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BTO report

European regulatory frameworks in relation to chemicals of emerging concern

BTO

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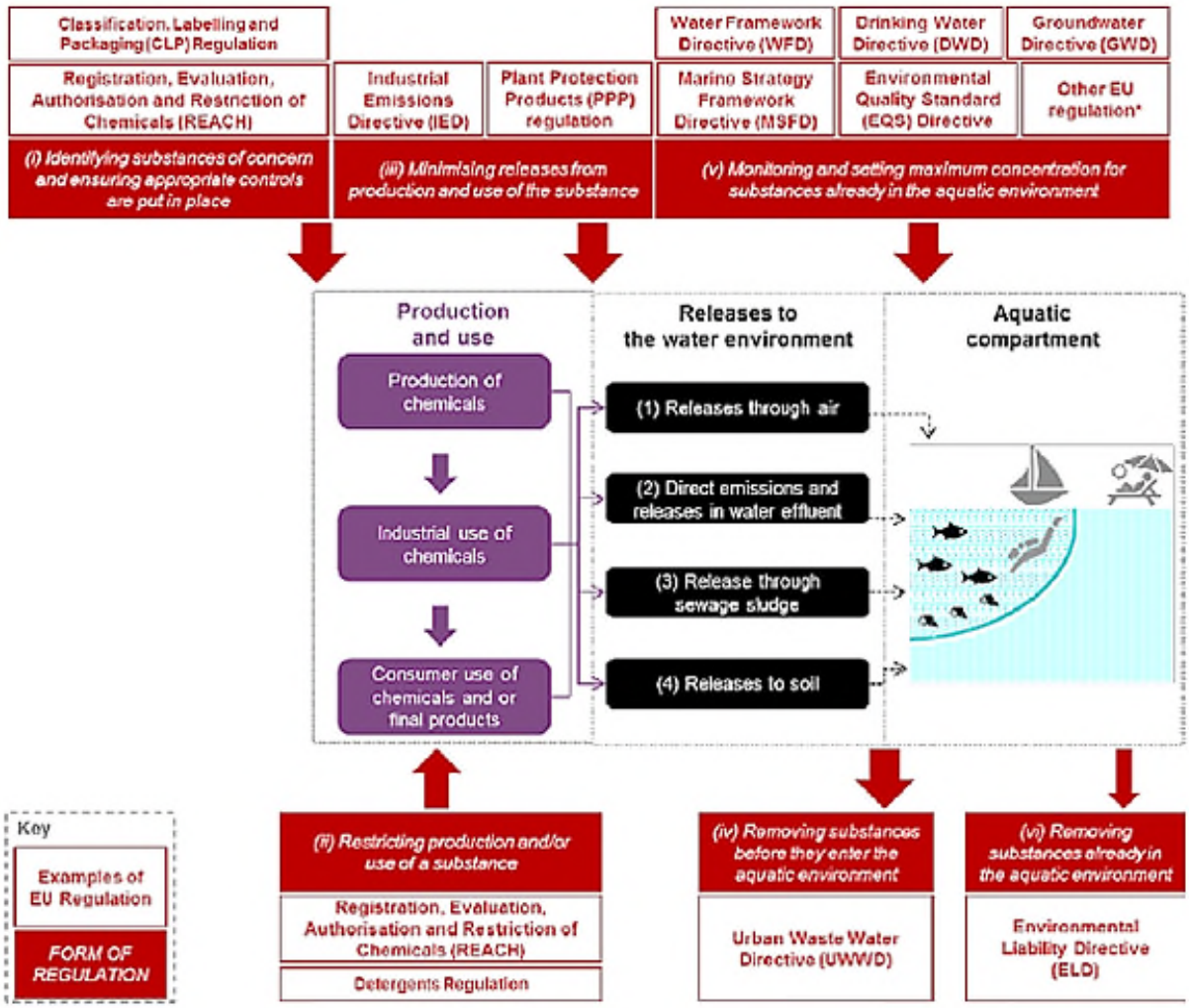
BTO *Managementsamenvatting*

Verbeteringen mogelijk in de bescherming van de kwaliteit van drinkwaterbronnen via Europese stoffenwetgeving

Auteur Dr. K.A. Baken

Het aantal nieuwe stoffen dat wordt geproduceerd en in drinkwaterbronnen wordt aangetroffen neemt toe, en zal naar verwachting blijven toenemen. Voor Vewin is een inventarisatie gemaakt van de relevante Europese regelgeving rond de toelating van chemische stoffen, zoals de REACH-wetgeving, met het doel na te gaan welke verbeteringen in de regelgeving nodig zijn om de kwaliteit van drinkwaterbronnen goed te beschermen. De inventarisatie laat zien dat er verbeterpunten zijn op drie belangrijke gebieden: restricties voor stoffen die drinkwaterbronnen bedreigen en stimulans voor alternatieven, meer samenhang in de wetgeving, en optimalisatie van de implementatie van restricties uit Europese wetgeving.



Europese wetgeving t.a.v. chemische stoffen in relatie tot de kwaliteit van het aquatisch milieu

Belang: bescherming van drinkwaterbronnen via Europese regelgeving

Het aantal stoffen dat wordt aangetroffen in drinkwaterbronnen neemt snel toe door groeiende productie en gebruik van chemische stoffen, door sociaal-demografische en klimatologische veranderingen en door verbeterde gevoeligheid van analysetechnieken. Gerenommeerde internationale autoriteiten zoals de Europese Commissie en de Verenigde Naties onderstrepen het belang van het terugdringen van de effecten van chemische stoffen op de gezondheid van mens en milieu. Beoordeling van gezondheidsrisico's en daaruit voortvloeiende restricties voor gebruik en emissie van stoffen vormen een onderdeel van de toelating van chemische stoffen op de Europese markt. Toch blijft het voorkómen van vervuiling van het aquatisch milieu met nieuwe stoffen een uitdaging, onder andere door de grote variëteit aan stoffen en de vele emissiebronnen. Incidenten met opkomende stoffen zoals pyrazool en GenX zijn daarom ook in de toekomst mogelijk. Er is in kaart gebracht of en hoe Europese wetgeving de bescherming van drinkwaterbronnen met chemische stoffen waarborgt en waar verbetering mogelijk is.

Aanpak: inventarisatie van aandacht voor het drinkwaterbelang in regelgeving over stoffen

Op basis van wetenschappelijke literatuur en rapportages omtrent evaluatie van Europese regelgeving, waaronder de opbrengsten van het SOLUTIONS-project, is een overzicht gemaakt van de Europese wetgeving over (i) toelating en gebruik van chemische stoffen, (ii) emissie van stoffen naar het milieu, en (iii) het ontvangend watermilieu. Vervolgens zijn de verbeterpunten met betrekking tot het waarborgen van de drinkwaterkwaliteit benoemd.

Resultaten: wetgeving voorkomt emissie van stoffen naar drinkwaterbronnen niet volledig

In verschillende Europese autorisatieprocedures voor chemische stoffen worden de emissie naar het aquatisch milieu en mogelijke gezondheidseffecten meegewogen. Op de volgende vlakken werden echter hiaten geconstateerd:

- **Gereguleerde stoffen**. De selectie van stoffen waarvoor restricties worden opgelegd is beperkt. Ze omvat niet alle zeer schadelijke stoffen en vaak geen transformatieproducten en opkomende stoffen.
- **Risicomanagement**. De vervanging van stoffen door veiligere alternatieven verloopt traag. Technieken om emissie te reduceren zijn niet toegespitst op probleemstoffen, en er is risico-beperkende maatregelen zijn onvolledig.
- **Drinkwaterbelang**. Er zijn geen restricties voor stoffen die persistent en mobiel zijn, er worden enkel algemene scenario's voor het berekenen van de impact op drinkwater-bronnen toegepast, en de aandacht voor stoffen in afvalwater is beperkt.
- **Integratie van regelgeving**. Elke afzonderlijke wetgeving spitst zich toe op een specifieke stof, gebruik en/of beschermingsdoeleinde. Er is geen overkoepelende wetgeving die de gehele levenscyclus van een chemische stof omvat.

Implementatie: lobby voor aanscherping en implementatie van regelgeving

De verbeterpunten die tot een betere wetgeving rondom chemische stoffen moeten leiden, vragen om acties op drie gebieden:

1. Restricties voor stoffen die specifiek nadelig zijn voor drinkwaterbronnen en stimulering van productie en gebruik van veiligere alternatieven, in Europees verband.
2. Meer samenhang in de wetgeving voor verschillende stadia van de levenscyclus van chemische stoffen en voor de bescherming van mens en milieu.
3. Optimalisatie van de implementatie van restricties die worden opgelegd in Europese wetgeving en regio-specifieke evaluatie van de impact op drinkwaterbronnen in nationale autorisatieprocedures.

Deze punten kunnen onderdeel vormen van de lobby in het kader van opkomende stoffen, lozingen en de bescherming van drinkwaterbronnen.

Rapport

Dit onderzoek is beschreven in rapport *European regulatory frameworks in relation to chemicals of emerging concern* (BTO 2018.079).

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Summary

The number and amount of chemicals detected in drinking water and sources is increasing due to the intensifying production and use of chemical compounds, sociodemographic developments, longer periods of reduced river discharge as a consequence of climate change, and improved sensitivity of analytical techniques. Renowned (inter)national organisations and authorities such as the United Nations and European Commission acknowledge the urge to reduce the impact of chemical contamination on environmental and human health. For market introduction and approved use of chemicals, health risk assessment is part of the authorisation procedure resulting in labelling, restricting, or banning the use of the most hazardous chemicals. Risk assessment and management of environmental contamination with chemicals is however challenging due to, amongst others, the large variety in chemicals and emission sources.

This report provides a quick scan of European legislation and regulation of chemical production and emissions in relation to impact on water quality, categorized by (i) market introduction and approved use, (ii) emission to environment, and (iii) receiving environment (immission), and indicates whether environmental emissions and environmental and human health protection are addressed. Many authorisation procedures for chemicals evaluate emission the aquatic environment and assess potential health effects. A number of gaps and issues for water quality protection were however identified:

- **Regulated chemicals**. The selection of chemicals for which restrictions may be demanded is limited. Not all hazardous compounds are restricted, and transformation products and emerging chemicals are often not included.
- **Risk management**. Substitution towards safer substances is proceeding slowly. Techniques required to prevent or mitigate emissions of chemicals during industrial production generally focus on 'classic' environmental pollutants, and risk reduction measures do not cover the total chemical life cycle.
- **Drinking water quality**. There are no restrictions for chemicals that are persistent and mobile, only general scenario's for estimating the impact of chemical use and emission on drinking water sources are applied, and the attention for chemicals in waste water is limited.
- **Integration of frameworks**. Each regulation or legislation applies to a specific chemical, use and/or protection goal. There is no overarching framework that covers the total chemical life cycle.

For improvement of water quality protection via legislative frameworks, actions are required at three different levels:

1. Regulation and restriction of substances of concern with respect to the aquatic environment and promotion of production and use of less hazardous alternatives.
2. Coherence of regulatory frameworks covering different stages of a chemical's life cycle, integration of environmental and human health protection, and cross-compliance by linkage between up- and downstream legislations.
3. Optimal implementation of restrictions and limitations requested in European legislation and application of site-specific evaluations in national authorisation procedures.

Although revisions of legislative frameworks are complicated and require considerable effort and time, there currently may be a unique opportunity in time now that many chemical and water-related regulations are reviewed and revised.

1 Introduction

Due to the intensifying production and use of chemical compounds (*Figure 1*), sociodemographic developments (Bernhardt et al., 2017), longer periods of reduced river discharge as a consequence of climate change (Sjerps et al., 2017), and improved sensitivity of analytical techniques, the number of chemicals that is detected in the aquatic environment is rapidly increasing (Sjerps et al., 2016; EC 2017a). The environmental and human health risks of these chemicals are often not fully understood. Contaminants of emerging concern (CECs) will thus continue to appear in the water cycle. Examples include industrial and household chemicals, personal care products, pharmaceuticals, pesticides, nanomaterials, microplastics, and their transformation products (Dulio et al., 2018).

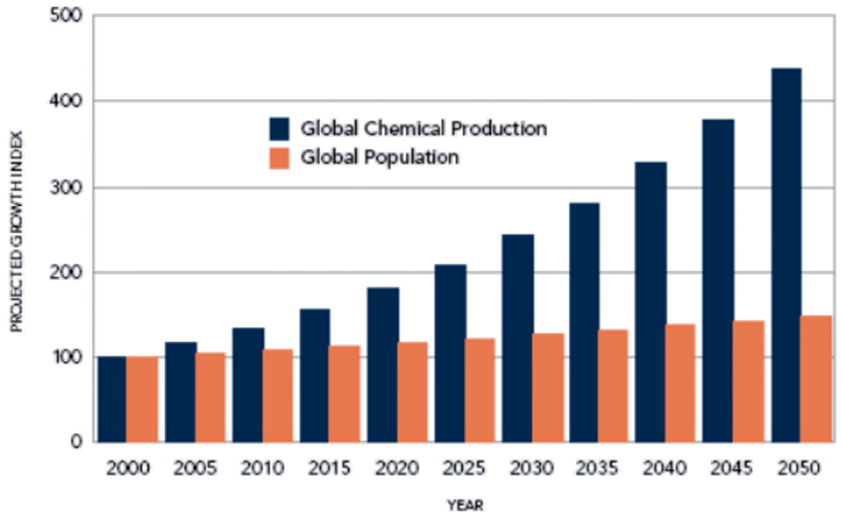


Figure 1. Projected growth in chemicals production in comparison to growth in global population (EC 2017a).

Chemical pollution has been proposed as one of the critical human activities that threatens earth system functioning within the Planetary Boundaries framework (Steffen et al., 2015). Increases in synthetic chemical production and diversification were concluded to outpace other agents of global environmental change such as rising atmospheric CO_2 concentrations, nutrient pollution, habitat destruction, and biodiversity loss (Bernhardt et al., 2017). The importance of reducing the negative impacts of chemicals on environmental and human health is recognised by several renowned international organisations. The United Nations (UN) 'Strategic Approach to International Chemicals Management' (SAICM) was initiated in 2006 with the aim to achieve a sound management of chemicals throughout their life cycle to minimise adverse impacts on human health and the environment by 2020. In a recent meeting initiated by the Swedish government, officials from governments, Inter-governmental organizations, civil society organizations and industry discussed the establishment of a global chemicals and waste framework comparable to the Paris Agreement on climate change, in order to strengthen both the protection of human health and the environment and advance UN's '2030 Agenda for Sustainable Development Goals'

(Government Offices of Sweden, 2018). This agenda specifically includes the aim to improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated waste water, and substantially increasing recycling and safe reuse globally. The European Commission (EC) has agreed to significantly reduce pressures on all Union waters in order to achieve, maintain or enhance good status, as stated in the '7th Environment Action Programme' (EAP), which guides European environment policy until 2020. The EAP includes a long-term vision of a non-toxic environment *that is conductive to innovation and the development of sustainable substitutes including non-chemical solutions*. A strategy to achieve this goal which complements, guides and frames the current laws and policies in relation to chemicals was published by the EC in 2017.

For market introduction and approved use of chemicals, health risk assessment is part of the authorisation procedure resulting in labelling, restricting, or banning the use of the most hazardous chemicals, preventing exposure, or setting limit values for e.g. contents in products or emissions to air or water. Risk assessment and management of environmental contamination with CECs is however challenging due to the large diversity of chemicals from multiple sources, high spatial and temporal variability, complexity of possible exposure situations, the impacts of cumulative exposures from multiple sources over time, the impact of combinations of chemicals, the constant engineering of new substances, and "unknown unknowns" (EC 2017a; OECD 2018). For only a small fraction of over 100,000 chemicals present on the EU market today, the environmental impact has been thoroughly evaluated and regulations are in place (EC 2017a). This report provides a quick scan of European legislation and regulation of chemical production and emissions in relation to impact on water quality, identifies gaps and issues, and concludes with recommendations to improve the protection of drinking water sources from CEC contamination.

2 EU regulations related to chemical impact on water quality

Various European regulatory instruments exist with respect to production, import, use, emission, and waste management of chemicals. All of these processes may cause release of chemicals to the aquatic environment (*Figure 2*).

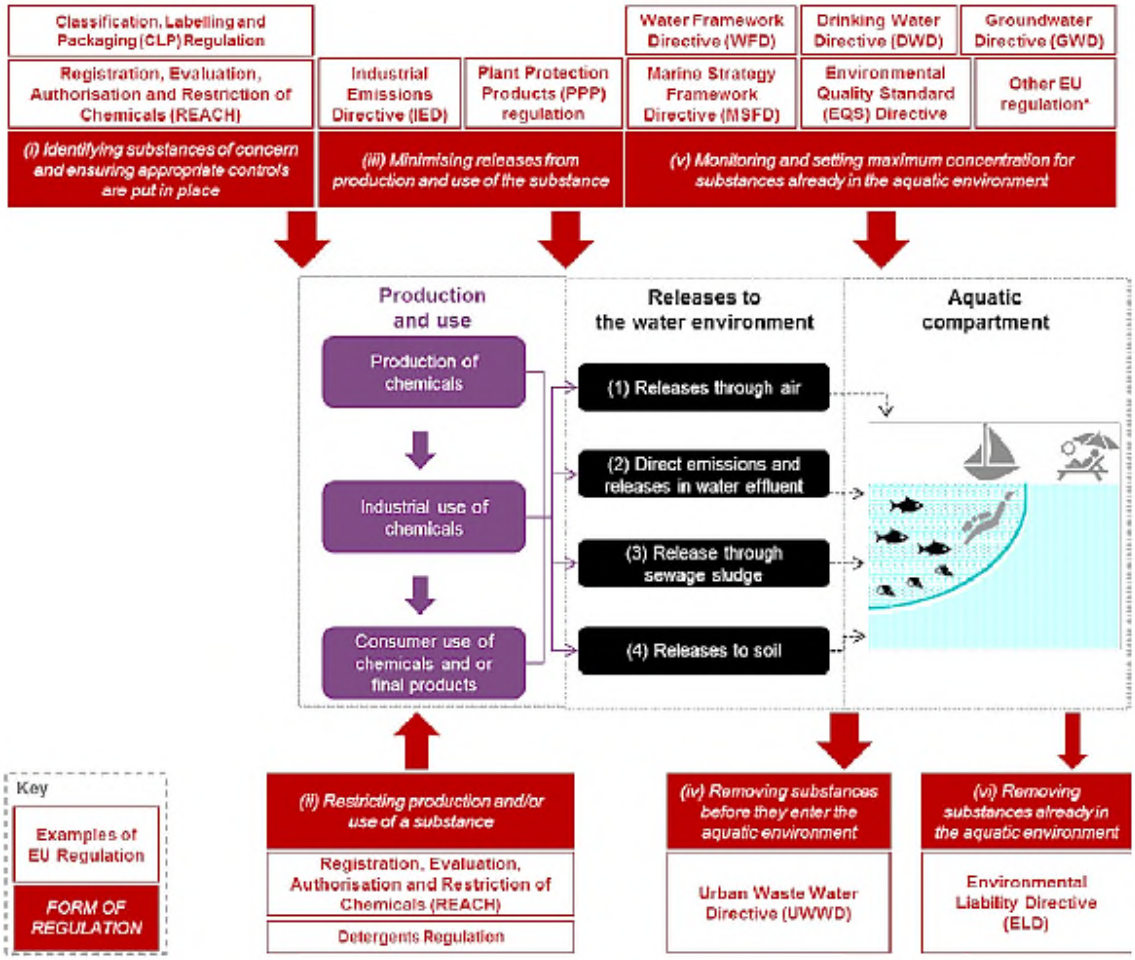


Figure 2. European regulatory instruments related to water quality (EC 2017b). The width of the arrow represents an approximation of the focus placed on each form of regulation by the EU acquis.

Table 1 lists European regulations, directives and conventions on chemicals, categorized by (i) market introduction and approved use, (ii) emission to environment, and (iii) receiving environment (immission) and indicates whether environmental emissions and environmental and human health protection are addressed. More information on the legislative frameworks can be found in Lexén et al. (2017). From this overview, a number of issues for water quality protection can be identified, which are summarized below.

Table 1. Characteristics of European legislative frameworks on chemicals with respect to impact on water quality (Lexén et al. 2017 with adaptations and extensions).

Legislation	Applicability domain	Exclusion criteria	Criteria for emission to aquatic environment	Criteria for other emissions	Environmental health protection	Human health protection	Risk management modifications
Market introduction and approved use							
REACH (1907/2006/EC)	Industrial chemicals; chemicals used in cleaning products, paints and consumer articles	SVHC, including: - CMR 1A or 1B - PBT - vPBT	Reporting of intended use and environmental release and exposure scenarios; limitation or ban of use	Reporting of intended use and environmental release and exposure scenarios; limitation or ban of use	✓ (risk assessment)	✓ (risk assessment)	Measures such as restrictions, identification of SVHC, harmonised classification or other actions
PIC regulation (EG) no 289/2008 (Rotterdam Convention)	Pesticides and industrial chemicals				✓	✓	
Community code relating to medicinal products for human use EU Directive (2001/83/EC)	Human pharmaceuticals				Reporting of potential risks presented by the product for the environment	✓ (risk assessment)	Post-marketing safety and efficacy monitoring
Community code relating to veterinary medicinal products (2001/82/EC)	Veterinary pharmaceuticals				✓ (risk assessment)	Reporting of potential risks presented by the product for human health	Post-marketing safety and efficacy monitoring, risk management system
Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency (726/2004/EC)	Pharmaceuticals				Risk assessment for genetically modified organisms	✓ (risk assessment)	Post-marketing safety and efficacy monitoring
Plant Protection Product Regulation (1107/2009/EC)	Plant protection products	- CMR - Endocrine disruptors - PBT - vPBT	Reporting of intended use, fate and behaviour in the environment	Reporting of intended use, fate and behaviour in the environment	✓ (risk assessment)	✓ (risk assessment)	Requires active substances meeting certain criteria for hazardousness to be considered as candidates for substitution; risk mitigation

							measures can be prescribed for pesticides
Biocidal Product Regulation (528/2012/EC)	Biocidal products, articles and materials treated with biocidal products and active substances	- CMR 1A or 1B - Endocrine disruptors - PBT - vPBT	May be restricted	May be restricted	✓ (risk assessment)	✓ (risk assessment)	Substitution criteria based on intrinsic hazardous properties of active substance in combination with use and potential exposure; risk mitigation measures can be prescribed
Food additives including enzymes and flavourings (1331-1334/2008/EC)	Food additives including enzymes and flavourings				✓	✓ (risk assessment)	Evaluation programme to re-evaluate the safety
Cosmetic Products Regulation (1223/2009/EC)	Cosmetic products	CMR 1A, 1B or 2				✓ (risk assessment)	Post-marketing safety monitoring
Directive on the Safety of Toys (2009/48/EC)	Toys	- CMR - Allergenic fragrances				✓	Replacement of dangerous substances and materials encouraged
Restriction of the use of certain Hazardous Substances in electric and electronic equipment (2011/65/EU)	Electrical and electronic equipment				✓	✓	Specific substances are prohibited when substitution is possible
Emission to environment							
Waste Framework Directive (2008/98/EC)	Waste management				✓	✓	Waste management options
Industrial Emissions Directive (2010/75/EU)	Industrial emissions		Emission limit values for water; reporting of emissions	Emission limit values for air; reporting of emissions	✓		Best available technique required; reporting of development and application of emerging techniques
Urban Waste Water Treatment Directive (91/271/EEC)			Emission limits; monitoring of discharges and receiving waters		✓		Requirements for treatment
Sewage Sludge Directive (86/278/EEC)	Sewage sludge used in agriculture			Treatment and limit values for use on land; reporting of amounts	✓	✓	Requirements for treatment

				and concentrations			
Mining Waste Directive (2006/21/EC)	Waste from extractive industries		Preventive measures for water pollution; monitoring results	Preventive measures for soil pollution; monitoring results	✓	✓	Waste management plan for minimization, treatment, recovery and disposal
EC regulation No 166/2006	Protocol on Pollutant Release and Transfer (PRTR)		Register of releases to water and pollutants in waste water	Register of releases to air and land and pollutants in waste	✓		
Regulation (EC) No 850/2004	Stockholm Convention on Persistent Organic Pollutants (POP) and Convention on Long-Range Transboundary Air Pollution on Persistent Organic Pollutants (CLRTAP)	23 intentionally produced POPs	Reporting of annual emissions to water	Exchanges of monitoring (concentrations in air, precipitation, dry deposition) and emission (air, land, products, residues) data	✓		Endeavour to minimize or, if possible, eliminate releases of unintentionally produced POPs
Receiving environment (immission)							
Water Framework Directive (2000/60/EC)	Aquatic environment		Emissions and concentrations in water, programme of measures		✓		Measures for progressive reduction of discharges, emissions and losses of priority substances and the cessation and phasing-out of discharges, emissions and losses of the priority hazardous substances
Ground Water Directive (2006/118/EC)	Ground water		Reporting of ground water concentrations		✓	✓	Required program of measures
Marine Strategy Framework Directive (2008/56/EC)	Marine environment		Assessment of current status, reporting of monitoring and measures		✓	✓	Required program of measures
Drinking Water Directive (98/83/EC)	Water intended for human consumption					✓ (risk assessment)	

CMR = carcinogenic, mutagenic or toxic for reproduction; (v)PBT = persistent, bioaccumulative, and toxic; POP = persistent organic pollutant; SVHC = substance of very high concern.

2.1 Regulated chemicals

- The traditional approach in chemicals legislation has been **substance by substance regulation**, which is time-consuming and not adequate to handle the range of chemicals known to be problematic (Van Leeuwen et al. 2007). For example, several hundred individual substances meet the criteria for being considered substances of very high concern (SVHC). The criteria for carcinogenicity, mutagenicity or toxic for reproduction (CMR) alone apply to about 600 different substances, and 1,200 of the 100,000 substances on the market today could be potential persistent organic pollutants (POPs) (EC 2017).
- Each instrument covers a limited number of specific (priority) chemicals that are rejected or restricted, while many more substances possess hazardous properties and/or meet criteria for persistence and bioaccumulation. In the REACH registration process, for instance, many substances meeting criteria for SVHCs and other substances of equivalent concern due to e.g. endocrine disruption, neurotoxicity, immunotoxicity, and developmental toxicity (endpoints which are currently not adequately addressed) have not yet been identified as highly hazardous substances (EC 2017). There are significant **gaps in coverage of the full range of chemicals** in legislative frameworks (Brack et al., 2017).
- Information concerning **chemicals present in (imported) articles**, for which a variety of exposure pathways for surface water exist (see *Figure 3*), and the resulting exposure is incomplete (EC 2017). In addition, the regulatory instruments allow only limited measures (registration or restrictions) to be taken for imported products (UBA 2018).
- Only the authorisation of plant protection products and REACH take environmental fate and risk of (identified) **transformation products** into account. REACH registration includes evaluation of environmental stability of parent substances; stable and/or toxic transformation products should be included in the environmental risk assessment. Transformation products or by-products formed during the production phase are not taken into account. Other legislation frameworks on market introduction do not cover risk assessment of transformation products that are formed in the environment or during water treatment. Information on human metabolites and environmental transformation products of pharmaceuticals is collected during authorisation, but environmental risk assessment for those substances is not actively applied in the authorization procedure (Ter Laak et al., 2015).
- No legislation is dedicated **specifically to CECs**. In particular, risk assessment and prioritisation of chemicals in the aquatic environment is often retrospective and reactive and thus based on chemicals already present in the environment (Munthe et al. 2017; OECD 2018).

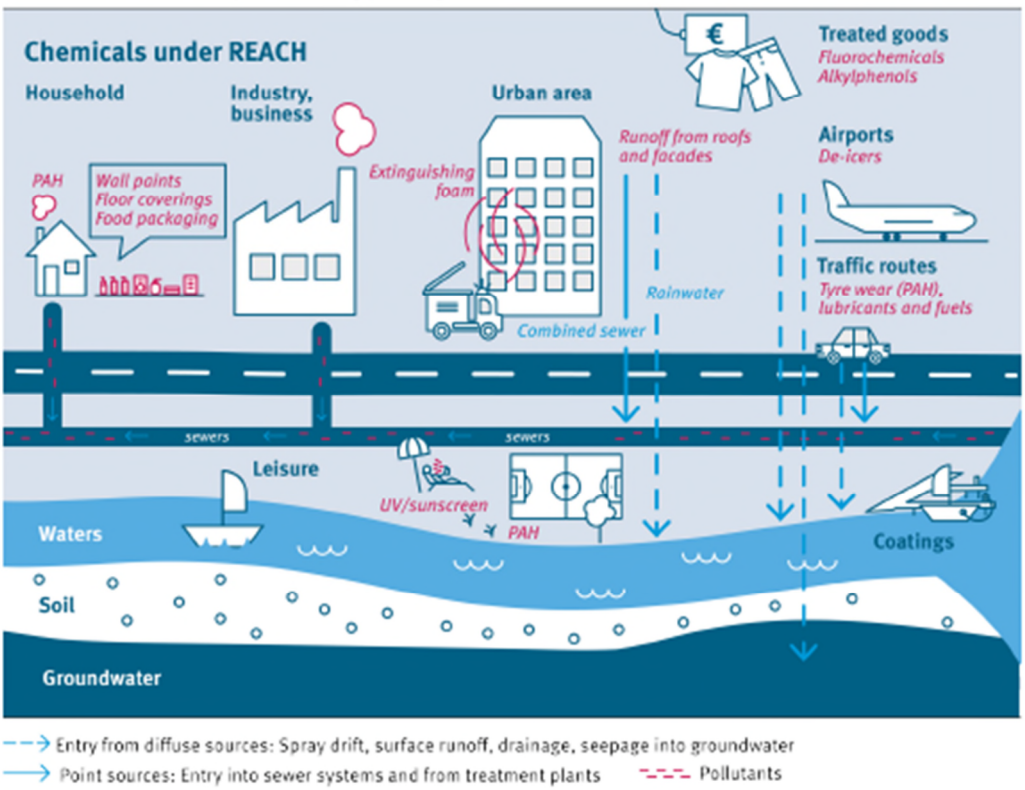


Figure 3. Possible entry pathways of chemicals in products into water (UBA 2018).

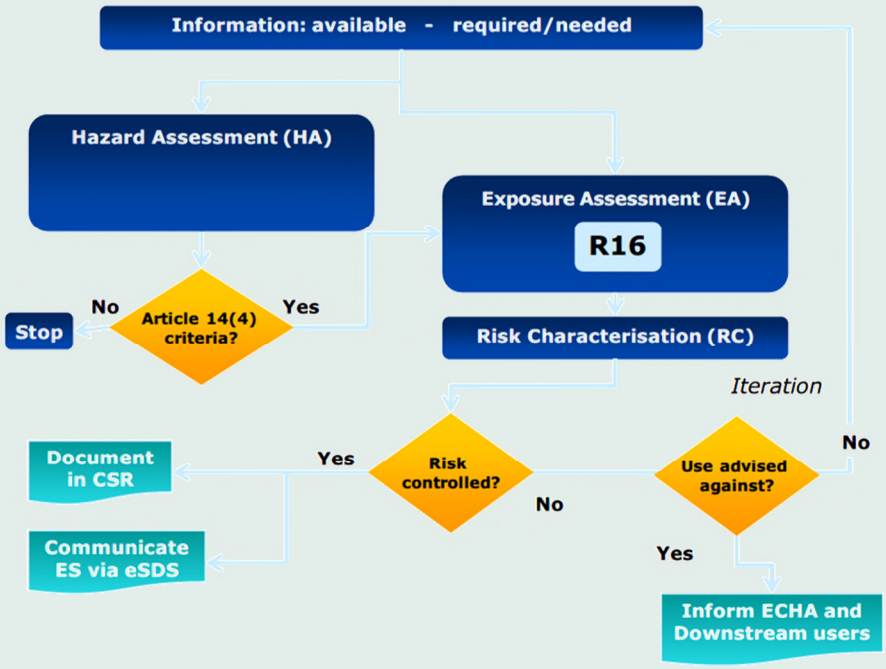
2.2 Risk management

- Risk management modifications may be prescribed, such as limits to doses or use frequencies, technologies for application, or treatment after use. High risk chemicals can be selected as 'candidates for substitution', to phase out over time when less harmful alternatives are available with similar use properties that can fulfil the intended service at comparable cost. **Substitution towards safer substances** is however proceeding slowly. Legislators may authorise candidates for substitution (albeit with additional dossier requirements) to maintain a proper chemical space in the range of active substances. Sackmann et al. (2018) showed that regulation of water-relevant SVHCs lead to a much higher decrease in the use of those substances than of unregulated polar mobile organic compounds. In addition, incentives, information on alternatives and tools for evaluation of alternatives appear insufficient. Manufacturers often use a structurally similar substance with similar properties, posing similar hazards to human health and the environment, but less well-studied and regulated ('regrettable substitution') (EC 2017; OECD 2018).
- The **best available techniques** (BAT) required to prevent or mitigate emissions of chemicals during industrial production, generally focus on 'classic' environmental pollutants such as heavy metals, organic halogens and nutrients and on standard parameters such as total oxygen demand, but not on the actually produced chemicals (Van Wezel et al., 2017).
- For chemicals used professionally (such as plant protection products), mandatory and non-mandatory **mitigation options** are available and applied to reduce the chemical loads in water systems. For non-professional uses, promotion of mitigation during the use phase is more difficult (Van Wezel et al., 2017).

2.3 Drinking water impact

- In approval of production and use of chemicals, special attention is paid to persistent, bioaccumulative, and toxic (PBT) and very persistent very bioaccumulative (vPvB) properties as a measure of environmental hazard potential. A common **framework for screening substances for persistence** and adequate requirements for persistence testing are however lacking. In addition, persistence is only regulated if bioaccumulative properties are also present (EC 2017).
- For the drinking water function of surface water and groundwater, **persistent, mobile, and toxic** (PMT) and very persistent and very mobile (vPvM) substances are even more of concern since these have a high water solubility and a low removal efficiency in water treatment. This allows transportation and recirculation after emission to the aquatic environment, posing a long term threat to the quality of drinking water (Reemstma et al., 2016). Chemicals detected in drinking water sources are often not labelled as priority substances or SVHC. A number of REACH registered chemicals with PMT properties and environmental emission potential were recently identified (Arp et al., 2017; Schulze et al., 2018), and some of these are detected in Dutch drinking water sources (RIWA 2018). Considerable data gaps (especially for experimental data) have however been identified that in many cases hampered the assessment of the criteria, especially for M and T (Berger et al. 2018).
- In legislation on production, use, and emission of chemicals, the **impact on sources of drinking water** is not specifically evaluated. In REACH dossiers, for instance, emission to water and chemical concentrations in drinking water sources are only modelled generically for hazardous substances as part of the decision making process, with the aim to prevent human health effects. According to UBA, the standard dilution factor of 10 for urban wastewater treatment plants used in the exposure assessment is often too high, especially in low-water conditions. Environmental concentrations may therefore be underestimated and potentially problematic substances may be missed (UBA 2018). REACH does not demand site-specific evaluation (including local hydrology, use, and other immission routes of the receiving water), and predicted concentrations are not compared to environmental or drinking water standards in the authorisation procedure (see *Text Box I*).
- In the practical implementation of REACH safety assessments, the **waste phase** (emissions to waste water, the efficiency of waste water treatment, emissions to water bodies, and the impact of sewage sludge utilisation) is not sufficiently considered and communication between all stakeholders is lacking (EurEau 2016).

Text Box I: Drinking water exposure in REACH regulation



Exposure assessment under the actual or anticipated conditions of use is mandatory for substances subject to REACH registration which are manufactured or imported in quantities equal to or greater than 10 tonnes/year, and where the registrant concludes in the **hazard assessment** that the substance fulfils the criteria for classification in specified hazard classes or categories or possesses PBT or vPvB properties.

Exposure assessment comprises calculation of concentrations in environmental compartments covering:

- Direct exposure of organisms and exposure via the food chain for predators;
- Exposure doses for humans via the environment in terms of inhalation and intake through drinking water, fish, leaf crops, root crops, meat and dairy products.

For each use, assessment of relevant exposure routes and risk characterisation must be performed for all hazards that have been identified. An assessment of indirect exposure of humans via the environment is generally only conducted if the tonnage >1000 t/y or the tonnage >100 t/Y and the substance is classified as a chemical causing specific target organ toxicity at repeated exposure, carcinogen or mutagen, or toxic to reproduction.
Exposure via **drinking water** is estimated based on the concentration in drinking water and the drinking water consumption (2L per day as a default). Concentrations in drinking water are modelled based on the predicted environmental concentrations in:

- *Groundwater*
  The concentration in porewater of agricultural soil is taken as an indication for potential groundwater levels. Transformation and dilution in deeper soil layers and purification are not taken into account (i.e. a worst-case assumption). Although several numerical models for groundwater concentrations are available (mainly for pesticides), such models require a characterisation of the soil on a high level of detail. This makes these models less appropriate for the initial standard assessment.
- *Surface water*
  Modelled annual average concentration after complete mixing of sewage treatment plant effluent (local assessment, near a point source of the substance) or steady-state concentrations in surface water (regional assessment covering a larger area) are used. In EUSES modelling, removal of the dissolved fraction of a chemical from the surface water is modelled by means of purification factors, based on octanol-water partition coefficient, Henry's law constant, and aerobic biodegradation rate. Two different water-treatment systems for surface water can be applied: system 1 includes storage in open reservoirs, while system 2 includes dune recharge.

It should be noted that in environmental exposure estimation, each use or contributing activity/technique for the environment is usually assessed independently. A combined assessment for several uses (or techniques for a same use) taking place at a same site is usually not covered in the registration dossier, as the variety of combination across the registrants market may be too wide. Each of the site operators downstream will have to ensure that the combination of all their activities carried out at the same site is still safe.

Risk characterisation comprises comparison of the estimated exposure to a Derived No Effect Level (DNEL). In specific cases, it is relevant to combine multiple exposure scenarios (indirect environmental exposure, occupation exposure, and use of consumer products) representing exposure from all sources and closely related analogues in the risk characterisation.
Risk management needs to limit the combined human exposure to below the DNEL. For non-threshold effects (e.g. non-threshold mutagens and non-threshold carcinogens) a DNEL cannot be established, but it may be possible to set a DMEL (Derived Minimal Effect Level): a reference risk level considered to be of very low concern, which can replace the DNEL in the risk characterisation. If human health hazards are identified (e.g. based on structural alerts) but a DNEL or DMEL cannot be derived, exposure via all routes needs to be minimized. The Regulation does not specify how to deal with substances for which toxicological information is absent.

Since the indirect human exposure estimation is based on a generic 'standard environment' and average exposure, it can only be used for screening purposes to indicate potential problems. The assessment should be seen as a tool for decision making, not as a prediction of the human exposure actually occurring at a specific place or time. If both local and regional-scale assessments do not indicate a potential risk, there is generally no reason for further assessment, unless there is some other indication that the modelling approach is not appropriate (e.g. for substances with physico-chemical properties that are not compatible with the modelling tool). However, if either local or regional-scale assessments indicate a risk, there is usually a need for refinement of the assessment before any decisions are taken to reduce risks (e.g. recommendations for more stringent risk management measures). It should initially be considered if the release estimates are realistic, and subsequently whether the concentrations in relevant environmental compartments are estimated adequately. Refinements may include:

- Using representative measured data (e.g. environmental concentrations or measured river flow rates). Measured environmental concentrations need to be i) of a suitable quality, (ii) representative of the operational conditions and risk management measures that were in place when measurements were performed, (iii) supported by sufficient contextual information, and (iv) assigned to the appropriate spatial scale.
- Adapting the characterisation of environmental compartments for site-specific assessment.

N.B.: no testing strategy is triggered by the indirect exposure estimation.

CONCLUSIONS

- Drinking water exposure is only evaluated for hazardous substances produced in certain tonnages.
- Only concentrations in porewater of agricultural soil are taken into account to predict groundwater concentrations and surface water concentrations are usually based on a specific, single use of a chemical.
- Human exposure estimation is based on generic scenarios and therefore only to be used for decision making, not as a prediction of actual exposure.
- If a human health risk is identified for the drinking water exposure route, modelling Is refined and risk management measures are required, but no testing strategy is triggered.

Source: ECHA Guidance on Information Requirements and Chemical Safety Assessment Part B (Hazard assessment), Part E (Risk characterisation) and R.16 (Environmental exposure assessment)

2.4 Integration of frameworks

- Chemicals may have multiple uses, risks, and impacts. **Legislation is fragmented** with a number of regulatory frameworks designed for specific groups of chemicals and types of use and protection of different endpoints. For example, the restrictions relating to the use of chemicals in articles are scattered in different legislation, lack a systematic basis, and do not take the overall exposures to chemicals in articles sufficiently into account (EC 2017). Additive exposure due to aggregated uses, combined exposure to multiple chemicals, and non-intentional mixtures are not included in the legislative frameworks (Van Wezel et al., 2017).
- Different regulations cover different parts of the chemicals life cycle. A more **holistic view on regulation of production, use, and disposal** of chemicals would provide the means of developing more efficient and transparent legislation (Lexén et al., 2017; Van Wezel et al., 2017). More specifically, there is a need to integrate chemical authorisation (production and use), emission, and water quality policies (receiving environment) in order to align risks based on chemical characteristics (e.g. toxicity, mobility, persistence) and receptors (e.g. groundwater, surface water, drinking water) and predict, identify, and mitigate future CECs. Structural links between source-related regulations and water legislation are currently missing (Brack et al., 2017). For instance, chemicals (1) authorized by product-related regulatory frameworks such as REACH, the Cosmetic Products Regulation, Medicinal Products Regulation, or Toy Safety Directive, which do not include emission restrictions and reporting requirements with regard to specific receiving media, (2) may be emitted during production processes according to the Industrial Emissions Directive, although safe environmental or human exposure limits do not necessarily exist in REACH or the Water Framework Directive, and (3) may leak from products during their life cycle or during the waste stage, regulated by e.g. the Urban Waste Water Treatment Directive, contaminating water resources which are regulated by the Water Framework Directive and Ground Water Directive (EC 2017). The lack of upstream measures, such as a restriction, may lead to a need for downstream remediation (EC 2017, OECD 2018).
- **Publically available, quality-assured data** on chemical production, use, emissions, occurrence, hazard, and exposure for all chemicals which have been prioritized and/or regulated are critical for regulatory or monitoring authorities to protect the aquatic environment, but are often missing or limited (Brack et al., 2017).

3 Policy recommendations

Current European legislation does not prevent CECs from entering the aquatic environment. The continuing appearance of CECs from new or newly detected sources and with varying properties will require the adaptation of regulatory frameworks to ensure protection of sources of drinking water (Lexén et al., 2017). Actions can be taken at different levels; a mix of source-directed measures and end-of-pipe measures will be required to effectively deal with CECs across their life cycle (OECD 2018).

3.1 Adjustment of legislation

- In line with the precautionary principle, pollution should be prevented and controlled as much as possible at the source (EurEau 2016). Lists of **banned chemicals or priority substances** in legislation on market introduction, approved use, and emission may therefore be expanded. REACH legislation gives room to inclusion of substances of equivalent concern as compared to current SVHCs. PMT/vPvM substances may be considered as such, since a number of properties are comparable to those of PBT/vPvB substances: contamination of pristine environments, unpredictable effects, and a potential for long-term contamination even after cessation of emissions (Neumann and Schliebner, 2017). Labelling PMT/vPvM substances as SVHCs would oblige applicants to perform an exposure assessment and risk evaluation and to demonstrate that risks associated with the use of these substances are adequately controlled by applying risk reduction measures (such as use and emission restrictions). These risks should then comprise threats to the quality of drinking water sources, for instance as evaluated using an exposure scenario for ground- and surface water. PMT/vPvM criteria and assessment procedures were recently proposed for implementation in REACH (Reemtsma et al., 2016; Neumann and Schliebner, 2017). Monitoring data of for instance groundwater may aid in identification of PMT/vPvM substances and validation of exposure scenarios. PMT/vPvM substances could also be added to the Water Framework Directive priority lists as an end-of-pipe solution, urging monitoring, inventory of emissions and discharges, and/or cessation or phasing out of discharges.
- Placing harmful chemicals on a watch list can encourage the innovation of more environmentally-friendly products. Information on environmentally harmful CECs needs to be developed and communicated to enable the use of the **substitution principle** in decision-making processes (OECD 2018), as is already applied in legislation of plant protection products. To counter the issue of regrettable substitution and to increase regulatory efficiency and effectiveness, the use of grouping strategies for assessing chemicals with structural similarities needs to be scaled up. This is doable as these methods have already been developed and applied in the context of REACH and the chemicals programme of the OECD. Other measures to consider include: streamlining legislation to provide more incentives for substitution; promotion of functional (as opposed to structural) substitution and non-chemical alternatives; active support and training on substitution; more research on grouping strategies for regulatory purposes (EC 2017a).
- A focus on developing chemicals that are more efficiently degraded in waste water treatment or in the environment seems promising (depending on the

purpose of the development). Full integration of all **green chemistry** principles appears to be a challenge for the chemical industry, regulatory bodies and society at large. Regulatory bodies might influence market penetration of novel benign products through tailored regulations. A wide implementation of safely designed chemicals and products has the ability to improve water quality long-lasting (Van Wezel et al., 2017).

- **Extended producer responsibility**, i.e. placing the responsibility for incidence reporting, post-market monitoring, and/or treatment or disposal by consumers of certain goods on producers, can be promoted by either providing incentives for waste reduction and supporting the achievement of public recycling and materials management goals or placing financial liability for environmental harm inflicted during the post-consumer phase on producers (EurEau 2016, OECD 2018). Although such measures are end-of-pipe measures to reduce environmental pollution, they also enable identification of contamination and adaptation of policy to new science (Brack et al., 2017; OECD 2018).

3.2 Coherence between regulations

- Some type of process or mechanism that acts horizontally across the various pieces of EU legislation that deal with chemical risks and pollution appears to be needed in order to ensure the protection of human health and the environment (EC 2017a; Dulio et al., 2018). **Cooperation between existing regulatory frameworks** and exchange of information can aid in more coherent and efficient exposure and risk assessment, prioritisation, and regulation (EEA 2018; Brack et al., 2017; Lexén et al., 2017). This includes explicit linkage of lists of substances of concern and corresponding restrictions in different regulations and cross-compliance mechanisms. A joint database system on uses and sources of chemicals would enable authorities responsible for different regulatory frameworks on chemicals to develop joint abatement strategies when necessary (Brack et al., 2017). Besides, information sharing by industry, academia and NGOs with governments is important to bring chemical safety and water quality problems to the attention of the chemical sector, policy makers, and the water sector (Munthe et al., 2017; OECD 2018).
- Increased efficiency can also be achieved if all regulatory frameworks consider the protection of both human health and the environment, in a consistent manner with the 'One Health' paradigm. To avoid gaps, a **systematic analysis of the substances life cycle** (in products or as chemicals used in industry or agriculture etc.) using a common approach and methodology would provide relevant information on all potential risks posed by releases of harmful substances or direct exposure (OECD 2018). This could be supported by integrated modelling to predict the transport, fate, and risk to ecosystems, aquatic environment and human health of defined chemicals based on information on production, use, and emission patterns (Munthe et al., 2017).

3.3 Implementation and enforcement

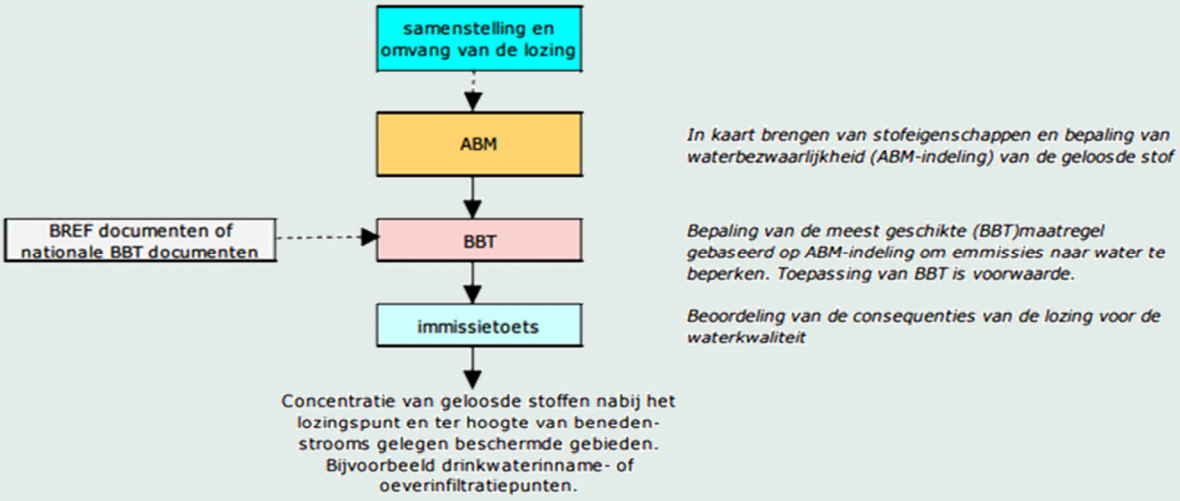
- **National implementation** of European legislation allows evaluation of local environmental impact. Authorisation of plant protection products, biocides, pharmaceuticals, and industrial emissions is performed by national authorities within European legislative frameworks. Plant protection products are authorised in relation to their specific, local applications. As authorisation of industrial chemicals only occurs via the REACH regulation, and not via a national authorisation procedure, environmental contamination with these chemicals should be reduced by restricting their use and emission in the REACH legislation

and/or via downstream legislations that either refer to REACH or regulate the same chemicals (see *Text Box II* for the Dutch implementation of industrial emission authorisation).

- **Existing restrictions and limitations** with respect to chemical use and emission should be fully utilised to reduce environmental CEC contamination. Binding limitations and restrictions for use and emission recorded in REACH registrations must be adopted by national authorities in authorisation procedures for industrial emissions and site-specific implementation of the Water Framework Directive. Another example would be the evaluation of whether the technologies described in the BAT reference documents (BREFs), that make part of the legislation procedure for industrial emissions, are efficient for reducing emissions of priority substances and SVHCs (Brack et al., 2017), ideally including PMT/vPvM substances.

Text Box II: Dutch procedure for industrial emission authorisation

Several instruments are applied in the Dutch authorisation procedure for industrial emissions. First, a general evaluation procedure ('Algemene BeoordelingsMethodiek', ABM) is used to determine potential adverse effects of the emitted chemicals on the aquatic environment. Next, the best available technique(s) ('BBT') to reduce the impact on water quality are determined. Finally, the consequences of the immission at the emission site and at downstream drinking water abstraction sites are assessed ('immissietoets').



The **ABM** first evaluates whether emitted substances (occurring in concentrations higher than trace elements) and their known by-products and transformation products formed during water treatment are classified as (potential) SVHC according European evaluations (including REACH registration), persistent or mobile. Next, the aquatic toxicity is evaluated. Tolerable intake levels relevant for human exposure are *not* assessed .

As part of the **Immissietoets**, predicted concentrations of the (in)directly emitted chemicals at drinking water abstraction sites are compared to legal standards for (sources of) drinking water. For (yet) unregulated chemicals concentrations are first compared to a signalling parameter of 1.0 µg/L. When this parameter is exceeded, a substance-specific drinking water standard needs to be derived if chemical properties indicate that the chemical may pose a risk for drinking water. Transformation products are *not* included in the Immissietoets.

The result of the REACH environmental exposure assessment (see *Text Box I*) is *not* consulted in the ABM or Immissietoets procedures.

Source:Ministerie van IenW (2018) Handreiking beoordeling van lozingen gericht op bescherming drinkwaterkwaliteit,

4 Road ahead

The policy recommendations described in the previous chapter may be summarized in three approaches to protect drinking water sources from contamination with CECs:

1. Regulation and restriction of substances of concern with respect to the aquatic environment (see *Text Box III* for REACH-specific measures) and promotion of production and use of less hazardous alternatives.
2. Coherence of regulatory frameworks covering different stages of a chemical's life cycle, integration of environmental and human health protection, and cross-compliance by linkage between up- and downstream legislations.
3. Optimal implementation of restrictions and limitations requested in European legislation and application of site-specific evaluations in national authorisation procedures.

Although revisions of legislative frameworks are complicated and require considerable effort and time, there currently may be a unique opportunity in time now REACH regulation is subjected to a review (REACH REFIT Evaluation), other chemical regulations undergo a 'fitness check' to assess the relevance, coherence, effectiveness, efficiency and EU added value of the legislative framework for the risk management of chemicals, and so many water-related directives are being revised (i.e. the Drinking Water Directive, Water Framework Directive including Groundwater Directive, Urban Wastewater Directive, and forthcoming Water Reuse Directive). The inclusion of PMT/vPvM criteria in REACH legislation has already been proposed by UBA and is supported by the Dutch drinking water sector and government. The OECD and the SOLUTIONS project consortium are both preparing publications on policy recommendations to reduce CECs in water bodies and their impacts on human health and ecosystems, which are expected at the end of 2018.

Text Box III: Proposed measures for implementation and adaptation of REACH regulation

In the REACH registration procedure, production, use and emission of substances labelled as SVHC can be banned or restricted. Emission to water can thus be reduced or prevented in the authorisation procedure. Therefore, (v)PMT chemicals are preferably added to the selection of SVHC chemicals.
Environmental exposure is only generally assessed in the REACH registration and only for chemicals in specified hazard classes or with PBT or vPvB properties (see *Text Box I*). Waste water treatment may be overestimated in this evaluation.
Risk management measures for other (potentially) hazardous and/or (v)PMT chemicals can only be commanded in national industrial *emission* authorisation procedures. The Dutch procedure includes substances that are SVHC, persistent, mobile and/or toxic to the aquatic environment in the first step (ABM) of the evaluation; other chemicals and potential human health hazard via drinking water exposure are part of the subsequent Immissietoets (see *Text Box II*).

Measures	Effectiveness	Substance-specific/broad spectrum	Costs	Effectiveness horizon	Feasibility
Using the REACH instruments of authorisation/restriction to reduce entry of individual substances that occur as micropollutants	n.d.	Spec.	n.d.	2–3	o
Avoiding the entry of substances critical to raw water into the environment in the regulatory scope of EU regulation REACH	+	Spec.	n.d.	2–3	o
Using a more realistic dilution factor for treatment plants in the exposure assessment of industrial chemicals	+	Br.	+	2	+

Expected effectiveness: (+ high), (o moderate), (n.d. uncertain because specific to substance, use or measures taken), (spec.: measure is substance-specific), (br.: measure has a broad spectrum effect)
Effectiveness horizon: (1 = short term < 5 years), (2 = medium term < 10 years), (3 = long term > 10 years); usually depends on acceptance and agreement processes at EU level
Costs: (+ low), (o moderate), (n.d. uncertain because specific to substance, use or measures taken), (- high)
Feasibility: (+ immediately feasible), (o depends on acceptance at EU level), (- still clear deficits/need for action (need for research, funding or acceptance))

Source: UBA (2018) Recommendations for reducing micropollutants in waters. German Environment Agency, Dessau-Roßlau, Germany.

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