High Concern (SVHCs) in a concentration above 0.1% (weight by weight). Firstly, suppliers of such articles need to provide the recipient (i.e. industrial or professional users or distributors, but not consumers) with sufficient information to allow safe use of the article. This is specified to include, as a minimum, the name of the substance. For consumers, Article 33(2) establishes the possibility to request similar information from a supplier of an article. This information has to be provided free of charge within 45 days of receipt of the request.

The use of company- or sector-specific restricted substance lists (RSL) is widespread particularly in the areas of textile and footwear, electric and electronic equipment and construction products. In the automotive sector, a Global Automotive Declarable Substance List has been developed. These approaches essentially rely on obtaining suppliers' commitment to either guarantee the absence of certain substances in the goods they supply, or, if the use of regulated substances is unavoidable, to provide information on their use and presence. In addition, information systems have been set up which facilitate the exchange of information between suppliers and customers on chemical content, often specific for a certain sector to ensure sufficient participation. Examples for such systems are e.g. the car industry's International Material Data System, the Bomcheck or Octopus databases, or the Japanese JAMP and ChemSherpa systems, mainly focused on electronics. Other systems are designed to provide information on chemicals typically contained in specific materials. Moreover, authorities and NGOs have devised solutions that assist consumers in requesting information on the presence of SVHCs in articles.

Despite these efforts, there remains the need for an improved flow of information, so that the actors in the waste sector receive adequate information on the presence of hazardous chemicals in articles, allowing better risk assessment and management strategies. Enhanced communication would also contribute in raising awareness of chemical exposure and its potential effects. This is critical for

[34] Around 200 chemical substances. Source: "German experiences with human biomonitoring, its impacts on policy and future perspectives", presentation by Marike Kolossa (Umweltbundesamt) during the conference "From HBM to policy" held in Brussels in October 2010. Available at: http://www.lne.be/en/environment-and-health/humanbiomonitoring-conference/kolossa-gehring.

[35] https://www.hbm4eu.eu/.

ensuring better protection of vulnerable populations, and would ultimately increase market pressure for substitution of hazardous substances with safer chemical or non-chemical alternatives.

Another challenge is presented by the current university system of educating chemists and chemical engineers, which tends to focus on the development of new chemicals to meet certain functional purposes, with insufficient attention to possible downstream impacts due to toxicity or persistence. This contributes to the lack of awareness among company product managers of the opportunities offered by green chemistry. There is also a lack of understanding and communication between researchers of different fields, in particular chemists and toxicologists.

There is also a lack of networking opportunities for actors interested in substituting hazardous chemicals and providers of safer chemical or non-chemical alternatives.

Finally, despite the increasing research on new and emerging risks and the existence of systems such as RAPEX, a centralised system that links all focus areas (food, consumer products, acute poisoning incidences, ecosystems, etc.) and rapidly exchanges information between the relevant actors is missing. Also, once an emerging risk has been identified, there is a lack of communication concerning the applicable risk management measures.

7.2.6 Resources, guidance and training

Deficits in guidance and training are closely related with the progress in developing analytical tools to generate information on the characteristics of the substances and to better assess and manage the risks (discussed in Section 6.2.4) and with gaps in communication and awareness (discussed in the previous subsection). In particular, guidance and training on the following methods and tools should be scaled up and improved:

- Hazard prediction methods alternative to testing and weight of evidence approaches for hazard screening;
- Tools for the chemical safety assessment of articles;
- Guidance on risk assessment of nanomaterials;
- Best Available Techniques guidance documents for industrial activities with control measures for very persistent substances.

More in general, there is a lack of university programmes on green chemistry and the development of non/less toxic chemicals, as well as training of company product managers on the opportunities related to such development. Academia curricula on chemistry should be strengthened with more courses on the (eco)toxicological aspects of chemical substances.

In terms of resources, a better prioritisation and more harmonisation of initiatives at European, national and local levels would greatly benefit the development and the industrial scale up of clean technologies and green chemistry.

7.2.7 Functioning of the market

Market failures are closely linked to information gaps (Sections 7.2.2 and 7.2.3), deficits in communication and awareness (Section 7.2.5), lack of resources, guidance and training (previous subsection), legislative gaps (following subsection) and poor enforcement (further discussed in Section 7.2.9).

Partial or missing information on the properties of chemical substances in different applications (because of the lack of the information or because of deficits in communication) is a major cause of the malfunction of the market, as different actors (chemical manufacturers and importers, formulators, manufacturers of articles, regulators, consumers) cannot make optimal choices. Markets may fail to

incentivise merit goods (safer alternatives), to form (markets for safer alternatives) or to control de-merit goods (hazardous substances), resulting in the failed internalisation of negative externalities by the market actors (e.g. price of articles containing hazardous substances failing to incorporate the cost of managing risks during the product waste stage).

The EU chemical legislative framework was implemented to generate the necessary information to make optimal choices, but partial legislative information requirements (not covering low production volume substances and some relevant health and environment end-points such as endocrine disrupting properties and persistence), the poor quality of the information submitted and the lack of enforcement are hampering the functioning of the market.

While some EU Member States resort to market instruments to address the market failures linked to the production and use of hazardous substances (e.g. Nordic countries applying taxes to the use of pesticides), the use of economic incentives should be encouraged and promoted at European level.

7.2.8 Functioning of the legislation

Stakeholders have identified legislative gaps that need to be addressed in order to solve many of the issues identified. Some of the legislative gaps have already been discussed in the previous subsections (partial information requirements in Sections 7.2.2 and 7.2.3, communication duties in Section 7.2.5).

REACH authorisation generally does not cover imported articles: although ECHA must consider if the use of the substance in articles poses a risk and if so, prepare a dossier which conforms to the requirement of an Annex XV dossier for restriction (Article 69(2)), some stakeholders suggest that the lack of an automatic restriction on imported articles containing Annex XIV substances may result in a potential competitive disadvantage for the companies opting for substitution. Moreover, if a substance is used only as a process chemical or otherwise is not present in the end product, there will be no impact for imported articles but EU manufacturers have to substitute where non-EU manufacturers don't, possibly leading to competitive disadvantage.

The current legislative practice may encourage incremental rather than fundamental change of chemical structure of the potential alternatives, resulting in these exhibiting the similar hazard profiles of the substances substituted (regrettable substitution). Some industry stakeholders noted that, once a substance comes under regulatory scrutiny, the time allowed for finding/developing and switching to suitable alternatives may not be adequate, resulting in regrettable substitutions or in second best solutions (such as minimizing occupational exposure but neglecting environmental fate at the end of life stage). Moreover, once an alternative is developed, where product approval by authorities is necessary (e.g. in aerospace or medical devices), this process can excessively prolong the product time to market.

Moreover, the imperfect synergies between the different chemical legislative acts may result in a limited or inefficient internalization of human health and environmental costs by the chemical or product manufacturers. For example, chemicals regulated by both the REACH Regulation and the Water Framework Directive may leak from products during their life cycle or during the waste stage. However, the costs to clean up such pollution is borne by the wastewater treatment companies and drinking water suppliers and, ultimately, by the citizens rather than the polluter.

Finally, attention to specific windows of vulnerability (e.g. neonates, infants, toddlers and adolescents) in the EU chemical legislation is sometimes missing, especially in those pieces of legislation such as the Drinking Water Directive that are of particular relevance to ensure the protection of certain vulnerable populations from chemical exposure.

7.2.9 Enforcement

Gaps and deficits in the enforcement of the chemical legislative framework have been discussed in Section 5.1.6. Poor enforcement affects all other broad categories of gaps and deficits identified, failing to ensure the generation and communication of information and a level playing field for the actors across the EU market, which currently have different levels of access to information and economic incentives.

7.3 IDENTIFIED RESPONSES TO GAPS AND DEFICITS (BUILDING BLOCKS FOR THE NTE STRATEGY)

7.3.1 Introduction

After identifying the most significant gaps and deficits in the current situation, each sub-study concludes with lists of identified responses to those gaps and deficits. These responses were identified in part through the literature reviews carried out for each sub-study, and in part by stakeholders at the June 2016 workshop in Brussels, with the overall objective in mind of reducing human and environmental exposures to hazardous chemicals to the lowest level possible. The responses can be viewed as potential building blocks for the strategy for the non-toxic environment (NTE).

This section aims to provide a horizontal analysis of the responses identified across the focus areas. It has been prepared by Milieu, with contributions from RPA. The table below presents the frequency of identified responses to various gaps and deficits by broad category per sub-study. Again, the colours indicate the level of frequency, blue indicating the lowest, red the highest frequency. Frequency is calculated by dividing the number of responses identified in each category of gaps and deficits, by the total number of responses per each sub-study. Because some of the identified responses ticked more than one broad category the percentages for each sub-study's row do not add up to 100%.

Table 2: Frequency of identified responses by broad category in each sub-study

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	3%	13%	13%	23%	30%	23%	23%	7%
Sub-study b: Chemicals in products (articles) and non-toxic material cycles	46%	33%	6%	44%	42%	29%	58%	15%
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	17%	0%	17%	24%	0%	0%	38%	3%
Sub-study d: Sub-strategy for very persistent chemicals	46%	37%	46%	24%	24%	17%	63%	12%
Sub-study e: Policy means, innovation and competitiveness	9%	12%	6%	18%	12%	21%	29%	6%
Sub-study f: Programme on new, non-/less toxic substances	10%	20%	10%	50%	60%	30%	40%	0%
Sub-study g: Early warning systems for examining chemical	21%	16%	63%	26%	11%	5%	5%	0%

	1. Information on hazard, risk, life cycle	2. Information on uses and alternatives	3. Analytical tools	4. Communication and awareness	5. Resources, guidance and training	6. Functioning of the market	7. Functioning of the legislation	8. Enforcement
threats to human health and the environment								

The table is based on Table B in the annex to this report, which lists the identified responses by sub-study and shows which gaps and deficits are addressed by each. The following subsections analyse the identified responses and discuss where synergies may be found. Note that parentheses are used to indicate the sub-study and the number of the suggested improvement responses identified, as referred to in Table B in the annex. Further details can then be found in the particular sub-study.

7.3.2 Information on hazard, risk, life cycle

Almost all of the sub-studies suggested practical responses to address gaps with respect to the information base on substance-based hazards, risks and risk assessment. The responses identified related to:

- Filling data gaps concerning substances and any related hazards
- Improvements in risk assessment methodologies
- More systematic monitoring and centralised data collection

Some gaps in data could be addressed by facilitating grouping of similar chemicals by structure (a.27, d.11). Several sub-studies suggested requiring more data, in particular for low volume substances (a.01, b.05, d.08, e.01). Other suggestions focused on speeding up identification of SVHCs by setting priorities for which SVHCs are really important because of hazard and exposure patterns (b.19), agreeing new properties such as mobility for determining which substances might be of equivalent concern under Article 57(f) (b.06), and automatic simulation testing requirements for persistence if initial dossier screening indicates that a substance may be very persistent (d.09). Inclusion of new hazard categories in the CLP Regulation, e.g. EDCs, (developmental) neurotoxins and PBT/vPvB, was also viewed as important (b.4). Several of these suggestions would require new legislation, and – in the case of CLP -- work at international level in order to ensure harmonisation with the GHS.

With respect to risk assessment of chemical substances, several sub-studies stressed the importance of requiring assessment of the impacts of multiple, compound and cumulative (aggregated) exposures (b.11, c.10, c.11, d.5, d.7). This might require additional research on the (synergistic) health and environmental effects of continuous, low-level chemical stress (b.12). Other suggestions in this vein included taking a life cycle approach towards assessing risk from chemical substances, which might require support for further research into chemical product life cycles (e.17), and accounting for health and environmental risks due to exposures to hazardous chemicals in house dust (c.22), substances in materials used in products such as food contact materials and personal care items (c.20, c.21) and during the waste stage (b. 03, b.15, b.47).

Policy instruments to use to achieve this included enforcement of existing requirements, such as ensuring that the chemical safety assessments in registration dossiers included quality information with respect to articles and waste streams. In order to facilitate a comprehensive early warning system, it was also suggested to modify or extend existing exposure and risk assessment procedures by incorporating additional and more specific toxicological end-points, in order to trace adverse effects in a timely manner (g.07).

More systematic monitoring was also viewed as critical, and as part of any effort to establish an operative early warning system. Monitoring with respect to very persistent substances was urged, in order to track the presence of vPs in products, waste streams, humans and other biota, as well as any accumulations in environmental media and humans (d.34). A practical suggestion to facilitate such monitoring was to require producers to deliver validated analytical/detection methods for the chemicals they place on the market, along with technical chemical standards and information on all transformation products, as per pesticides/pharmaceuticals (d.10, e.37), and to design sampling and monitoring programs to look for contamination of natural resources where point sources of discharges have been identified, e.g., PFAS around all airfields (d.36).

Finally, centralised (EU-level) data collection of exposure and hazard information (g.09) was suggested, including on quantities of vP substances produced and used, in order to determine overall loads of vPs in the environment (d.16).

7.3.3 Information on uses and alternatives

One of the puzzles in moving towards reduced exposure to toxic chemicals and the safe materials streams necessary for a viable Circular Economy is to address the current lack of knowledge about which chemicals are used in products and articles, especially imported articles. This gap, as well as a deficit in information on alternatives to support substitution efforts, was viewed as important to overcome as part of an overall strategy. Suggested responses could be grouped as follows:

- Horizontal legislation on toxic substances in articles
- Tools for tracking substances in articles
- Databases on substances in articles, including alternatives
- Quality standards for material flows
- Support for substitution and design of alternatives

Again, a life cycle approach was urged with respect to risks from chemicals used in products (b.01, a.16), including funding of research in this area. One suggestion was to enact some type of horizontal, life cycle based legislation on toxic substances in articles, including provisions regarding content of any toxics in articles and material cycles, and how to communicate that information (b.02). In view of the goal of a Circular Economy, this would need to ensure that risks from 'multiple loops' would be considered in risk assessment and management (b.48), and could include an extended producer responsibility approach. To help close the loops, it was advised to change REACH Art. 2.7d so that recyclers placing materials on the market would be required to register and assess any uses not covered by the main registration (b.35). This might require development of more specific REACH use descriptors (b.10).

Development of tools to track hazardous chemicals in articles was proposed (a.13, e.15), through to end-of-product-life material waste streams (b.46). These could include labelling of products where substances such as vPs were present, together with traceability to prevent passing on accumulations of vP chemicals via materials recycling (d.26), material declaration requirements for toxic substances in materials along the supply chain (b.27), and an obligation to declare content (in concentration ranges/intervals) of all classified substances if exceeding 100 ppm for all consumer products (b.30). Suggestions for addressing knowledge gaps at the end-of-life product stage included revision of the EU rules for classification of waste as hazardous to harmonise with the CLP (b.46) and development of approaches for a better application of information about product composition in waste management (e.g. automatic readable/sensing coding, for use in the daily practice of waste treatment) (b.44).

Databases on substances in materials and/or articles, based either on reporting obligations or published data, were suggested as important tools (b.9) for managing reductions in exposures to toxins. To support substitution efforts, these databases could be enhanced with information on alternatives (a.14, e.16), including non-chemical and low-toxic options. Specific database-related proposals aimed at the

problem of very persistent (vP) substances included to establish central registries of products containing vP substances, along with annual statistical data of the volumes of vP substances produced, used and emitted (d.27), and inventories of all vPs produced, used in products and/or released as emissions or waste, in order to understand overall loads of vPs in the environment (d.38).

Quality standards for the content of toxic substances in materials (virgin and recycled) (b.25) were seen as important for ensuring the quality of material flows. Such standards would have to balance the performance of certain substances such as vPs, against the health and environmental risks of the substance (d.29). They might also be used to enhance depollution via e.g. specific requirements for additional waste streams (b.47), and to set safety limits for use of secondary raw materials in specific articles (b.39). How this could relate to the implementation of end-of-waste criteria (b.25) would need to be defined.

In addition to signalling toxics content, it was also viewed as important to provide positive support for substitution and design of alternatives, including funding (a.25, d.33, e.26), in particular for SMEs. Expanding the scope of the Ecodesign Directive to any article and developing implement guidance and methods to define substance related eco-design criteria for specific product groups (b.23) was suggested. To enhance take-up by product designers and manufacturers, opportunities identified included campaigns to raise awareness on the benefits of – and to stimulate market demand for - safer alternatives (e.18) and implementation of help desks to support substitution activities (b.26).

7.3.4 Analytical tools

The sub-studies identified a number of opportunities for the development or strengthening of analytical tools. Upstream of the data analysis, all sub-studies underlined the need for improved screening tools on hazards, exposure and life cycle impacts of chemicals or articles (a.26, b.07, b.13, c.12, d.35, e.27, f.10, g.08). Hazard screening tools should be developed that help to identify and assess EDCs (c.17), nanoparticles (c.18), persistent chemicals (d.2, d.4), mobile substances (d.35), and chemicals with insufficient evidence of risks (g.03). Exposure screening tools are needed that take into account results from human biomonitoring (c.16) and that consider aspects such as age, consumption patterns, behavioural characteristics, geographical location, lifestyle factors and cultural differences (c.12). Life cycle impacts screening tools would be helpful to assess the consequences of the persistent characteristics of chemicals (d.2, d.4), for linking waste stages to article categories (b.14) and for developing standardised test methods for recycling materials (b.45).

Tools that can combine screening results of these tools were also called for (a.26, e.27, d.3). Such tools were in particular seen as essential contributions to the design of early warning systems capable of detecting, strengthening and acting upon signals (g.01, g.04, g.06, g.08). For example, they were seen as important for bridging the silos of different focus areas, i.e. environment, consumers and workers either by creating a common tool or by enabling information-sharing between different platforms (g.18). Such data analytical tools would benefit from requiring the input of experts in environmental epidemiology, ecology and nature conservation in order to improve the assessment of causality between exposure and impacts of chemicals (g.19).

The development of these analytic tools we seen as dependent on various information-based instruments as well as on support for capacity building. They would in turn accelerate and facilitate the processes of data gathering and analysis.

7.3.5 Communication and awareness

The sub-studies identified over 30 opportunities to respond to current gaps in communication towards and awareness among the industry, the public and policy-makers. The opportunities can be divided in four main categories:

- the development of communication and awareness raising tools;
- the development of strategies to raise awareness on certain points;
- the promotion of dialogue among stakeholder groups; and
- the establishment of platforms that facilitate the exchange of information among relevant stakeholders.

In the first category, four tools were called for: (i) a comprehensive, longitudinal databank including harmonised environment and health indicators, based on human biomonitoring data collected during all life stages (c.15); (ii) an EU substance-regulation navigator that includes implemented and upcoming international and national legislation by substance/application (a.12, e.14); (iii) tools such as the chemical footprint project[36] or ecolabel awards (a.29, b.38, e.33); and (iv) a database and map viewer that cover all contaminated natural resources in the EU (d.39).

Regarding the need to raise awareness and trigger dialogue, a distinction was made between two different audiences: industry and the general public. Depending on the audience, the interests and communication methods will be different. It was suggested to raise the awareness of industry on several issues: the identification of applications for which the use of certain chemical groups raise concerns that are higher than the benefits delivered (a.15); the existence and benefits of safer alternatives (a.17, f.01, f.05); opportunities for the development of new, non-toxic substances (f.05) and on the possibility for functional substitution (a.23, e.24, b.33); on the potential and content of circular economy business models (a.19, e.20); and finally on the content of products across the supply chain (c.27).

Topics where raising the awareness of the public (and policy-makers) were in particular suggested regarding the presence of hazardous substances (including persistent substances – d.25) in household products (c.23); the exposure of vulnerable groups such as women in child-bearing age, pregnant women, children (c.25), workers (c.28) and the elderly (c.29). A specific suggestion was to explore how to reduce chemicals in indoor environments where the elderly live and in kindergartens and schools where children spend a lot of their time, e.g., through better ventilation systems (c.24).

Platforms for facilitating information exchange on new and emerging chemicals (NERCs) (g.05) were seen as particularly important as part of developing an EU-wide early warning system. Key elements of an EWS methodology would be to establish a blue print for a communication plan and options to approach relevant stakeholders (g.12, g.17).

Dialogue should be promoted among actors that are part of the same supply-chain on the hazardous substances used (b.33, e.19), on the benefits and opportunities of developing new, non-toxic substances (f.05), and on NERCs (g.02). Such dialogues could take place and be supported by the establishment of platforms that link the work of scientist and industry on the development of new, non/less-toxic substances (f.07, g.02) and that connect scientist and regulators to ensure that the available information allows meaningful risk assessment and policy making (c.13). This would include collecting information from REACH CSAs on risks for the waste stage and identifying potential priority areas, exchanging information with the waste sector on (specific, article related) information needs, and identifying options to satisfy them (b.47).

Addressing such gaps requires two main types of policy responses: information-based instruments as well as support and capacity building measures. Such policy responses are dependent on the availability of information (see sections on information on hazards, risk, life cycle; information on uses and alternatives; analytical tools) and would hence be complemented by legal requirements on industry and public authorities to communicate information along the supply chain or towards the public (b.38, f.01).

[36] http://www.chemicalfootprint.org/

7.3.6 Resources, guidance and training

The responses in this category of gaps and deficits were quite specific to the respective topic of focus. Each sub-study called for support, capacity building, resources and legislation targeting specific needs, and few opportunities for synergy were found.

For example, sub-study a (substitution) suggested co-ordination of substitution initiatives across Member States around prioritised chemicals of concern (a.07), development of ECHA and Member State competent authorities capacity to support substitution (a.20, e.21), creation of an expert knowledge platform to support authorities and industry with substitution initiatives (a.22, e.23), and supply chain collaboration and engagement through, e.g. shared performance testing and evaluation and the creation of demonstration sites (a.18).

Sub-study b on chemicals in products and the Circular Economy proposed REACH guidance defining chemical product safety, e.g., with respect to environmental protection, including guidance and best practice examples to support implementation (b.37). It also suggested developing an overall approach for the management of waste decontamination based on life cycle thinking. This would need to include guidance concerning obligations for assessment of the waste stage in REACH CSAs and subsequent promotion and enforcement of the use of the ECHA guidance ('Chapter R.18'[37]) (b.14), and clarification of waste treatment priorities on decontamination and related decision criteria (b.41). Other suggestions included developing guidance documents on potential contaminations of secondary raw materials (b.40) and on the identification of substances recovered from wastes, including how to deal with "impurities" (b.36), reviewing existing technologies in order to identify best practices on e.g. molecular recycling of polymers (b.50), and sector-specific manufacturing best practices for articles (b.34).

According to sub-study d, the regulation of very persistent chemicals would require a revision of all BAT guidance documents to take account of all potential releases of vP substances to the environment, and to keep such releases to a minimum (d.18) as well as the establishment of a European infrastructure for the safe transport, disposal of and final destruction (e.g. high temperature incineration) of vP substances/products, at end of product life (d.32). Because very persistent substances are already accumulating in the environment, it suggested designing and implementing programmes for limiting further contamination and for prioritising clean-up – potentially backed-up by liability and redress mechanisms for funding the costs of clean-up (d.40). Such programmes would need to be further supported by the development of and knowledge sharing on remediation methodologies/ technology (d.41).

Sub-study f on a programme for the development of new, non- and less toxic substances called for the development of clear guidance on what is "non-toxic". Such guidance documents and other disseminating tools would allow R&D staff and the market actors to get clear signals on the goals of substance development and certainty about potential future regulatory priorities (f.02). In the same line of awareness and knowledge raising, scientific institutes and Member States agencies could provide education and training on (new), non/less-toxic substances to scientists, workers, company managers, engineers etc. in order to increase the competences and capacities of all relevant actors (f.06). To support all actors in the implementation of programmes on new, non- and less toxic substances, funding should be made available for the development of R&D programmes on the topic (f.08). As for existing research programmes on chemicals, these should systematically integrate the question of the development of non-toxic substances (f.09).

[37] ECHA Guidance on information requirements and chemical safety assessment, Chapter R.18: Exposure scenario building and environmental release estimation for waste life stage.

Related to these needs of developing skills, sub-study e on policy means suggested that overall further investment should be made in skills related to Key Enabling Technologies (KETs), a.o. through partnerships between industry and education providers (e.31).

Regarding ways of addressing current gaps towards the development of early warning systems (sub-study g), the development of data should be supported by Making expertise centres mandatory in every EU member state by means of legislation (g.10). Ultimately a centralised (EU) early warning system should be designed and established based on the different identified steps involved going from signalling through management of NERCs (g.11). A first step would be to design blue prints/options on how to organise an early warning system including estimated costs for the various options (g.14). The design of the early warning system should make it possible to align it with or connect to existing (consultative) structures and institutes as much as possible (g.11)

7.3.7 Functioning of the market

Some of the problems identified in the sections on state of play stem from market failures to incorporate the full costs of toxics or the lack of incentives for implementing alternatives. Several responses for addressing various gaps and deficits pointed to measures to help correct skewed marketplace forces.

Suggestions aimed at sending positive signals included rewarding or incentivising sustainable substitution (e.g. through VAT reduction) (a.09, e.11), reducing regulatory fees for non-toxic substances (f.04), and enhancing government green procurement programmes by favouring the functional substitution of hazardous chemicals (a.11, e.13). Improving access to markets through trade agreements to facilitate investment opportunities in sustainable low, toxic chemistry and substitution was also proposed (e.09, e.30), if care was taken to balance the rights of corporations with the protection of human health and the environment.

Ideas for internalising the external costs of using hazardous substances included promoting taxation of use of hazardous substances among member states (a.10, e.12, f.04) and establishing recycling fees for products requiring specific end-of-life treatment, including decontamination of toxic substances (b.43). It was suggested that parts of the fees could be allocated to setting up related enforcement activities (b.43). Another proposal was to consider cradle-to-grave producer responsibility for vP substances, from production to subsequent use phase, to collection and destruction at the end of the product's useful life (d.31).

Voluntary, self-regulatory measures were also considered potentially useful, including encouraging product designers, manufacturers and retailers to voluntarily reduce or eliminate the use of vP substances in products (d.24) and facilitating public-private investment partnerships for supporting research into safer alternatives and for the provision of technical support to SMEs, in particular on technical feasibility of alternatives (a.21, e.22).

7.3.8 Functioning of the legislation

Quite a few suggestions were focused on strengthening the current regulatory framework for chemical substances. Several proposals were put forward aimed at speeding up the identification of SVHCs (c.09, b.18), including by more use of REACH Article 57(f) possibility of naming additional substances such as vPs as giving rise to equivalent concern (d.01). Ideas for improving the operation of the REACH provisions on authorisation included increase authorities' capacities to handle applications and developing overarching principles for granting authorisations (b.18**)** and refusing authorisations for use of Annex XIV substances for which alternatives are available on the market (a.05, e.05). Imposing an automatic restriction on imported articles containing authorised substances (a.02, e.02) was proposed, as well as the possibility of defining a concentration limit for SVHC in

articles as a general requirement, with even lower limits for substances / articles of particular concern (b.22).

Suggestions relating to REACH's restriction provisions included introduction of options for quick inclusion or revision of substance restrictions upon new evidence in product legislation (b.24), extending the scope of REACH Article 68 to PBT/vPvB or EDCs in consumer products (b.20), and establishing [hazard-based] bans on all unessential releases of vP substances to the environment, e.g., use of PFAS-based foams in fire-fighting training (d.23). It was also suggested to limit the use of persistent substances to certain essential uses which due to technical reasons/functionality absolutely required such persistence (d.28).

Amending CLP to include additional categories for hazards or properties of concern, such as P, vP, PBT, vPvB and M (mobility), was put forward (c.14, d.12), which may require work at international level on the GHS framework. It was also suggested to consider the possibility of an additional classification for extreme persistence for those chemicals that may not degrade for decades or longer (d.14). Significant gap in the EU framework for POPS could be filled by including additional unintentionally produced vP chemicals such as polybrominated dioxins/furans (d.13) and by encouraging more ambitious international implementation of controls over vPs through the Stockholm Convention mechanism (d.15).

From the sub-study on vulnerable groups came several overarching suggestions to improve the EU regulatory framework. Proposals included to agree a comprehensive definition of the term 'vulnerable groups', particularly for those pieces of EU legislation relevant to the protection of vulnerable groups (c.01), to add provisions referring to specific windows of vulnerability, e.g. in the Toy Safety Directive (c.02) or Drinking Water Directive (c.04), and to review legislation related to work, food, products, environment/air for opportunities to ensure consistent coverage for vulnerable groups (c.03). Suggestions aimed particularly at the protection of children, e.g., to reduce and/or phase-out the use of EDCs in medical equipment, particularly for neonates (c.19) and to extend the Toys Directive regime to cover all products aimed particularly at children, such as furniture, bedding, clothing (c.08).

The Drinking Water Directive was flagged as an opportunity for improvement, in particular through a review and updating of the number of chemicals listed in Annex I, part B (c.05) e.g. by adding highly fluorinated (PFAS) and other vP substances to the list. Because of the large number of PFAS, it was suggested to consider a group limit value, similar to the current group limit value for pesticides in drinking water and groundwater protection (d.6). The Food Contact Materials Regulation was also viewed as an opportunity to reduce exposure to hazardous substances, by setting in place specific rules for the 12 types of food contact materials not yet covered at EU-level, and starting with those where chemical contamination problems have already arisen, e.g. printing inks migrating into food, bisphenol A, certain phthalates, PFAS, and other harmful chemicals in paper/board packaging (c.06, c.07).

With respect to vP substances used in production and manufacturing, it was suggested to require all emissions of vPs from all industrial activities to be subject to permit, including those from smaller installations (e.17). Alternatively, the production and/or industrial use of vP substances could be required to take place only in closed systems (d.19). In any case, it was urged to not use emission limit values (concentration levels) for controlling vP substances in discharges, but rather to set fixed maximum amounts for restricting vP substances released to the environment (d.20). It was also proposed to set fixed limits at EU level to amounts of vPs produced/used, as per restrictions for ozone-depleting substances, and allocate allowances via economic instruments such as tradeable permits (d.22)

An overarching legal approach to separation and decontamination of waste streams (b.03) was seen as important to facilitate Circular Economy goals. This would include development of a regulatory system that would incentivise article producers to create minimised dismantling and depollution efforts for the waste sector, e.g. by extending producer responsibility until after waste entered a second

product life (b.42) This improvement opportunity linked back to the proposals to implement more restrictions for SVHCs in articles under REACH or for substances with certain hazardous properties in product legislation (b.20).

Opportunities that did not require new legislation but rather streamlining implementation of existing legislation included several ideas for reducing the administrative burden for the private sector. Extending the available time to identify and move to sustainable alternatives (a.03, e.03) was proposed, along with providing SMEs more time to comply with the legislation (a.06, e.08). To encourage the development of alternatives, it was proposed to lower regulatory burdens for registration and approval for non-toxic substances and to provide longer protection periods e.g. for patents (f.03). It was also suggested to speed up replies to consumer requests for information on substances in products and to support the development of related consumer apps or labelling (b.29).

Possibilities to reduce burdens on regulatory authorities without enacting new legislation included to ease up on requirements to demonstrate risks and to increase opportunities to restrict substances based on a hazard-based, precautionary approach under REACH (b.21), to apply grouping strategies systematically when regulating a substance (a.08, e.07), and to co-ordinate substitution initiatives across Member States around prioritised chemicals of concern (e.6).

7.3.9 Enforcement

Some of the improvement suggestions aimed at enforcement deficits were quite broad, e.g., to dedicate more resources to enforcement of every aspect of the chemical legislation (a.28, b.32, e.32), to continuing support for further Member State work on harmonization and enforcement, including on sanctions (b.31), and to enhance chemical monitoring programmes (a.30, e.34).

Other proposals were more targeted. For example, more Member State enforcement of the REACH provisions on communication of safe use of substances in articles and safe disposal in safety data sheets (b.17) was suggested, with particular focus on the Article 33 obligation on suppliers of articles containing SVHCs above certain concentrations.

Ideas also included ways to improve enforcement efficiency. A suggestion to set limit values (standards) for vPs in products also recognised the need to develop screening and analytical methods for use in checks for compliance with those standards (d.30). Another suggestion related to standards for secondary raw materials was to implement random tests and (unheralded) control measures, and to use enforcement information for policy making (b.32).

7.3.10 Monitoring

In almost all the sub-studies, emphasis is placed on the importance of enhancing the monitoring programmes (a.30; c.15, d. 16, e.34) that have been carried out in the last decades in Europe, on specific substances and populations exposed and with varying geographical scope. Various databases concerning chemicals exposures already exist. For example, the European Commission is developing an EU-wide human biomonitoring (HBM) initiative and the European Commission Joint Research Centre is working on an information platform for chemical monitoring data (https://ipchem.jrc.ec.europa.eu) that will gather together the available experiences in Europe to enhance access to data on chemicals.

Nonetheless, additional monitoring efforts were proposed to address the gaps and deficits they had identified. Sub-study c on vulnerable groups urged development of a comprehensive, longitudinal, human data bank (c.15), including harmonised environment and health indicators; HBM data and human tissue measurements translated into daily exposure estimates; and HBM data collected during all life stages, reflecting total exposures from all sources, complemented with data on individual susceptibility based on gender, age, genetic background and body composition, living environment

(urban vs rural), lifestyle habits, medical history, etc. in order to determine additional risk factors of higher body burden of chemicals.

Sub-study d on very persistent (vP) substances also stressed the need for monitoring to guard against build-ups of vP substances in the ambient environment and technosphere which might lead to irreversible harm. Suggestions included systematic environmental monitoring and surveillance of vPs, including human bio-monitoring and in waste streams, to track presence and mark any accumulations (d.34), and particularly where point sources of discharges have been identified, e.g., PFAS around all airfields (d.36).

And not least of all, sub-study g on an early warning system for examining chemical threats to human health and the environment suggested a number of ways to strengthen the signals picked up by environmental and human monitoring data sources in order to set priorities for assessment, evaluation and initiation of risk management measures (g.08). It called for centralized collection of exposure and hazard information at the EU level (g.09); cooperation and exchange of information on new and emerging risks from chemicals (NERCs) (g.02; g.05); and interlinking and coordinated monitoring of exposures for three focus areas, namely environment, consumers and workers (g.19).

7.4 THE RANGE OF POLICY INSTRUMENTS SUGGESTED

The responses identified for each sub-study also corresponded to a range of policy instruments. It is worth noting that the European chemical legislative framework already uses a similar range of policy means that provides an important base for responding to the gaps and deficits identified in the sub-studies, as summarized in the table below.

Table 3: Overview of current policy instruments

Type	Sub-type	Examples of current use
Legislation	Data gathering	REACH Regulation
	Assessment of data for regulatory controls	REACH & CLP Regulations
	Restrictions & bans	REACH Annex XVII, Ozone Depleting Substances Regulations
	End-of-pipe control	Industrial Emissions Directive, Landfill Directive
	Quality standards	Drinking Water Directive, Water Framework Directive
	Product standards	Toys Directive, Food Contact Materials Regulation
Streamlining legislation		EU 'Better Regulation' Initiative
Economic instruments	Taxes and subsidies	Fertilizer taxation e.g. Denmark, Finland, Norway, Netherlands, Sweden
	Fees and payments	Fees for substance registration under REACH to support ECHA
	Tradable rights	CO2 emissions trading scheme, EU
	Public procurement	Chemicals Action Plans of the cities of Gothenburg and Stockholm
	Liability/insurance	EU Environmental Liability Directive
Information based instruments	Targeted information provision	Children's health public campaign, Denmark REACHReady, UK
	Registration, labelling and certification	EU Ecolabel The Green Dot, EU
	Naming and faming/ shaming	Bathing water interactive map, EU E-PRTR interactive map, EU
Civic, co- and self-regulation	Circular business models	Chemical Leasing, Chemical Management Services, Cradle to Cradle
	Covenants and negotiated	Environmental Covenants, Netherlands Nanomaterials voluntary reporting, UK

Type	Sub-type	Examples of current use
	agreements	
	Self-regulation	ISO14001, global Chemical Footprint BASF Supplier Code of Conduct, global
Support and capacity building	Research and knowledge generation	REACH Regulation requirements for substance testing Horizon 2020
	Demonstration projects/ knowledge diffusion	Eco-Innovation Program Lighthouse Projects, LIFE, Denmark National Demonstration Test Catchments Network, UK
	Network building and joint problem solving	European Technology Platform for Sustainable Chemistry (SusChem), EU ResearchGate, global
Enforcement		ECHA compliance check, Enforcement Forum for REACH and CLP RAPEX
Monitoring		EU Watch List (Water Framework Directive) EU biomonitoring programme

The table below is based on Table C in the annex to this report, which compiles all of the responses identified across the seven sub-studies and the type(s) of policy instruments considered appropriate for addressing particular gaps. It shows the frequency of identified responses by policy instrument. Frequency is calculated dividing the number of responses identified in each category of responses, by the total number of responses per each sub-study. Because some of the identified responses were scored as involving one more policy instrument (e.g. legislation -> monitoring -> enforcement), the percentages for each sub-study's row do not add up to 100%. Rather, the table is an indicator of the frequency for each policy instrument per sub-study, with blue indicating the lowest level of frequency and red the highest level of frequency.

Table 4: Frequency of identified responses by policy instrument.

	Strengthening Legislation	Streamlining legislation	Economic instruments	Information based instruments	Civic and self-regulation	Support and capacity building	Enforcement	Monitoring
Sub-study a: Substitution, including grouping of chemicals & measures to support substitution	10%	17%	17%	37%	7%	33%	3%	7%
Sub-study b: Chemicals in products (articles) and non-toxic material cycles	48%	13%	6%	25%	4%	29%	6%	4%
Sub-study c: The improved protection of children and vulnerable groups from harmful exposure to chemicals	34%	24%	0%	24%	0%	31%	0%	3%
Sub-study d: Sub-strategy for very persistent chemicals	37%	41%	2%	46%	41%	34%	7%	22%
Sub-study e: Policy means, innovation and competitiveness	18%	18%	15%	15%	3%	44%	3%	6%
Sub-study f: Programme on new, non-/less toxic substances	20%	30%	10%	30%	50%	60%	0%	0%
Sub-study g: Early warning systems for examining chemical threats to human health and the environment	5%	0%	0%	53%	0%	53%	0%	0%

The table thus provides an overview of the relative usefulness of various types of policy instruments for addressing the gaps and deficits identified per sub-study. Its policy messages could be summarised as follows:

- A need to strengthen existing legislation, particularly with respect to chemicals in products ('articles'), very persistent chemicals, and the protection of children and other vulnerable groups
- Identification of a need for improved monitoring of very persistent chemicals
- Additional effort and resources needed across the board for improved information, and for the use of information-based instruments
- Not much enthusiasm for the use of economic instruments as a means of achieving the desired policy objectives
- Opportunities for streamlining legislation and for civic and self-regulation by stakeholders, particularly with respect to the development of new, non/less-toxic substances
- A clear need for support and capacity building across all of the sub-study areas

7.5 BRINGING IT ALL TOGETHER

- The findings of the sub-studies summarized in the previous sections indicate the need for an additional, overarching, horizontal policy process or platform with the overall objective of minimising human and environmental exposures to chemicals of concern and drawing on a range of different instruments and measures. The purpose of such a policy process/platform would be to provide: Improved identification and tracking of all substances meeting the criteria for SVHCs and including very persistent substances as well as substances of concern meeting other endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.
- Improved integration across the many different policy areas that, in one or another, address chemicals of concern and chemical pollution e.g. chemicals legislation, air and water quality legislation, industrial pollution controls, product legislation (toys, cosmetics, pharmaceuticals, pesticides, biocides, etc.), food legislation, waste legislation, etc.;
- Additional hazard identification and risk assessment processes that allow for more rapid screening and identification of potential chemicals of concern and that can cope more efficiently with the huge numbers of existing chemicals as well as the ever increasing numbers of new chemicals being invented and placed on the market;
- Support for improving the functioning of existing legislation and policy approaches e.g. through better information sharing, and more training and capacity building; and
- More focus and clarity on the long-term perspective and goals of sustainable chemicals management, including the international commitments of the SDGs, WSSD 2020 and SAICM.

The risks related to chemical substances may be present at various points throughout a substance's life-cycle: during production, when they are transported, in the manufacture of mixtures and articles, during the use of the mixtures and articles which contain the substances, when they are (eventually) recycled and when they are then discarded. Because of these various stages, it is crucial to manage substances of concern sustainably throughout their life-cycle.

This is particularly relevant regarding very persistent (vP) substances that, once produced, will remain in the environment for a substantial amount of time. Product regulations rarely evaluate the risk of a vP during a product's entire life-cycle: they usually are limited to requiring an assessment of the risk associated with the exposure to the chemical during the use phase. This failure to take account of the substance's fate at the end of a product's life risks build-ups of vP substances in waste materials recycled as part of the circular economy, along with accumulations in the environment, which could form reservoirs for future exposure.

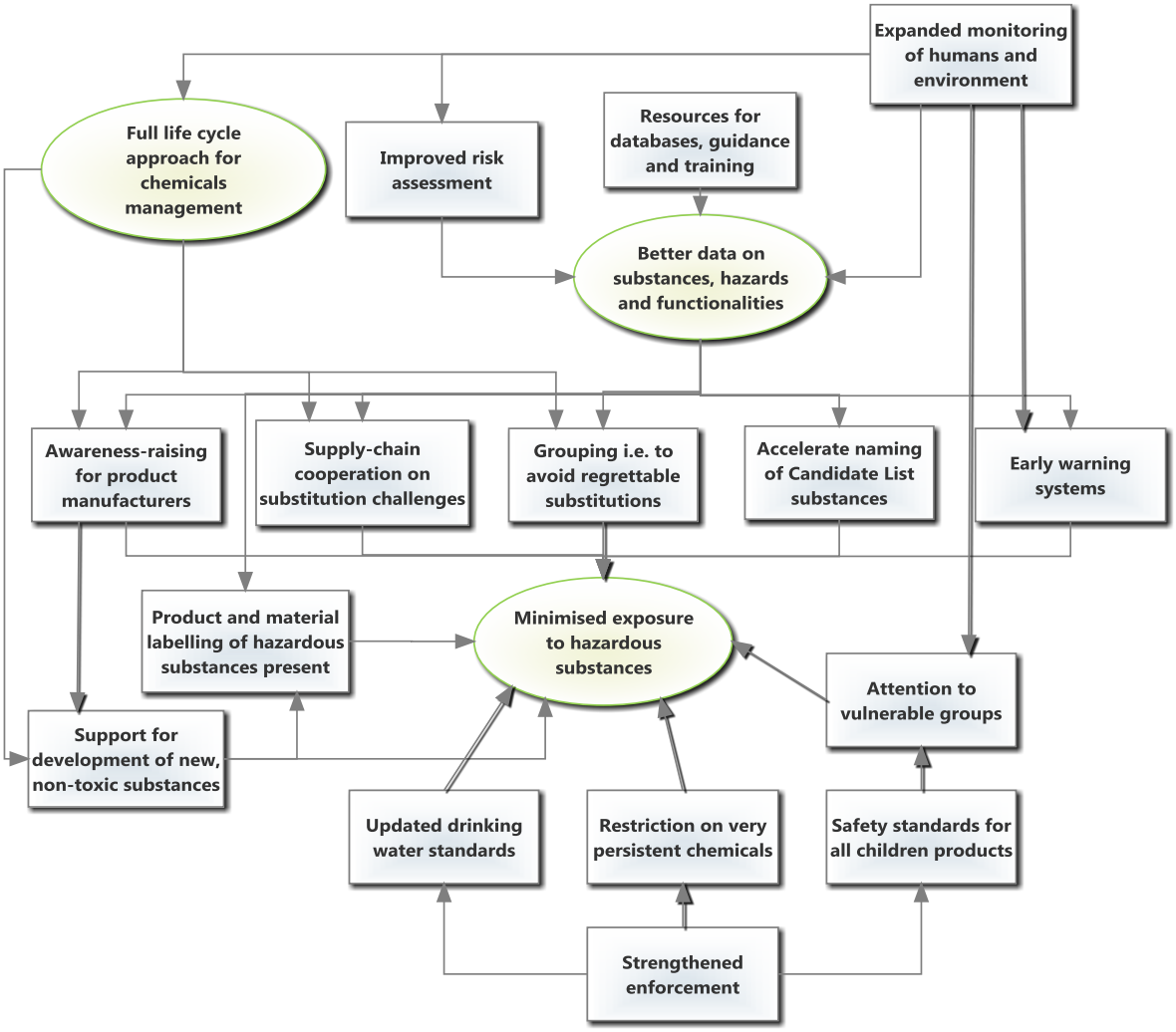
Several sub-studies (and stakeholders) therefore argued for a life cycle approach to chemicals

management. This would include more understanding of chemical product life cycles, in order to identify the responses that might be needed to address the health and environmental impacts of a substance of concern throughout its life cycle, from production through use and including releases into waters and land during use and at the waste stage.

The figure on the next page illustrates some of the key elements identified throughout the sub-studies that could form part of a strategy for a non-toxic environment. Three focal points help to structure the relationship among the various elements, e.g.:

- Full life cycle approach for management of chemicals, including in articles
- Better data on substances, hazards and functionalities/uses
- Minimised exposure to hazardous substances

Figure 8: Overview of elements for a strategy for a non-toxic environment



REACH already recognises the importance of assessing risks from chemical substances from a life cycle perspective. All substances placed on the market in quantities of 10 tonnes per annum or more are required to be subject to a chemical safety assessment (CSA). REACH Annex I, paragraph 0.3 states:

> *"The assessment shall consider all stages of the life-cycle of the substance resulting from the manufacture and identified uses. The chemical safety assessment shall be based on a*

comparison of the potential adverse effects of a substance with the known or reasonably foreseeable exposure of man and/or the environment to that substance taking into account implemented and recommended risk management measures and operational conditions."

This assessment is to be carried out primarily as part of the description of the 'exposure scenario', and to involve an 'emission estimation' (Annex I, paragraph 5.2.2) that *"considers the emissions during all relevant parts of the life-cycle of the substance resulting from the manufacture and each of the identified uses…cover[ing], where relevant, the service-life of articles and the waste stage."* Note that this is one of the few places in REACH where the service-life of articles and the waste stage are mentioned with respect to a substance's life cycle.

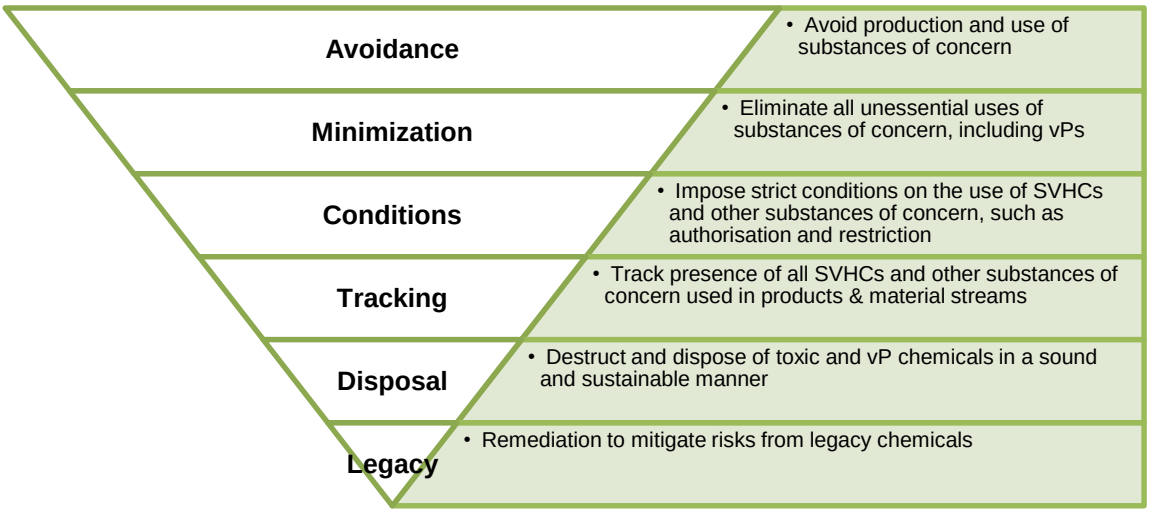
These life-cycle aspects are neglected in many chemical assessment tools, though they are essential for identifying trade-offs, avoiding regrettable substitutions and burden shifting. Even when life-cycle impacts are considered, the available information may not be sufficient for a proper assessment. Moreover, life-cycle assessments are also resource and time intensive and rely on extensive and good quality data that, despite the implementation of the REACH Regulation, are not yet available for most of the chemicals of concern. Introducing additional layers of data demands in a situation where health and environment data is still insufficient for assessments in chemicals policy might not be currently realistic.

Hence it is important to differentiate between a chemical safety assessment, which is often aimed at estimating how much of a substance can be used safely, and a life-cycle **approach,** which aims to minimize all exposures to hazardous substances as much as possible. This involves applying life cycle thinking that prioritises avoidance and minimisation of uses of hazardous substances, with all stakeholders motivated or pushed to design more sustainable substances or find non-chemical solutions.

This involves aligning the design process of articles and substances to the principles of Green Chemistry and to consider life-cycle aspects in the wider context of the chemicals' applications in consumer products and their impacts during service-life and end-of product life. Increased information on the life-cycle aspects of chemicals will also be critical for the goal of a Circular Economy, since waste treatment operators often lack information to decide on a sound basis which treatment options to choose, including recycling.

A strategy for a non-toxic environment could therefore consider a type of hierarchy in chemicals policy and management, similar to that which guides EU waste management policy, as per the figure below.

Figure 9: Hierarchy on uses of chemicals



Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where the use is sufficiently well contained and where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

8 CONCLUSIONS

8.1 PROGRESS ALREADY MADE VIA THE CURRENT EU REGULATORY APPROACH

The chemicals regulatory framework put in place by the European Union is widely regarded as the most advanced and comprehensive legal framework for the control of chemicals in the world. It applies to all industry sectors dealing with chemicals and along the entire supply chain, making companies responsible for the safety of chemicals they place on the market.

Because of the REACH Regulation and its registration requirement, significant progress is being made towards filling the previous data gaps concerning the potentially hazardous properties of the more than 100,000 substances on the EU market. Moreover, in theory, the burden for generating this information and for ensuring that the risks linked to substances in commerce are managed safely has shifted from governments to the industry. However, regulators still face considerable hurdles in their efforts to show that a particular substance or group of substances should be subject to authorisation or restriction.

Under its better regulation programme (REFIT), the Commission is carrying out a comprehensive fitness check of all chemicals legislation, except REACH, and a REFIT evaluation of REACH that together will present a stocktaking of chemicals legislation. While this work is ongoing, so far there are no indications of problems that would allow to conclude that the EU legislative framework governing the risk management of chemicals is not fit for purpose on an overall level.

The EU chemicals industry has demonstrated the capacity to remain competitive within this framework and growth over the coming decade is expected to be robust. The use of chemicals is ever increasing. EU production of industrial chemicals is now at 400 million tonnes a year, with some 35,000 chemicals marketed in volumes over 1 tonne a year. However, it is also important to recognise that the production is growing faster in some regions outside the EU. This will have consequences for such aspects as what chemicals will enter the EU market in different kinds of articles.

This poses new challenges for the goal of protecting humans and the environment from chemicals-related harm. Of the chemicals on the EU market today, an estimated 60% by volume are considered hazardous to human health or the environment. Though the data gaps are slowly being addressed, only a few of the large number of chemicals currently on the market have been subjected to a full assessment of the risks they may pose to human health and the environment and impacts, and only some of these are actually controlled under REACH through authorisation or restriction. As the 7th EAP notes, there is particular concern for impacts on children and other vulnerable populations.

An additional challenge is the EU goal of achieving a Circular Economy by e.g. increasing reuse and recycling of material. It will be important to consider how to manage chemicals throughout the material cycle, from manufacturing of the chemicals to manufacturing and use of products, during waste management and recycling as well as in connection to use of recycled materials. If materials contain residues of hazardous substances, these may build up, leading to increasing concentrations of contaminants in recycled materials, and their increased dispersal and presence in the technosphere as well as the natural environment. This is an additional impetus for the sustainable management of chemicals.

8.2 SUMMARY OF GAPS IDENTIFIED AND NEED FOR A STRATEGY FOR A NTE

The seven sub-studies and the June 2016 workshop carried out in the context of this study have identified a range of gaps and deficits in the respective focal areas which are important to consider in

the overall effort to reduce exposure to harmful chemicals. Some of the major knowledge gaps and deficits in legislation identified include:

- Slow progress in identification of Substances of Very High Concern, and in substitution of hazardous chemicals in industrial processes and products
- Lack of information concerning hazardous chemicals in articles, including imported articles
- Insufficient attention to hazardous chemicals in material flows important for a Circular Economy
- Deficits in the framework for protection of children and other vulnerable groups, e.g. from chemicals in products such as textiles and other everyday consumer products
- Lack of consideration of the combination effect of exposure to multiple chemicals, both in chemical risk assessment and horizontally across legislation, as well as cumulative exposure from multiple sources and long-term and low-dose exposure
- Insufficient means to address risks posed by chemicals on the basis of persistence alone
- Lack of monitoring of environmental compartments concerning possible build-ups of contamination and health risks thereof, in particular with respect to water intended for human consumption
- Need for better incentives for development of new, non/less-toxic substances as well as non-chemical solutions
- Need for more comprehensive compilation of monitoring data at EU level and establishment of an early warning system.

Further, the scale of the problems identified in the sub-studies highlight the need for additional action, as per the box below.

The scale of the problem with respect to SVHCs and other chemicals of concern

- As global production of chemicals increases, so does the production and international trade of articles made from these chemicals. The yearly import of manufactured goods to the European Union has almost tripled between 2000 and 2015, including from countries with insufficient regulatory controls over chemicals. In 2016, 3.4 tonnes of products (2.1 raw, 0.4 semi-finished and 0.9 finished products) per capita were imported in the EU, with some 20% from China.
- Human biomonitoring studies in the EU point to a growing number of different hazardous chemicals in human blood and body tissue including pesticides, biocides, pharmaceuticals, heavy metals, plasticisers, flame retardants, etc.
- Over 200 synthetic chemicals have been detected in umbilical cord blood, including ingredients in consumer products, food packaging, and chemical by-products from burning coal.
- Combined exposure to several substances, including substances in articles, can have greater impacts than exposure to a single substance. Combined prenatal exposure to several chemicals led to reduced foetal growth and lower birth rates, indicating the need for a greater safety margin for exposures, in particular for foetuses and neonates.
- The cost to the EU of female reproductive disorders and diseases as a result of exposure to endocrine-disrupting chemicals is estimated at close to €1.5 billion annually.
- Extremely persistent chemicals, such as the more than 3,000 highly fluorinated PFAS on the market today, do not break down in the natural environment. The risk is that concentrations will build up in nature and in the technosphere such that levels of exposures to humans and other biota are irreversible.
- Some 3.5 million sites around Europe are already contaminated by hazardous substances, including vPs. Contamination of natural resources has severe economic consequences, ranging from the extremely high costs of remediation to loss of natural resources such as drinking water, land, soils and fish stocks from productive use.

These findings indicate the need for an additional, overarching, horizontal policy process or platform with the overall objective of minimising human and environmental exposures to SVHCs and other chemicals of concern and drawing on a range of different instruments and measures. The purpose of such a policy process/platform would be to provide:

- Improved identification and tracking of all substances meeting the criteria for SVHCs and

including very persistent substances as well as substances of concern meeting other endpoints not yet adequately addressed, e.g., endocrine disrupters, neurotoxins, immunotoxins, and developmental toxins.
- Improved integration across the many different policy areas that, in one or another, address chemicals of concern and chemical pollution e.g. chemicals legislation, air and water quality legislation, industrial pollution controls, product legislation (toys, cosmetics, pharmaceuticals, pesticides, biocides, etc.), food legislation, waste legislation, etc.;
- Additional hazard identification and risk assessment processes that allow for more rapid screening and identification of potential chemicals of concern and that can cope more efficiently with the huge numbers of existing chemicals as well as the ever increasing numbers of new chemicals being invented and placed on the market;
- Support for improving the functioning of existing legislation and policy approaches e.g. through better information sharing, and more training and capacity building; and
- More focus and clarity on the long-term perspective and goals of sustainable chemicals management, including the international commitments of the SDGs, WSSD 2020 and SAICM.

The overall conclusion is that an additional, more horizontal approach for reducing exposure to hazardous substances, i.e., a strategy for a non-toxic environment, should be set in place as a matter of urgency. In this context, it is important to recall the principles of environmental protection enshrined in the Treaty on the Functioning of the European Union (TFEU), including the principles of prevention and of taking precautionary action when the potential risks are such that to delay action could mean irreversible damage.

8.3 WAYS FORWARD

During this project, a broad outline of the types of measures that could be considered as relevant for a strategy for a non-toxic environment has been emerging. It could include the following themes:

Improve knowledge on chemicals

- Commit long-term to develop chemical knowledge bases (hazardous properties, uses, presence of chemicals in articles, monitoring data);
- Develop and implement an early warning system for identifying new chemical threats;
- Move from the current chemical-by-chemical to groupings of chemicals approaches in risk assessment and risk management.

Promote innovation, development of non-toxic chemicals and non-chemical solutions, and substitution

- Promote innovation: develop non-toxic chemicals as well as non-chemical solutions and promote their use;
- Promote circularity: promote chemical re-use solutions and non-toxic material cycles;
- Support substitution: increase access to knowledge crucial for those who can substitute and support substitution activities.

Reduce chemical exposures and promote circular economy

- Address very persistent chemicals;
- Establish a hierarchy for hazardous substances (e.g. avoidance, minimisation, strict controls, disposal/destruction) and introduce an auditable system of application;
- Establish a system of tracking chemicals in products (articles) and promotion of the development and use of non-toxic materials and articles;
- Improve protection of children and vulnerable groups

Finally, as explained in section 7.5 above, a strategy for a non-toxic environment could also consider moving to a stronger life-cycle approach aimed at minimising exposures to hazardous substances at all chemical and product life stages, from the manufacturing of chemicals, materials and products to the service life and end-of-life of products and to a new life cycle through recycling of materials. It could be translated into the overall principle that hazardous substances of particular concern (e.g substances corresponding with the criteria of SVHC in REACH and equivalent) should as far as possible be phased out in uses which are not sufficiently well contained/controlled during their life cycle. Further, there should be a constant striving towards minimising the exposure to all hazardous substances, including those of lower concern. This would include a range of different activities such as avoiding uses that are not essential, development of non- or low toxic chemicals and non-chemical solutions, product and material design, reducing volumes used, avoiding uses involving large exposure, improving information and different protective measures. Choice of substances, design of products etc. should also meet the needs of reuse and recycling and aim to as far as possible achieve non-toxic material cycles.

In connection to this a type of **hierarchy in chemicals policy and management**, similar to that which guides EU waste management policy, is envisioned. Such a hierarchy could start with the principle of avoiding the production and use of chemicals of particular concern (i.e. SVHCs and equivalent including very persistent chemicals) as far as possible and limiting any uses to situations where exposure does not occur. The next step would be minimisation of exposure by different means and applying also to hazardous chemicals of lower concern. In addition, emphasis would be placed on the design of non/less-toxic chemicals and of products that would allow for toxic-free reuse and/or recycling. Finally, it would include workable approaches to address legacy chemicals, including systems for decontamination of recycled materials as well as recovery and destruction of hazardous substances in production wastes and at end-of-life product disposal.

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