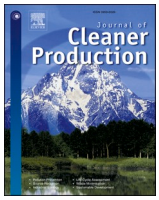
Journal of Cleaner Production 434 (2024) 140260

Contents lists available at ScienceDirect

Journal of Cleaner Production

journal homepage: www.elsevier.com/locate/jclepro



Navigating quality, health and environmental risk: A novel framework for wastewater resource recovery products

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ARTICLE INFO

Handling Editor: Cecilia Maria Villas Bôas de Almeida

Keywords:
Resource recovery framework
Quality monitoring
Risk assessment
Health risk
Environmental risk

ABSTRACT

The aim of this study is to establish a universal framework for the quality monitoring and risk evaluation of resource recovery products. This innovative framework addresses challenges inhibiting the uptake of wastewater resource recovery products by addressing quality, health, and environmental concerns. In contrast to the current European regulations, which primarily govern wastewater reuse for irrigation and limited nutrient recovery cases, this framework has a broader scope that includes various recovery scenarios, such as cellulose fibers, biocomposites, building materials and biochar. The framework is structured as three pillars: (i) ensuring access to a product of good quality, (ii) safeguarding public health, and (iii) environmental protection. It applies quantitative microbial risk assessment (QMRA) and quantitative chemical risk assessment (QCRA) to enable transparent monitoring and reporting for different actors across resource recovery value chains. The framework offers a means to cluster and leverage existing regulations, bridging gaps to ensure comprehensive oversight across various unregulated resource recovery scenarios and products.

1. Introduction

Rapid population and economic growth present challenges in terms of food provision, water, and energy supply for fast-growing cities globally (Gondhalekar et al., 2021; Penserini et al., 2023). In response to the pressing issue of resource scarcity, the European Commission has adopted a circular economy action plan within the broader framework of the European Green Deal (EC, 2019a, 2020a). Simultaneously, the revised Urban Wastewater Treatment Directive strengthens removal standards, increases reuse of treated water, promotes nutrient recovery, and establishes clear objectives for energy neutrality, paving the way for circular economy practices (EC, 2022a; EPRS, 2023). Energy, clean water, fertilizers, and valuable materials can be recovered from wastewater. Over several decades, the need to address the scarcity of resources has driven the transition from conventional wastewater treatment plants (WWTPs) to water resource recovery facilities (WRRFs). Yet there are still barriers to the wider uptake of the recovered products, due to low public acceptance based on product quality, health concerns, and environmental issues (Pratap et al., 2023; Radini et al., 2023).

Innovative technologies and recovery concepts have been thoroughly researched in both pilot and full-scale plants (Yadav et al., 2021). This has enabled the recovery of resources of varying quality to meet demand across different sectors, including industry and agriculture. Resource recovery can result in high-quality tradeable goods, offering an equivalent value proposition to traditional products. To demonstrate the viability of these products in the global market, validating product quality becomes the key imperative for market uptake (Gregson et al., 2015; Russell, 2018).

Besides product quality, recovering resources from contaminated sources, like wastewater, presents inherent risks to human health and the environment (Oishi et al., 2023; Trimmer et al., 2020). Vast quantities of synthetic and natural chemicals from the production of goods enter the environment annually (Petrie et al., 2015; Tran et al., 2018). Some of these end up in wastewater, which can lead to contaminants in wastewater recovery products (Ofori et al., 2021). New measures are necessary to protect human health and the environment and to support the development of the markets for recovery products (Alaranta and Turunen, 2021).

Several challenges and key considerations have emerged from recent research on wastewater resource recovery. Josa and Garfí (2023), and Bodar et al. (2018) emphasize the significance of social acceptance and

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https://doi.org/10.1016/j.jclepro.2023.140260
Received 29 May 2023; Received in revised form 30 November 2023; Accepted 15 December 2023
Available online 17 December 2023

the absence of robust regulatory frameworks. In view of the need for integrated assessment of product quality, health, and environmental impacts, improving regulatory frameworks have a pivotal role in driving product uptake (Cipolletta et al., 2021). Aligning quality and safety assessments with regulatory aspects can establish a systematic foundation for responsible wastewater resource recovery practices.

Several frameworks have been developed to address the circular economy and resource recovery concerns in the wastewater sector. Smol et al. (2020) introduced a circular economy framework based on the waste management hierarchy. Chrispim et al. (2020) proposed a framework for cost-effective and sustainable resource recovery planning, while Dulia et al. (2021) focused on evaluating risks within circular economy supply chains. Bodar et al. (2018) introduced a scheme for risk assessment when reusing materials containing hazardous substances based on a limit concentration of 0.1% w/w. Penserini et al. (2023) proposed an integrated health risk assessment framework for emerging contaminants, and Sanitation Safety Planning by the WHO (2022) centered on safe wastewater reuse guidelines for agriculture and aquaculture, prioritizing public health.

Existing frameworks predominantly address health risks, circular economy strategies, and sustainable business models. In contrast, a pivotal aspect of a sustainable business model lies not only in its environmentally friendly activities but also in its ability to generate revenue through successful market uptake. Furthermore, public concerns about wastewater resource recovery mainly relate to health risks and environmental safety (Alaranta and Turunen, 2021; Pratap et al., 2023). The challenges of disconnected legal frameworks remain unresolved across previous frameworks.

Given this consideration, establishing competitive products, ensuring health and environmental safety, and aligning with existing regulations are critical to fostering wider market uptake of resource recovery products. Compliance with regulations is important for both legal and ethical reasons. To the best of the authors' knowledge, a universal framework that provides a scientific basis and effectively integrates product quality, health and environmental safety assessment to support implementation and informed decision-making, in order to safely place resource recovery products in the market, is currently lacking. To address this gap, this paper introduces an integrated and evidence-based framework to guide the development of a comprehensive monitoring plan, assess product quality, and quantitatively evaluate risks to human health and the environment. This combined approach aims to overcome barriers to the wider uptake of wastewater resource recovery products by addressing concerns pertaining to quality, safety, and regulatory compliance.

2. Guiding quality compliance

2.1. Bridging regulatory gaps

Wastewater resource recovery encompasses a wide variety of products and activities, ranging from energy, nutrients, minerals, biopolymers, and metals to numerous valuable substances. The categorization of each product is subject to specific legislation that must be considered when embarking on resource recovery activities (Hermann and Hermann, 2019). These activities can, in principle, be classified under EU policy frameworks as outlined below:

(i) Water recovery under the Water Framework Directive (EC, 2000),
(ii) Energy recovery under the Renewable Energy Directive (EC, 2021),
(iii) Nutrient recovery under the Fertilising Products Regulation (EC, 2019b),
(iv) Material recovery included in the Waste Framework Directive (EC, 2018, 2008), the European Regulation on Registration, evaluation, authorization and restriction of chemicals (REACH) (EC, 2006), the Persistent Organic Pollutants Regulation, the European Food Safety Authority policy, and CEN bio-based, depending on the materials and their intended use.

Classifying wastewater resource recovery activities according to EU policy frameworks serves as a guiding compass for stakeholders in identifying pertinent regulations that warrant compliance. This classification also aligns with the resource recovery taxonomy used by Kehrein et al. (2020) and Diaz-Elsayed et al. (2019).

The EU regulations to establish quality benchmarks for products derived from wastewater are currently limited to Regulation (EU) 2020/741 on Minimum requirements for water reuse (EC, 2020b) and Regulation (EU) No. 2019/1009 on EU Fertilising products (EC, 2019b). It should be noted, however, that the current water reuse regulation is limited in scope, solely encompassing agricultural applications.

The quality compliance challenges relate mainly to the absence of regulations specific to particular products and their intended reuse scenarios. Notably, there is currently no EU legislative framework to support the use of renewable raw materials, nor is there an EU law applicable to bio-based, biodegradable and compostable plastics (DG Environment, 2022; European Bioplastics, 2016).

To encompass a wide variety of resource recovery products, the scope of the new framework must extend beyond regulatory boundaries. For novel resource recovery categories, such as biopolymer or biochar briquettes, which remain unregulated, a new approach is required to demonstrate product quality and safety. A viable strategy involves formulating a monitoring plan for product quality using reference specifications from comparable conventional goods in the market. Concerning parameters linked to health and environmental risks, such as pathogens and pharmaceutical residues, their compliance thresholds can be established using a reverse risk calculation. This approach aligns with the recommendations set by the WHO for defining quality or technical performance levels to meet health outcome targets (WHO, 2016). A practical example can be observed from Cui et al. (2023), where a threshold value of exposure concentration for bioaerosols in a wastewater treatment plant is calculated to ensure that the health risk remains below the WHO risk target. In the same way, a reverse risk assessment approach can be applied to deduce monitoring threshold values for emerging microbial and chemical contaminants currently devoid of regulation, and across various product applications and risk scenarios.

2.2. Points of quality compliance

Within this framework, the assessment of product quality involves assigning points of quality compliance based on the roles of two primary actors and the products they handle:

i. The first actor is WWTPs/WRRFs. Their product is secondary raw materials, referred to as recovered resources in this paper.
ii. The second actor is production facilities or industries. Their product involves utilizing at least one recovered resource and is referred to as the final product in this paper. A production facility's main activity concerns processing to achieve the final product composition. This can encompass various operations, such as blending or quality polishing.

In wastewater resource recovery, WWTPs/WRRFs and production facilities often operate as the same entity. In scenarios such as water reuse, a WWTP/WRRF typically also oversees the operation of a reclaimed water facility. However, in instances where WWTPs/WRRFs and production facilities constitute different entities, clearly defining the point of quality compliance between recovered resources and final products becomes necessary. This clear definition serves a twofold purpose: firstly, it accounts for multi-actor contributions to both product quality and risks; and secondly, it establishes responsibility for each

actor within the value chains. Such clear definition can be further reinforced through well-defined regulations.

The point of compliance for product quality is verified when products leave WWTPs/WRRFs or production facilities/industries. In contrast, the primary focus on evaluating health and environmental risks begins when the general public gains access to the products. Examples of points of compliance and their assigned quality requirements, in accordance with EU regulations and product references, are provided in Table 1.

A circular economy involves a series of activities ranging from material recovery, production, and application, to end-product disposal. The successful implementation of a circular economy thus relies on seamless synergy between different EU regulations across various domains (Bodar et al., 2018). In addition to the quality compliance regulations outlined in Table 1, the use and disposal of product residues may require different regulatory frameworks. To comprehensively assess health and environmental risks throughout the product's life cycle, other legislative instruments, such as the Environmental Quality Standard Directive 2013/39/EU and the REACH Regulation 1907/2006, will often apply. A summary of the pertinent regulations relevant to the use of resource recovery products is listed in the supplementary material, S1.

2.3. Risk assessment methods

The challenge of improving public acceptance of resource recovery products often relates to perceived health and environmental risks, as highlighted in studies by both Ofori et al. (2021) and Foglia et al. (2023). To address these concerns, the implementation of data-driven quantitative risk assessment methods is crucial to improving public confidence in using wastewater recovery products. By adopting a quantitative approach, a more informed and realistic risk perception can be established (Siegrist and Árvai, 2020). Quantitative microbial risk assessment (QMRA) and quantitative chemical risk assessment (QCRA) stand out as methodologies that share these attributes. Both methods follow a consistent four-step process: problem formulation, exposure assessment, dose-response analysis, and risk characterization (ECHA, 2016a; WHO, 2016). They also rely on collected monitoring data and traceable model inputs to estimate the health and environmental impacts (Penserini et al., 2023). Consequently, they facilitate comprehensive auditing and transparent disclosure of the risk evaluation process to both government authorities and public end-users.

Table 1
Regulations used for defining and evaluating recovered resources and final product quality in different recovery cases.

Recovery case	Resources recovered from WWTPs/WWRFs	Final products from production facility/industry
Water recovery	Effluent water Quality compliance according to the Urban Wastewater Treatment Directive 91/271/EEC	Reclaimed water Quality compliance according to Regulation (EU) 2020/741 on Minimum requirements for water reuse
Fertilizer recovery	Precipitated struvite Quality compliance according to Component Material Category (CMC)-12: Precipitated phosphate salts and derivates; quality requirements under the EU Fertilising Products Regulation (EU) No. 2019/1009	Struvite-based fertilizers, marketed as organic mineral fertilizers Quality compliance according to the Product Function Category (PFC)-1 under the EU Fertilising Products Regulation (EU) No. 2019/1009 Struvite-based fertilizers, marketed as plant biostimulants Quality compliance according to the PFC-6 under the EU Fertilising Products Regulation (EU) No. 2019/1009
	Dewatered digestate Quality compliance according to CMC-5: Digestate other than fresh crop digestate; quality requirements under the EU Fertilising Products Regulation (EU) No. 2019/1009	Soil improver Quality compliance according to the PFC-3 quality requirements under the EU Fertilising Products Regulation (EU) No. 2019/1009
	Effluent water Quality compliance according to the Urban Wastewater Treatment Directive 91/271/EEC	Nutrient-embedded biochar, made by adsorbing nutrients from treated wastewater Quality compliance according to the PFC quality requirements under the EU Fertilising Products Regulation (EU) No. 2019/1009 and the European Biochar Certificate (European Biochar Foundation, 2016)
Energy recovery	Sewage sludge Quality compliance according to the Sewage Sludge Directive 86/278/EEC	Biochar fuel briquettes Quality compliance according to reference thermal properties (calorific value, burning rate, CO_2 emission, ash content, etc.) of similar products, such as conventionally marketed charcoal, combined with the WHO guidelines for indoor air quality and household fuel combustion (WHO, 2014) and the Renewable Energy Directive (EU) 2018/2001
	Biogas Quality compliance according to the Renewable Energy Directive (EU) 2018/2001	Heat and electricity Quality compliance according to the maximum limit values for CO_2 and H_2S for combined heat and power unit specifications, typical methane content and calorific values, or according to the Renewable Energy Directive (EU) 2018/2001
	Biogas Quality compliance according to the Renewable Energy Directive (EU) 2018/2001	Biogas fuel (biomethane) Quality compliance according to the quality specifications of methane content and calorific values from the local injection gas grid and the Renewable Energy Directive (EU) 2018/2001
Other material recovery	Recovered cellulose Quality compliance according to the reference composition of recycled waste-cellulose such as Recell® cellulose or typical pathogens and heavy metals composition in primary sludge Recovered lime pellets Quality compliance according to the reference composition of lime pellets, e.g., from AquaMinerals BV	Biocomposite material, made from recovered cellulose and lime pellets Quality compliance according to the reference composition of biocomposite specifications, in line with the intended application, e.g. canal bank protection, street signs, or façade panels
	Recovered polyhydroxyalkanoate (PHA) biopolymer Quality compliance according to the reference composition of PHA products from residual waste mix culture	PHA-biopolymer Quality compliance according to the reference composition of commercial PHA pellets, e.g. PHA Biopol®, PHBH™ from Kaneka polymers, Nodax™ from Danimer Scientific

2.3.1. Quantitative microbial risk assessment (QMRA)

QMRA is a structured risk assessment method that combines empirical and theoretical data with mathematical modeling, to predict the probability of infection or illness when a population is exposed to pathogens. Originating in the food and drinking water sectors, QMRA initially estimates disease burdens resulting from the consumption of contaminated products (Haas et al., 2014; Petterson and Ashbolt, 2016). The method is increasingly used in the environmental field (Bichai and Ashbolt, 2017; Zhiteneva et al., 2020). Using this method, the framework aims to quantify human health risks posed by pathogens in various reuse scenarios.

Important input parameters for QMRA comprise monitoring data on reference pathogens in recovered products, dose-response models, and pathogen characteristics, such as inactivation rate and persistence. Additionally, exposure scenarios are important, allowing for the consideration of factors such as typical ingested volumes, inhalation rates, consumption patterns, and susceptibility fraction. These inputs are derived from internationally accepted guidelines including those provided by the WHO (2016), and the exposure factors handbook of the US EPA (2011). The resulting model output is the risk of illness, quantified in terms of disability-adjusted life years per person per year (DALYs pppy).

2.3.2. Quantitative chemical risk assessment (QCRA)

Toxic chemicals such as arsenic, cadmium, lead, mercury, asbestos, benzenes, dioxins, dioxin-like substances and highly hazardous pesticides have been recognized as chemicals of significant public health concern by the WHO (2020). When present in recovered products, these substances pose a risk to both human health and the environment. Traditional chemical risk assessment methods typically address uncertainties by employing conservative values, which involve using high exposure concentrations, or lower-bound estimates of health-based guideline values (Bokkers et al., 2017; Cantoni, 2022). Subsequently, the deterministic benchmark quotient, expressing the ratio between exposure concentrations and health-based guideline values, is calculated to indicate the risk level. However, replacing these deterministic values with probabilistic values enables the evaluation of conservatism levels in the estimated risks, including the primary sources of uncertainty (Cantoni et al., 2021).

Within our framework, QCRA is used to estimate the probability of toxic chemicals exceeding predefined environmental thresholds or health-based precautionary values. Important inputs for QCRA include monitoring data for hazardous chemicals in the recovered products and the environment. Additionally, typical exposure factors and guideline values such as tolerable/acceptable daily intake (TDI/ADI) and predicted no-effect concentration (PNEC), play pivotal roles. Similar to QMRA, problem formulation and defining exposure scenarios are the crucial steps. These processes allow us to consider various factors, including typical product application, consumption patterns, and environmental conditions. The resulting model output is the estimated chemical risk expressed as the risk characterization ratio (RCR) or risk quotient (RQ) for each endpoint, whether it pertains to human health or environmental compartments such as soil, water, air, biota and microbiota.

3. The framework

The framework presented in this paper is based on three pillars demonstrating specific levels of protection: access to a high-quality product and regulatory compliance (Pillar 1), minimizing the impact on human health (Pillar 2), and minimizing the impact on the environment (Pillar 3). The framework starts in the design phase, to validate that the resource recovery scheme not only ensures optimal product quality but also guarantees safety for both humans and the environment.

During the early stage of resource recovery implementation, the quality evaluation and risk assessment in the framework serve as a validation process. This validation seeks to assess the effectiveness of the overall system, ensuring that it attains the required product quality, manages potential hazards, and remains responsive to timely corrections. A key aspect in this phase involves data collection, a process that is initiated with the development of a meticulous monitoring plan encompassing appropriate parameters, specific sampling locations, and sampling frequency. For validation purposes, the collected monitoring data is then used as inputs to perform quality and risk assessment. Once the system is validated, the focus shifts to the operational control and compliance process, requiring continuous monitoring to verify the ongoing functionality of day-to-day recovery and production activities. Depending on the results of the validation assessment, adjustments can be made to the number of parameters, sampling locations, and monitoring frequencies for compliance checks.

Within Pillar 1, the monitoring plan and quality evaluation of recovered resources and final products can be based on current EU regulations. Nonetheless, this framework has the flexibility to extend beyond current regulations, particularly when applied to novel recovered resources or new application scenarios that have yet to be classified. In cases involving unregulated innovative products, a set of quality indicators is collaboratively established by stakeholders, drawing upon inherent characteristics and the product's value propositions.

Within Pillar 2 and Pillar 3, the risk evaluation requires more comprehensive analysis to verify that the quality measures effectively manage health and environmental concerns (WHO, 2022). This risk evaluation should be undertaken at regular intervals or whenever risk scenarios are revised. The development of monitoring plans for Pillar 2 and Pillar 3 is based on the problem formulation principle in QMRA and QCRA, where exposure scenarios guide the acquisition of monitoring data, influencing the choice of applicable regulations, including microbial and chemical standards, for instance, when the recovery of biochar fuel intended for household cooking and industrial use is considered. Exposure pathways throughout the product's lifetime involve emission of air pollutants from household and industrial combustion. In this context, the Ambient Air Quality Directive 2008/50/EC and the WHO Guidelines for indoor air quality and household fuel combustion serve as suitable monitoring benchmarks.

The formulation of the monitoring plan across all three pillars requires coordination with relevant authorities and end-user representatives. This ensures the construction of a cohesive dataset presenting quantifiable indicators for quality compliance and risk assessments. Using a quantitative method, collected data is transparently and consistently assessed, allowing for prompt corrections when new information becomes available. This could encompass newly introduced regulations or updated toxicological data.

3.1. Pillar 1: Product quality and compliance

Pillar 1 serves as the foundation for establishing product quality and regulatory compliance. This framework provides a guideline for the systematic development of a monitoring plan. Within Pillar 1, the quality of the recovered product is demonstrated while ensuring alignment with current EU regulations. A key indicator for Pillar 1 is when the recovered raw materials and their associated final products fulfill the quality requirements set out by regulations or market demands. The flow scheme guiding the development of a monitoring plan is outlined in Fig. 1. The initial step involves determining whether the recovered resource and final product fall within the scope of specific regulations. If they do, these regulations provide a starting point for defining quality specifications. However, if no relevant regulations apply, the formulation of quality specifications must be based on either reference products available in the market, or customer demands. The objective is to demonstrate the new product's market value and its capacity to match the quality standards upheld by comparable conventional products.

This flow scheme extends to resources recovered from WWTPs/WRRFs, as well as the final products from the production facility or

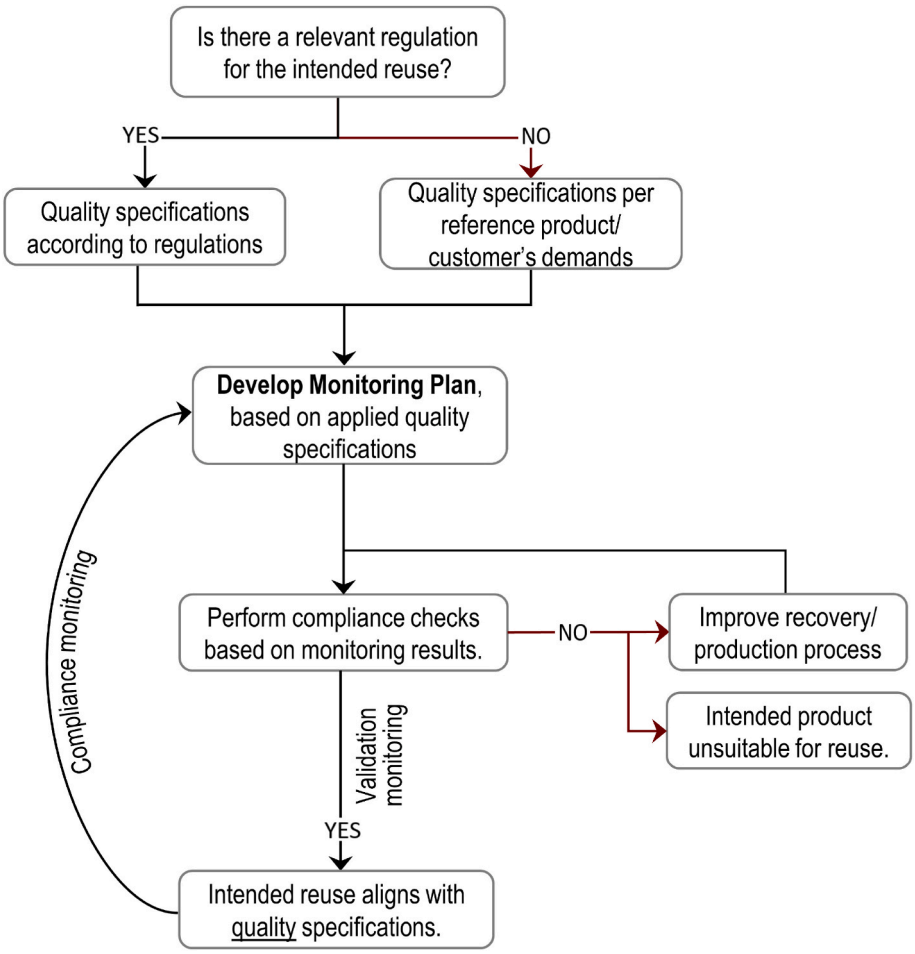

Fig. 1. Pillar 1. Product quality compliance flow scheme.

industry. For Pillar 1 evaluation, necessary data includes the measured product composition. Successful conformity with quality specifications means that the products possess market value and meet the same quality standards as conventional alternatives. In instances of non-conformity, improvements within the recovery and/or production processes become imperative. Alternatively, exploring different applications for recovered products with lower quality specifications is a possible option. During the validation process, Pillar 1 serves as an initial screening to determine whether the product can leave the recovery or production facility and enter the market.

3.2. Pillar 2: Human health protection

By implementing the precautionary principle of REACH (EC, 2006), responsible actors are obliged to ensure public health protection prior to introducing resource recovery products to the market. The second pillar of this framework outlines a systematic approach to protecting human health. This involves conducting a thorough evaluation of human health risks by applying QMRA and QCRA.

Fig. 2 presents a flow scheme for the monitoring plan, designed to evaluate and control health risks. This scheme is initiated with the identification of potential hazards and the formulation of exposure scenarios. In specific recovery cases, certain pathogens and chemical hazards may already be included in Pillar 1's monitoring plan. When this is not the case, responsible actors are tasked with proposing pertinent hazards, based on the characteristics of recovered resources and final products. Even when specific hazards are already addressed by regulations and Pillar 1, to foster public acceptance, it is important to challenge the identified hazards by using different health guidelines and regulations. This ensures that problematic pollutants like priority substances and contaminants of emerging concern are not overlooked. The regulations relevant to the initial identification of hazards are summarized in Fig. 2. The draft monitoring plan is assessed during the scoping process and the identified hazards and exposure scenarios are communicated. To promote transparency and the inclusivity of all actors impacted by the resource recovery, the involvement of health authorities and representatives of exposure groups is paramount. The outcome of this process is a comprehensive list of agreed-upon hazards and exposure scenarios, which are subsequently used for conducting health risk assessments.

Key indicators for Pillar 2 encompass: (i) microbial risk below the WHO health-based target of 10^{-6} DALY per person per year (pppy) (WHO, 2016); and (ii) a chemical health Risk Quotient (RQ) below 1 (ECHA, 2016b). The health RQ is calculated by dividing the intake dose by TDI or ADI values. In terms of microbial risk, the disability-adjusted life year (DALY) metric is selected to compare different health outcomes. This metric quantifies time lost due to disease-related disability or mortality, relative to a life free from disease (Haas et al., 2014). To illustrate, 10^{-6} DALY corresponds to the disease burden attributed to mild diarrhea at an annual risk of approximately one case of watery diarrhea in 1000 individuals (WHO and UNEP, 2006).

3.3. Pillar 3: Environmental protection

The implementation of wastewater resource recovery carries the risk of introducing hazardous substances that enter or re-enter the environment (Bodar et al., 2018). Preventing the risk of persistent, bio-accumulative, and toxic substances staying in the circular loop is

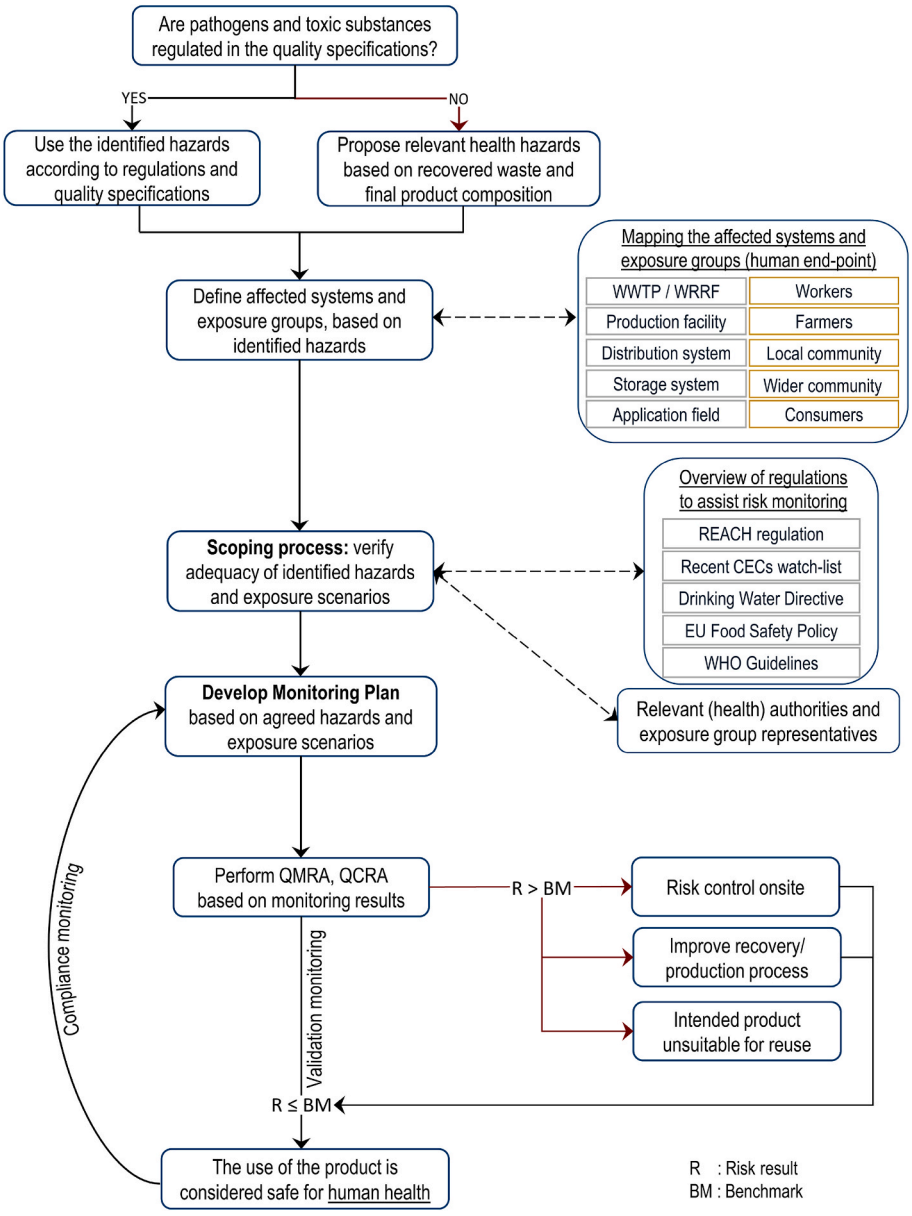

Fig. 2. Pillar 2. Human health protection flow scheme.

imperative. To address this challenge, the flow scheme in Fig. 3 helps to identify harmful substances and their exposure pathways.

Traditionally, product quality specifications tend to omit parameters linked to environmental hazards. In response, Pillar 3 emerges as a proactive risk management measure, utilizing a structured flow scheme similar to Pillar 2. The scheme outlined in Fig. 3 begins with the problem formulation for hazard identification and exposure pathways. Depending on the identified hazards and exposure scenarios, certain contaminants may already be integrated into the monitoring plan under Pillar 1. Should this not be the case, the important monitoring parameters and monitoring points can still be captured and included in the monitoring plan using the problem formulation principle. In scenarios where environmental endpoints are well-defined, the regulations referenced in Fig. 3 assist in identifying required monitoring parameters. For instance, when surface water is impacted, the monitoring parameters can be aligned with key regulations such as the EU Water Framework Directive, the Environmental Quality Standards (EQS) Directive, and the recent watch-list for Contaminants of Emerging Concern (CECs) (EC, 2022b, 2013, 2000).

Given the complexity of defining appropriate exposure scenarios and pathways, consultation with relevant environmental authorities becomes an integral aspect of the scoping process. This collaborative input serves as an additional layer of assurance, further validating the comprehensiveness of the monitoring plan. Similar to Pillar 2, the outcome of the scoping process is a list of agreed-upon hazards and exposure scenarios for the risk assessment.

The key indicator of Pillar 3 is when the environmental risk quotient (RQ) is below 1 (ECHA, 2016b). The environmental RQ is expressed by the ratio of the predicted environmental concentration (PEC) to the reference value of predicted no-effect concentration (PNEC) (ECHA, 2016b). PEC values are estimated via the environmental exposure assessment or obtained directly through monitoring activities. A risk is considered unacceptable when the PEC/PNEC ratio exceeds 1, signifying that risk control measures are necessary. Conversely, a ratio below 1 indicates an acceptable risk.

The scope of environmental risk evaluation primarily centers on the direct impacts of recovered products. In scenarios involving food chains within ecosystems, the evaluation is confined to the impact on primary

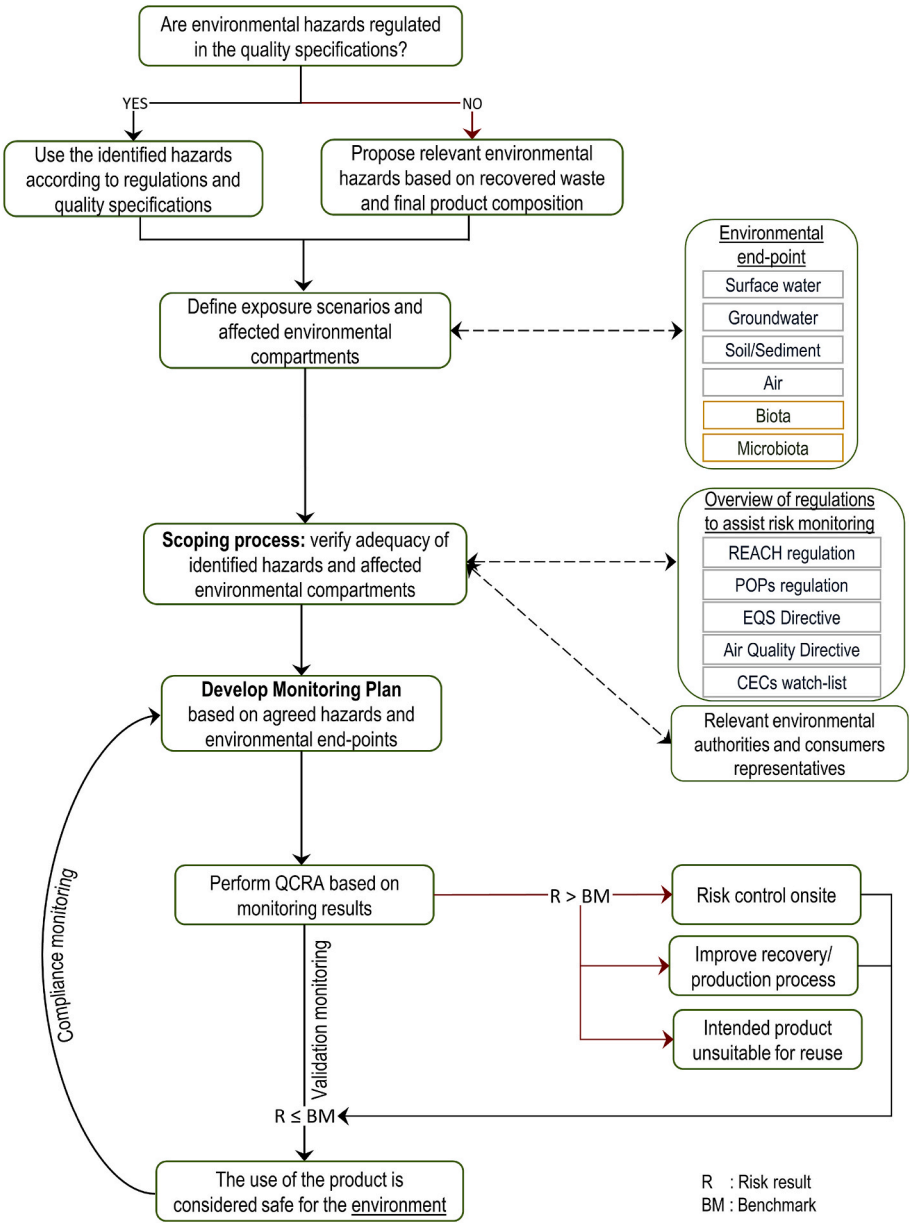

Fig. 3. Pillar 3. Environmental protection flow scheme.

consumers. The decision to conduct a secondary evaluation of environmental impacts will be determined collaboratively by resource recovery actors and stakeholders during the scoping process.

3.4. Framework application

Implementation of a circular economy entails synergy between different EU regulations (Hartley et al., 2020). It applies not only during recovery and production, but also during the application and end-life of the products, such as the generated emissions and the handling of residues (Bodar et al., 2018). It is important to note that currently not all regulations are systematically grouped under one framework directive, as exemplified by the Water Framework Directive applied to water recovery. An illustrative water recovery case can be found in the EU guidelines to support the implementation of Regulation (2020)/741 (EC, 2022c). In scenarios beyond water recovery, a schematic example depicting the process of identifying and applying various regulations within the framework is illustrated in Fig. 4.

The graphical representation in Fig. 4(a) serves as an exemplary guideline to determine the applicable regulations and directives in the context of fertilizer recovery, and specifically soil improver. This illustration considers plausible pathways of soil improver to surface water, soil, and groundwater through runoff and infiltration. It outlines hazardous events and exposure routes for both health and environmental risk assessment. Additionally, examples of exposure groups and environmental endpoints are provided. The figure highlights regulations and directives that could be pertinent, subject to the designated fertilizer application. Further insight into a monitoring plan for fertilizer recovery is available in the supplementary material, S2.

Fig. 4(b) outlines a graphical example illustrating how to determine relevant regulations and directives applicable to energy recovery concerning biochar briquettes. The figure visualizes potential pathways of pollutants to ambient air during household cooking and industrial use. It outlines hazardous events and exposure routes relevant to health and environmental risk assessment. The figure highlights the pertinent regulations and directives applying to the intended application of biochar.

Information concerning the intended product application and the associated risk scenarios is needed to identify the appropriate

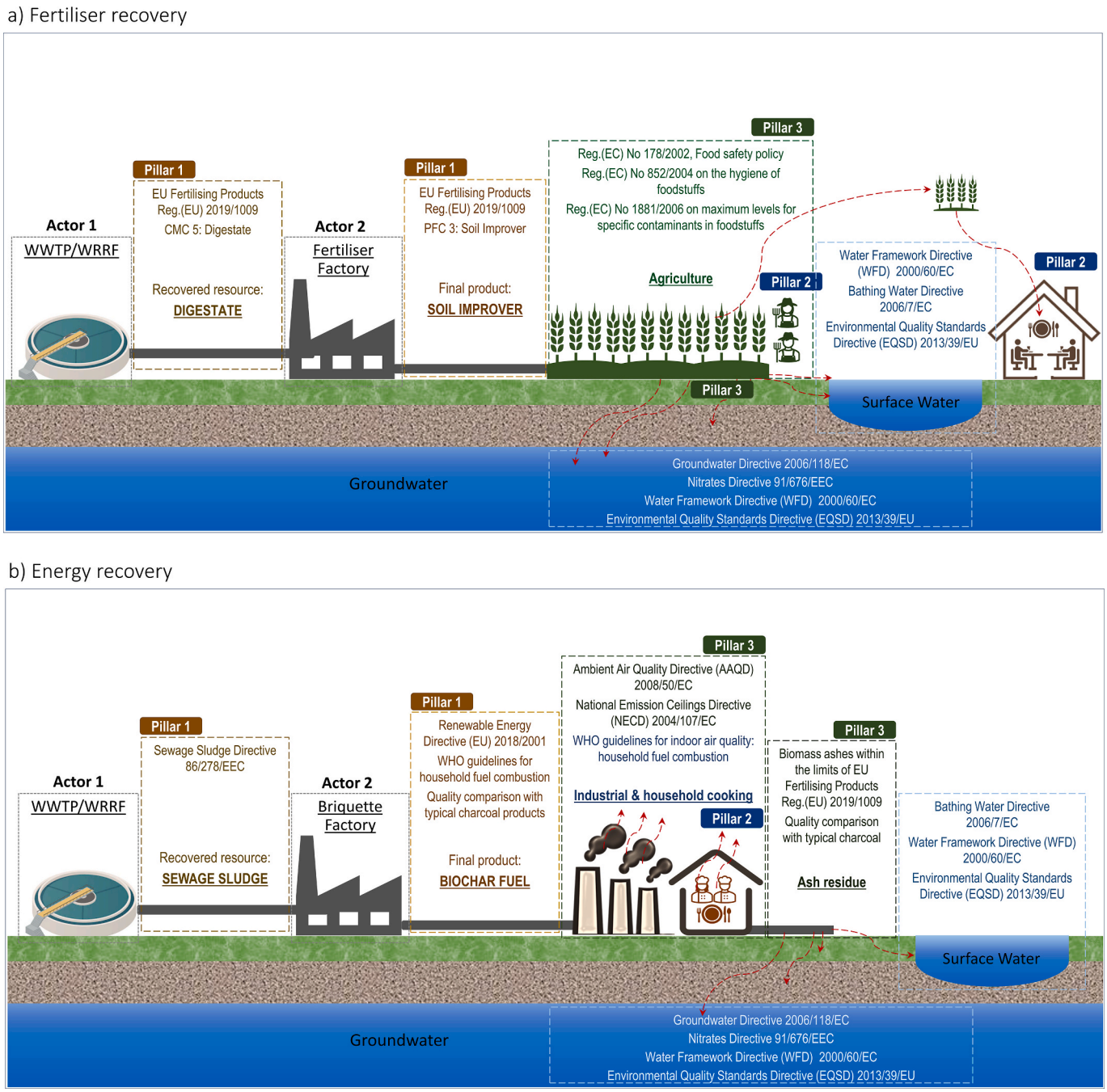

Fig. 4. Application of quality monitoring and risk evaluation framework for (a) fertilizer recovery in soil improver product and (b) energy recovery in biochar product.

regulations used as monitoring reference values. In Pillar 1, the monitoring reference values represent the product quality specifications. Conversely, in Pillar 2 and Pillar 3, the regulations listed in Fig. 4 outline indications for ADI/TDI and PNEC values for chemical hazards, as well as threshold values for microbial hazards. However, it is important to note that the exposure dose and concentration of pollutants in the environment must be either measured or modeled using a risk assessment approach.

3.5. Target audience and risk communication

The target audiences of this framework are WWTPs/WRRFs, industries using wastewater-recovered resources, public health and environmental regulatory bodies, and end-users using resource recovery products. For effective communication, the results of Pillar 1 can be integrated into material safety data sheets. These data sheets should also incorporate summaries of health and environmental risk assessments derived from Pillar 2 and Pillar 3 results.

To ensure transparent communication and data accessibility, comprehensive risk assessment documents and product quality monitoring data should be made available and regularly updated on the official websites of recovery actors. This practice would foster informed decision-making, facilitate regulatory compliance, and empower stakeholders to make choices aligned with health, environmental, and quality considerations.

4. Discussion

Wastewater resource recovery can potentially expose humans to harmful substances present in the recovered products. In some cases, contaminants originating in wastewater, such as heavy metals, personal care products, pharmaceuticals and organic pollutants, can in certain cases be detected in the recovered products (Mohapatra et al., 2016; Nunes et al., 2021). Establishing safety statements for a circular economy product requires assessing risks across the product's entire life cycle and this implies the use of different guidelines and regulations. To ensure safety, a collaborative approach engaging resource recovery actors, WWTPs/WRRFs, industries, relevant authorities, risk assessors, and end-users, is imperative.

Our framework facilitates the simultaneous evaluation of product quality, human health, and environmental risks. The aim is to give equal emphasis to both the product value propositions and the safety aspects. Our approach, which combines risk assessment with quality monitoring, seeks to enhance society's acceptance of resource recovery products and to substantiate their safety, particularly when public trust in regulations alone falls short, as highlighted by Josa and Garfí (2023).

The contaminants that the framework can assess encompass quantifiable microbial and chemical contaminants. Hence, these contaminants can be monitored. The contaminants must also have a discernible impact. In cases where specific health and environmental guidelines or threshold values are not explicitly defined for each recovered product or application, this framework allows for the derivation of these values using available references such as toxicological data, drinking water guidelines, or environmental quality standards. It is important to note, however, that the framework is currently tailored for conducting risk assessments of single chemical contaminants, as guideline and threshold values for chemical mixtures are not yet available. Furthermore, the framework can only evaluate measurable microbial pathogens that have dose-response models.

In theory, quality, health and environmental protection requirements can be transformed into a quality specification and enacted as regulatory measures. One might argue that conducting quality compliance and risk assessment is redundant. However, the European Green Deal action plan and the circular economy have made it imperative for central directives such as REACH, the Waste Framework Directive, and the Water Framework Directive to work together in an accelerated way. Nonetheless, disparities still persist among these legislative frameworks (Bodar et al., 2018). In such cases, the risk assessment results can serve as compelling evidence of product safety. In the future, leveraging insights from resource recovery projects, coupled with reverse risk assessment, can be used to suggest revisions or to propose new guideline values.

Health risk scenarios encompass potential exposure to pharmaceutical residues within the recovered fertilizer, particularly when agricultural products are consumed. Ideally, within Pillar 2, monitoring efforts should include direct measurement of trace pharmaceuticals in the harvested products (Penserini et al., 2022; Verlicchi et al., 2023). However, a situation may arise where such monitoring is no longer feasible, due to budget constraints or other resource limitations. In such cases, the concentration of contaminants in the harvested products can still be estimated, using risk assessment methodologies. Similarly, in energy recovery scenarios, if the direct measurement of outdoor air emissions is not possible, the emissions can be simulated using specific local conditions such as relative humidity and wind speed.

Currently, existing guidelines for TDI, ADI, and PNEC, which are used in chemical risk assessment, are based on the effect of individual chemicals. The effect of chemical mixtures on human health and the environment remains an active research area (Bopp et al., 2019). Transparent and structured assessments within this framework allow benchmark values to be updated as new regulations or new toxicological data become available.

In risk assessments, integrating uncertainty and variability analysis to provide a probabilistic range is preferable to a discrete point estimate (Cantoni et al., 2021). At the start of monitoring, certain risk events, such as chemical accumulation, may go undetected, due to limitations in data collection, potentially failing to capture the incremental buildup of chemicals within an environmental compartment. It is worth noting, however, that it is only over the long run that the developed monitoring plan will provide a robust dataset capable of improving risk analysis and proposing a realistic harmonized standard for unregulated wastewater-recovered products and contaminants.

5. Conclusions

This study aims to develop an integrated new framework to improve market acceptance of recovery products derived from municipal wastewater, with the ultimate goal of increasing their market uptake. To achieve this objective, a threefold evaluation approach was created, demonstrating specifications for a high-quality product and regulatory compliance, while minimizing the impact on human health and the environment. During the initial stages of resource recovery implementation, our framework serves as a validation process. This validation seeks to assess and confirm whether the overall system effectively achieves the required product quality and controls the identified hazards. Once the system is validated, the operation and compliance process can take place as continuous monitoring to ensure that the day-to-day recovery and production activities function as intended.

By applying the flow schemes in this framework, resource recovery actors across the value chain can develop monitoring plans enabling the delivery of raw materials or products that meet stringent quality and safety requirements, encompassing both regulated and unregulated pollutants. This approach not only identifies potential quality or contamination challenges in different parts of the value chain, but also aligns seamlessly with the principles of a symbiotic circular economy, where such risk control is imperative. In addition, the evaluation results generated by this framework can serve as comprehensive documentation and communication tools for utilities, industrial partners, regulators, and end-users, further fostering transparency and trust.

The limitation of this framework lies in its primary focus on the foundational aspects needed to improve the market acceptance and safety of wastewater resource recovery products. It does not address broader issues of circularity, governance, and business models. In terms of future research directions, there is a need to delve into governance, regulation, and policy considerations that can facilitate the integration of existing regulations into a unified framework that effectively addresses health and environmental concerns throughout the entire product life cycle. Furthermore, concerning business sustainability, future studies should focus on devising strategies that integrate cleaner production principles, sustainable business practices, and effective resource recovery methods in creating closed-loop systems. These systems would collectively reduce waste generation, mitigate pollution, and promote more sustainable industrial practices. The efforts could be augmented by fostering cross-sector collaboration between utilities, agriculture, manufacturing sectors, industries, and SMEs, to secure market uptake of resource recovery products.

CRediT authorship contribution statement

Rizza Ardiyanti: Conceptualization, Formal analysis, Visualization, Writing – original draft, Writing – review & editing. **Kamal Azrague:** Conceptualization, Supervision, Writing – review & editing. **Gertjan Medema:** Conceptualization, Writing – review & editing. **Cynthia Hallé:** Conceptualization, Supervision, Writing – review & editing.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

Data availability

No data was used for the research described in the article.

Acknowledgements

This work was funded by the project "Achieving wider uptake of water-smart solutions — WIDER UPTAKE" (grant agreement number: 869283), financed by the European Union's Horizon 2020 Research and Innovation Programme. The WIDER UPTAKE website can be found at https://wider-uptake.eu/

Appendix A. Supplementary data

Supplementary data to this article can be found online at https://doi.org/10.1016/j.jclepro.2023.140260.

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