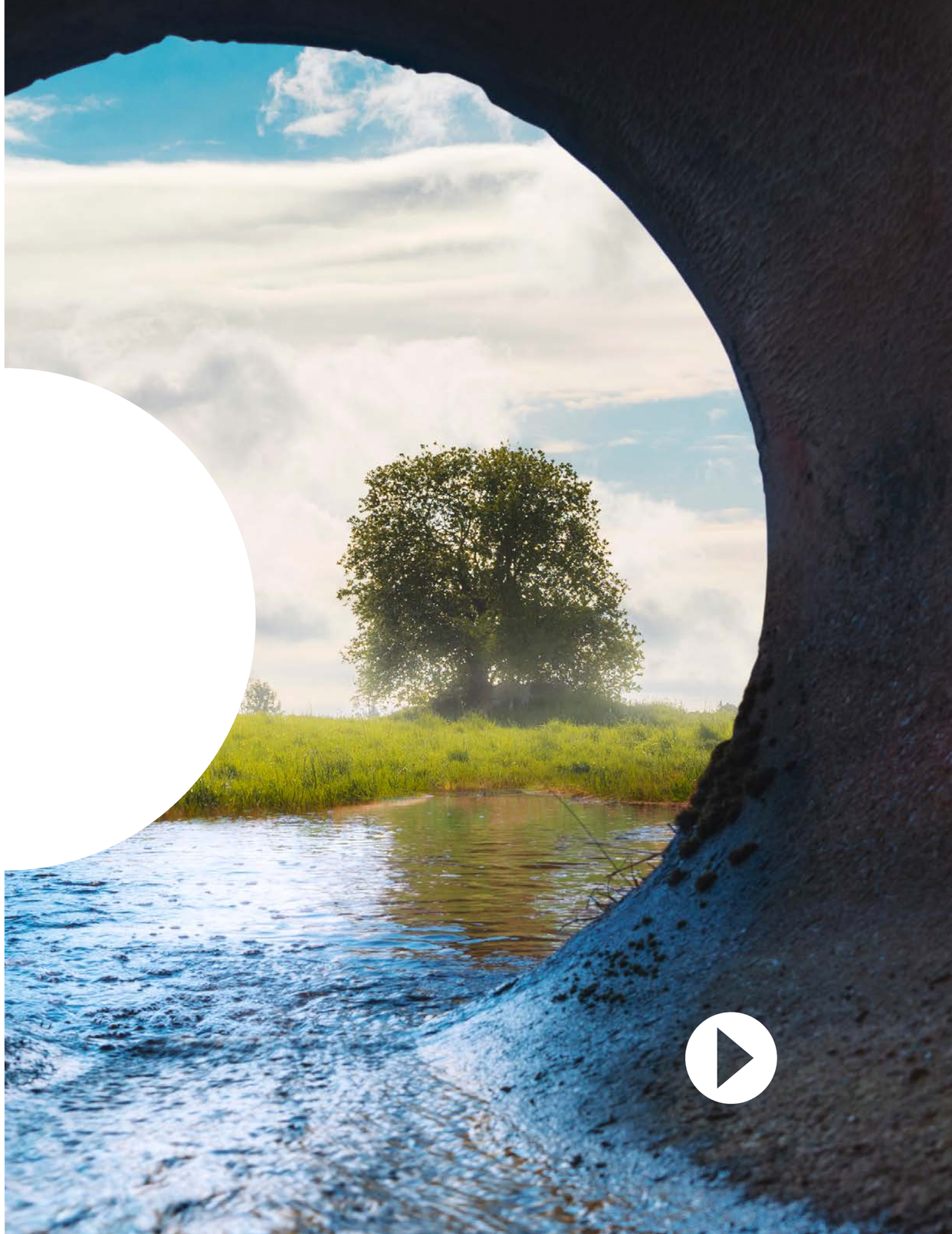
A GRIP ON HAZARDOUS SUBSTANCES

FEBRUARY 2020



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SUMMARY

Society is increasingly shaken up by reports of hazardous substances that widely occur within the physical environment and that prove to be dangerous, or for which the risks are still unclear. For example, recently, the presence of PFAS in soils has been a general concern. Other examples are growing concerns about microplastics and the possible presence of pharmaceuticals and plant protection products in drinking water. These concerns cause anxiety among the population and the costs to society are substantial. Although government policy on the safe handling of hazardous substances has reduced the risks to people and the environment in recent decades, the current approach no longer seems sufficient to manage future developments.

Having more control of the risks that are associated with hazardous substances in the physical environment has become even more urgent now that the transition towards a ‘circular economy’ has been set in motion. In the coming decades, the Netherlands will be working towards a closed-loop system of production and consumption and more efficient use of raw materials. Prerequisite, here, is the safety of people and the environment. Without such safety, the circular economy will not be achieved.

The safe handling of hazardous substances in the physical environment also imposes conditions on how we anticipate and react to unknown risks

and how we deal with new developments and insights. Prevention and precautions are important seeing the fast pace at which new substances are introduced on the market and in view of the increasing production volumes. Assessing the risks of certain substances is complex and insights change regularly. Something that was initially considered safe may turn out to be hazardous, at a later stage. It can take years to reach scientific consensus on the long-term effects of certain substances.

The Council for the Environment and Infrastructure (Rli) has therefore studied the question of whether a safer handling of hazardous substances in the physical environment is necessary and what steps would need to be taken to achieve this. This is the subject of this advisory report.

Problems with hazardous substances in the physical environment

In recent decades, the government has taken measures to address the problems around hazardous substances in the physical environment. As a result, the concentrations of many known substances have been reduced. In addition, the European REACH Regulation has led to a better understanding of the properties of substances that companies are introducing on the European market. Nevertheless, the Rli finds that the three following problems are currently occurring:

- The dispersion of hazardous substances in the physical environment has not decreased sufficiently, in recent years. Substances are found in unexpected places and unforeseen risks are occurring. In short, emissions of hazardous substances are insufficiently controlled.
- The risk of simultaneous (i.e. cumulative) exposure to different substances has increased, in recent years. Previously, the main risk to humans and the environment was due to locally confined, relatively high concentrations of individual substances, whereas these days, there are much more diffuse mixtures of substances, each of which at a low concentration level, but together they may have an at least equally harmful effect.
- With the transition to a circular economy, new issues are arising with respect to the use of hazardous substances. In cases of reuse and recycling, hazardous substances such as in the form of ‘secondary raw materials’ end up in new product chains, creating new risks of exposure. Non-degradable hazardous substances can also accumulate in products if they are recycled frequently. These may even be substances that have already been banned.

Recommendations

In this advisory report, the Rli makes 10 recommendations to effectuate a better grip on the dispersion of substances within the physical environment, reduce the adverse effects of cumulative exposure and move towards a safe circular economy by 2050. These recommendations focus primarily on government action, although improving the quality of the physical environment is a joint task of government authorities, the business community, citizens, civil society organisations and knowledge institutions. The recommendations are partly aimed at involving social parties more actively in assessing the usefulness and necessity of chemical substances. This requires greater transparency, also in view of the required shift

towards the safe use of substances in a circular economy. Knowing which substances are in which products and what risks are involved is crucial to achieve safe closed-loop systems.

Recommendations for improved control of the dispersion of substances into the environment

1. Oblige companies that bring substances and potential substances of the category 'very high concern' into a product chain to implement a track-and-trace system to keep track of the volume of these substances'[1]. This will enable competent authorities and companies to identify 'leaks' in all phases of the chain and act accordingly. These data are also important for obtaining better insight into the cumulative exposure in the physical environment.
2. Only grant temporary environmental permits, so that it becomes easier to hold companies accountable for their duty of care, which includes minimising the impact on the physical environment.
3. Increase the use of counter-expertise when granting environmental permits, to validate the information companies provide about the properties of substances.
4. Strengthen government knowledge and capacity for policy implementation, enforcement and monitoring, so that they can adequately assess whether companies are doing enough to minimise the impact of their emissions on the physical environment. This will require additional funding.
5. Promote opportunities for citizens and social parties to exert pressure for the purpose of reducing the use of hazardous substances in products. Ensure companies are more transparent about their handling and use of substances. This will enable citizens and investors to make more informed choices in purchasing or investment decisions.
6. Encourage industrial sectors to use positive lists of chemicals that can be used safely, also in a circular economy.

Recommendations to limit the adverse effects of cumulative exposure

7. Consider the effect of cumulative exposure in environmental standards. The national government needs to provide guidance on how to determine the risk of cumulative exposure in humans and the environment.
8. Review policy effectiveness using a monitoring programme to measure the toxic impact on humans, animals and the environment, in areas where an increased risk is expected. When adverse effects of substance accumulation in the physical environment are identified, standards for issuing permits may be tightened or the authorisation of specific substances may be reconsidered.

Recommendations to ensure safe handling of substances in the circular economy

9. In the European Union, address the need for safe use and application in substance and product design throughout the life cycle of such products and substances (Safe by Design). For risk assessments, this requires additional criteria for traceability, degradability and removability.

1 For an explanation of categories see Section 3.1

10. Investigate the possibilities of introducing a material passport for the chemical composition of products. Such a material passport can be the basis for exchanging information between parties within chains and provide insight into the possibilities for reusing products and substances.

PART 1 | ADVICE

1 INTRODUCTION

1.1 Chemical substances in the physical environment

Pharmaceutical residues, plant protection products, microplastics, nanomaterials and other chemical substances are increasingly being found in the physical environment. People may be exposed to these substances via air, food or drinking water. This may cause health problems ranging from minor skin irritations to an increased risk of cancer. Plants and animals can also be harmed by substances that end up in the physical environment. Many chemical substances end up in surface water, soil, groundwater and the sea, adversely affecting environmental quality and biodiversity.

Current policy on the safe handling of chemicals seems insufficient to curb present developments. New substances are rapidly coming onto the market and existing substances are being used in increasing volumes (United Nations Environment Programme, 2019a). Society is increasingly startled by reports about substances that are widely distributed in the physical environment and that, according to the latest insights, have turned out to be hazardous or of which the risks are still insufficiently known. These concerns cause anxiety among the population and costs to society are substantial. An example, is the recent concerns about the risks of PFAS.[2]

2 PFAS is a collective term for a group of about 6,000 substances. They are oleophobic and water- and dirt-repellent and can be found in products such as extinguishing agents, textiles, food packaging materials and cosmetics. The risks of some of these substances are already reasonably well-known, but the knowledge about most PFASs is as yet insufficient for conducting a risk assessment.

In a number of cases, exposure to these substances increases the risk of cancer and their dispersion within soils poses considerable problems in the construction sector. Previously, unexpected discharges of plant protection products and increased concentrations of pharmaceutical residues in the Meuse meant that surface water extraction for drinking water had to be suspended. There are also growing concerns about the dispersion of microplastics. These minuscule pieces of plastic are now found in the bodies of humans and animals. At current concentration levels there is no evidence of widespread risk, but little is known about the long-term effects (Sapea, 2019).

Safe handling of chemical substances has become even more urgent now that the transition to a 'circular economy' has been set in motion. In the coming decades, the Netherlands will work towards closed-loop production and consumption systems in which raw materials are used more efficiently and fewer natural resources are needed.[3] However, when products are recycled, those containing potentially hazardous substances also remain in circulation. If we want the circular economy of the future to be safe for people and the environment, policy needs to be formulated, today, about which substances are allowed to be reused and under which conditions.

The safe handling of chemicals in the physical environment also imposes conditions about how to anticipate and react to unknown risks and how to deal with new developments and insights. Assessing the risks of substances is complex and insights change regularly. Something that was initially considered safe may turn out to be hazardous, at a later stage, and it may take years before scientific consensus is reached about any long-term effects of certain substances. This is due to the fact that the studies take a long time, but especially because results often still carry considerable uncertainty. This can be seen, for example, in the studies conducted on the risks of glyphosate in plant protection products and on the risks of PFAS substances in consumer products.

1.2 Central question

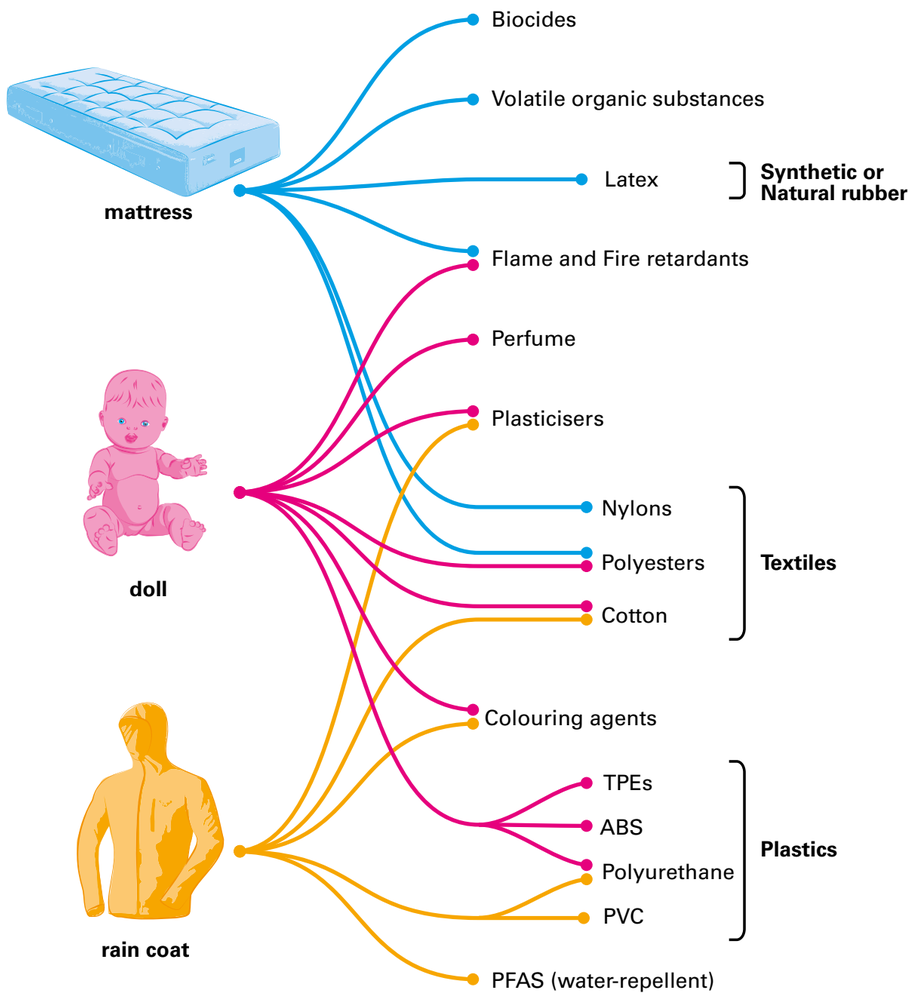
For this advisory report, the Council for the Environment and Infrastructure (*Raad voor de Leefomgeving en Infrastructuur* (Rli)) has studied whether there is sufficient insight into the dispersion of hazardous substances within the physical environment, whether there is sufficient knowledge about the actual risks of these substances, and whether these risks are sufficiently managed. The transition to a safe circular economy makes these questions even more urgent. The central question for this advisory report, therefore, was whether a safer handling of hazardous substances in the physical environment is needed. And, if so, what steps would need to be taken and what role the government should have, in this respect.

3 Various levels of circularity are being distinguished (Rli, 2015). This advisory report focuses on types of reuse and recycling.

1.3 Outline and definitions

This advisory report focuses on hazardous substances and includes all the substances that are used, processed or produced by humans and that may have adverse effects if dispersed within the physical environment or if humans are exposed to them. Such substances can either be of natural origin or be fully synthetic and made by humans. For this report, the RIi also looked at substances that are not available on the market, but which may nevertheless end up in the physical environment via production processes, decomposition processes or in other ways. The RIi uses a broader definition of hazardous substances than the legal definition used in the government policy on substances and the environment, because it is important for policy to take into account all possible risks related to substances within the physical environment.[4]

Figure 1: What substances are contained in a rain coat, a doll and a mattress?[5]



4 However, the report does not include exposure to substances in the work environment. This subject is part of another policy dossier, to which other legislation and regulations apply

5 Figure 1 is based on information obtained from www.waarzitwatin.nl

In international policy on priority substances, the term ‘hazardous substance’ is used in the identification and labelling of substances. In legal terms, a substance is considered ‘hazardous’ when, on the basis of its properties, it falls into one of the internationally defined ‘hazard classifications’.[6] In addition, environmental policy in the Netherlands focuses on the most hazardous substances classified as ‘priority substances’, ‘Zeer Zorgwekkende Stoffen’ (ZZS) and ‘potentieel Zeer Zorgwekkende Stoffen’ (pZZS)[7]. These classifications overlap to some extent; see Figure 2.

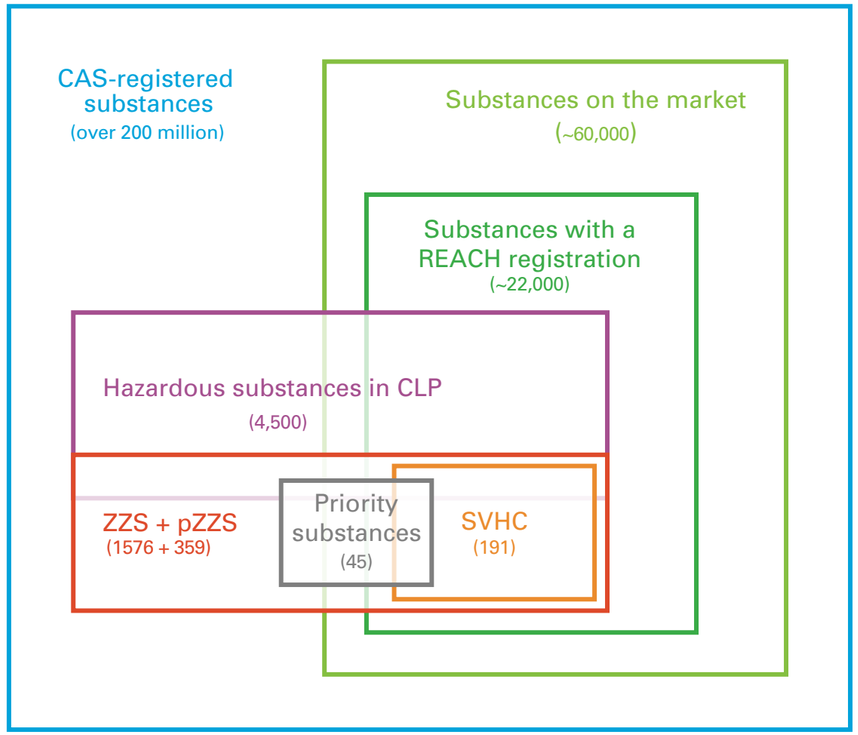
European and Dutch regulations apply authorisation regimes for chemical substances that are placed on the market. These regimes differ greatly per product or application. Examples are the separate regimes for plant protection products, biocides, medicinal products and the group of ‘industrial chemicals’.

National rules and regulations for the safe handling of substances are largely based on EU regulations. This advisory report, therefore, focuses not only on the possibilities for a more effective national policy on substances, but also on matters that the Dutch Government should put on the EU agenda.

6 For more information on classification of substances, see Chapter 1 of Part 2 of this advisory report.

7 The Dutch term ‘Zeer Zorgwekkende Stoffen’ (ZZS), translates literally as ‘Substances of Very High Concern’, (SVHC). However, the ZZS category of substances is larger than the SVHC indicated by ECHA under REACH Regulation. The pZZS category under Dutch policy indicates substances for which the harmful properties have not yet been fully established. To avoid confusion, this report uses the Dutch abbreviations.

Figure 2: Estimated number of chemical substances in certain categories[8]



1.4 Reader, Part 1

Part 1 of this advisory report first outlines three current problems caused by hazardous substances in the physical environment (Chapter 2). Subsequently, it explains the extent to which the Dutch Government policy

8 For an explanation of the abbreviations used, see Appendix Glossary.

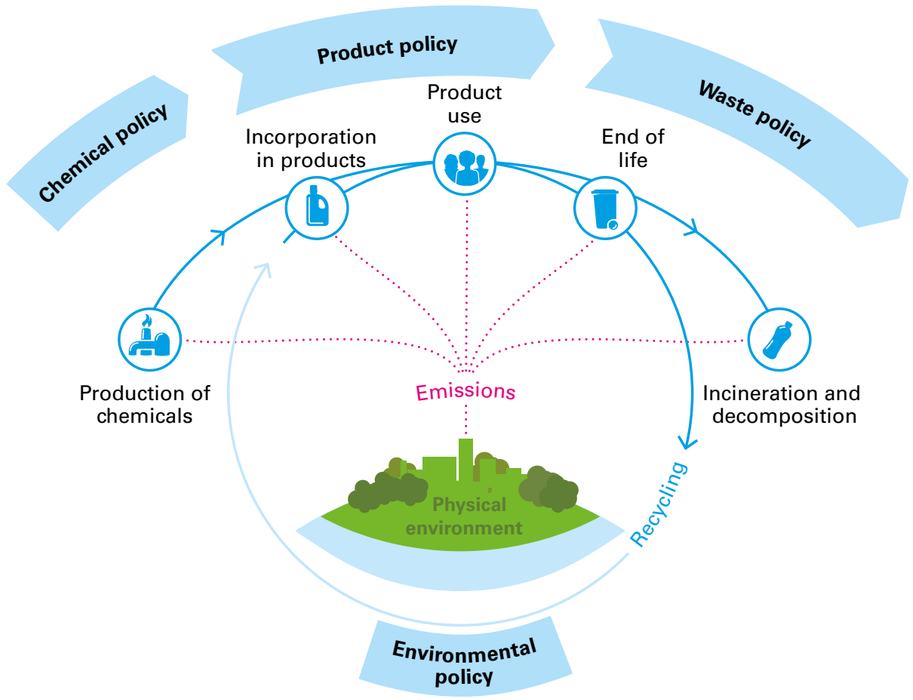
on substances, environment and products responds to these problems (Chapter 3). Finally, Part 1 formulates recommendations that can help to gain more control over the dispersion of hazardous substances within the physical environment, limit their adverse effects and work towards a safe circular economy by 2050. As the RIi cannot completely avoid using technical jargon in its advice, the report also includes a glossary.

2 PROBLEMS WITH HAZARDOUS SUBSTANCES IN THE PHYSICAL ENVIRONMENT

Over the past decades, the emissions of many known substances into the environment have been reduced, partly thanks to Dutch policy (see Figure 3). Where policy has focused on the reduction in specific substances, concentrations in the physical environment have decreased substantially. In addition, implementation of the REACH Regulation in the European Union has led to a better understanding of the substances on the European market, their properties and applications.[9]

9 See Chapter 3 of Part 2 of this advisory report, for more information on the elements of the policy

Figure 3: Core elements of current policy on the handling of hazardous substances in the physical environment



The RIi, nevertheless, hereby draws attention to three problems. The current policies provide insufficient grip on: (1) the dispersion of hazardous substances, (2) the risks of cumulative exposure to hazardous substances and (3) the new issues that arise with the use of hazardous substances in a circular economy. The first two problems are acute and have already emerged. The third problem will increase as the transition towards the circular economy progresses further. These three problems are discussed successively in the following sections.

2.1 Continuing dispersion of hazardous substances

The RIi observes that the dispersion of hazardous substances in the physical environment has failed to decline sufficiently, in recent years, despite government policy:

- In both surface water and air, the decline in the concentration levels of hazardous substances for which specific policies are in place is stagnating.
- In soils, the dispersion of persistent substances leads to long-term soil quality problems.
- Substances are regularly found in unexpected places, where they present unforeseen risks.

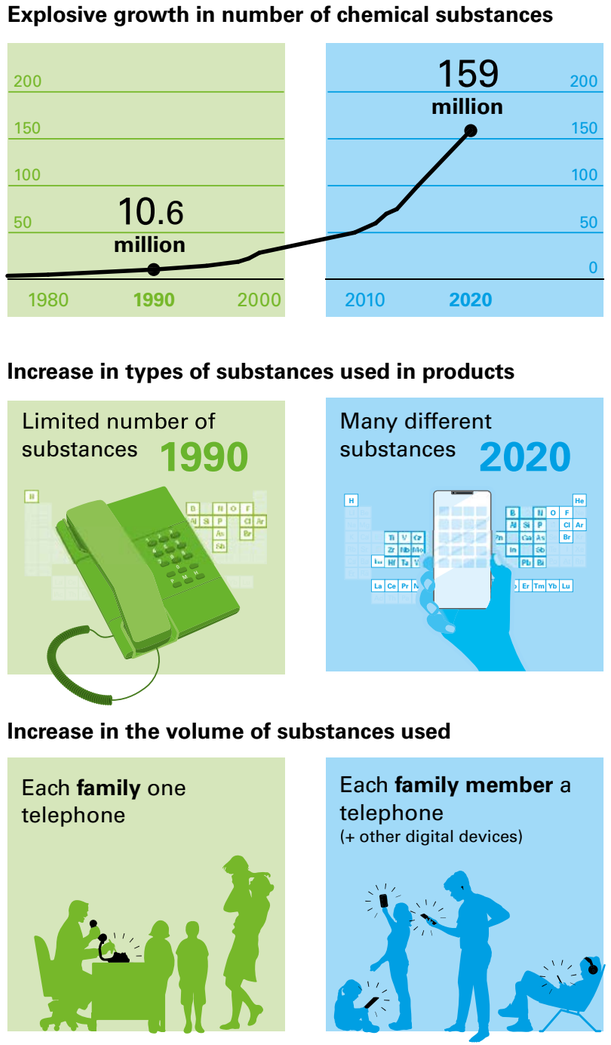
Insufficient control of over the dispersion of substances poses risks to human health and the environment, which should in fact be prevented or reduced through policy.

There are also signs that the dispersion of chemicals within the physical environment will continue to increase, in the future. The production of chemical substances has grown strongly in recent decades, both in number of substances and their volume (see Figure 4). The United Nations Environment Programme (UNEP, 2019a) expects the global turnover in the chemical sector to double in 2030, compared to that of 2017. Within the EU,

the market for chemical substances is growing at a slower pace, but the International Energy Agency foresees a substantial growth for the European chemical sector as well, for the coming decades (Cefic, 2019).[10]

This increases the likelihood of higher concentrations of hazardous substances in the physical environment. Concentration levels of various substances have already increased in recent years; for example, those of certain plant protection products in surface water (CBS, 2018). The dispersion of microplastics and pharmaceutical residues is also a growing problem, resulting from the ever-increasing use of these substances (see Box 1).

Figure 4: Increase in the production and use of substances[11]



10 See Chapter 2 of Part 2 of this advisory report, for more information on the increasing use of substances.

11 Source of figures on certain registered chemical substances: https://www.cas.org/about/cas-history. The CAS Registry contains many more substances than will eventually be placed on the market. However, the substances on the market are following a similar trend.

Box 1: Trends in specific substance groups

Pharmaceutical residues

Surface water is increasingly negatively affected by the growing use of medications. There are concerns about the impact this has on drinking water preparation and on the condition of ecosystems. In 2018, these concerns prompted the Dutch Government Authorities to jointly launch an initiative called 'Chain approach to pharmaceutical residues in water' (House of RepresentativesTweede Kamer, 2018a). Government authorities and a broad representation of stakeholders from the health care sector, the pharmaceutical sector and the water sector are working in this partnership to reduce the impact of pharmaceutical residues on water quality.

Plastics

The increasing use of plastics has led to the distribution of litter and microplastics in the physical environment. Litter has demonstrable adverse effects on ecosystems. Microplastics are also found in human blood and tissues, but little is known about the possible adverse effects. The recent ban by the European Commission on the use of disposable plastics is intended to prevent plastics from ending up in the environment. This also applies to the recent restriction proposal by ECHA, the European Chemicals Agency, for microplastic particles that are intentionally added to consumer products. In the Netherlands, government authorities and private stakeholders have entered into agreements to use fewer plastics.[12]

Plant protection products

In the 1990–2016 period, total sales (in kg) of chemical plant protection products decreased by approximately 10%. Model calculations also show that emissions to the physical environment have decreased. Between 2013 and 2018, calculated emissions from open cultivation to surface water decreased by an average of 9%. Despite these decreases, the calculated environmental pressure of plant protection products, expressed in toxic equivalents, increased by an average of 3%. The reason for this is that the substances used in current plant protection products are more toxic than before (Tiktak et al., 2019).

Furthermore, there are still important gaps in knowledge about the risks of certain substances. Although policy on substances, including EU REACH Regulation, has improved the understanding of the properties of chemical substances, there is still insufficient knowledge about the long-term effects of a large number of substances to determine whether they should be treated as 'substances of very high concern' (SVHCs) (European Commission, 2018).

Finally, there is a specific group of substances that pose an increasing problem: the so-called *persistent*, *mobile* and *toxic* substances (PMTs).

12 See Chapter 5 of Part 2 of this advisory report, for more information on the use of plastics.

These are poisonous ('toxic') substances that hardly degrade ('persistent') and spread easily within the physical environment via water ('mobile'). They also do not adhere to any other materials, which is why they are difficult to remove from either soil or water. Nor do they disappear from the physical environment by themselves and, thus, pose an imminent threat to the drinking water supply, for example, by their dispersion in groundwater (VEWIN, 2018). With their increased use, the concentration levels also increase and, with it, the risk to people and the environment.

An example of such substances are PFASs, which have been released into soil and groundwater through discharges (whether legal or illegal) by industry or via their use in consumer products (Timmer et al., 2018). The dispersion of these PMT substances within the physical environment and the measures that must be taken to control the related risks can lead to considerable costs to society. In the preparation of drinking water, the presence of PMT substances, including melamine (a building block for plastics) and 1.4-dioxane (a solvent), also leads to problems (RIWA-Maas, 2018).

2.2 Risks of cumulative exposure to substances are increasing

A large number of scientific studies show that human and environmental exposure to combinations of various substances leads to an increased risk (see Figure 5). As more and more substances are produced in ever larger volumes, this problem may grow in the future.[13] Various studies show mixtures of foreign substances in human tissue, and mixtures of hazardous substances are also measured in the physical environment (water, soil and air).[14] Previously, the main exposure risk to humans and the environment was related to local, relatively high concentrations of an individual substance, whereas now there are more diffuse mixtures of substances, each of which of a low concentration level. Together, however, these substances can have an equally harmful effect (Rudén et al., 2019). For example, there are indications that exposure to combinations of different endocrine-disrupting substances poses an increased risk to pregnant women (Bergman et al., 2019).

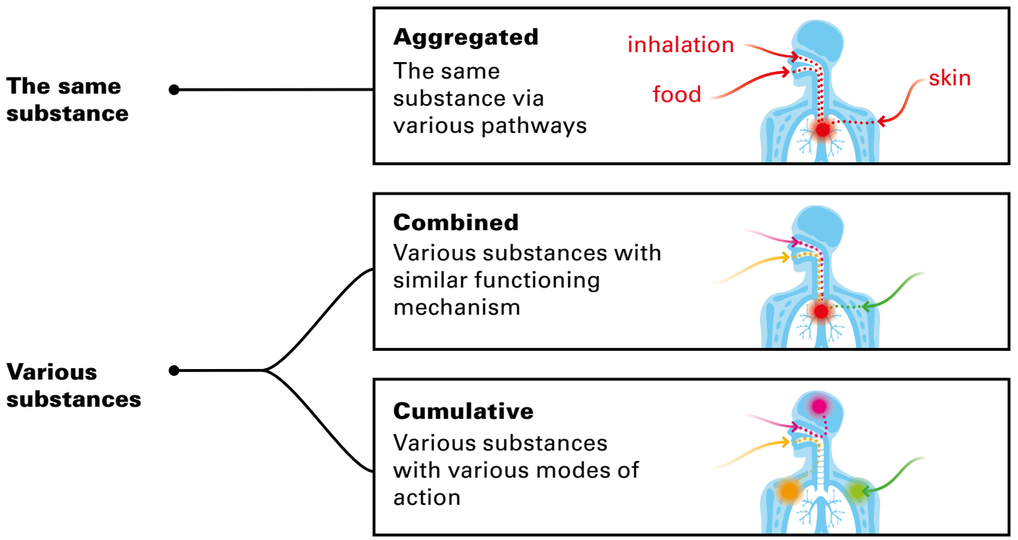
In ecosystems, simultaneous or consecutive exposure to various substances demonstrably leads to 'toxic pressure, which increases the likelihood of negative effects. Recent research into methods for monitoring and evaluating environmental risks has shown that, in various Dutch water systems, concentration levels of individual substances are below the standard, but together they still cause ecological damage. One of the conclusions of the study is that an average 30% of the decline in biodiversity in European water systems can be attributed to this toxic pressure (Posthuma et al., 2019). Another study shows that the use of plant protection products leads to combined exposure for pollinating insects,

13 See Chapter 4 of Part 2 of this advisory report, for more information on cumulative exposure.
14 The term 'mixtures' is used here to refer to unintentional mixtures of substances that may have cumulative effects on humans or the environment, on the physical environment or in tissue. This is different from how the term is used in policy on substances, where it refers to intended compound mixtures of substances, or to substances occurring naturally as a mixture.

such as bees. Therefore, the risk of adverse effects in these species is higher than the estimated risk of the individual substances at the time of authorisation (David et al., 2016).

The European Commission already put this risk of 'cumulative' exposure on the agenda in 2009 (European Commission, 2012a). There is now broad scientific consensus that, at currently measured concentration levels, exposure to combinations of substances in the physical environment poses a greater risk than does the exposure to individual substances (see also Section 3.3 below).

Figure 5: Types of cumulative exposure



2.3 In the transition towards a circular economy, hazardous substances raise new questions

The transition towards a circular economy makes the current issues surrounding the safe handling of hazardous substances in the physical environment more pressing and also raises new issues (see Figure 6).[15] As a result of reuse and recycling, hazardous substances end up as 'secondary raw materials' in product chains, something that was not envisaged when these substances were developed. This can lead to new and unexpected exposure pathways. Residues of recycled plastics (i.e. plasticisers) have been found in, for example, toys and pizza boxes (Health Council of the Netherlands, 2018). Concentrations of zinc, cobalt and mineral oil have been found in recycled rubber that is applied in granular form to artificial grass pitches (i.e. *rubber crumb infill*, used to keep artificial grass fibres in an upright position), which can seep into surface water and soil (De Groot et al., 2017).

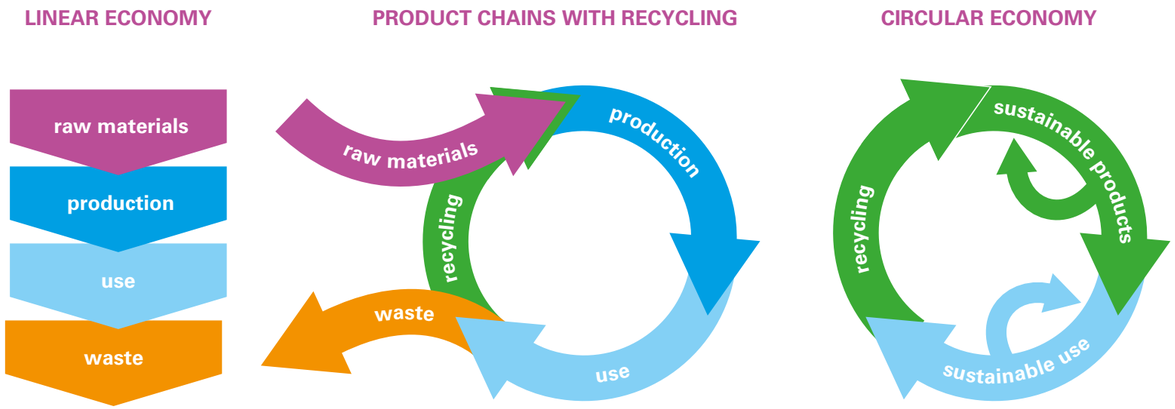
In addition, in cases of frequent recycling, hazardous substances may accumulate in products. If, during repeated recycling, non-degradable substances continue to be added to products, the concentration levels of substances in those products can become so high that, over time, such products no longer meet the safety requirements. This is already the case in the paper production and recycling chain, as printing inks contain hazardous substances that accumulate in recycled paper and cardboard products (Koch et al., 2018).

15 See Chapter 6 of Part 2 of this opinion for more information on circular economy

In addition, existing and old products may contain substances that have since been banned because of the risks involved. If such products are reused or recycled, people once again may become exposed to these banned substances. In the transition towards a circular economy, a solution must be found for products that contain substances that cannot be safely reused or recycled and must therefore be phased out.

If we do not find solutions to these problems, the transition to a circular economy will be even more difficult. Prevention through safe design of substances and products is therefore of great importance.

Figure 6: Transition from a linear to a circular economy (based on: Tweede Kamer, 2014)



In the scientific community, views differ about the handling of hazardous substances in a circular economy. Roughly speaking, there are two schools of thought. The first is of the opinion that there is no room for hazardous substances in a circular economy. According to these scientists, creating sustainable closed-loops of raw materials calls for all substances in the economy to be without risk to people and the environment. The second school of thought is less stringent about the subject and sees possibilities for hazardous substances being used in a circular economy, provided these substances continue to circulate in controlled closed-loops of raw materials and are permanently reused – and, thus, are never emitted to the environment. Nor should they end up in product chains where they could give rise to undesirable exposure risks.

Both schools aim for the transition towards a circular economy to also be an incentive to reduce both emissions and the dispersion of hazardous substances within the physical environment. After all, substances and materials 'leaking' away, from such closed-loops in emissions or as waste is not circular. Where such leakage is unavoidable, substances ideally should be biodegradable, and degraded products must not lead to adverse effects for either people or the environment.

Microplastics in table salt

3 CURRENT POLICY DEVELOPMENTS NOT YET SUFFICIENT

Various initiatives have been launched, in recent years, to improve policy on hazardous substances and reduce the risks to people and the environment, in the European Union as a whole or in the Netherlands in particular.

In the EU, following the evaluation of the REACH Regulation in 2018, an action plan was set up to improve the policy on substances. According to this plan, the information provided by producers about the properties and risks of substances should be reviewed more intensively (ECHA & EC, 2019). The RIi has high expectations of the 'group approach' announced in this context, whereby substances with similar toxic properties are not assessed individually but as a group (EC, 2018). This will speed up assessment procedures, help to prevent risks to the physical environment and reduce the likelihood of hazardous substances being replaced by those with similar hazardous properties (regrettable substitution) (Rudén, 2019; Tweede Kamer, 2018b).

In the Netherlands, recent policy developments are aimed at improving environmental policy. One such example is the implementation programme 'addressing emerging substances in water' (*Aanpak opkomende stoffen in*

water). This programme takes a broader look at the environmental risks by also considering non-authorised substances whose hazardousness have not yet or not fully been established and for which the environmental standards have not yet been set (Tweede Kamer, 2018c).

The RIi notes that current government policy has taken major steps to control the risks of hazardous substances, but that this policy does not appear to be sufficient to address problems in the future. Six points of attention are identified, in addition to current policy developments, and are discussed and explained in the following sections.

3.1 Incomplete risk assessment in the implementation of policy on substances and the environment

In the implementation of hazardous substances policy and environmental policy, the RIi finds a number of shortcomings regarding the risk assessment; for example, the information provided by producers on substance properties is inadequate, there are gaps in the assessment of substances, there is a lack of coherence between emission standards for air, water and soil, and there is insufficient knowledge on the part of authorities acting as enforcers and licensing authorities. An explanation of these shortcomings is given below.

Information in REACH dossiers is inadequate

Most of the substances produced in the chemical industry are covered by the European REACH Regulation.[16] The regulation stipulates that producers/importers of substances must register these substances for access to the European market. Depending on the market volume, these companies must provide information about the properties and risks of the substances in question. The responsibility for investigating the properties and risks related to those substances lies with the companies concerned. The information provided is included in registration dossiers and reviewed in a process of random sampling by EU authorities.

The information in these REACH dossiers is often insufficient. The European Commission found too many of the dossiers to be incomplete or not up to date and therefore strives to intensify the dossier review process (EC, 2018). To this end, the EC decided to increase the number of REACH dossiers subject to review from 5% to 20% (ECHA & EC, 2019). The Dutch Government supports this proposal (Tweede Kamer, 2018d).

The risk assessment of substances under the REACH Regulation should, in principle, cover the whole life cycle of a substance, from its production and incorporation into products, to the use of these products and its ultimate transformation in waste. In practice, REACH dossiers usually do not provide a full picture. Producers and importers of substances usually do not have a complete understanding of the products in which a substance will

16 See Chapters 1 and 3 of Part 2 of this advisory report, for more information on the REACH Regulation

eventually end up. Nor do they have any insight into possible exposure and the related risks. One of the reasons for this lack of insight is the absence of transparency about how and where substances are used, as well as their practical applications.

Gaps in the evaluation of plant protection products and medicinal products

Plant protection products and medicinal products are subject to an authorisation regime under current environmental policy. A substance can only be marketed after the information supplied by its producer has been reviewed. In this way the government can gather the necessary information for reviewing these substances prior to them being introduced to the market. The government then draws up instructions for use for each specific application of these substances, so that risks are controlled.

However, there are 'gaps' in government assessments of plant protection products and medicinal products. For example, when assessing the latter, the government only considers the effects on humans and does not take into account the adverse effects on the environment, although these do exist due to the growing use of medications.

As indicated earlier (see Box 1 in Section 2.1), since 2016, the Dutch Government has been working with various partners in the supply chain to reduce the environmental risks of pharmaceutical residues by means of the 'Chain approach to pharmaceutical residues in water' (Tweede Kamer, 2018a). In this context, agreements are made with the pharmaceutical industry, for example, to take environmental effects into account as early as in the developmental phase of medicinal products and in the case of hospitals to investigate how emissions could be reduced there. According to the Rli, these are the first steps into the right direction, but they do not provide a systematic solution to the problems described. It is therefore as yet unclear whether this approach will prove to be sufficient.

In the case of crop protection, the environmental impact is taken into account in the process of authorisation. Nevertheless, as indicated in Section 2.1, the total environmental impact of the use of plant protection products has increased, in recent years. This is partly due to the fact that the substances used are more toxic than before and also because the authorisation does not sufficiently take into account the concentrations already present in the environment from applications other than the one applied for. The Ministry of Agriculture, Nature and Food Quality's recently published 'Toekomstvisie gewasbescherming 2030' (Future vision for crop protection 2030) (Tweede Kamer, 2019a) acknowledges the problem of pollution caused by plant protection products and has announced a change in policy. The Minister wants to focus on the development of resilient crops and cultivation systems to prevent the use of plant protection products, as much as possible. This is in addition to the existing integrated plant protection policy that is aimed to ensure virtually no emissions to the environment and virtually no residues in products.

Lack of coherence between air, water and soil standards

Current policy includes separate standards for the emission of hazardous substances to air, soil and surface water. For each of these

'environmental compartments' the policy has a certain risk approach. The emission standards do not take account of the relationship between the environmental compartments, although such relationships are a given. After all, emissions of substances into the air (which meet the standard) can later end up in the soil through precipitation, where they contribute to an exceedance of the standards for their use in soils. The same applies to substances that end up in water and on soils via sludge or in groundwater through infiltration. This lack of coherence is mainly a problem in the use of PMT (persistent mobile and toxic) substances (see Section 2.1). These can easily spread throughout our physical environment and, via soil or air, pose a threat to drinking water quality, for example (Vewin, 2018).

Insufficient knowledge on the part of competent authorities acting as enforcers and permit issuers

The REACH Regulation has created a comprehensive database of informational dossiers on individual substances placed on the European market in quantities above 1 tonne per year. However, for monitoring and authorisation purposes, the available information appears to be used insufficiently by authorities. Moreover, the information is often not sufficient to adequately assess any emission-related risks to humans and the environment. This is because governments themselves often do not have the necessary capacity and knowledge to properly interpret and control the information provided by companies on the risks related to the production, use and emission of substances (Meer et al., 2017; see also Box 2). This applies particularly to substances that are not placed on the market, but serve as intermediate products in the production of, for example, medications, pesticides and dyes, or substances below the volume limit of REACH.[17] In 2018, evaluation of the REACH Regulation also found that national enforcement during the assessment of imported goods needs to be strengthened (EC, 2018).

Box 2: Risks of substances are not always stated in authorisation application forms

Research by Rijkswaterstaat has shown that government authorities regularly fail to identify the risks in the environmental permits they issue because those are not reported by the producing companies. A pilot project of 66 environmental licences showed one third of the licences to relate to the production of several 'substances of very high concern' whose risks were not mentioned in the permit application, neither were they part of the consideration by the licensing authority (Tweede Kamer, 2019b).

The government has only limited knowledge and capacity to interpret and control the information provided by companies. This is a consequence of the decision to place the responsibility for risk assessment with market parties, and the responsibility for policy implementation with local and regional authorities.

17 Pyrazole is an example of such an intermediate substance. In 2015, an unexpected discharge of pyrazole into the Meuse led to the suspension of surface water abstraction for drinking water.

With the current limited knowledge and capacity and the rapid pace of substance development, adequate government review is not feasible. In implementing and enforcing environmental policy, local and regional authorities regularly lag behind: substances are often already in production or on the market before thorough risk assessments can be carried out. The competent authority can then draw up a provisional indicative standard, but this also requires knowledge and capacity. The result is that some hazardous substances unintentionally end up in the physical environment, without the government being prepared for this. This undermines the confidence of citizens in the government; citizens expect the government to monitor the risks in the physical environment.

A number of efforts to improve the supply of knowledge and information have already been started. With the implementation programme, addressing emerging substances in water', a start has been made to increase government knowledge about hazardous substances; for example, by combining and sharing knowledge more quickly (Tweede Kamer, 2018c). In addition, since 2016, companies that emit a 'substance of very high concern' to air are now required to provide information, every five years.[18]

18 The five-yearly information obligation has been included in the Activities Decree since 2016 (Article 2.4(3)); this means that, as yet, there is no practical experience of its effectiveness

3.2 Lack of coherent risk management throughout the lifecycle

Current environmental policy focuses on specific phases in the life cycle of hazardous substances. As a result, the total in emissions during the entire life cycle is not sufficiently clear (see Box 3). Environmental policy is mainly limited to regulating the phases of production and waste. There is hardly any policy to reduce the risk of emissions in the use phase. As a result, there are 'blind spots' in the life cycle of substances and there is insufficient coherence in government control. There is a need for comprehensive policy, enforcement and monitoring throughout all the phases the substances go through: from the production phase, the use phase (including re-use and recycling) to the waste phase.

For the production of hazardous substances, the government's environmental policy has various rules with which producing companies must comply. These include standards for emissions to soil, air and surface water. The condition for an environmental permit is that a company limits its emissions as far as possible by using the best available clean technology.

Environmental policy also has rules for the waste processing of hazardous substances. During this phase, comparable standards apply to emissions to water, soil and air, which are regulated by environmental permits.

Although there is regulation through environmental permits in the production and waste phases, each permit is granted within its own system.

Because these processes are separate from each other, it is not possible to carry out overarching and coherent supervision over the entire chain (ILT, 2019). In practice, this means that environmental monitoring of waste disposal is less adequate than in the production phase. For example, the risk of emissions of a highly toxic substance such as PFOA is better controlled in the production phase than in waste disposal (see Box 3).

Box 3: Lack of insight into PFOA in waste streams

In recent years, PFOA emissions to air, water and soil from the production location of the chemical company DuPont / Chemours in Dordrecht has been greatly reduced. This is partly due to enforcement in the production phase. By far the largest amount of PFOA (90% of the total PFOA stream) has left the company via the waste product stream. For a long time, the competent authority failed to control this stream, because the waste stream was not included in the environmental permit. The waste processing companies were not informed about PFOA in the waste stream because the mandatory limit of 0.1% by weight was not being exceeded. In recent years, much of the highly toxic PFOA ended up in the physical environment unnoticed, particularly via waste disposal (ILT, 2019). PFOA is now no longer used at this location.

In the use phase, i.e. after a substance has been incorporated in an intermediate or end product and before it enters the waste phase, there is hardly any regulation of emissions. Regulation of the safe use of products focuses mainly on safety for humans. The protection of the environment, in this phase, is often not included in regulations (e.g. product regulations). This is a gap in risk management, because a significant amount of emissions may occur in the use phase of a substance. In the case of microplastics and medicinal products, most of the emission into the physical environment even takes place during this phase (CBS, 2018; Tweede Kamer, 2019c; Lahr et al., 2019). In the case of plant protection products, authorisation includes instructions for use, in order to limit the emission of hazardous substances during use. After the authorisation, however, there is no limit on the amount used and no emission ceilings are set. In practice, this leads to plant protection products in water systems exceeding the standards (Tiktak et al., 2019).

3.3 Risks of cumulative exposure are insufficiently assessed

Existing policy does not address the risks of 'unintended mixtures'.[19] These are mixtures of substances that are simultaneously present in water, soil, air, food, organisms or human tissue and that have ended up there from various sources and along various pathways. There are concerns about whether humans and the environment are adequately protected in practice (Rudén, 2019; Posthuma et al., 2019; Carvalho et al., 2019). In 2012, the European Commission already concluded that, under the current European framework, there is no mechanism for systematic, wide- ranging and comprehensive assessment of the adverse effects that exposure (along

19 See Chapter 4 in Part 2 for more information on mixtures and cumulative exposures.

various pathways) to mixtures of substances may have on humans and the environment. Monitoring, assessment and control of cumulative exposure is necessary, simply because of the increase in the number of substances (European Commission, 2012a). The multitude of chemical substances that are not included in REACH registration because of their low production volume, contribute to the cumulative effect, as well.

The risk of cumulative exposure has been discussed for much longer (Tweede Kamer, 1989). But, for many years, there was no agreement about how cumulative risks could be assessed. Now, however, there seems to be consensus on a suitable method for summing up risks, the basis of which is formed by the so-called *concentration addition approach* (Rudén, 2019).

Current risk assessment of substances is based on exposure to individual substances. The assessment and authorisation of substances applies a number of uncertainty factors, but the potential cumulative exposure of humans and the environment is taken into account only to a limited extent.[20] Environmental quality standards for air, water and soil, which are set as safe limit values for individual substances, also fail to address the risk of cumulative exposure. The risks of cumulative exposure are also not taken into account in setting emission standards for air and water.

20 The human health standard sets a safety margin for exposure to a single substance from different compartments of the environment, but not for simultaneous exposure to several substances.

3.4 Insufficient enforcement of corporate duty of care under the law

The safe handling of hazardous substances in the physical environment requires that the state of the art in technology and current insights into the risks and potential risks of substances are quickly and adequately translated into precautionary measures. This is crucial, because the risk assessment of substances is often surrounded by uncertainty, especially when it comes to long-term effects.

The so-called precautionary principle provides government authorities with a guide for situations when there is a potential risk about which there is no scientific consensus.[21] If, for example, a company's actions (e.g. the discharge of a substance) could cause irreversible damage to society or the environment but there is no scientific consensus about the possible damage, the burden of proof under the precautionary principle lies with the company – i.e. the producer must first demonstrate the safety of his substance.

The precautionary principle is reflected in the Dutch policies on substances, the environment and products, in the form of duty of care stipulations for companies. Under the Environmental Management Act, for example, companies have the duty of care to minimise their negative impact on the physical environment. If a company has reasonable grounds to suspect

21 The precautionary principle is one of the basic principles of EU environmental legislation and is laid down in the REACH Regulation and the Plant Protection Products Regulation. See Chapter 3 in Part 2, for more information on principles in environmental legislation.

that certain emissions may have an adverse effect on the environment, it is obliged to refrain from releasing these emissions or take measures to prevent, limit or reverse their impact as much as possible. In concrete terms, this means that companies must apply the best available techniques to control their emissions (cost-effectively) and avoid or minimise the use of 'substances of very high concern'.

The RIi observes that, in practice, companies are insufficiently stimulated to fulfil their duty of care, and, in the event of a suspected risk, to opt, for example, for the use or development of safer alternative substances, or for further research into such a substance. In this regard, a persistent problem is that when a substance is banned, it is sometimes replaced by a substance that is scarcely less hazardous but is not (yet) banned.[22] The RIi identifies a number of causes for this limited interpretation of the duty of care by companies.

In the first place, there is a lack of legal enforcement. After companies have been issued with an emission permit, the duty of care stipulation is only enforced to a limited extent. For example, companies are hardly held to account for the timely implementation of the best available techniques (Meer et al., 2017). In addition, during a permit period and when renewing environmental permits, competent authorities barely test for new insights into the risks of substances or the availability of less hazardous alternatives. In practice, there is therefore no question of continually minimising the impact on the environment. It appears that environmental permits are not being updated within the required timeframe. An inventory of environmental permits issued by Rijkswaterstaat showed that 75% appeared to need updating, a quarter of which preferably in the short term (Tweede Kamer, 2019c). To facilitate such updating, since 2016, licence holders have been obliged to provide information every five years on the reduction in the emission of substances of very high concern to the air (Activities Decree, Article 2.4, clause 3); with the entry into force of the Environment and Planning Act, this also applies to emissions to water.

Secondly, the market provides little incentive for companies to act in accordance with their duty of care. From a commercial point of view compliance is unnecessary, as there are no financial consequences. Companies are rarely held liable for damages (De Jong, 2016). Incidentally, the RIi also sees a positive trend, with companies increasingly being confronted by retailers and investors with questions about the use of hazardous substances. The use of such substances is seen as a business risk (Torrie et al., 2009; Tickner, 2019).

Finally, there is hardly any societal pressure on companies to fulfil their duty of care. Citizens, generally, do not join the debate on the safe handling of hazardous substances, whereas – with the choices they make as consumers and with their activism towards companies and governments – they could be an important driving force for social and business communities to work towards a safe and healthy physical environment. In practice, however, people are far from being involved in risk assessment, in this complex

22 This phenomenon is also known as *regrettable substitution.*

dossier. The risks related to substances and the considerations for their use are often not known to the general public; it is often unclear to consumers which substances are contained in the products they buy. Only when things go wrong certain concerns arise. Incidentally, there are a number of NGOs, such as ChemSec, who do confront retailers and companies within the EU with the use of hazardous substances in products.

The Dutch policy on substances from the category ZZS and, in particular, the list of potential ZZS, can be an important instrument to stimulate precautionary action. The latter list contains substances that are suspected of being dangerous, but which are not yet subject to concrete restrictions on use. It can be argued that companies should act in a precautionary manner when using these substances by minimising their use, seeking safer alternatives or carrying out further research into the risks posed by the substance. At the moment, companies are not being called to account on this subject.

3.5 Chemical policy not in line with circular economy

The European Union, including the Netherlands, is aiming for a safe circular economy by 2050. In Europe, this also includes the goal of achieving a non-toxic environment by 2050 (European Commission, 2013). The transition towards a circular economy means that more and more raw materials will be reused, possibly after processing. In order to do this safely, the entire lifecycle of substances and products need to be taken into account in their development and design, including their reuse in new product chains. The Dutch Government encourages companies, through projects such as 'Safe by Design' and 'Safe & Circular', to weigh up the risks to people and the environment at the earliest possible stages of substance and product development. In doing so, the government is pointing to the importance of considering reuse when developing substances and to include attention for unforeseen new applications (Tweede Kamer, 2018d; 2018e).

The RIi notes that the extent to which safe reuse is possible is currently not included in the government's decision on whether or not to restrict the use of certain substances on the European market. The REACH dossiers available to the government provide no information on the particular risks of substances ending up in in circular chains. These dossiers are not intended for that purpose and, as a result, developers of substances are not obligated to carry out any research into this.

In a circular economy, companies will be using each other's residual products and consumer waste streams as their raw materials. The RIi notes that there is still too little transparency in product chains about the composition of those 'secondary raw materials' that are to be reused as well as about the pathways followed by these substances. As a result, buyers of these types of secondary raw materials cannot be certain about

the safety of their products.[23] In the case of primary raw materials, their composition is clearer and safety can be guaranteed. The EU is currently working on a database of the substances of concern that are incorporated into products.[24] For some of the hazardous substances, this will provide insight in their location within the product chain.

The use of secondary raw materials (from waste streams) is subject to a different risk assessment regime than that of primary raw materials. The authorisation rules under waste policy apply to the first case, whereas, in the second case, the applicable rules are those from the policy on substances based on the REACH Regulation.[25] The Task Force reassessment of waste product policy (*Taskforce Herijking Afvalstoffen*, Tweede Kamer, 2019d) notes that this difference is an obstacle to closed-loop cycles. The task force calls for the REACH approach to also be used in risk assessments of secondary raw materials (waste). The RIi endorses this proposal.

23 There are, however, a number of obligations. Under waste regulation, producers are obliged to report about the presence of substances from the ZZS category within waste or product streams when mixtures contain more than 0.1%. In the case of highly toxic substances, even lower concentrations may pose a problem; particularly in a circular economy, where accumulation of substances and unexpected exposure pathways can occur. The Dutch Human Environment and Transport Inspectorate (ILT) has rightly noted that, due to their duty of care, companies are actually required to provide this information at values below 0.1% (ILT, 2019). However, this is not done consistently

24 This is the SCIP database of the European Chemicals Agency (ECHA). SCIP stands for Substances of Concern. In individual items or in more complex products

25 See Chapter 6 of Part 2 of this advisory report for more information on the difference in the risk assessment regime

4 RECOMMENDATIONS

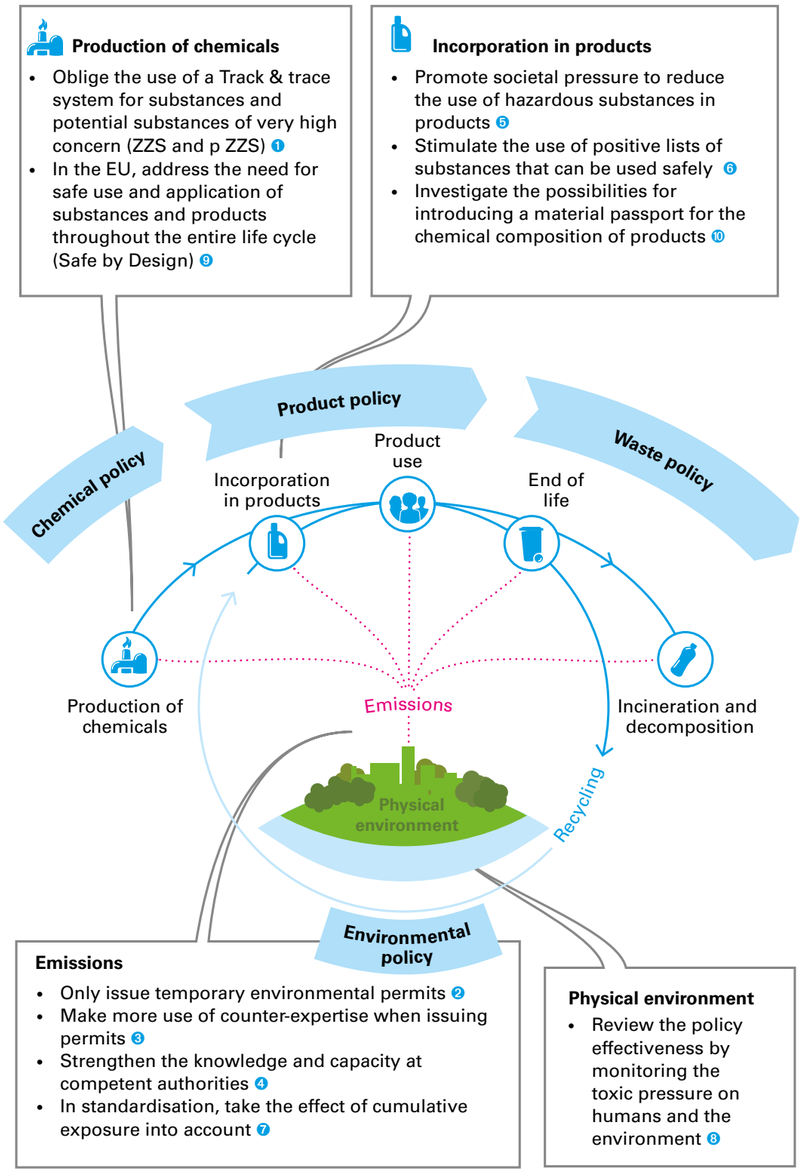
Much has been achieved, in recent years, with the chemical policy. Risks have been reduced and the quality of the physical environment has improved. More information about substances has also become publicly available. At the same time, the RIi notes there are problems that are expected to increase, in the years to come, and for which the existing policy will be insufficiently effective. On the basis of the current analysis, the RIi concludes that improvements are needed, in both policy and its implementation, in order to permanently reduce the occurrence of hazardous substances in the physical environment and thus also reduce the risks to people and the environment.

This chapter presents 10 recommendations that can help to gain more control over the dispersion of substances within the physical environment, reduce the adverse effects of cumulative exposure and work towards a safe circular economy by 2050 (see Figure 7). These recommendations are partly aimed at strengthening the use of existing policy instruments to avoid emissions, and reduce the use of hazardous substances. They also concern new policy measures, focusing on the EU objective for a non-toxic environment by 2050 (European Commission, 2013).

Although the recommendations described below focus on government action, improving the quality of the physical environment is not a task for government alone. Government authorities, businesses, citizens, civil society organisations and knowledge institutions will all need to work together. This requires greater transparency about and understanding of the properties and risks of substances, in order to increase the involvement of shareholders and citizens in weighing up the usefulness and necessity of substances. This transparency is also important in view of the movement towards the safe use of substances in a circular economy. Knowing which substances are in which products and what risks are involved is crucial for the formation of safe closed-loop cycles.

The RIi is aware of the international character of the chemical sector and that Dutch policy partly depends on EU rules and regulations. A European approach is necessary on a number of points, if only because the material cycles transcend Dutch borders. However, the RIi sees opportunities for the Dutch Government to address the problems within the international context.

Figure 7: Ten recommendations regarding the policy on dealing with hazardous substances in the physical environment



4.1 Recommendations for more control of the dispersion of substances within the environment

1. *Oblige companies that introduce substances and potential substances of category ZZS into the product chain to use a track & trace system that follows the volume stream of the substance throughout the chain. Establish this in national legislation.*

- Competent authorities could use the information from this track & trace system to identify 'leakages' in all phases of the chain, including those related to use and waste, and to focus policy, supervision and enforcement on the riskiest leaks. Increased transparency also incentivises companies to avoid the use of substances of very high concern.
- Competent authorities could also use the information to obtain a full picture of the effects of cumulative exposure in the physical environment.
- The national government should create a database in which this information can be recorded and ensure that the development of such a system is in line with developments within the EU (ECHA, 2019a).

2. *Competent authorities are recommended to grant temporary environmental permits in order to be able to hold companies more accountable for their duty of care in order to minimise the impact on the physical environment.*

Instead of the current practice of long-term environmental permits or tacit renewal of environmental permits, the Rli recommends issuing temporary permits more often.[26] When renewing the temporary environmental permits, they should be assessed on the following elements:

- the way companies implement their obligation to gather additional information in the event of uncertainties or changing insights into the risks of a substance;
- the application of current best available techniques;
- the progress made in avoiding substances of very high concern and substituting dangerous substances with safer alternatives.

For existing long-term environmental permits, the Rli recommends investigating whether updating may be appropriate and, if so, assessing the permits based on the same criteria.

3. *Competent authorities are recommended to make more use of counter-expertise when granting environmental permits.*

Such counter-expertise could be used to validate the information provided by companies; for example, by having this information checked by consultancy firms. The resulting information and experience can then be shared with others. In the Province of South Holland, this was shown to be useful (Provincial Executive of South Holland, 2019).

26 This is possible where there is an 'overriding reason relating to the public interest'; protection of the environment can be regarded as such.

4. *Strengthen knowledge and capacity in implementation, enforcement and monitoring. Support this through additional funding by the national government.*

Assessing emissions within the entire chain, reviewing the efforts made by companies when granting temporary environmental permits, and interpreting the results of counter-expertise require a further strengthening of the current implementation force. In addition, the increase in the use of substances underlines the need to invest in the development of knowledge about the risks of new substances and in the systems to monitor and assess the cumulative effects of substances. This will require additional funding for implementation, enforcement and monitoring.

5. *The national government is recommended to promote opportunities for citizens and societal stakeholders to exert pressure to reduce the use of hazardous substances in consumer goods.*

Ensure companies show greater transparency about their handling and use of substances, in order to strengthen market and societal incentives. This will enable citizens and investors to make more informed purchasing or investment decisions. At the same time, companies that demonstrably reduce their impact on the physical environment will be rewarded in this way. It will also make it easier for citizens and societal parties to claim damages from companies that have not taken precautions in the production or use of hazardous substances. Impending liability is an important incentive for companies to act and take precautionary measures.

Transparency in companies can be increased by:

- promoting certification systems that make products containing relatively safe substances recognisable on the market, in addition to the current mandatory provision of information;
- making information from companies on the use of dangerous substances publicly available. This can be done by promoting an annual environmental report describing the use of hazardous substances and their impact on the physical environment.

6. *The national government is recommended to encourage business sectors to use positive lists of substances that can be used safely, even in a circular economy.*

The positive lists in the clothing industry made by Stichting Zero Discharge of Hazardous Chemicals[27] are an example of this. Positive lists help all parties within a chain to work together on safer substances and also lead to a competitive advantage for companies.

4.2 Recommendations to limit the adverse effects of cumulative exposure

7. *When setting standards, competent authorities are recommended to take into account the effect of cumulative exposure in the physical environment. The national government could provide guidance on determining the risk of cumulative exposure in humans and the environment.*

27 See https://www.roadmaptozero.com

- When setting environmental quality standards, use a safety factor for cumulative exposure, taking into account the increase in substances in the physical environment.[28]
- For sensitive areas, in addition to the current standards per substance, a maximum allowable toxic pressure should be used. The carrying capacity of individual areas should be taken as a starting point.[29] Methods that can be used for this purpose have been developed and tested in SOLUTIONS, the European research programme.

8. *The national government is recommended to review the effectiveness of policy with a monitoring programme to measure the toxic pressure on people and the environment, in areas where an increased risk is expected.*

For example, use listed track & trace systems to identify such areas. Use new monitoring techniques, such as non-target screening (which substances are present in the environment?), human biomonitoring (which substances are present in tissues?) or biological effect monitoring (which effects of substances are seen in the environment?). This makes it possible to measure a much broader range of substances or their joint impact on humans and animals. If the monitoring shows adverse effects of substance accumulation in the physical environment, for example, the standards for permits can be tightened up or the authorisation of specific substances can be reconsidered.

28 There are various methodologies for assessing the risk of cumulative exposure, ranging from the concentration of mixtures to the total effect in organisms or tissue (see Rudén, 2019).

29 For the quality of water systems, the register of protected areas established under the Water Framework Directive can serve as a guide.

4.3 Recommendations to ensure safe handling of substances in the circular economy

9. *The national government is recommended to promote discussion at EU level about the need to take into account safe use and application of products and substances in the design phase, looking at their entire life cycle ('Safe by Design').*

This requires additional criteria for traceability, degradability and removability in the risk assessment of all substance groups.[30]

a. *Traceability*. Under continuous reuse of substances in the closed-loop cycles of a circular economy, there is the risk of unexpected exposure pathways and accumulation of hazardous substances. In order to monitor these processes, it is important that substances are easily traceable.
b. *Degradability*. Even in a circular economy, certain substances will end up in the environment. Some even immediately after first use, such as plant protection products and medications. The substances in these 'open chains' can be circular if they can be broken down quickly and without adverse effects to the environment.
c. *Removability*. Situations will continue to arise in which advanced insights cause substances to be considered too dangerous to use in a circular economy. It therefore pays to develop substances that can be easily removed from the economy.

30 Humane medications, veterinary medications, plant protection products, biocides, waste and secondary raw materials, and industrial chemicals.

10. *The national government is recommended to investigate whether material passports can be introduced to register the chemical composition of products and consider the possible role of the government in their use and management.*

A material passport may serve as the basis for the exchange of information between parties in product and material chains. The information on the composition of products provides insight into the reusability of products and substances and offers the opportunity to take this into account during production. For the right implementation and impact of material passports, it is important that proper agreements are made about how data are stored and shared, and ensure that those agreements are in line with those of European projects around the SCIP database (ECHA, 2019a).

PART 2 | ANALYSIS

READER

This second part of the advisory report provides background information on issues related to substances in the physical environment. In addition, it provides further explanation and additional examples to certain subjects of the analysis presented in Part 1.

1 SUBSTANCES: CATEGORIES AND CLASSIFICATION

This advice concerns substances that are used, processed or produced by humans and that may have adverse effects when dispersed within the environment or when exposed to humans (see also Chapter 1). These substances may be of natural origin or made entirely synthetically (i.e. man-made), and are incorporated in a range of products, such as building materials, paper, cars, textiles, pesticides, electronics, food, toys, furniture and pharmaceuticals. They include substances produced and applied in large quantities, such as plastics, as well as those with very specific applications, such as the active ingredients in pharmaceuticals or plant protection products. This chapter gives an overall indication of the number of various substances that occur and the categories that can be distinguished.

The number of substances registered is immense (see Figure 8). The international database, the so-called CAS Registry, has 158 million unique substances.[31] Only between 40,000 and 60,000 of these concern substances that are traded on the market, on an industrial scale (UNEP, 2019a). The number of marketed substances that are used in all types of consumer products has risen sharply in recent years and is expected to increase further in the coming years (Cefic, 2019).

In principle, any substance can be harmful to health and the environment. The likelihood of harm – the risk – depends, among other things, on the level of exposure. There are various systems for characterising substances and their harmful properties. The following classifications present an image of the nature and extent of the different types of substances.

Hazardous substances

The European Union's CLP Regulation on the classification, labelling and packaging of substances (European Parliament & Council, 2008a) has identified approximately 4,500 substances as being 'hazardous'. A hazardous substance is a substance or mixture that meets one of the criteria for physical hazards (explosive and flammable), health hazards (including acute toxicity, carcinogenicity and mutagenicity[32]) or environmental hazards (in particular to the aquatic environment, either acute or chronic). CLP Regulation requires companies to apply specific hazard identification labelling for these substances. This classification and the related rules are identical to the international agreements about the labelling of dangerous substances (United Nation's Globally Harmonized System of Classification and Labelling of Chemicals (UN GHS)).

31 Chemical Abstract Service of the American Chemical Society. CAS Register, accessed on 18 December 2019. See https://www.cas.org/support/documentation/chemical-substances

32 Mutagenic substances slowly alter the DNA in cell nuclei.

Industrial chemicals

Substances brought onto the European market (both existing and new substances) have to be included in the REACH Registry (ECHA, 2019b).[33] This registry now contains around 98,000 dossiers covering 22,500 substances.

In the REACH Registry, 201 substances[34] have been designated as substances of very high concern (SVHC). These are substances with one or more of the following properties (see Glossary in Part 1):

1. carcinogenic (i.e. substances that promote the formation of cancer)
2. mutagenic (i.e. substances that cause mutations to genetic material (usually DNA))
3. reprotoxic (i.e. substances that have a negative impact on reproduction)
4. persistent (i.e. substances that are hardly degradable), bioaccumulative (i.e. substances that accumulate in organisms) as well as toxic (i.e. substances that are poisonous)
5. very persistent and bioaccumulative
6. otherwise seriously threatening human health or the environment (e.g. endocrine disruptors).

33 This register contains information provided by companies on the properties and risks of the substances they produce or import. Maintaining this register is mandatory in all EU Member States under EU REACH Regulation. REACH Regulation describes the compliance obligation for companies and authorities that produce and/or trade chemical substances. It applies to all EU Member States (also see Chapter 3).

34 Situation on 16 July 2019: https://echa.europa.eu/nl/-/four-new-substances-added-to-the-candidate-list.

The REACH Registry contains many, but not all, substances that are made or processed by humans and that may end up in the environment. Those not registered include, for example:

- substances of which less than 1 tonne is produced per year;
- substances that are created during production processes but that, themselves, are not marketed (process substances);
- substances that emerge due to wear and tear, weathering or biological conversion (metabolites);
- substances that were produced in the past and are, today, still present in products or the environment;
- polymers[35];
- plant protection products, biocides and pharmaceuticals.

Plant protection products and biocides

The register of the Dutch Board for the Authorisation of Plant Protection Products and Biocides (Ctgb, 2019) contains 2,996 substances registered to be used as plant protection products, biocides or additives. These substances are not covered under REACH Regulation, but are subject to many other European regulations, European directives and national legislation.

35 Polymers are components in plastic materials. REACH Regulation applies not to polymers but to the additives used in plastics as well as to the monomer building blocks.

Medicinal products

The register of the Dutch Medicines Evaluation Board (CBG/MEB, 2018) contains 19,941 human medicinal products and 2,733 veterinary medicinal products.

Dutch lists of substances of very high concern and potential substances of very high concern

Dutch chemical policy refers to the category of substances that cause the most concern as 'Zeer Zorgwekkende Stoffen' (ZZS)[36]. This includes both the substances designated as 'substances of very high concern' (SVHC) in the REACH Registry, and those contained in one or more other European or international substance frameworks (the CLP Regulation, the *chemicals for priority action* identified by the OSPAR Commission[37], the priority substances from the EU Water Framework Directive and the European POPs Regulation) that, based on the same criteria as for SVHC, must be regarded as ZZS (De Poorter & Van Leeuwen, 2016). The Dutch National Institute for Public Health and the Environment (RIVM) manages the non-exhaustive list of ZZS, which currently lists 1,600 substances[38] (RIVM, 2019a).

In addition, RIVM manages a list of 'potential ZZS' (pZZS). This list serves as a tool for companies and licensees, among others, to reduce the emissions of these substances as a precautionary measure. The list includes substances undergoing the procedure for registration under REACH that are suspected of being of very high concern, but for which insufficient information is yet available. The qualification pZZS currently applies to 359 substances.[39]

Priority substances

Substances that pose a high risk in and via the aquatic environment and therefore have priority to be brought within the legally determined environmental quality standards are classified as 'priority substances'. The European Union's Water Framework Directive (European Union, 2000) contains a list of priority substances that is being supplemented on a national level with substances that are considered most relevant in the Member State concerned. The Dutch *Decree on Quality Standards and Monitoring for Water* contains a list of 45 priority substances.[40]

Emerging substances

Finally, the *Delta Approach to Water Quality and Freshwater Supply* and the Dutch soil policy (Tweede Kamer, 2018c) distinguish 'emerging substances'. These are substances that are suspected of having adverse effects on water or soil, but for which no standard has yet been set. They may be included

36 The Dutch term 'Zeer Zorgwekkende Stoffen' (ZZS) translates literally as 'Substances of Very High Concern' (SVHC). However, ZZS indicates a larger category of substances than the SVHC group as indicated by ECHA under REACH Regulation. The pZZS category in Dutch policy indicates substances for which its harmful properties have not yet been fully established. To avoid confusion, this report will use the Dutch abbreviations.

37 In the Oslo-Paris Convention (OSPAR), 15 countries that discharge into the Eastern North Atlantic work together to protect the marine environment. OSPAR's list of substances includes pollutants whose discharges, emissions and losses to the environment should be stopped.

38 Situation on 25 February 2019, derived from: https://rvszoeksysteem.rivm.nl/ZZSlijst/TotaleLijst

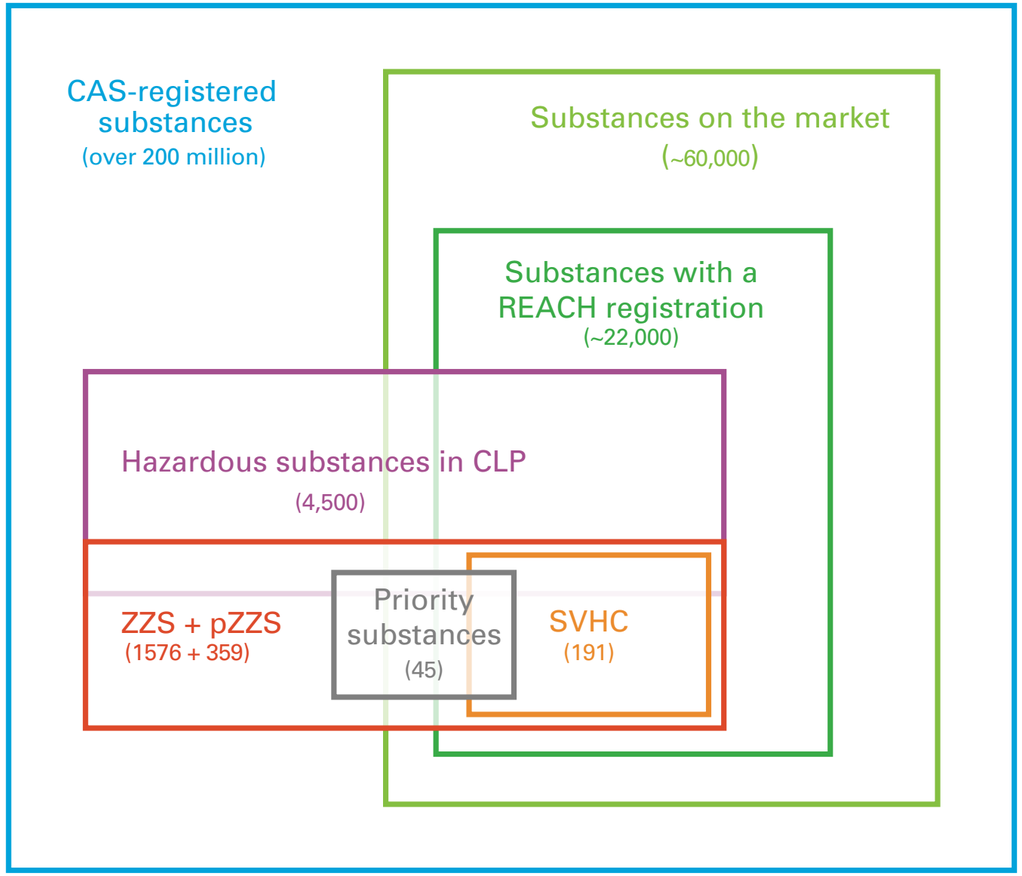
39 Situation on 11 November 2019: https://rvs.rivm.nl/stoffenlijsten/Zeer-Zorgwekkende-Stoffen/Potentiele-ZZS.

40 Appendix X of the WFD (2000/60/EG): https://eur-lex.europa.eu/legal-content/NL/TXT/PDF/?uri=CELEX%3A02000L0060-20141120&rid=1#page=89&zoom=100

in one or more of the categories discussed above. Sometimes these are substances that have already been introduced on the market and for which a REACH dossier has been created that has not yet been assessed by the European Chemicals Agency (ECHA). This means that environmental quality standards have not yet been set for those substances. This is, for example, the case for many nanomaterials (Bleeker et al., 2014) and also applies to substances such as PFOA and GenX. These last two had been in use for some time and were able to disperse throughout the environment before environmental quality standards were set.

Emerging substances may also include those not placed on the market (such as pyrazole,[41] which is used as an intermediate substance or is a by-product), or substances released in production processes or during the use of products (such as microplastics).

Figure 8: Estimated number of chemical substances in certain categories



41 Increased concentrations of pyrazole in the Meuse, in 2015, resulted in suspension of surface water abstraction for drinking water for a long time. In response, standards were set in 2017 for pyrazole levels in surface water intended for the drinking water supply, in 2017 (Staatscourant, 2017a). This case formed the basis for the Implementation Programme on Emerging Substances, aimed at addressing substances in surface water, groundwater and drinking water for which no quality standards have been set (see also Box 7). This made pyrazole an emerging substance avant la lettre.

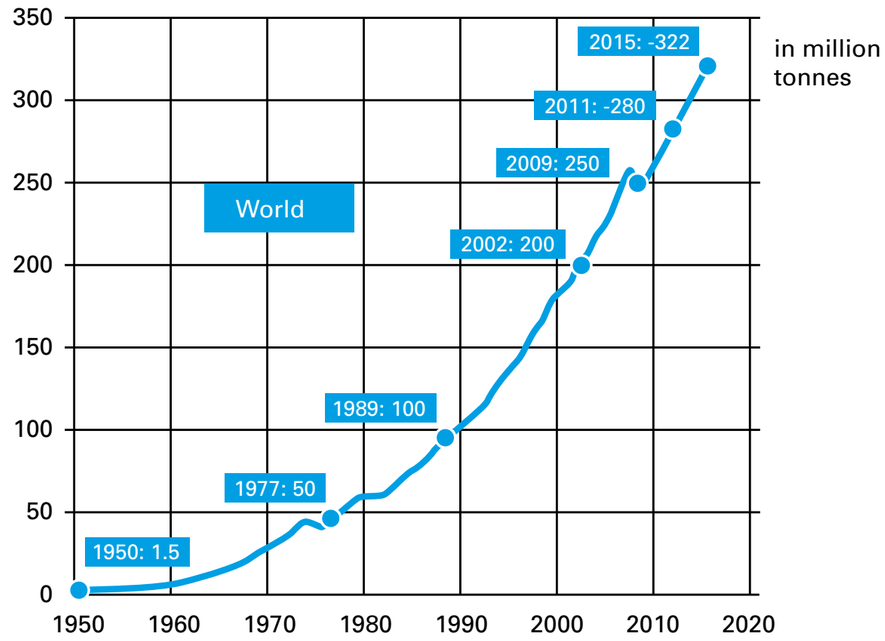
2 FACTS AND FIGURES ABOUT CHEMICAL SUBSTANCES IN THE ENVIRONMENT

The use of chemicals is on the increase, around the world, in terms of both volume and diversity. Even if individual substances remain below their risk-based screening values, this trend creates a growing problem. After all, the risk to people and the environment is not only determined by exposure to a single substance, but also by simultaneous exposure to several substances.

2.1 Global developments in the chemical sector

Worldwide, the production volume and diversity of man-made (i.e. synthetic) substances have increased, considerably, since 1955. The chemical sector has doubled in turnover over the past decade. This can be seen, for instance, in the growing volume of plastics produced on a global level (see Figure 9).

Figure 9: Developments in global plastics production between 1950 and 2015



Source: PlasticsEurope Market Research

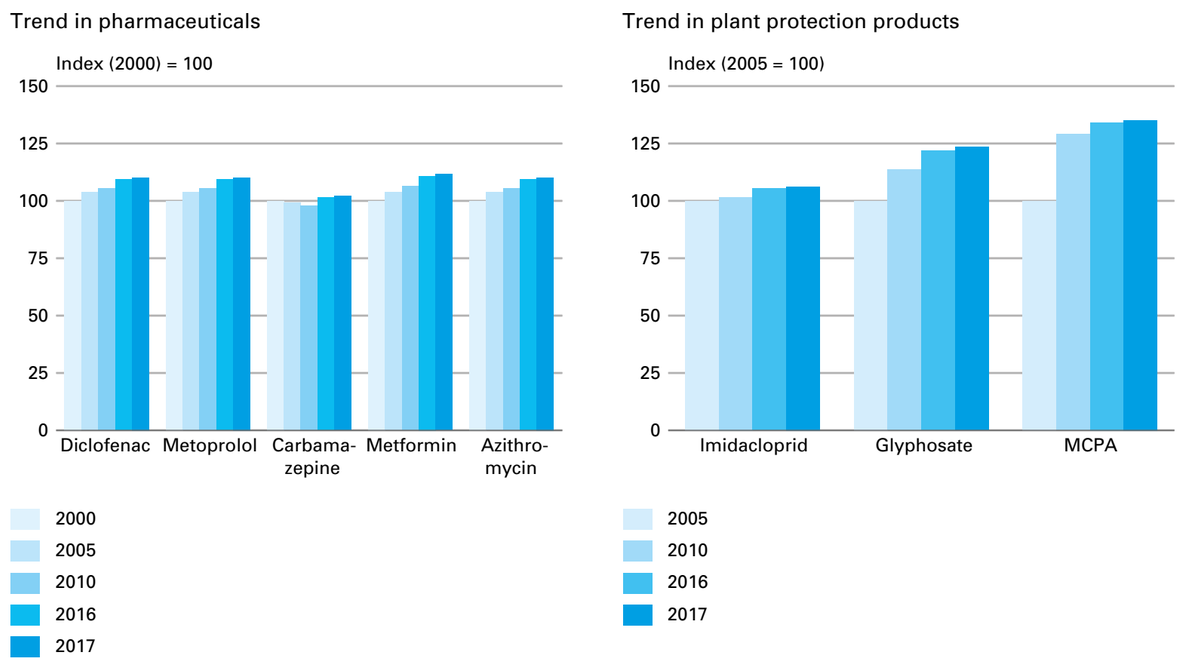
This trend is expected to continue and global turnover is expected to double by 2030, compared to 2017 levels (UNEP, 2019a). The European market for chemicals is growing at a slower pace, but the International Energy Agency projects substantial growth also in the European chemical sector, for the coming decades (Cefic, 2019). The European chemical sector is the second largest production region, after China. At the same time, Europe is also one of the largest markets for imports of chemical products. Innovations in

many areas, from plant protection products to consumer products, lead to new applications of existing substances, but, in many cases, also involve the development of new chemicals (UNEP, 2019a). The energy transition and the transition towards a circular economy, in the coming years, are driving forces to develop new substances, change production processes and develop new business models (Cefic, 2019).

2.2 Concentrations of hazardous substances in the environment

Man-made (i.e. synthetic) substances are found not only in the products for which they are intended; they also end up in other production chains through recycling. Residues of recycled plastics (i.e. plasticisers), for example, have been found in toys. Chemical substances are also dispersed within the environment (via discharges, wear and tear during use, or as waste) and pose a risk in that way. For example, various drinking water companies have expressed concern about pharmaceuticals in drinking water sources (Vewin, 2019). In the past, they already pointed to worrying trends in the quality of the groundwater as a source for drinking water production. Plant protection products that were banned from the market years ago, such as DDT, appear to still occur in groundwater. There are also concerns about substances such as PFOA and pyrazole, which spread very easily in water and are poorly biodegradable (Timmer et al., 2018). And, recently, microplastics have even been found in the Arctic region (Bergmann et al., 2019).

Figure 10: Trend in the pollution of surface water caused by the active ingredients in pharmaceuticals and plant protection products in waste water and wastewater treatment systems (CBS, 2018)



Concentration levels of certain plant protection products and pharmaceuticals in surface water have been found to be increasing, in recent years (see Figure 10). PBL Netherlands Environmental Assessment Agency concludes that the number of exceedances of the maximum residue levels (MRLs) of plant protection products at drinking water abstraction locations remains high (Tiktak et al., 2019). RIVM previously reported that,

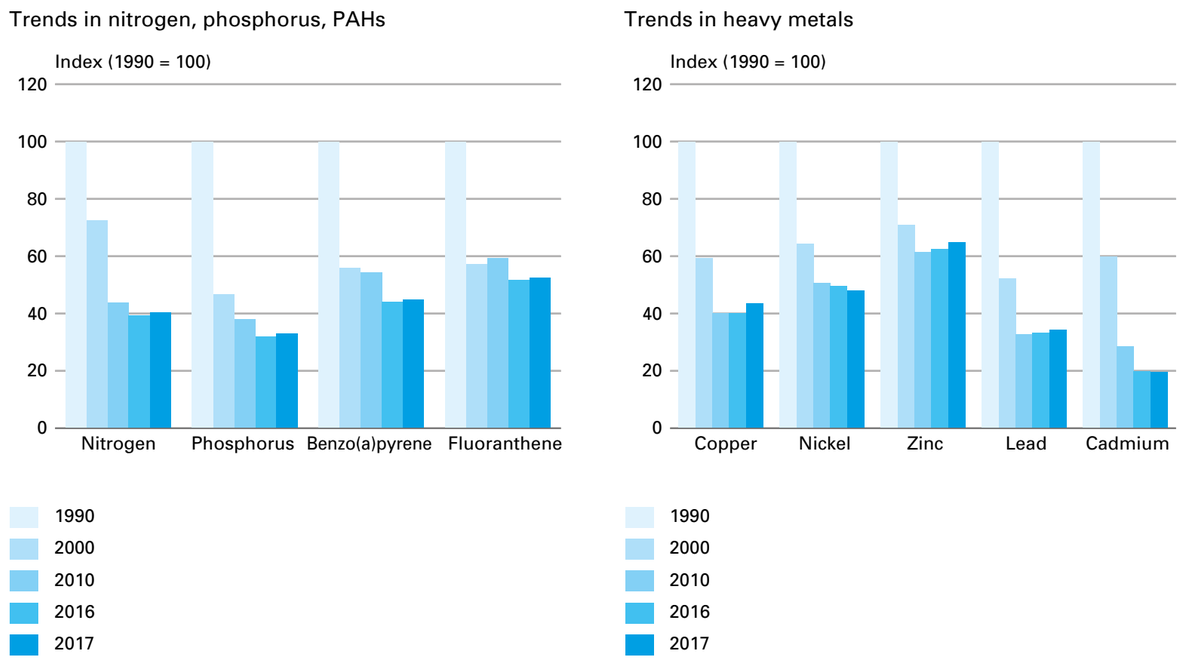
in the Netherlands, at least 140 tonnes of pharmaceuticals end up in open waters, each year (Moermond et al., 2016). The use of medicinal products and industrial chemicals is expected to grow further (CBS, 2018). Without additional measures, concentration levels of these substances in surface water will continue to increase.

For many other substances, concentration levels fell sharply between 1990 and 2000, both in the air and in surface water (see Figure 11). This mainly concerned priority substances that are addressed in water policy, for which the government has imposed regulations and permit conditions. Human exposure to these substances, therefore, also shows a declining trend. Since 2010, the decline in concentration levels in the environment has been less pronounced (Tweede Kamer, 2018d).

Concentration levels in the air have also decreased to a lesser degree, over the last decade. The average concentration levels in the Netherlands are still below the related health limit values (CBS, 2019).

For substances in the soil, hardly any data are available on trends in concentration levels. What is clear, however, is that toxic substances with low solubility may cause problems. For example, advancing insight into the hazardous properties of the PFAS group, in 2019, led to commotion about the presence and possible risks of PFAS in the environment. Limit values have since been set. However, there is still incomplete insight into their presence in the Dutch soil and about contributing sources. At various locations, the presence of PFAS now causes problems for the application and processing of soil and sludge (Tweede Kamer, 2019e; Bouwend Nederland, 2019; Tweede Kamer, 2019f).[42]

Figure 11: Trend in the pollution of surface water caused by specific substances in waste water and wastewater treatment systems (CBS, 2018)



42 The European Environment Agency recently published an overview of the risks of PFAS and the occurrence of these substances in the European environment (EEA, 2019).

2.3 Effects of hazardous substances within the environment

Research shows that only 40% of European waters have a good ecological status (EEA, 2018). Dutch water systems score no better than average when it comes to surface water biodiversity. The influence of physical interventions in watercourses plays a role in this respect, but the presence of various substances has also caused a certain amount of damage. Research shows that approximately 30% of the biodiversity loss in the water systems studied has been due to the presence of substances that do not belong in the water (Posthuma et al., 2019). This is mainly due to the combined effect of substances (see Section 4.1).

Recent annual data on the Rhine and Meuse rivers show a stagnation in water quality improvement. In periods of drought, this quality can even be seen to deteriorate, as there is less water to dilute the concentrations of substances. This has led to concerns among drinking water companies that rely on surface water (RIWA-Meuse, 2019; RIWA-Rhine, 2019).

People can become exposed to dangerous substances in the environment along various pathways; for example, through inhalation, food intake or drinking water. There is no national monitoring programme in the Netherlands that monitors the development of human exposure to specific substances. However, the Netherlands does contribute to certain elements of the European Union's biomonitoring project HBM4EU (Tweede Kamer, 2019c). In specific areas, in the event of incidents, studies are carried out into exposure occurring in the environment. In most cases, elevated concentration levels are measured, but there are no indications that health limit values are also being exceeded (Timmer et al., 2018). However, regularly, there are incidents involving increased exposure to hazardous substances, such as recent incidents among people living in the vicinity of Tata Steel, Chemours or flower fields (see Box 4).

Box 4: Exposure to plant protection products demonstrated

Various studies have shown that people are being exposed to hazardous substances, for example, via air, house dust or food. Around the homes of people living near flower fields, pesticide residues were found in the air outside and in the house dust inside their houses. Pesticides were also found in the urine of residents. The concentration levels measured did not exceed any thresholds and there was no evidence of health problems as a result of exposure. However, it could be demonstrated that a significant part of the exposure was caused by the use of pesticides in nearby flower fields (Montforts et al., 2019).

In Belgium, a national monitoring programme has been in place for some time now that, for various substances, provides insight into trends in the exposure of newborns, young people and adults (Steunpunt milieu en gezondheid, 2015).

3 FOUR PILLARS OF POLICY FOR THE SAFE HANDLING OF SUBSTANCES IN THE ENVIRONMENT

The policy for the safe handling of substances in the environment (excluding the Working Conditions Policy) is based on four pillars, which are shown in the diagram below (see also Figure 3 of Part 1 of this advisory report).

Box 5: Four pillars of policy

1. Chemical policy	2. Product policy	3. Waste policy	4. Environmental policy
Rules governing the production of and trade in hazardous substances, including industrial substances, plant protection products, biocides and pharmaceuticals	Rules for the safety of consumer products, including food and cosmetics, but also drinking water quality	Rules for the production, treatment, reuse and disposal of waste materials	Rules for the environmental compartments air, water and soil, aimed at both desired quality and allowable environmental load

The first three pillars focus on the three most important phases in the product chain: production, use and waste. Environmental policy focuses on emissions from various points along the product chain as well as on the impact (immissions) on the environment (Section 3.4).

The underlying principles for policy on the safe handling of substances in the environment are derived from European environmental policy and are explicitly included in the Dutch Environment and Planning Act (Article 3.3). In the Explanatory Memorandum to the Quality of the Physical Environment Decree,[43] the principles are described as follows:

1. The *precautionary principle* means that government authorities may take measures if there are reasonable grounds for concern that activities by companies may have a negative impact on the environment but the available scientific data are insufficient to make comprehensive risk assessments.
2. The *principle of preventative action* means that adverse effects on the environment must be avoided as much as possible, from the premise that prevention is better than cure.
3. The *principle that, as a priority, environmental damage/degradation must be combated at the source* is based on the premise that rectifying a problem at its source is more effective than combating its negative effects.
4. The *polluter pays principle* implies that the party carrying out certain activities is financially responsible for preventing, reducing and, if necessary, remedying any harmful effects of those activities on the environment.

43 Besluit kwaliteit leefomgeving (Staatsblad 2018, 29), Memorandum of explanation 16.3.2.

In addition to these principles of environmental policy, the general principles of good governance also play a role in government action, such as proportionality: the extent to which the government may expect parties to act must be proportionate to their contribution to the ultimate objective. This ensures that the freedom of citizens and businesses will not be unnecessarily restricted by government requirements for a general objective.

3.1 Substances legislation

Dutch legislation on substances, products and waste is largely based on EU Directives and international treaties. The substances legislation consists of separate components for various substance groups (such as industrial chemicals, plant protection products and pharmaceuticals), with major differences in the applicable authorisation regimes and risk assessments used.

REACH Regulation

For the production of and trade in industrial chemicals, which is by far the largest group of substances, REACH Regulation applies on an EU level (European Commission, 2012b). This regulation aims to better protect human health and the environment from the risks posed by hazardous substances, while improving the competitiveness of the EU chemicals industry. Furthermore, the regulation aims to promote the use of alternative assessment methods in order to reduce animal testing.

The REACH Regulation requires the producer of a substance to submit information on the properties and risks of the substance concerned. Without a consistent assessment of the hazardous properties, a substance may not be traded in the EU (with the guiding principle: 'no data, no market'). With the correct information in a REACH dossier, a substance may be traded throughout the EU unless there are prohibitions or restrictions ('authorisation and restriction rules') that apply due to specific hazards. The European Commission may impose restrictions on the use of a substance based on substance properties. It can also determine that a substance should be phased out. Mandatory phase-out is applicable to substances covered by the criteria for substances of very high concern, under REACH Regulation. A decision on phasing out or restricting the use of a substance will include a consideration of its socio-economic impact and the availability of a safe alternative. In practice, a phase-out is a lengthy process, which means that the production of a substance may continue for several years after a phase-out decision has been taken.

Producers and importers of substances are obliged to investigate the risks related to any substance they intend to introduce on the market. The nature and extent of the information depends on the volume of trade in the substance. From 1 tonne per year (see Chapter 1) onwards, as the tonnage increases, so does the required research obligation. Since the REACH Regulation entered into force in 2007, the responsibility for knowledge development on substances has shifted to the market. Once a dossier has been submitted, a substance may be introduced on the market. REACH dossiers are subject to random substantive testing by ECHA, and Member

States are involved in the evaluation process. For the Netherlands, the RIVM is involved in the investigation of REACH dossiers. Following the most recent evaluation of REACH Regulation, the European Commission decided that, henceforth, instead of the practice of checking 5% of dossiers, 20% would be checked (ECHA & European Commission, 2019).

Groups of specific substances

Medicinal products, plant protection products and biocides do not fall under REACH Regulation but under other specific regulation that is also based on EU Directives. Plant protection products and biocides are subject to an authorisation regime (the 'no, unless' principle) established by the independent Board for the Authorisation of Plant Protection Products and Biocides. The Board assesses the efficacy and the risks to humans and the environment and also determines the conditions for safe application. The Board is funded through fees paid by the market parties involved. Medicinal products are also subject to an authorisation regime. The emphasis here is on the assessment of efficacy and health risks. Although an environmental risk assessment is mandatory for human medicinal products (European Parliament & Council, 2001a) and veterinary medicinal products (European Parliament & Council, 2001b), in practice the adverse effects on the environment are not taken into account in the authorisation process.

3.2 Product regulation

The second pillar of the policy comprises product regulations, which in the Netherlands are laid down in the Commodities Act. The Commodities Act provides a framework for the safe use (by both professionals and consumers) of all products placed on the market. The Act includes rules relating to the safety of products and those related to the provision of safety information on substances used in products. There are specific rules, for example, for cosmetics, toys and food packaging materials, which relate to the maximum concentration of certain substances in products.

3.3 Waste regulation

Waste regulation in the Netherlands is based on the Waste Framework Directive (European Parliament & Council, 2008b) and the European Waste Shipment Regulation.[44] The latter regulation regulates the transboundary transport of waste materials.

The Waste Framework Directive contains rules for sustainable materials management. The aim of these rules is to protect, preserve and improve the quality of the environment, protect human health and use natural resources prudently, efficiently and rationally. The safe use of waste in a circular economy falls within these objectives.

The concept of waste is defined in the Waste Framework Directive as: 'any substance or object which the holder discards or intends to or is required to discard'. With this definition, the Directive explicitly provides the possibility for considering residues from a production process as by-product rather

44 The Waste Framework Directive is implemented in the Netherlands in the Dutch Environmental Management Act.

than waste. The Directive also offers the possibility of no longer considering treated (i.e. cleaned) residues as waste. One of the conditions is that such waste may only be reused if this does not lead to 'overall adverse effects on the environment or human health'. The Netherlands has elaborated this precondition in its Third National Waste Management Plan (Staatscourant, 2017b) with guidelines for the responsible reuse of waste streams containing substances in the ZZS category. Companies can apply to the Dutch Ministry of Infrastructure and Water Management for a legal decision to determine whether or not something must be considered a waste product. If the judgement is against something being a waste product, the REACH Regulation applies and the producer is responsible for the related research (i.e. Extended producer responsibility) (Section 3.1).

In addition, there are a number of EU rules on waste disposal that strongly relate to product regulations. This concerns the EU legislation on the management and disposal structure for specific waste streams, such as end-of-life vehicles, packaging and packaging waste, discarded batteries and accumulators, discarded electrical and electronic equipment and animal by-products.

3.4 Environmental legislation

There are roughly two angles of approach to Dutch environmental legislation, namely regulating the emission of harmful substances (emissions policy) and protecting the quality of air, water and soil (immissions policy).

Box 6: Emission and immission

Emission refers to the amount of harmful substances emitted from a certain source. The emitted substance then disperses through air or surface water and ends up in the environment. The latter is referred to as *immission* (intrusion).

The environmental compartments air, water and soil are interconnected, but legislation and policy on these three compartments have developed separately, over time. Part of the legislation also has a European basis. The new Dutch Environment and Planning Act that will soon come into force must provide a framework for a more integrated environmental policy. For the time being, the law does not alter the existing compartmentalisation of the policy.

The Dutch lists of 'substances of very high concern' (ZZS) and 'potential substances of very high concern' (pZZS) are important tools in environmental policy. The lists support competent authorities in enforcement and licensing. RIVM manages these lists. Companies are obliged to report the use and occurrence of ZZS (if more than 0.1% by weight). The policy is aimed at phasing out the use of these substances, if possible, and preventing or minimising exposure. For potential ZZS, competent authorities may, as a precautionary measure, impose measures to further limit emissions (RIVM, 2019a).

Policy on emissions

If a company wants to emit hazardous substances, it must comply with certain regulations. The standards for emissions are set out in the permit requirements (for companies subject to authorisation) and in the general rules for facilities and activities.[45]

When assessing emissions to soil, the 'stand-still' principle applies: there may be no additional environmental impact on the soil. Emissions to air and water are assessed on the basis of permissible emissions and an emission limit value is set. An important criterion here is cost-effectiveness and the use of 'best available techniques'.

In the case of emissions to air, a stricter regime applies if the emissions contain substances of the ZZS category. Companies are then obliged to investigate the possibilities of avoiding the use of the particular substance and minimising emissions. Maximum emission values for the assessment of the remaining emissions of ZZS are based on a maximum tolerable risk level (MTR).

In the case of the emission of hazardous substances to surface water, the government uses the 'General Assessment Methodology'. This method has four categories of descending negative impacts on water. This refers to 'the degree to which there is a chance of adverse effects on the aquatic environment'. These negative impacts then determine the amount of remediation effort to be undertaken by the permit applicant. Substances in the ZZS category fall into the highest water concern category. However, substances that are not classified as ZZS are also subject to the obligation to assess whether additional reduction effort at the source would be cost-effective. An immission test (see below) determines whether more far-reaching measures are required. Criteria for this are the status (i.e. quality) of the receiving surface water to which a company intends to discharge and the emission limit values that apply to that particular stretch of surface water. For companies not subject to authorisation, there is no obligation to carry out continuous improvements.

Immissions policy: quality of environmental compartments

The government's immissions policy includes the minimum standards for air quality, water quality and soil quality in the Netherlands.

Many of the legal air quality standards are derived directly from EU Directives. They are laid down in the Environmental Management Act, and include:

- *limit values* to be achieved in the Netherlands within a given period;
- an *alert threshold* for nitrogen dioxide and ozone, the exceedance of which requires that government authorities take immediate action and alert the public to the presence of serious smog;
- an *information threshold* for ozone, the exceedance of which requires that government authorities immediately inform vulnerable population groups about the presence of moderate smog;

45 These rules originate from the Dutch Environmental Licensing (General Provisions) Act (Wabo) and from general administrative measures, such as the Environmental Management Act (Activiteitenbesluit milieubeheer).

- *distance requirements* – the distance within which an investigation obligation applies for particulate matter (PM10) and nitrogen dioxide.

Standards from the EU Water Framework Directive are used to assess water quality. There are two types of standards:

- standards for priority substances: EU standards, laid down for the Netherlands in the Decree on Quality Standards and Monitoring for Water 2009;
- standards for specific pollutants: Dutch standards, laid down in the Monitoring Regulation Water Framework Directive.

Assessment of soil quality (including groundwater) is conducted on the basis of standards for the remediation of soils and for the reuse of soil and sludge:

- *Standards for soil remeditation* are laid down in the remediation section of the Soil Management Act, in which (a) the seriousness is tested against the intervention value for soil and groundwater, and (b) the urgency is tested on the basis of a location-specific risk assessment system.
- *Standards for reuse* are laid down in the Soil Quality Decree, whereby (a) municipalities are authorised to develop area-specific policy, and (b) the standards for reuse are determined by the type of reuse and by the function (nature/agriculture, housing, businesses) and the quality of the receiving soil.

A general list of substances is used in soil quality assessments, which contains a large number of substances in the ZZS category, although these are not specifically listed as such.

Emerging substances

For many substances that are suspected of being harmful to health and the environment, no environmental quality standards have yet been set. These include pharmaceutical residues, plastics and substances that have not yet been sufficiently researched. These substances are referred to as ‘emerging substances’. In order to develop an approach for these groups of substances in surface water, intergovernmental working so-called ‘Administrative Acceleration Tables Delta Approach to Water Quality’ have been established (Tweede Kamer, 2018c), see Box 7.

Box 7: Good examples of knowledge sharing and cooperation between national government and regional authorities

The *Veluweberaad*, the Implementation Programme on Emerging Substances in Water and the Implementation Programme of the Soil and Subsoil Covenant 2016–2020 are examples of how national and regional government can get a better grip on developments through cooperation and knowledge sharing. Here, government cooperation has taken the form of 'acceleration tables'. This cooperation will make it easier to establish links between sectors (water, soil and air). The entire chain can then be taken into account when analysing problems. There are three of such 'administrative acceleration tables', or working groups: one for agriculture (fertilisers, plant protection products), one for emerging substances and pharmaceuticals, and a broad umbrella table.

4 EFFECTS OF AND SETTING STANDARDS FOR CUMULATIVE EXPOSURE

In the Netherlands, the concentration levels of hazardous substances in air, soil and water have decreased, in recent decades, as a result of policy and regulations. The levels are now often below the official standards. However, the greater the number of substances present in the environment, the greater the chance of exposure to combinations of those substances. This is referred to as 'cumulative' exposure (see also Figure 5 in Part 1).

4.1 Effects of cumulative exposure

Mixtures of hazardous substances are widely found, both in the environment and in human tissues, as monitoring data show (Rudén, 2019). Therefore, relevant exposure risks shift from high concentration levels of one particular substance at specific locations to a diffuse presence of a multitude of substances, often at relatively low concentration levels.

The effect of cumulative exposure on the environment can be seen, among other things, in the results of water quality measurements. Recent comparative research on the water quality in all European countries reveals the significance of exposure to mixtures (Posthuma et al., 2019). It shows

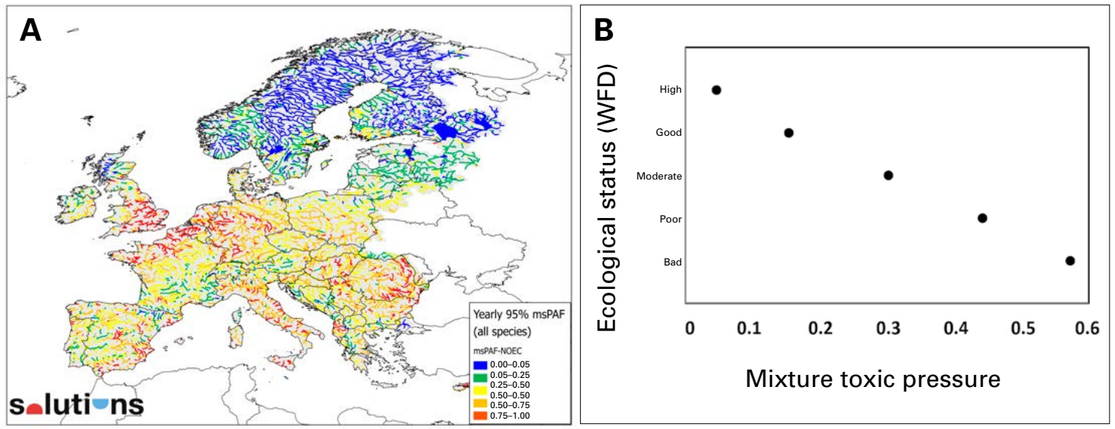
cumulative exposure to a large number of substances by expressing the chemical loading as a 'toxic pressure of mixtures' on surface water ecosystems. *Toxic pressure* is an indicator related to the magnitude of the effects of exposure to mixtures. Where such pressures have too great a negative impact, measures must be taken to protect the ecological status of the water.

In Europe, in accordance with the Water Framework Directive (WFD), water quality is assessed on the basis of both ecological status and chemical quality. Under the WFD, problems with chemical water quality are defined as exceedances of the protective standard for one or more substances on an (exhaustive) list of priority substances. This is a limited approach to the problem. The list contains only a fraction (0.2%) of the substances that are on the market and may occur in water. Moreover, the substances on the list are each assessed on an individual level.

How important it is to include the effects of exposure to mixtures can be seen from the comparison made in the aforementioned study between the chemical and ecological water quality of the Netherlands and Sweden, as laid down in the WFD reports of the European Environment Agency (EEA). In Sweden, the chemical quality of all surface waters is insufficient, but the ecological status of the water appears to be well above the European average. The main explanation for this phenomenon is that, in Sweden, the cumulative pressure of multiple substances on ecosystems is significantly lower and therefore the toxic pressure of the mixtures is also lower.

Part A of Figure 12 below (the map on the left) shows that the toxic pressure of mixtures in Europe varies greatly from location to location. The redder the colour, the more likely it is that ecosystems will be adversely affected. Part B of Figure 12 (the map on the right) shows that such a mixture of toxicity indeed projects adverse effects on ecosystems.

Figure 12: The effect of toxic pressure of mixtures of substances on the ecological status of surface waters (Posthuma et al., 2019; Vijver, 2019)



Left: the toxic pressure of substance mixtures in surface waters of Europe varies greatly. Right: an increase in the toxic pressure means that the effects are increasing and that the ecological status deteriorates proportionately.

The study also shows that, on average, about 30% of the decline in biodiversity in European water systems is due to toxic pressure resulting from cumulative exposure to mixtures of substances (Posthuma et al., 2019). In field trials, Pond (2019) shows that exposure to multiple substances increases the likelihood of adverse effects in aquatic organisms.

Cumulative exposure to substances also has effects on human health. This has been demonstrated both in epidemiological studies on humans and in rodent studies. Studies on exposure to endocrine-disrupting substances from different sources in pregnant women show that the effects were underestimated in the current assessment (Bergman et al., 2019). In rodent studies, effects on reproduction (lower birth weight) are found for combined pesticide exposure at concentrations below individual limit values (Hass et al., 2017). An advisory commission of the Swedish Government concludes that there is scientific consensus on the occurrence of effects on humans and the environment from combined exposure at concentration levels below the individual limit values (Rudén, 2019).

4.2 Developing standards for cumulative exposure to substances

In 2012, the European Commission already concluded that current regulations do not provide a basis for managing the effects of exposure to mixtures of substances from different sources and exposure pathways (European Commission, 2012a). The current standards for individual substances do not do sufficient justice to the cumulative effect of exposure to different substances (Van Klaveren, 2016).

Box 8: 'Dealing with risks'

Since the 1980s, Dutch environmental policy has taken partial account of cumulative exposure. Target values were used for the immission of substances in air and water (Tweede Kamer, 1989). These target values were a factor of 100 below the so-called 'maximum tolerable risk level'. They were therefore at the level of 'negligible risk'. This safety factor of 100 was geared to uncertainties in the risk assessment and in particular the assumed increased risk due to cumulative exposure. The target values are no longer used as a policy objective, because there is no basis for this within the European frameworks (Smit, 2011).
The target values are, however, still published on the RIVM website, so that competent authorities can use them when assessing the minimisation objective for reducing emissions of substances in the ZZS category.

When assessing and authorising substances, so-called 'uncertainty factors' are used. However, with the exception of a number of specific groups of substances, the possible cumulative exposure of humans and the environment is not taken into account. REACH Regulation does, for example, look at substances that occur naturally as a mixture or substances that are marketed as a mixture, such as mineral oil distillates or compound products.

The environmental quality standards for air, water and soil, which are set as safe limit values for individual substances, also fail to take into account the risk of cumulative exposure. Only a few specific groups of substances with the same hazard properties are taken into account. The Swedish Commission of Inquiry (Rudén, 2019) advised its government to take greater account of the risks of cumulative exposure to mixtures in the regulations and to address the current underestimation of risks (see Box 9). Assessing risks from this cumulative exposure requires more consistency between the individual substance regimes (plant protection products, pharmaceuticals, biocides and industrial chemicals).

Box 9: Recommendations by the Commission of inquiry of the Swedish Government

The following recommendations were made by the Commission of inquiry, chaired by C. Rudén, which carried out research in 2019 on behalf of the Swedish Government into the risks of cumulative exposure to hazardous substances in the environment:

- include provisions for risk assessment of mixtures explicitly and consistently in all national and European legislation relevant to the handling and evaluation of substances;
- develop a cross-sectoral European policy framework on environmental pollution, with a special focus on combinations of substances;
- develop a European health directive to protect people from chemical and non-chemical environmental stressors;
- establish a database with data on the use of substances in products and emissions of substances, so that the presence of hazardous mixtures can be better identified and predicted;
- establish a research programme on real-life exposure patterns to chemical mixtures;
- introduce a default factor of 10% of the maximum acceptable exposure level above which safer alternatives should be sought;
- take advantage of the forthcoming revision of the Water Framework Directive to embed risk assessments for mixtures more firmly in the system.

When assessing the risk of an individual substance, a safe concentration value is determined below which no adverse effects are to be expected. Such assessments apply uncertainty factors to the safe concentration value for humans, which is derived from the results from, for example, animal or tissue testing. This concerns uncertainty about differences in sensitivity between laboratory animals and humans, about translating tissue testing into risks for humans and about differences in vulnerability levels between humans. However, these uncertainty factors only take limited account of combined exposure to substances of people and the environment, in practice.

Moreover, the methods for deriving these safe concentration values and the uncertainty factors used vary widely between the various substance regimes for medicinal products, biocides, industrial chemicals and plant protection products (Rudén, 2019). The safety factors used may vary by a factor of 100. Finally, there is a multitude of substances that remain under the radar, because no hazardous properties have been determined for them, while they do occur in the environment and contribute to the toxic pressure (see Chapter 1).

In 2019, the European Food Safety Authority (EFSA) published a manual for harmonised risk assessment of the exposure of humans, animals and the environment to various substances (EFSA Scientific Committee, 2019). Several scientists recommend assessing cumulative exposure at low concentration levels by adding the different concentrations as a fraction of the individual standards (concentration addition). An alternative is to use a default factor of 10% of the maximum acceptable exposure for each individual substance. Safer alternatives should then be sought at exposures above 10% (Rudén, 2019).

In order to protect the environment against the risks of cumulative exposure to mixtures of substances, more data are needed, in addition to new standards. EFSA recommends, among other things, the integration and retrieval of data and methods from various sources and domains and the development of specific physiological testing methods for combined exposure. Others call for a database with information on application and use of substances, on both quantities and specific locations, in order to better understand concentrations of mixtures in the environment (Rudén, 2019).

5 EMISSIONS FROM DIFFERENT PARTS OF CHAIN

Dutch environmental policy aims to prevent and limit the emission of hazardous substances and protect the quality of the environment. The specific regulations and standards in the environmental policy focus mainly on the production phase of substances; there are far fewer rules that apply to the phases of use and waste. In the phase in which substances are used, in general, only qualitative regulations apply (e.g. effort obligations and good housekeeping). In the waste phase, there are quantitative emission standards and specific guidelines for dealing with substances, but the overview of waste streams is often incomplete – and, therefore, so is policy.

Sometimes there are agreements within the chain about reducing emissions. But there is a lack of effective control at important points along the chain. Emissions are recorded in very different ways (or not at all), resulting in a fragmented picture of substance emissions at those points.

Two examples are given, on plastics (5.1) and pharmaceuticals (5.2), to illustrate the emissions that occur at the various points along the chain in the three phases of production, use and waste.

5.1 Plastics

The transition agenda for plastics (Tweede Kamer, 2018f), a follow-up of the Raw Materials Agreement of 2018, provides a global overview of the plastic streams in the Netherlands.

In the Netherlands, approximately 2,000 kt of plastic products are marketed, annually. Plastics are used in Europe in packaging (40%), building materials (20%), the automotive sector (9%), the electrical engineering industry (6%) and an assortment of other applications (25%).

Plastics are ‘synthetic polymers’. These are large molecules made up of a sequence of small molecules: monomers. The properties of plastics depend on the composition of the monomers and on polymer length. Most plastics are made to be persistent, so they are poorly degradable.

A wide variety of plastics are used in all types of articles, such as tyres, textiles and paints (RIVM, 2019b). Depending on the product, other substances are added to plastics (additives). This gives them the properties that make them suitable for various applications. Examples of additives are plasticisers, blowing agents, dyes, UV stabilisers, flame retardants, biocides and solvents. Plastics may contain additives that are regarded as substances in the ZZS category, such as phthalates and cadmium. Some monomers used may also be classified as hazardous substances (e.g. vinyl chloride and styrene).

Microplastics can be included as an additive to certain products. This happens for example in cosmetics, personal care products, detergents, paints, applications in the oil and gas industry and sandblasting agents.

Emissions to the environment can occur at any point (i.e. production, use, reuse, waste) along the plastics chain.

Production phase

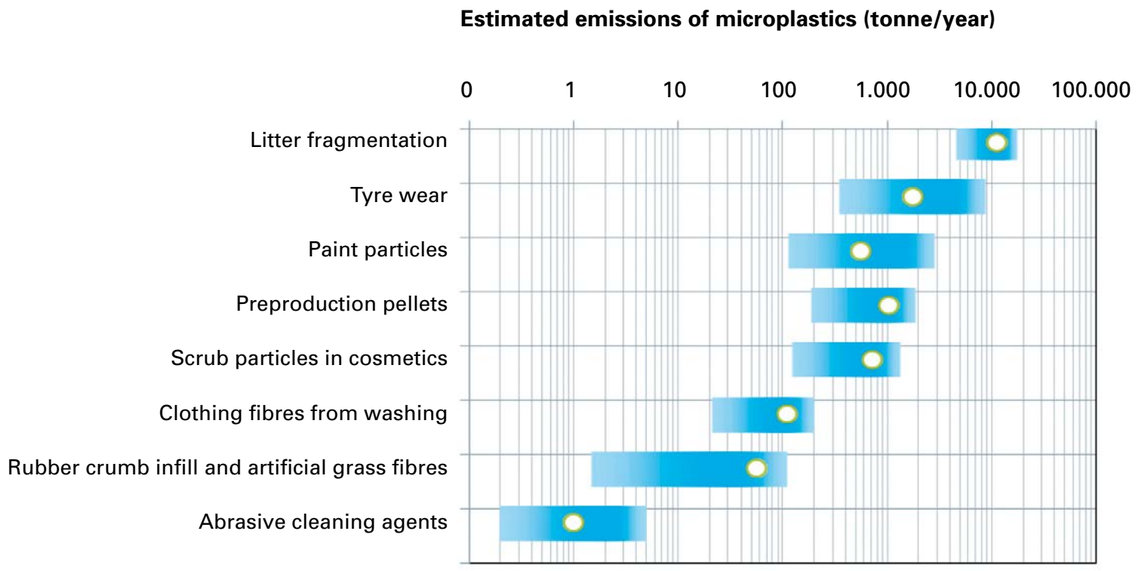
Emissions during the production of plastics mainly consist of CO2. Emissions of nitrogen oxides (NOx), sulphur oxides (SO2) and particulate matter (PM10) are relatively limited in the production of plastics in Europe, as a result of the implemented emission standards (CPB, 2017). The extent to which plastics themselves (or building blocks of plastic products such as polymers and monomers) are emitted into the environment is unknown. Certain polymers and monomers are included in the emission registration, but there are no recent overviews of the annual quantities discharged to air and water. In order to limit emissions from the production phase, the government has identified the 'best available techniques' for the most common production processes (Infomil, 2019).

Use phase

During the use phase (including distribution and storage), the environment can be polluted with plastics in litter and by wear and tear from product use. Only global estimates are available on the quantities of plastic litter. In its analysis based on the transition agenda for plastics, the Netherlands Court of Audit estimates that approximately 2.5% of the total annual volume of plastics on the market ends up as litter (Algemene Rekenkamer, 2019). This amounts to approximately 50,000 tonnes of plastic litter, each year. RIVM arrives at comparable estimates (RIVM, 2019b).

According to RIVM, the most important sources of microplastics in the environment are due to decomposition and degradation of this plastic litter, in addition to tyre wear, plastic clothing and the microplastics added to products (see Figure 13) (RIVM, 2019b). The data show that the estimated total environmental loading of microplastics is of the order of 15,000 tonnes, annually.

Figure 13: Estimated emissions of microplastic to surface water in the Netherlands, for the various types of use (Verschoor and De Valk, 2018)



During the use phase of plastics, there is also a risk of exposure. This risk is mainly determined by additives such as plasticisers (e.g. phthalates) and coatings (e.g. bisphenol A, better known as BPA). For example, there are indications that BPA may have a harmful effect on the immune system of unborn and young children. In general, exposure to BPA remains below the official standard. However, for specific groups, exposure may be higher, especially in young children requiring prolonged medical care and who are in contact with medical devices containing BPA (RIVM, 2019c).

Waste phase

Approximately 1,700 kt of plastic materials are discarded annually (Tweede Kamer, 2018f). By far the largest part (about three quarters) of this is incinerated and about one quarter is recycled or reused. No separate data are available on the generation of litter during waste collection and processing. These data are part of the estimate of the total amount of litter in the Netherlands.

Virtually no data are available on emissions from plastics or components that may arise from the incineration of plastic waste. Dioxin levels in flue gas have been measured since the 1980s. These emissions are now virtually nil at waste incineration plants (CBS, 2019).

5.2 Pharmaceuticals

The register of the Medicines Evaluation Board includes 19,941 medicinal products and 2,733 veterinary medicinal products (CBG/MEB, 2019).

The total annual use of medicinal products is estimated at approximately 3.5 million kilograms. These drugs contain just over 2,000 different active substances (Moermond et al., 2016). In 2017, approximately 480 tonnes of active substances were sold in the form of veterinary medicinal products (including digestive stimulants, vitamins and minerals). Antibiotics account for the vast majority of these; the annual use of antibiotics as veterinary medicinal products is about 200 tonnes (Moermond et al., 2019).

Production phase

The environmental impact of the production of medicinal products and veterinary medicinal products in the Netherlands is lower than the emissions from the use phase (see below). There is no overview of the exact magnitude of the emissions of pharmaceuticals and residues at production locations (incidentally, there are virtually no production locations left, in the Netherlands).

Use phase

Pharmaceutical residues enter waste water via urine and faeces (micropollution). These substances are not completely removed at wastewater treatment plants (WWTPs), which means they can end up in the environment (surface water, groundwater). The main pathway is via the human body; it is estimated that 95% of pharmaceutical discharges end up in the environment in this way. The largest part of the supply to WWTPs (around 90%) comes from sewer discharges from households. Not more than 10% comes from hospitals and nursing homes (Tweede Kamer, 2018a).

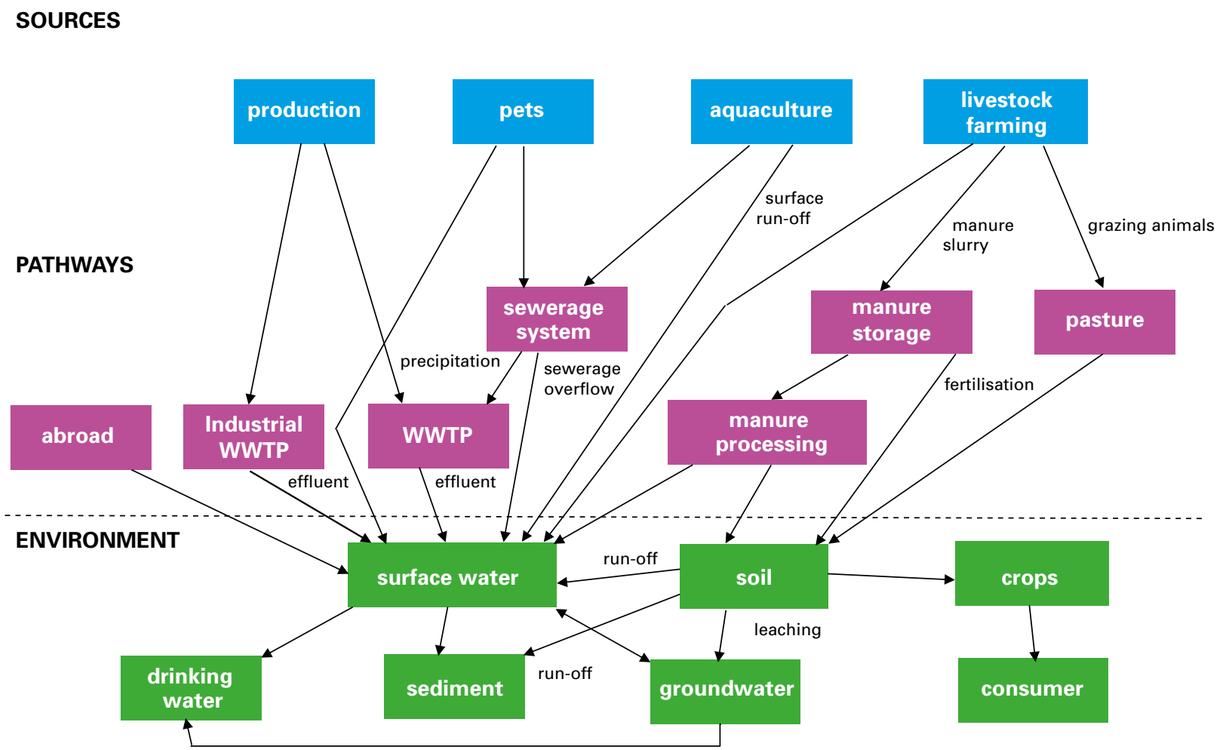
Current WWTPs focus on the removal or decomposition of organic matter and nutrients, and not specifically on micropollutants. The properties of pharmaceuticals are very diverse, which means that the extent to which they can be removed from the water in a WWTP also varies greatly – from fully to not at all. During purification, degradation products are sometimes formed that can still have a biological effect (Moermond et al., 2016).

Based on currently available data, it is estimated that at least 140 tonnes of active substance (excluding metabolites and X-ray contrast agents) are discharged, annually, to surface water via the sewerage system in the Netherlands. It is also estimated that at least 30 tonnes of (x-ray) contrast agents are discharged to sewers, each year (Tweede Kamer, 2018a).

The Environmental Data Compendium (CBS, 2018) states that the magnitude of the environmental risk of pharmaceutical residues cannot be determined because data on quantities and effects in the environment are known for only a fraction of the active substances. CBS bases its indicators on the available data for five commonly used drugs, i.e. the painkiller diclofenac, the blood pressure reducer metoprolol, the antibiotic azithromycin, the anti-epileptic carbamazepine and the anti-diabetes drug metformin (see also Figure 10, Section 2.2).

Veterinary medicinal products end up in surface water via run-off and leaching after fertilisation of the land, or via waste water from manure processing plants and fish farms. The main pathways along which environmental pollution can occur are presented in Figure 14 (STOWA, 2019).

Figure 14. Main emission pathways of veterinary medicinal products to the environment from industrial wastewater treatment and sewage treatment (STOWA, 2019)



However, the different pathways cannot be quantified. Nor are there any estimates available on the total environmental loading of (residues from) veterinary medicinal products . The total pharmaceutical emissions from veterinary products to water is probably smaller than those from human medicinal products. On the one hand, because fewer veterinary medicines are used, and, on the other hand, because the soil causes some of the medicinal product to break down or bind to soil particles (STOWA, 2019).

Waste phase

Citizens can drop off old and unused (leftover) pharmaceutical drugs at the pharmacy or at a municipal handover point for small chemical waste. However, this is far from properly regulated in all municipalities. For hospitals and other professional care institutions, it is customary to collect unused pharmaceutical drugs. Some hospitals are experimenting with a filter installation for pharmaceutical residues, before their waste water is discharged into the sewers. Such an installation treats both biodegradable solid waste and waste water (sewage). This allows pharmaceutical residues to be removed from the waste water to a level below the detection limit (STOWA, 2012).

5.3 Management of emissions from certain points along the chain

The cases discussed above show that, both in the plastics chain and in the pharmaceutical chain, there is little control over the emissions that occur in certain phases. The control mainly focuses on limiting emissions during the production phase, by means of authorisation policy and regulation. However, important emission pathways in the use and waste phases remain out of view. The available figures do give an indication of the emissions at

various points along the chain, but not of the contribution of the various pathways to total emissions.

In both chains, however, there are initiatives in place to obtain a better understanding of emissions throughout the chain and, where possible, to limit them.

More and more policy is being developed on the plastics chain, aimed at preventing emissions in the use phase. One example is the recent European Commission's ban on the use of disposable plastics. In addition, there is the recent recommendation by the European Chemicals Agency (ECHA) of banning the addition of microplastics to consumer products.

In recent years, more attention has also been paid to the spread of litter and microplastics within the environment. Better measurements provide a more complete picture of emissions throughout the entire chain. The available data, as yet, provide little insight into the quantitative extent of emissions at the various points along in the chain. However, it is clear that by far the largest amounts of emissions are generated in the use phase. By means of the 'chain approach to pharmaceutical residues from water' (*Ketenaanpak Medicijnresten uit Water*), the joint authorities and a broad representation from the health, pharmaceutical and water sectors in the Netherlands are working to reduce the pharmaceutical pollution of water, for example by improving wastewater treatment plants.

6 NEW QUESTIONS DUE TO THE TRANSITION TOWARDS A CIRCULAR ECONOMY

The ambition to achieve a circular economy entails challenges for the chemical sector. New, reusable substances are needed and alternative production processes and chains must be formed. At the same time, a circular economy brings new risks, because when recycled, potentially hazardous substances such as 'secondary raw materials' enter production chains, creating new pathways of exposure to these substances. This means that more government regulation is needed, as well as more transparency and cooperation within and between product chains.

6.1 Ambitions for a circular economy

The Netherlands has the ambition to have a fully circular national economy by 2050 (Tweede Kamer, 2016). In a circular economy, materials will remain in the product chain for a longer time and in a higher quality form, instead of being discarded after being used only once – as happens in the current linear system (Rli, 2015). The aim is to achieve infinite reuse of materials, with no residual waste and no need to add new raw materials (see Figure 6 in Part 1 of this advisory report).

The Dutch ambitions are in keeping with the European agenda. The European Commission has fleshed out the ambition for a circular economy in an action plan (European Commission, 2015). In the Netherlands, the first steps in this transition have been taken in the Government-wide programme for a Circular Economy: 'A circular economy in the Netherlands by 2050' (Tweede Kamer, 2016), the Raw Materials Agreement (Tweede Kamer, 2017) and the five associated transition agendas (Tweede Kamer, 2018g). The objective of the 'Netherlands Circular' programme is to reduce the use of primary materials (mineral, fossil and metals). This means, among other things, more efficient use and recycling of materials and the use of secondary raw materials with no harmful emissions to the environment.

6.2 Objectives for the chemical sector

The transition towards a circular economy will involve a change in the current streams of materials and the composition of numerous products. This will also bring change to the chemical sector. New substances are needed that are reusable and based on renewable materials. New production processes and production chains will also have to be formed in order to achieve closed-loop cycles in the material chains. This transition can reduce the ecological footprint of the chemical sector. At the same time, the sector will become less dependent on the availability of primary materials. The latter, in particular, plays a role in the extraction of metals.

In a circular economy, chemicals will have to be used/reused for a longer period of time and in a more qualitative way. And substances that do leak from the economic chain must be easily biodegradable. A circular economy also means that the chemical sector will have to replace its current – largely fossil – raw materials with materials that are renewable. Currently, 95% of raw materials used in the chemical sector come from mineral oil or gases (Cefic, 2019). The transition calls for a different way of designing substances, taking circularity into account (UNEP, 2019b).

Production chains will look different in a circular economy. Waste will become a raw material, value preservation of used products will become more important, product parts or substances in products can be extracted and used in other products, and consumers will not always own the products they use. This is a major challenge for the chemical sector, with its complex system of often global chains (UNEP, 2019b). In modern consumer products, from toothpaste to smartphones, a huge variety of man-made substances are processed by an equally wide variety of producers. Ultimately, new material cycles must be realised for all these substances.

6.3 Another economy equals other risks

The transition towards a circular economy leads to new questions about the safe handling of hazardous substances. The internationally active NGO ChemSec (2019) emphasises that a circular economy requires rethinking not only the design and composition of products, but also the alternatives

to current hazardous substances. According to ChemSec, the avoidance of hazardous substances in products and product chains is the missing link in the transition towards a circular economy.

New risks will arise. Through reuse and recycling, substances may end up in new products and therefore humans and the environment will become exposed to those substances along other pathways. It is as yet unknown to what extent this exposure through recycling will occur in practice. Hazardous substances will, however, be circulating in various product chains. But what will end up in recycled products is not certain, because few measurements are currently taken with respect to certain substances in recycled products. The risks to people and the environment can therefore not yet be properly assessed.

In its advisory report of 2018, the Health Council of the Netherlands gives various examples of cases in which recycling of products leads to the unintended exposure of people to hazardous substances. For example, flame-retardant substances that had been incorporated into electronic equipment were found in food packaging material produced from recycled waste. While there are strict rules about the use of recycled plastics in food packaging, other materials such as cardboard or coatings are not yet harmonised within the EU. This would explain the plasticisers found in cardboard pizza boxes. Another example concerns newspaper printing ink that was found in food packaging materials made from recycled paper (Gezondheidsraad, 2018).

Increasing reuse of raw materials can also lead to an accumulation of hazardous substances within a chain. This hampers the achievement of closed-loops in production chains. The production of paper and cardboard, for example, is a virtually closed-loop cycle, but the accumulation of hazardous substances in printing inks hampers infinite reuse. This concerns the specific components in printing inks that are added to the paper at each consecutive printing run. These substances do not break down and cannot be removed when reused. As a result, the concentration of these substances in paper and cardboard increases after each recycling, to the point where the paper is no longer safe to use. To prevent these substances from coming into contact with food when recycling into packaging materials (see example above), the cycle must be broken. Waste paper is then disposed of and fresh paper is added to control concentration levels (Koch et al., 2018).

Both in the case of accumulation and new pathways of exposure to substances, this may involve substances that have been banned for a long time (Gezondheidsraad, 2018), but to which people nevertheless become exposed as a result of reuse. Internationally, agreements have been made on the ‘phasing out’ of hazardous substances for people and the environment. A substance may then no longer be traded or used in a product. This, in itself, is a favourable development, but if a hazardous substance is not readily biodegradable or removable, it will continue to circulate within the chains of production in a circular economy, even after phase-out. Substances that have been banned and are no longer used in

new products can thus hamper reuse and recycling, unless emissions to the environment can be prevented for 100%.

6.4 Current policy

Safe by Design

The safe handling of substances in a circular economy is one of the driving forces behind the 'Safe by Design' project (Tweede Kamer, 2018d). Within the project, the Safe & Circular Design component is aimed at the safe use in circular chains as early as in the design and development phases of new products. The aim is to make manufacturers aware of the risks and to encourage them to start with identifying the potential risks to people and the environment throughout the 'circular' life cycle of products and – as much as possible – find solutions already in the design phase.

In the broader chemical policy, the aim of the 'Safe by Design' project is to stimulate the development of safer alternatives to hazardous substances. These alternatives may be other substances or other ways of fulfilling the function of the substances of concern ('non-chemical' solutions; e.g. see Bougas et al., 2018). Examples are resilient plants and cultivation systems as an alternative to harmful plant protection products (Tweede Kamer, 2019a), and the concept of moisture and fungus control by improving ventilation instead of applying coatings.

Differences between the risk assessments of waste materials and primary resources

With the transition towards a circular economy, the use of secondary materials will increase at the expense of primary material streams. Current policies on primary and secondary materials differ. The use of primary materials is currently regulated through the chemical policy, mainly on the basis of the 'no data, no market' principle under REACH Regulation, which states that, if a producer or a producing collective has submitted a dossier containing certain prescribed information about a given substance, this substance can be marketed, provided that the dossier is judged sufficient and the substance is not banned at a certain point in time (the 'yes, provided that' principle). On the other hand, the use of secondary materials is regulated under waste policy. Here the 'no, unless' principle applies. This difference in principles can limit the use of secondary materials, because market introduction will take more time. It is conceivable that these two principles existing in parallel cannot be sustained in the long term, if the markets for secondary and primary materials become more intertwined.

Waste regulations include criteria for the reuse and recycling of waste. The 'Leidraad afvalstof of product' published by the Dutch Ministry of Infrastructure and Water Management (IenW, 2018) contains guidelines for determining whether processed waste has reached 'final waste status'. Depending on the nature and type of waste, the national government, province or municipality is the competent authority to decide on this. The Ministry may be asked to give a legal opinion. The 'Taskforce Herijking afvalstoffen' (Tweede Kamer, 2019d) observes that, in practice, there are

different interpretations, as a result of which businesses experience legal uncertainty. In her response, the State Secretary of IenW (Tweede Kamer, 2019g) describes the measures taken to share knowledge and experience in order to promote a level playing field.

6.5 Safe closed-loop cycles require transparency

The formation of new product chains in a circular economy requires transparency and cooperation within and between product chains. On the one hand, to form closed-loop cycles by using each other's products and residual products as reliable raw materials, and, on the other, to ensure that a product is used by other parties in such a way that it can be reused or recovered safely (alignment within the chain). In its Chemical Outlook (UNEP, 2019a), the UN advocates full disclosure of the composition of materials and products and knowledge sharing throughout the supply chain.

The council notes that there is currently a lack of transparency between parties in the chain, which makes it difficult to establish safe closed-loop cycles. Buyers of secondary materials must be able to be certain of the safety of a product. The current rules do not provide sufficient guarantees to this end. For example, producers are only obliged to inform their customers of the presence of ZZS in their product if the concentration of that substance exceeds 0.1%. In practice, however, this information is lost further down the production chain and is therefore also lacking in the waste chain.

In the case of waste disposal, there is no lower limit for notification of the presence of substances in the ZZS category. Lower levels than 0.1% should therefore also be reported if they are environmentally relevant (Environmental Management Act, Article 10.39). However, subordinate legislation (the Decree on the Reporting of Industrial and Hazardous Waste) does not impose this obligation. Reporting on ZZS in waste with a content of less than 0.1% are therefore not customary, although these are substances that may cause problems – even at a much lower content (cf. ILT, 2019). The State Secretary of IenW has announced that the legal basis for the obligation to provide information on ZZS in waste streams will be strengthened by enshrining it in the Decree on the Reporting of Industrial and Hazardous Waste (Tweede Kamer, 2019h).

Box 10: Lists of substances to be used and those not to be used

The foundation *Stichting Zero Discharge of Hazardous Chemicals* (ZDHC, 2019) focuses on limiting the emission of hazardous substances from the textile and footwear industry. It was founded in 2011 from the ambition of six major clothing brands, and has since grown to 28 brands, 81 chain partners and 17 other parties. Participants comply with the guidelines and are checked by the foundation on their use of raw materials and production methods, among other things.

The foundation has a list of substances that cannot be used in production, as well as a positive list, with substances that may be used as substitutes. The German Government has decided to use the lists of

Stichting Zero Discharge of Hazardous Chemicals – compiled by market parties – in their policy-making processes.

The two lists help companies to realise their ambition to become more sustainable. Previously, each brand had its own collection of fabrics for production, whereas companies today are increasingly using the same fabrics. This saves on storage, logistics and production processes. In addition, fewer 'checks and balances' are needed to control risks on the shop floor and to be accountable to customers. For brands, the advantage lies mainly in shaping a positive public image.

The United States Environmental Protection Agency (US EPA, 2019) also uses a 'Safer Chemicals Ingredients List' of alternative raw materials within functional categories. The use of positively labelled raw materials results in end products that are considered safer choices.[46]

There are various initiatives that help stakeholders along product chains to establish safe closed-loop cycles. For example, a number of large fashion chains have made agreements in the supply chain about the safety of raw materials and about safe production processes. Important instruments in this respect are the raw materials lists, i.e. the list of restricted raw materials and the list of substitutes. Another example is the 'Safer Chemicals Ingredients List' published by the US EPA (see Box 10).

46 See https://www.epa.gov/saferchoice/safer-ingredients

Within the EU, a product database containing substances on the REACH candidate list ('substances of very high concern') is being developed by the European Chemicals Agency ECHA (see Box 11).

Box 11: ECHA database of products containing substances of very high concern

In a circular economy, more transparency is needed on the risks posed by substances incorporated in articles and products. ECHA is developing a database for articles containing substances on the REACH candidate list. This database makes information on substances of concern available, in particular, to waste processors and consumers. The so-called SCIP database complements the existing communication and notification obligations related to substances on the candidate list in articles under the REACH Regulation. In addition to producers and importers, distributors who place articles on the market also have to provide information.

The database is an important step towards the safe handling of substances in closed-loop cycles. It helps in the safe reuse and recycling of articles and substances. In addition, the ECHA expects the database to also provide an incentive to replace substances of very high concern and to reduce the waste stream of non-recyclable materials (ECHA, 2018; 2019a).

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APPENDICES

GLOSSARY

Bioaccumulation Bioaccumulation is the increase in the concentration level of a substance present in living organisms due to the intake of contaminated air, water or food. It occurs, for example, when substances cannot be broken down and thus remain in the body.

CAS Registry Number A CAS Registry Number (CASNR) is a unique numerical identifier assigned by the Chemical Abstracts Service (CAS) to every known chemical substance, including chemical elements, components, polymers and alloys. The CASNR has been in existence since 1907 and now contains over 150 million unique numbers for as many chemical compounds.

Cefic Conseil Européen des Fédérations de l'Industrie Chimique: European umbrella organisation for the chemical industry.

CLP CLP Regulation is the EU Regulation on **C**lassification, **L**abelling and **P**ackaging, based on the United Nations Globally Harmonised System of Classification and Labelling of Chemicals (GHS). It aims to ensure a high level of protection of human health and the environment as well as the free movement of substances, mixtures and goods.

CMR substances These are substances that are carcinogenic or that damage DNA and, thus, may cause mutations in genetic material (mutagenic) or that are harmful to reproduction (reprotoxic).

ECHA ECHA is the European Chemicals Agency in Helsinki, which manages all REACH dossiers. It is the central body for the implementation of the European REACH Regulation.

EFSA European Food Safety Authority.

GenX GenX is the name of a technology used in the production of fluorinated polymers (including Teflon). GenX technology aims to replace the use of perfluorooctanoic acid (PFOA) (since 2005), because PFOA hardly decomposes in the environment and tends to bind to proteins within the bodies of animals, especially those in the liver and blood. GenX makes use of other intermediate substances that, themselves, are also among the substances of very high concern (since June 2019).

Glyphosate This is a herbicide, also known under the product name *Roundup*. It is a controversial herbicide, the use of which is nevertheless still permitted within the EU until at least 2022.

GMO Genetically Modified Organism.

Grouping and Read across Addressing more efficiency in substance assessments within REACH. Relevant information from analogue substances is used to predict the properties of other substances. As a result, fewer experimental tests are required to register a substance. An entire family of chemical substances can thus be assessed in one go. In grouping, this is done by testing several analogue substances at the same time. In read across, the results for one substance are used to assess another.

Water Framework Directive European directive from the year 2000, with the aim of ensuring the quality of surface water and groundwater in Europe. The Water Framework Directive (WFD) is aimed to achieve a ‘good status’ of water, both chemically and ecologically.

MSDS *Material Safety Data Sheet.* These sheets describe the hazards and risks of certain substances. They are often recommendations on how to work safely with a particular substance.

Metabolites Intermediate or finished products resulting from a chemical substance in a process of biodegradation.

Microplastics These are small solid plastic particles (smaller than 5 mm). They are virtually insoluble in water and non-biodegradable. Microplastics can be used as ingredients in products and end up in surface waters via waste water. They can also be generated through disintegration of litter or during the production and use of plastic products. Specific risks to humans and the ecosystem are as yet largely unknown.

Nanomaterials Nanomaterials are chemicals or materials with a particle size of between 1 and 100 nanometres (nm) in at least one dimension. Due to the larger specific surface area per unit of volume, nanomaterials may have different properties than the same material without nanoscale characteristics. Thus, the physio-chemical properties of nanomaterials may differ from those of larger particles or bulk material.

No data, no market This is a principle under the REACH Regulation, which states that a substance shall not be admitted to the market until adequate information (i.e. data) on the substance's properties has been made available.

PBT substances PBT stands for *persistent, bioaccumulative and toxic.* Substances in this category are considered 'of very high concern' under the REACH Regulation. Persistent means that they degrade only slowly in the environment; bioaccumulative means that they can accumulate in plant and animal organisms. REACH also contains the vPvB category (very persistent and very bioaccumulative (regardless of toxicity)).

PEC PEC stands for *predicted environmental concentration*. This is the expected concentration level (in water, sediment or organisms) at a certain location or in a particular water system to which the water, sediment or organisms concerned may be exposed, given a certain emission or discharge.

PFOA PFOA stands for *perfluorooctanoic acid*. It is an intermediate substance in the preparation of Teflon, which is used, among other things, to make non-stick coatings in frying pans. PFOA can end up in the environment during a manufacturing process, during use and also during the waste disposal process of products in which it is incorporated. It can also be formed in the environment as a degradation product of other fluorinated chemicals. PFOA accumulates in the body, is not biodegradable, has a negative impact on the reproductive system, and is potentially carcinogenic. In addition, it is also known to impact the liver.

Plastics, examples A wide variety of substances fall within the group of plastics, including thermoplastic elastomers (TPE), acrylonitrile butadiene styrene (ABS) and polyvinyl chloride (PVC).

PMT substances PMT substances are *persistent, mobile* and *toxic*. Substances in this category easily move around in the environment and can accumulate, for example, in groundwater. Nitrate is an example of a PMT substance.

PNEC PNEC stands for predicted no-effect concentration. It represents the concentration level below which no adverse biological effects can be expected. The probability of such effects of substances is determined on the basis of studies into acute and chronic toxicity or is calculated on the basis of so-called *quantitative structure–activity relationships* (QSARs).

POPs POPs are persistent organic pollutants. These chemicals can be widely dispersed and, as they are resistant to degradation, they persist in the environment. They have the potential for accumulation in ecosystems, and for significant adverse effects on human health and the environment. The term is used in international regulations and agreements, such as by the World Health Organization (WHO), the Organisation for Economic Co-operation and Development (OECD) and the United Nations. The term is not used in REACH Regulation.

Priority substances Substances that pose a relatively high risk within the physical environment and, as a matter of priority, must therefore be included in the group of substances to which the official environmental quality standards apply.

Pyrazole Organic nitrogen compound used as an intermediate in, for instance, the production of pharmaceuticals, dyes and pesticides. In 2015, its discharge via a wastewater treatment plant at the Chemelot site polluted the Meuse. This meant water companies in the Dutch Province of South Holland had to stop extracting water from the Meuse, for a period of time. At the plant in question, pyrazole was a by-product in the production of acrylonitrile.

REACH Regulation REACH stands for the Registration, Evaluation, Authorisation and Restriction of Chemicals. The 2006 REACH Regulation lays down rules for the registration and regulation of the production and import of substances into the EU.

Registrant Under the REACH Regulation, producers and importers are responsible for registering a dossier on marketed substances (from 1 tonne per year). They are the registrants, in REACH terms. Producers and importers can share information and compile a dossier in collaborative ventures. In such cases, one lead registrant and one or more member registrants are distinguished.

Regrettable substitution This describes the replacement of hazardous products by others that have possibly similar but as yet unknown unfavourable properties.

Safe by Design This is a concept that aims to ensure that the safety of materials, products and processes for people and the environment is included as much as possible in the design phase.

SSD model *Species Sensitivity Distributions*. This model concerns *Species Sensitivity Distributions*. An SSD model is a probabilistic analysis model that describes the distribution of tolerances between various species. This method is mainly used to derive water quality criteria for aquatic organisms. The SSD analysis uses all available toxicity data and thus provides a picture of the impact on the entire ecosystem. The criteria are then derived on the basis of concentrations with a demonstrable hazardous effect in more than 5% of species (*concentration hazardous to 5% of the species*).

SVHC list *Substances of Very High Concern.* The list of these substances includes those from the REACH Register that are hazardous to humans and the environment; for example, because they are carcinogenic, inhibit reproduction or accumulate in the food chain. The use of these substances may be subject to restriction. See also 'Zeer Zorgwekkende Stoffen'.

Toxic pressure Criterion for the total effect of concentrations of various substances in water, soil or any other part of the physical environment. Toxic pressure is not a standard measurement unit and there are several methods for measuring it.

Triclosan Triclosan is a biocide, bactericide and antifungal agent used in cosmetics, toothpaste or soap. This product is under investigation because of an endocrine-disrupting effect found and because of the risk of accumulation in the environment.

Plasticisers These substances are added in the production of plastics to provide a plastic product with flexibility. Well-known plasticisers are the so-called phthalates, such as bisphenol A (now banned) and the substitutes bisphenol S and bisphenol F.

Zeer Zorgwekkende Stoffen (ZZS) Dutch category of substances that are hazardous to humans and the environment; for example, because they are carcinogenic, inhibit reproduction or accumulate in the food chain. The list of ZZS includes those on the SVHC list under the REACH Regulation, as well as process-related substances, metabolites and substances produced in the past and still found. The Dutch Government addresses these substances as a matter of priority. Companies are obliged to prevent the discharge and emission of ZZS to air and water. Only in cases where this is infeasible, emissions must be limited as much as possible (obligation to minimise). If this concerns substances that are also on the SVHC list of ECHA, there is an obligation to inform customers, and for the use of these substances there is an obligation to notify ECHA.

RESPONSIBILITY AND ACKNOWLEDGEMENT

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2019

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2013

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2012

Keep Moving: Towards Sustainable Mobility. Edited by Bert van Wee. October 2012 (Rli/EEAC)

Original title
Greep op gevaarlijke stoffen

Text editing
Saskia van As, Tekstkantoor Van As, Amsterdam, The Netherlands

Infographic
Vizualism: Frédérik Ruys, Utrecht, The Netherlands
(pages 11, 15, 16, 19, 32)

Photo credits
Cover: EyeEm GmbH / Hollandse Hoogte
Page 5: EvertJan Pol / ontwerp door bureau StudioKCA
Page 14: Jana Fernow / Hollandse Hoogte
Page 21: Mary Evans Picture Library Ltd. / Hollandse Hoogte
Page 31: Robin Utrecht / Hollandse Hoogte

Graphic design
Jenneke Drupsteen Grafische vormgeving, The Hague, The Netherlands

Publication RIi 2020/01
February 2020

Translation
Dunfield Editing, Musselkanaal, The Netherlands

Preferred citation
Council for the Environment and Infrastructure (2020). *A grip on hazardous substances.* The Hague.

ISBN 978-90-77166-86-4
NUR 740