

POLICY BRIEF

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Increase coherence, cooperation and cross-compliance of regulations on chemicals and water quality

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Abstract

An analysis of existing regulatory frameworks for chemicals reveals a fragmented situation with a number of regulatory frameworks designed for specific groups of chemicals; for protection of different end-points and covering different parts of the chemicals' life cycle stages. Lack of- and fragmented information on chemicals (properties, use, emissions as well as fate, occurrence and effects in the environment) limit the ability for assessment and early action, and existing legislation would benefit from more transparency and openness of information and knowledge. To achieve harmonisation of existing legislation and an efficient control of chemical contamination of European waters, a solution-focused approach is proposed including increased ambitions (in monitoring, modelling, and risk assessment), cooperation and dialogue. More holistic and efficient development and implementation of existing legislation can be achieved by better cooperation, harmonisation and information exchange between different regulatory frameworks and by improved science-policy interactions. The introduction of an organisational structure and incentives for cooperation are proposed. Cooperation should focus on harmonisation of advanced monitoring activities, modelling, prioritisation, risk assessment and assessment of risk prevention ('safe by design') and minimisation options. A process for dialogue and information exchange between existing policy frameworks and with stakeholders (industry, NGO's, etc.) should be included to identify feasible options for mitigation as well as regulatory gaps—on local and EU-scales. There is also a need to increase international cooperation and strengthen global agreements to cover the full life cycle of chemicals (produced and consumed globally) and for exchanging knowledge and experiences to allow early action. This recommended action would also provide knowledge and a framework for a shift towards a sustainable chemistry approach for chemical safety based on a "safe by design" concept.

Challenge

The focus of this study is the Water Framework Directive (WFD) and how to implement and develop legislation to ensure the protection of European waters from chemical contaminants. Many of the potential chemicals threats to water quality are, however, regulated under other regulatory frameworks, or not at all, and the starting point is

thus an overview and assessment of existing legislation on chemicals focussing on other areas than water quality.

Several regulatory frameworks (EU Directives and Regulations, international agreements and Conventions), which aim to prevent and reduce risks and impacts of chemicals and their mixtures to both the environment and human health, have been developed and implemented over the last decades [1]. These regulatory frameworks have different and sometimes overlapping scopes covering chemicals (as such or in mixtures) in articles, emissions or concentration levels in the environment on different geographical scales (local, regional and global). The regulatory frameworks are also developed

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for specific parts, or the whole, life cycle of the chemicals or for ecosystem protection as depicted in Fig. 1. The number of chemicals regulated per framework spans from only a few to thousands of substances, whilst potential cumulative effects of substances in mixtures are often not or only partially considered or assumed to be

covered by application of uncertainty or assessment factors in the risk assessment. In some of the frameworks, the regulated chemicals constitute an important fraction of the total number of chemicals used in society and present in the environment. In other legislation, focus is on a smaller subset of chemicals, which are considered to pose



Fig. 1 Graphic representation of the life cycle of chemicals (red) and coverage by different regulatory frameworks (blue = covered, grey = not covered, see list of abbreviations below). The centre represents four regulatory frameworks addressing chemical pollution and water quality [1]. BPR—Biocidal Products Regulation (EC/528/2012); Cosmetics—Cosmetic Products Regulation (EC/1223/2009); DWD—Drinking Water Directive (98/83/EC); GWD—Ground Water Directive (2006/118/EC); IED—Industrial Emissions Directive (2010/75/EU); Medicinal Products—Regulation on Procedures for the authorisation and supervision of Medicinal Products for human and veterinary use and establishing a European Medicines Agency (EC/726/2004; Mining Waste—Mining Waste Directive (2006/21/EC); MSFD—Marine Strategy Framework Directive (2008/56/EC); PPP—Plant Protection Products Regulation (EC/1107/2009); PRTR—European Pollutant Release and Transfer Register (E-PRTR), <https://prtr.eea.europa.eu/#/home>; REACH—Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC/1907/2006; RoHS—Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065>; Rotterdam Conv.—Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; SAICM—Strategic Approach to International Chemicals Management SSD—Sewage Sludge Directive (86/278/EEC); Stockholm Conv.—The Stockholm Convention on Persistent Organic Pollutants; Toys—The Toy safety Directive, https://ec.europa.eu/growth/sectors/toys/safety_en; UWWTD—Urban Waste Water Treatment Directive (91/271/EEC); WFD—Water Framework Directive (2000/60/EC)

the highest hazards. Different frameworks also focus on different end points, e.g. risks for human health, ecosystem effects or both, and account for different contexts (e.g. plant protection products in relation to food production). Therefore, they apply different procedures for identifying these potential risks to compare with different forms of benefits. The mixture risks are often neglected (although possibly covered indirectly by the application of uncertainty or assessment factors in risk assessment) despite the common co-occurrence of many chemicals in the environment, the goal of the non-toxic environment [2] and EC-incentives to consider mixtures [3].

Chemicals that are not regulated in terms of desired environmental quality but represent a potential risk are sometimes denoted as emerging chemicals or Chemicals of Emerging Concern (CECs). CECs present in the environment are not necessarily new chemicals. They can also be substances that have been present in society and the environment for a long time but whose presence and potential impacts are now being elucidated. The continued appearance of emerging chemicals from new or newly detected sources and with varying properties will require continuous adaptation and updation of current regulatory frameworks, complemented with a pro-active 'safe by design' and 'sustainable chemistry' approach. It will also require continuous adaptation of risk assessment and management to ensure protection of human health and the environment.

The Water Framework Directive (WFD) has a strong focus on status assessment, with a chemical status defined on the basis of a small set of priority substances (PS), among them many legacy and ubiquitous chemicals with frequent Environmental Quality Standard (EQS) exceedance. These are chemicals for which no straightforward management options exist. According to the "one-out-all-out" principle this means that the chemical status cannot be improved with existing management although there are plenty of abatement options that would significantly reduce the risk to ecosystems and human health posed by the mixture [4]. Thus, incentives and solution-focused approaches are required to improve water quality even if the final goal of a good chemical status cannot be achieved yet.

Identification of CECs by means of advanced monitoring or modelling approaches requires both expert knowledge and resources. Not all individual countries or water district authorities currently have these capacities, whilst coverage of the increasing number of chemicals in commerce remains a challenge in itself. Increased cooperation and knowledge sharing on methods and procedures for monitoring and modelling as well as for the development of efficient abatement strategies and action plans are necessary.

Recommendations

An innovative and comprehensive regulatory framework for chemicals should be designed and implemented, based on a solution-focused approach and building upon existing legislation. The approach should focus on linking conventional prospective risk assessment of individual compounds with retrospective risk assessment for environmental compartments, but also on evaluating which measures can best be taken to avoid and prevent novel risks or reduce existing risks. This concept for a solution-focused approach was introduced by the U.S. National Academy of Sciences [5] to improve the utility of risk assessments and has been further elaborated in the SOLUTIONS project with the WFD as the starting point [6]. The project has provided methods and tools for implementing such a solutions-focused approach, i.e. for testing and evaluating water quality by both monitoring and modelling and for identifying abatement options.

This approach implies a continual work with focus on operational prevention and reduction of chemical risks applied to any stage of the life cycle of a chemical. It also ensures that adequate measures can be taken when need arises or when feasible to gradually reduce risks for exposures in a stepwise manner. The solution-focused approach and the knowledge gained by applying it, can also provide a basis for a long-term shift towards risk reduction via 'safe by design' approaches [7].

The solution-focused approach also entails a strong link between knowledge on chemical use and occurrence in society, emissions and presence in the environment and associated exposure of nature and humans, as illustrated in the conceptual framework (Fig. 2, upper and lower right). Chemical and environmental risk information is collected and combined to design and evaluate abatement options and developments in society (Fig. 2, lower and upper left). This necessary integration could, to a large extent, be achieved by better linking existing prospective regulatory frameworks (e.g. REACH, PPP, BPR) with those more focused on assessing and protecting the environment (e.g. WFD). Prospective regulatory frameworks generate information on use patterns and amounts and regulate the use of potentially hazardous chemicals via authorisation or restrictions. By combining these legal instruments for reducing releases to the environment and resulting exposures with the application of advanced monitoring for assessing the status of water bodies, a scientifically sound and more comprehensive basis for action can be developed.

To implement a solutions-focused approach as an overarching principle for implementing regulations, several recommendations can be given:

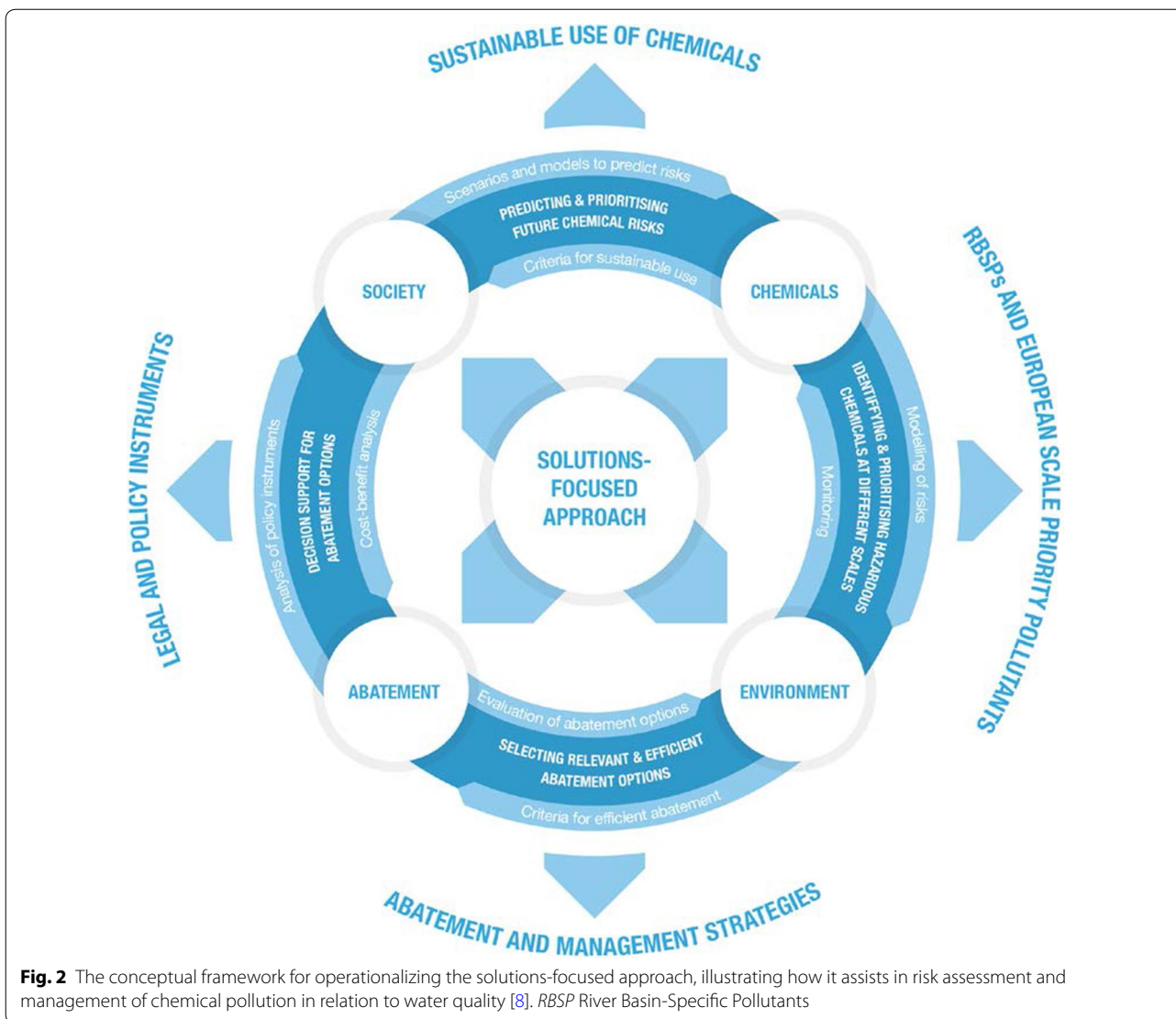


Fig. 2 The conceptual framework for operationalizing the solutions-focused approach, illustrating how it assists in risk assessment and management of chemical pollution in relation to water quality [8]. *RBSP* River Basin-Specific Pollutants

- Introduce a common strategy and an organisational framework for cooperation and action to prevent and reduce risks of emerging substances. This should build on existing legislation and existing structures and should include the following components (related to Fig. 2):

Chemical safety assessment: Develop and apply harmonised procedures for assessment, prioritisation, and identification of CEC utilising experiences and knowledge from both prospective risk assessment and environmental quality assessment.

Environmental quality assessment and management: Initiate and promote cooperative programs and activities for advanced monitoring and modelling based on harmonised methodologies for CEC

in European waters and other ecosystem compartments.

Abatement options and efficacy: Develop a common information platform for storage and retrieval of information on abatement options (technical and non-technical measures), enabling exchange of information and experiences between different stakeholders.

Society: Engage in dialogue between stakeholders and different regulatory bodies to identify actions to prevent and reduce the production, use and emissions of hazardous compounds and to identify the needs for policy evaluation and adaptation

- Specifically, for improved implementation of the WFD, current status assessment with should be com-

plemented with incentives and guidance for a solution-focused approach to identify abatement priorities and to reduce risks of chemical mixtures, even if good chemical status cannot be achieved. Consider new policy instruments beyond the exceedance or non-exceedance of EQS for individual compounds that demand for and reward progressive improvement of water quality. With effect-based monitoring [9], chemical screening [10] and models [11] to identify potentially hazardous chemicals, component-based methods for mixture risk assessment [12] and ecological tools [13] results from the SOLUTIONS project provide the necessary means to detect and quantify the progress.

Engagement of all relevant stakeholders including industry, agriculture, scientific community and public representatives is a necessity for the above approach to be implemented successfully.

In a slightly longer perspective, it will become necessary to introduce a more pro-active approach by promoting and requiring 'safe by design' and 'sustainable chemistry' before introducing new substances on the market. The current approach with mainly per-chemical safety assessment can thus gradually be replaced.

Requirements

To support the solutions-focused approach for the WFD, whilst including potentially more than 145,000 chemicals [14] and their mixtures, sharing of information on use, properties occurrence and environmental and human exposure of CEC is necessary, to embody a sensible prioritisation of management action. Mandatory monitoring and modelling covering all EU member states and all water bodies with the aim to identify potentially all CECs is not realistic in the short term due to costs and efforts required. Nevertheless, increased ambitions and efforts by member states on monitoring, modelling and (mixture) risk assessment are required. To support this and to ensure knowledge exchange joint European efforts should be encouraged. An organisational structure and a science-policy interface would be required for harmonising and increasing the efficiency of efforts to prevent and reduce chemical contamination of European waters.

The following activities are proposed as the main components of a joint European program for monitoring, modelling, assessment and abatement of chemical contamination of European Waters:

- Collaborative efforts for advanced monitoring and data sharing: Modern analytical tools, e.g. Effect-Directed Analyses (EDA), Non-Target Screening (NTS), and arrays of bioassays are increasingly

applied to identify chemical compounds with potentially adverse effects on the aquatic environment [9, 10]. Applied methods often require significant resources and knowledge and results may depend on the choice of a specific method for an individual case. This activity provides knowledge-transfer and works for harmonisation of methods, knowledge sharing and science to policy communication to facilitate a maximised use of knowledge and data gained for further risk assessment, prioritisation and assessment of mitigation options.

- Modelling fate and distribution of chemicals across the EU: Modelling is a useful complement to monitor for bridging gaps in geographical and temporal coverage of monitoring and identifying potential risks from CECs not included in monitoring programs [11]. This activity provides data and guidance to identify "no, low, or negligible risk" chemicals, to guide monitoring efforts (selection of substances and sampling sites) and to interpolate between results from monitoring which are limited to specific sites and points in time. In addition, modelling can also be used to simulate the outcome of different abatement scenarios to support the selection of the most effective way forward.

In addition to a modelling and monitoring centre, a coordinated activity on assessment, abatement and legal instruments is also proposed. This activity would have as focus:

- Assessment of the current status and the needs and options for abatement, using concepts and modelling methods for chemical footprints [13], linking chemical and ecological status as well as mixture exposure and effects. The results of these efforts would support the implementation of existing legislation by assessing and evaluating potential abatement options including technical and non-technical measures [15, 16].

Organisational aspects

The proposed actions should build upon the considerable experiences and knowledge gained from existing activities on monitoring, modelling and assessment of chemical status by, e.g. dedicated efforts in member states and by engaging the scientific community.

The work performed under the Common Implementation Strategy (CIS) of the Water Framework Directive (EC 2000) (2000/60/EC) can be taken as a good example of collaboration. The CIS was developed to allow a coherent and harmonious implementation of the Directive

with focus on methodological questions on technical and scientific issues. A number of Guidance Documents have been prepared including several on monitoring (https://ec.europa.eu/environment/water/water-framework/facts_figures/guidance_docs_en.htm). The guidance documents are non-binding and are directed to experts who are directly or indirectly involved in implementing the Directive.

For non-regulated substances, the NORMAN network (<https://www.norman-network.net/>) provides an existing platform for chemical monitoring, prioritisation and risk assessment—including, e.g. development of methods, knowledge sharing and sharing of information on results of monitoring. For monitoring data, the EU has also launched the Information Platform for Chemical Monitoring (IPCHEM) where data are made available under four modules: Environmental monitoring, Human Bio-Monitoring, Food and Feed, Products and Indoor Air (<https://ipchem.jrc.ec.europa.eu>). Other examples of international collaborations such as the Joint Danube Survey (<https://www.danubesurvey.org/jds4/>) organised by the International Commission for the Danube River (<https://www.icpdr.org/main/>) and joint monitoring programs organised by the International Commission for protection of the Rhine river (<https://www.iksr.org/en/>) can also serve as good examples of existing cooperation. The European Environment Agency (EEA) should also have a central role in integrating knowledge and identifying needs for action, as detailed in <https://www.eea.europa.eu/highlights/more-action-needed-to-tackle>.

There is currently no organisational structure for joint international modelling activities of CEC but a starting point would be to coordinate existing initiatives in the scientific community. This component can potentially be aligned with and become integrated with the current NORMAN network activities.

The previously proposed activities should be linked to the on-going efforts by the European Commission to evaluate and improve existing legislation (https://ec.europa.eu/environment/chemicals/index_en.htm) with increased efforts to establish links between, e.g. the WFD and REACH and other relevant legislation as well as with global agreements such as Stockholm Convention and SAICM. The EU-goal of a non-toxic environment by 2020 [2] requires swift advancements of approaches for safe chemical design, not limited to some few but including all chemicals on the EU market.

A key factor of the solutions-focused approach outlined above is that it can also be introduced and implemented on a local scale. By combining local knowledge on sources of emissions and water quality status, and by engaging local stakeholders in dialogue, rational and realistic solutions to identified problems of chemical

contamination of local water bodies can be identified and implemented.

Achievements

The SOLUTIONS project used the solutions-focused approach based on the Conceptual Framework to achieve significant progress in providing science-based and application-ready methods related to protection, monitoring, modelling and abatement of CEC, whilst also evaluating future societal developments and emerging (mixture) risk to anticipate on measures needed to avoid future damage. The results of the SOLUTIONS project can be found at RiBaTox [17], accessible at <https://solutions.marvin.vito.be/>, which helps to select and use SOLUTIONS Tools and Services that relate to the diversity of water-related challenges. RiBaTox is a practical example of the translation of the solutions-focused approach into a web-based tool. Recommendations on how to implement these scientific developments for a further development of the WFD have also been formulated [18]. A number of these results also forms the basis for specific recommendations on, e.g. Effect-Based Methods [9], emission, exposure and effect modelling [11] and technical- and non-technical abatement [15].

In addition to the assessment of chemicals' life-cycle coverage by different regulatory frameworks as presented in Fig. 1, existing regulatory frameworks differ since they are developed for specific groups of chemicals and for protection of different end-points. An increased efficiency could be achieved if all regulatory frameworks considered protection of both human health and the environment. Cooperation between existing regulatory frameworks on, e.g. exchange of information on use, emissions, occurrence and effects in the environmental can also give rise to a more coherent and efficient regulation. Another step towards cooperation and harmonisation would be to introduce common procedures for risk assessment and prioritisation. And as the market for chemicals is global, there is a need to discuss chemical management on a global level and thereby strengthen the cooperation between EU and relevant international organisations. Information on the different regulatory frameworks and regulated substances can be found in the form of a database accessible at <https://apps.ivl.se/solutions> and via www.solutions-project.eu. The need for database support on which substances are regulated has recently been recognised by the European Commission who have announced the development of a website providing information on EU-legislation for different chemicals to be launched in 2020 <https://newsletter.echa.europa.eu/home/-/newsletter/entry/which-pieces-of-eu-legislation-apply-to-your-substances>.

Building on the Conceptual Framework designed in an early stage of the SOLUTIONS project to define necessary components of the solutions-focused approach to chemical regulation [8], (Fig. 2) the SOLUTIONS project has shown that the necessary knowledge base needed for a more proactive and efficient regulation for risk minimisation from CEC is available and achievable.

Abbreviations

BPR: Biocidal Products Regulation (EC/528/2012); CEC: Chemicals of Emerging Concern; Cosmetics: Cosmetic Products Regulation (EC/1223/2009); DWD: Drinking Water Directive (98/83/EC); EDA: Effect-Directed Analysis; EEA: European Environment Agency; EQS: Environment Quality Standards; GWD: Ground Water Directive (2006/118/EC); IED: Industrial Emissions Directive (2010/75/EU); IPCHEM: EU Information Platform for Chemical Monitoring; Medicinal Products: Regulation on Procedures for the authorisation and supervision of Medicinal Products for human and veterinary use and establishing a European Medicines Agency (EC/726/2004); Mining Waste: Mining Waste Directive (2006/21/EC); MSFD: Marine Strategy Framework Directive (2008/56/EC); NORMAN: Network of reference laboratories, research centres and related organisations for monitoring of emerging environmental substances; NTD: Non-target screening; PPP: Plant Protection Products Regulation (EC/1107/2009); PRTR: European Pollutant Release and Transfer Register (E-PRTR), <https://prtr.eea.europa.eu/#/home>; PS: Priority substances; REACH: Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (EC/1907/2006); RoHS: Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment. <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32011L0065>; Rotterdam Conv: Rotterdam Convention on the Prior Informed Consent Procedure for Certain Hazardous Chemicals and Pesticides in International Trade; SAICM: Strategic Approach to International Chemicals Management; SSD: Sewage Sludge Directive (86/278/EEC); Stockholm Conv.: The Stockholm Convention on Persistent Organic Pollutants; Toys: The Toy safety Directive, https://ec.europa.eu/growth/sectors/toys/safety_en; UWWTD: Urban Waste Water Treatment Directive (91/271/EEC); WFD: Water Framework Directive (2000/60/EC).

Acknowledgements

The authors would like to thank all participants in the SOLUTIONS project for the many fruitful discussions held on the topic of improving the chemical status in European waters as well as on minimising the risks of chemicals in society in general.

Authors' contributions

JL, TS performed the initial assessment of chemical legislation and drafted conclusions together with JM, EBL and MR. JM drafted the manuscript with contributions from LP and WB. All other authors helped to further elaborate the manuscript and contributed specific aspects. All authors read and approved the final manuscript.

Funding

This article has been prepared as an outcome of the projects SOLUTIONS (European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement No. 603437), with further support of the Foundation of the Swedish Environmental Research Institute (SIVL).

Availability of data and materials

Not applicable.

Ethics approval and consent to participate

Not applicable.

Consent for publication

Not applicable.

Competing interests

The authors declare that they have no competing interests.

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Received: 29 May 2019 Accepted: 22 July 2019

Published online: 30 September 2019

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