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Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge

Towards a legal instrument on water reuse at EU level

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Title Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge

Abstract
As an input to the design of a Legal Instrument on Water Reuse in Europe, this report recommends minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge based on a risk management approach.

Contents

Acknowledgements

The authors gratefully acknowledge the useful comments and suggestions provided by the experts consulted Anders Daalsgard (University of Copenhagen, WHO representative on water reuse issues for the EC), Jörg E. Drewes (Technological University of Munich, Chair of the IWA Specialist Group Water Reuse), Valentina Lazarova (SUEZ Environnement), Gertjan Medema (Water Cycle Research Institute (KWR)), Alfieri Pollice (Water Research Institute, Italian National Research Council (IRSA-CNR)), Jaroslav Slobodnik (Environmental Institute), Thomas Ternes (German Federal Institute of Hydrology (BfG)), and Thomas Wintgens (University of Applied Science and Arts Northwestern Switzerland (FHNW)).

Executive summary

At present, the uptake of water reuse solutions remains limited in comparison with their potential, which remains largely untapped. In the 2015 Communication '*Closing the loop – An EU action plan for the Circular Economy*' (COM/2015/614) and in the Inception Impact Assessment of the EU, water reuse initiative at hand, agricultural irrigation and aquifer recharge were identified as main potential sources of demand for reclaimed water. This is because both applications have the greatest potential in terms of its higher uptake, scarcity alleviation and EU relevance: agricultural irrigation as the biggest user of treated wastewater and the links with the Internal Market and aquifer recharge due to the cross-border nature of many aquifers. A primary goal is hence to encourage efficient resource use and reduce pressures on the water environment, in particular water scarcity, by fostering the development of safe reuse of treated wastewater. As an input to the design of an EU Legal Instrument aiming at these two water reuse applications, this report recommends minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge based on a risk management approach.

Policy context

This report provides the scientific support for the development of a Legal Instrument on minimum quality requirements for water reuse at EU level for two specific uses, agricultural irrigation and aquifer recharge. This document has been requested by DG ENV and developed with additional inputs from experts in the water reuse field.

The opportunity to take action at EU level with a view to increasing water reuse was already identified in the 2012 Commission Communication "*A Blueprint to Safeguard Europe's Water Resources*" (COM(2012)673). This initiative would contribute to the achievements of some key objectives under the 7th EU Environment Action Programme to 2020 (i.e. protecting, conserving and enhancing the Union's natural capital and turning the Union into a resource-efficient economy). In the Communication "*Closing the loop – An EU action plan for the circular economy*" (COM(2015)614), the Commission already committed to develop a series of non-regulatory actions to promote safe and cost-effective water reuse. The Commission published in April 2016 an Inception Impact Assessment on "*Minimum quality requirements for reused water in the EU (new EU legislation)*" stating that the initiative of a regulation on minimum quality requirements for reused water in agricultural irrigation and aquifer recharge will encourage efficient resource use and reduce pressures on the water environment, provide clarity, coherence and predictability to market operators, and complement the existing EU water policy, notably the Water Framework Directive and the Urban Wastewater Treatment Directive.

The intention to address water reuse with a new legislative proposal was noted with interest by the Council in its conclusions on Sustainable Water Management (11902/16). Furthermore, the European Parliament, in its Resolution on the follow-up to the European Citizens' Initiative Right2Water in September 2015, encouraged the Commission to draw up a legislative framework on water reuse, as well as the Committee of the Regions, in its opinion on "*Effective water management system: an approach to innovative solutions*" in December 2016.

Key conclusions

The development of minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge is based on a risk management framework, which is recommended to tackle health and environmental risks and assure a safe use of reclaimed water for agriculture and aquifer recharge. The minimum requirements defined here ensure an appropriate health and environmental protection and thus provide public confidence in reuse practices. This document will contribute to establish a common approach on water reuse across the EU providing clarity, coherence and predictability to market operators, who wish to invest in water reuse in the EU under comparable regulatory conditions.

Additional guidance on the application of a risk management framework is identified as a need to complement a future regulation on water reuse.

Main findings

The document recommends specific minimum requirements for reclaimed water quality taking into consideration the health and environmental risks related to water reuse practices.

A risk management framework has to be applied to water reuse systems to assure a safe use of reclaimed water for agriculture and aquifer recharge, following the World Health Organization recommendation. Therefore, the main elements to implement a risk management framework are established, including the steps to develop health and environmental risks assessments. The related EU legislation has been always considered when appropriate.

Minimum quality requirements including microbiological and physico-chemical parameters, associated limit values and monitoring frequencies are established for agricultural irrigation. Preventive measures to be adopted are also defined.

The Groundwater Directive is the overarching framework for aquifer recharge with reclaimed water, and this Directive is embedded in the risk management framework to be applied.

Flexibility is given to Member States to define more stringent limits and to assess risks considering site specific conditions, especially for environmental risks.

Related and future JRC work

The JRC report "*Water Reuse in Europe: Relevant guidelines, needs for and barriers to innovation. A synoptic overview*" is an antecedent to the present document, also related to the water reuse topic. JRC support to forthcoming guidance on water reuse may be expected as a follow-up from this report, as a complement to a future legal instrument on water reuse.

Quick guide

Water reuse is defined as the use of treated wastewater for beneficial use. Synonymous to water reuse are also water reclamation and water recycling. A risk management framework involves identifying and managing risks in a proactive way, being a dynamic and practical system that, applied to water reuse, incorporates the concept of producing reclaimed water of a quality that is '*fit-for-purpose*'. It is also a systematic management tool that consistently ensures the safety and acceptability of water reuse practices. A central feature is that it is sufficiently flexible to be applied to all types of water reuse systems.

1 Introduction

More and more Europe's water resources are increasingly coming under stress, leading to water scarcity and quality deterioration. Pressures from climate change, droughts and urban development have put a significant strain on freshwater supplies (EEA, 2012). In this context, Europe's ability to respond to the increasing risks to water resources could be enhanced by a wider reuse of treated wastewater. As stated in COM (2015)614: "*Closing the loop – An EU action plan for the circular economy*" the Commission will take a series of actions to promote the reuse of treated wastewaters, including development of a regulatory instrument on minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge.

Information sources agree on the significant potential for further development of water reuse projects in the EU (BIO, 2015). Water reuse can help lower the pressure on freshwater resources. Other benefits include decreasing wastewater discharges, even if sometimes, during the summer period, the discharges are needed to achieve the ecological flow, and reducing and preventing pollution of surface water. In addition, development of reuse in the EU is a market opportunity for the water industry and other industries with a strong eco-innovation potential in terms of technologies and services around water recycling in industry, agriculture and domestic water systems. It will provide new and significant opportunities for Europe to become a global market leader in water-related innovation and technology.

Water reuse needs to be considered as a measure within the context of the water policy hierarchy. The EC Communication on Water Scarcity and Droughts (COM (2007)414) sets out the water hierarchy of measures that Member States (MS) should consider in managing water scarcity and droughts. This communication states that water saving must become the priority and all possibilities to improve water efficiency must therefore be explored. Policy making should be based on a clear water hierarchy. Additional water supply infrastructures should be considered as an option when other options have been exhausted, including effective water pricing policy and cost-effective alternatives. Water uses should also be prioritised: it is clear that public water supply should always be the overriding priority to ensure access to adequate water provision. It also states that in regions where all prevention measures have been implemented according to the water hierarchy (from water saving to water pricing policy and alternative solutions) and taking due account of the cost-benefit dimension, and where demand still exceeds water availability, additional water supply infrastructure can in some circumstances be identified as a possible other way of mitigating the impacts of severe drought.

Although the use of reclaimed water is an accepted practice in several EU countries experiencing water scarcity issues (e.g. Cyprus, Greece, Italy, Malta, Portugal, Spain), where it has become a component of long-term water resources management, overall a small proportion of reclaimed water is currently reused in the EU, even in those countries. Hence, there is significant potential for increased uptake of water reuse solutions in countries with several regions of water scarcity (Hochstrat *et al.*, 2005).

One of the main barriers identified is the lack of harmonization in the regulatory framework to manage health and environmental risks related to water reuse at the EU level, and thus a lack of confidence in the health and environmental safety of water reuse practices.

The health and environmental safety conditions under which wastewater may be reused are not specifically regulated at the EU level. There are no guidelines, regulations or good management practices at European Union (EU) level on water quality for water reuse purposes. In the Water Framework Directive (WFD) (2000/60/EC), reuse of water is mentioned as one of the possible measures to achieve the Directive's quality goals: Part B of Annex VI refers to reuse as one of the "*supplementary measures*" which Member States within each river basin district may choose to adopt as part of the programme of measures required under Article 11(4). Besides that, Article 12 (4) of the Urban

Wastewater Treatment Directive (91/271/EEC) concerning the reuse of treated wastewater states that "*treated wastewater shall be reused whenever appropriate*".

Even though the lack of common water reuse criteria at the EU level, several Member States (MS) have issued their own regulations, or guidelines for different water reuse applications. However, after an evaluation carried out by the EC on the water reuse standards of several MS it was concluded that there are important divergences among the different regulations regarding the permitted uses, the parameters to be monitored, and the limiting values allowed (JRC, 2014). This lack of harmonization among water reuse standards within the EU might create some trade barriers for agricultural goods irrigated with reclaimed water. Once on the common market, the level of safety in the producing MS may not be considered as sufficient by the importing countries.

The relevance of EU action on water reuse was identified in the Impact Assessment of the "*Blueprint to Safeguard Europe's Water Resources*" published in November 2012. The Blueprint made clear that one alternative supply option- water reuse for irrigation or industrial purposes- has emerged as an issue requiring EU attention (COM(2012)673). Reuse of appropriately treated wastewater is considered to have a lower environmental impact than other alternative water supplies (e.g. water transfers or desalination), but it is only used to a limited extent in the EU. This appears to be due to the lack of common EU environmental/health standards for water reuse and the potential obstacles to the free movement of agricultural products irrigated with reclaimed water (COM(2012)673).

After the 2015 Communication "*Closing the loop - An EU action plan for the Circular Economy*" the Commission published in April 2016 an Inception Impact Assessment on "*Minimum quality requirements for reused water in the EU (new EU legislation)*" stating that the initiative of a regulation on minimum quality requirements for reused water in agricultural irrigation and aquifer recharge will encourage efficient resource use and reduce pressures on the water environment, provide clarity, coherence and predictability to market operators, and complement the existing EU water policy, notably the Water Framework Directive and the Urban Wastewater Treatment Directive.

To support this initiative the EC (DG ENV) asked its science and knowledge service, the Joint Research Centre (JRC) to develop a technical proposal for the minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge.

Considering the sensitivity of the health and environmental issue and public confidence in water reuse practice, the scientific advice of the independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the European Food Safety Authority (EFSA) has been be requested and taken into consideration in the final document.

2 Scope of the document

The purpose of this document is to propose minimum quality requirements for water reuse for two specific water reuse applications: agricultural irrigation and aquifer recharge. These requirements should ensure appropriate health and environmental protection and thus provide public confidence in reuse practices in order to enhance water reuse at EU level. This technical document is expected to support the proposal of EU legislation on water reuse.

The only source of wastewater considered in this document is the urban wastewater covered by Directive 91/271/EEC (Urban Wastewater Treatment Directive UWWTD) where urban wastewater is defined as domestic wastewater or the mixture of domestic wastewater with industrial wastewater and/or run-off rain water. The industrial wastewater considered is from the industrial sectors listed in Annex III of the UWWTD, which are the following:

— Milk-processing

— Manufacture of fruit and vegetables products

— Manufacture and bottling of soft drinks

— Potato-processing

— Meat industry

— Breweries

— Production of alcohol and alcoholic beverages

— Manufacture of animal feed from plant products

— Manufacture of gelatin and of glue from hides, skin and bones

— Malt-houses

— Fish-processing industry

This document does not deal with reclaimed water from other industrial sources: industrial wastewaters may have very particular characteristics in relation to quality and they may require specific quality criteria.

A **water reuse system**, as defined in this document, includes the following:

— Raw wastewater entering the wastewater treatment plant (WWTP)

— The wastewater treatment technologies included in the WWTP

— The additional treatments to produce reclaimed water of the required quality for reuse

— The storage and distribution systems

— The irrigation system (in case of agricultural irrigation), or the recharge method (in case of managed aquifer recharge)

For the purposes of developing the present work, a review of the available scientific, technical and legal knowledge on water reuse in agricultural irrigation and aquifer recharge has been carried out. Specifically, the documents that have been the basis to establish the minimum quality requirements for agricultural irrigation and aquifer recharge are the following:

— The regulatory framework at EU level on health and environmental protection

— The MS water reuse legislations and guidelines in place, along with their experience in water reuse systems

— Worldwide reference guidelines and regulations on water reuse

— Additional scientific references considered relevant for the topic

Selected experts in water reuse, whose contributions are gratefully acknowledged, have been consulted to provide comments and input through critical discussion on the document along the process. However, the content of this document has not been endorsed by these experts and reflects only the scientific opinion of the JRC. It is important to note that no risk assessment specifically for the establishment of the minimum quality requirements has been performed.

3 Framework for water reuse management

The approach to develop minimum quality requirements for the safe use of reclaimed water for agricultural irrigation and aquifer recharge is a **risk management framework**, as recommended by the World Health Organization WHO (WHO, 2006) and included in the Directive 2015/1787 that amends Directive 98/83/EC on the quality of water intended for human consumption.

The WHO, in order to tackle the health and environmental risks caused by microbiological and chemical contaminants potentially present in water, recommends to implement the principles of a risk management framework (WHO, 2001). The WHO suggests that a risk management approach should be applied to drinking water, reclaimed water, and recreational water. A risk management approach provides the conceptual framework for the WHO Guidelines for Drinking Water Quality (WHO, 2004 and 2011), and the Guidelines for the Safe use of Wastewater, Excreta and Greywater (WHO, 2006). A risk management approach involves identifying and managing risks in a proactive way, rather than simply reacting when problems arise being a dynamic and practical system that, applied to water reuse, incorporates the concept of producing reclaimed water of a quality that is 'fit-for-purpose'.

The Guidelines for the Safe Use of Wastewater, Excreta and Greywater (WHO, 2006) are divided into four volumes, devoted to different topics: Volume I, Policy and regulatory aspects; Volume II, Wastewater use in agriculture; Volume III, Wastewater and excreta use in aquaculture; and Volume IV, Excreta and greywater use in agriculture.

Following the risk management approach, the Australian government developed the Australian Guidelines for Water Recycling and the Australian Drinking Water Guidelines (NHMRC-NRMMC, 2011). The Australian Guidelines for Water Recycling provide a generic framework for management of reclaimed water quality and use that applies to all combinations of reclaimed water and end uses, including agricultural irrigation and aquifer recharge. These guidelines are structured in two phases. Phase I document (NRMMC-EPHC-AHMC, 2006) provides the scientific basis to assist and manage health and environmental risks. The three Phase II documents cover the specialized requirements for augmentation of drinking water supplies (NRMMC-EPHC-NHMRC, 2008), storm water harvesting and reuse, and managed aquifer recharge (NRMMC-EPHC–NHMRC, 2009). It is to note that the Australian Guidelines for Water Recycling are currently under a review that will draw on the advances and implementation of water recycling schemes.

The comprehensive risk management approach in the WHO Guidelines for Drinking Water Quality is termed "Water Safety Plan (WSP)" (WHO, 2009). The elements of a WSP build on many of the principles and concepts from other systematic risk management approaches, in particular the multiple-barrier approach and the hazard analysis and critical control points (HACCP) system (WHO, 2011). The WHO, and also the Australian guidelines, recommends the implementation of a risk management plan including a risk assessment for water reuse systems. For this purpose, the WHO has launched a Sanitation Safety Planning (SSP) manual as guidance on implementation of the WHO guidelines for water reuse (WHO, 2015). A SSP is a step-by-step health risk based approach for managing, monitoring and improving sanitation systems. The SSP is in line with the concept of the WSPs manual issued for drinking water supply systems (WHO, 2009).

The United States Environmental Protection Agency (USEPA) issued, in 2012, the last version of the Guidelines for Water Reuse (USEPA, 2012). These guidelines include a wide range of reuse applications (e.g. agricultural irrigation and aquifer recharge) and apply a similar approach as described in the WHO and the Australian guidelines for controlling health and environmental risks.

In 2015, the International Organization for Standardization (ISO) published the Guidelines for treated wastewater use for irrigation projects, including agricultural irrigation (ISO 16075, 2015). These ISO guidelines provide guidance for healthy, environmentally and hydrologically good operation, monitoring, and maintenance of water reuse projects for unrestricted and restricted irrigation of agricultural crops, gardens, and landscape areas using treated wastewater. The guidelines are divided into four parts: The basis of a reuse project for irrigation, that considers climate, soils, design, materials, construction, and performance (Part 1); Development of the project (Part 2) that includes water quality requirements like microbiological and chemical parameters, potential barriers and potential corresponding water treatments; and Components of a reuse project for irrigation (Part 3) that includes recommendations for irrigation systems, and distribution and storage facilities, and Monitoring (Part 4). The ISO guidelines include recommended parameters and limit values that are elaborated on the basis of international regulations, like the WHO and the USEPA guidelines, to assure health and environmental safety of water reuse projects in irrigation.

The State of California has been a pioneer in issuing water reuse regulations and the water quality requirements that California establishes have become a global benchmark, and they have provided a basis for the development of water reuse regulations worldwide. The State of California regulatory approach on water reuse is based on stringent treatment technology targets with specific performance requirements for several uses, including also agricultural irrigation. Statutes and regulations related to water reuse in California are based on a risk assessment and the multiple-barrier principle and are included in the California Health and Safety Code, the California Water Code, and the California Code of Regulations. In the last update of the water reuse regulations, the Division of Drinking Water (DDW) (formerly known as CDPH) included also indirect potable reuse considering aquifer replenishment by surface and subsurface application (CDPH, 2014).

In EU countries, the most comprehensive water reuse regulations and recommendations issued by MS (i.e. Cyprus, France, Greece, Italy, Portugal, Spain) (DM, 2003; NP, 2005; RD, 2007; CMD, 2011; JORF, 2014; KDP, 2015) are based on the referenced guidelines and regulations cited above, all of them including several modifications for some uses (Paranychianakis *et al.*, 2014).

A **risk management framework** is a systematic management tool that consistently ensures the safety and acceptability of water reuse practices. A central feature is that it is sufficiently flexible to be applied to all types of water reuse systems, irrespective of size and complexity.

The risk management framework incorporates several interrelated elements, each of which supports the effectiveness of the others. Because most problems associated with reclaimed water schemes are attributable to a combination of factors, these factors need to be addressed together to ensure a safe and sustainable supply of reclaimed water. The elements, based on the recommendations of international guidelines (WHO, 2004, 2009 and 2011; NRMMC-EPHC-AHMC, 2006) are the following:

— Assembly of a risk management team.
— Description of the water reuse system.
— Identification of hazards and hazardous events, and risk assessment.
— Determination of preventive measures to limit risks.
— Development of operational procedures.
— Verification of the water quality and the receiving environment.
— Validation of processes and procedures.
— Management of incidents and emergencies.

In this context, it is of paramount importance that MS apply the principles of a risk management framework for the safe use of reclaimed water for agricultural irrigation and aquifer recharge.

4 Management of health and environmental risks for water reuse in agricultural irrigation

This section includes the definition of the key elements of a risk management framework that MS have to apply to manage health and environmental risks when reclaimed water is used in agricultural irrigation. It also includes the definition of common (not site specific) minimum quality requirements and preventive measures to be applied to all EU water reuse projects for agricultural irrigation, with the associated justification.

Regarding the source of wastewater to be reclaimed, as a minimum requirement, it has to be stressed that the Directive 91/271/EEC (UWWTD) that concerns the collection, treatment and discharge of urban wastewater, establishes quality requirements that have to be satisfied by discharges from urban wastewater treatment plants (UWWTP) including also specific requirements for discharges in sensitive areas (Annex I of UWWTD). Water from wastewater treatment plants destined for reuse is considered a discharge under the UWWTD at the point where it leaves the water treatment plant (after treatment) (EC, 2016). Therefore, as the only source of wastewater considered in this document is the wastewater covered by the UWWTD, all treated wastewater potentially considered for reclamation and reuse (i.e. wastewater coming from an UWWTP) has to comply, **at least**, with the quality requirements specified in the UWWTD Annex I, table 1 and, when applicable, with the requirements from Annex I, table 2 for sensitive areas.

In order to assure that wastewater that enter a UWWTP is included in the Annex III of the Directive 91/271/EEC, thus, it is necessary to establish source control programs and oversight of industrial and commercial discharges to the sewer systems connected to a wastewater treatment plant.

4.1 Agricultural irrigation uses

Agricultural irrigation is defined in this document as irrigation of the following types of crops:

— Food crops consumed raw: crops which are intended for human consumption to be eaten raw or unprocessed.

— Processed food crops: crops which are intended for human consumption not to be eaten raw but after a treatment process (i.e. cooked, industrially processed).

— Non-food crops: crops which are not intended for human consumption (e.g. pastures, forage, fiber, ornamental, seed, energy and turf crops).

These definitions are based on the categories of use described in water reuse guidelines and some MS legislations (NRMMC-EPHC-AMHC, 2006; WHO, 2006; USEPA, 2012; JRC, 2014). Definitions included in EC food safety regulations 178/2002 and 852/2004 also apply to these classification.

4.2 Risk management framework for agricultural irrigation

It is recommended that MS have to apply the following elements of a risk management framework to manage health and environmental risks derived from the use of reclaimed water for agricultural irrigation.

4.2.1 Assembly of a risk management team

This step involves assembling a multidisciplinary team of individuals with adequate experience and expertise in protecting public and environmental health that understands the components of the water reuse system and is well placed to assess the associated risks.

4.2.2 Description of the water reuse system

The aim of this element is to provide a detailed understanding of the entire water reuse system from source to end use. A definition of a water reuse system is provided in Section 2. It is necessary to assess the historical water quality data, taking into account the variability, and to construct a flow diagram of the water reuse system from the source to the application or receiving environments.

4.2.3 Identification of hazards and hazardous events, and risk assessment

This element involves identifying all hazards and hazardous events of the water reuse scheme, and assessing the level of risk they pose to health and the environment.

Risk assessment can be defined as a characterization and estimation of potential adverse effects on health and environmental matrices associated with the intended use of reclaimed water. Different approaches to risk assessment are proposed in water reuse guidelines with varying degrees of complexity and data requirements. The risk assessment process can involve a quantitative or semi-quantitative approach, comprising estimation of likelihood/frequency and severity/consequence, or a qualitative approach (NRMMC–EPHC–AHMC, 2006; WHO, 2009 and 2015).

4.2.3.1 Health risks

Minimum quality requirements for the safety of human and animal health when crops are irrigated with reclaimed water, derived following a human health risk assessment, and considering animal health protection, are defined in Section 4.3 to be applied to all EU water reuse projects for agricultural irrigation independently of the site specific conditions.

Additional microbiological or physico-chemical parameters may be included as quality requirements by MS after a health risk assessment has been performed to justify this modification. Guidance on health risk assessment to be performed by MS is given below.

Health risk assessment includes the following steps:

— **Hazard identification:** identification of hazards that might be present in wastewater and the associated adverse effects to health.

  Health hazards to be considered are associated with the agricultural uses, thus including human and animal health.

  Biological (pathogens) and chemical hazards are to be assessed. Therefore, a characterization of the reclaimed water to be used for irrigation has to be performed to identify the concentrations of the health hazards present. Variations in hazards concentration are to be considered. Historical data may be of additional use to establish the concentration variation of a specific hazard.

— **Dose-response**: establishment of the relationship between the dose of the hazard and the incidence or likelihood of illness.

  A dose-response model specific for each of the pathogens selected as a risk has to be used, based on the scientific knowledge (e.g. Haas *et al.*, 1999; Messner *et al.*, 2001; Teunis *et al.*, 2008).

  Chemical compounds are evaluated by defining the NOAEL (*No Observed Adverse Effect Level*), the LOAEL (*Lowest Observed Adverse Effect Level*), and the RfD (*Reference Dose*) according to scientific knowledge.

— **Exposure assessment:** determination of the size and nature of the population exposed to the hazard, and the route, amount and duration of exposure.

  The route of exposure, exposure volumes and frequency of exposure of the hazards has to be defined considering local conditions. Scientific knowledge is limited, thus some conservative values are sometimes use, if no other data is available in the literature (NRMMC-EPHC-AHMC, 2006; WHO, 2006).

— **Risk characterisation:** integration of data on hazard presence, dose-response and exposure obtained in the first three steps.

The tolerable health risk defined in this document is 10^{-6} DALYs per person per year. For microbiological hazards, performance targets for the reference pathogens selected and water quality targets for indicator organisms are to be determined as health-based targets. For chemical hazards, most frequently, health-based targets are water quality targets, taking the form of chemical guideline values. A chemical guideline value is the concentration of a chemical component that, over a lifetime of consumption, will not lead to more than 10^{-6} DALYs per person per year.

The WHO performed a health risk assessment to derive maximum concentrations in soils for a set of organic and inorganic chemicals based on human health risks (WHO, 2006) and this data may be taken as a guidance if no updated scientific data is available.

4.2.3.2 Environmental risks

It is recommended that MS have to assure that the use of reclaimed water for agricultural irrigation has no adverse effects on environmental matrices (soil, groundwater, surface water, and dependent ecosystems, including crops to be irrigated) and that reclaimed water use is in compliance with the related EU directives for environmental protection.

Regulatory requirements of related EU Directives for environmental protection have to be always fulfilled. MS have to ensure that water reuse system does not compromise the objectives for surface water, groundwater, and dependent ecosystems established by the following EU directives:

— Directive 2000/60/EC (Water Framework Directive (WFD)).

— Directive 2008/105/EC (Environmental Quality Standards Directive (EQSD)) amended by Directive 2013/39/EU.

— Directive 2006/118/EC amended by Directive 2014/80/EE (Groundwater Directive (GWD)).

— Directive 91/271/EEC (Urban Wastewater Treatment Directive (UWWTD)).

— Directive 91/676/EEC (Nitrates Directive).

— Other related EU Directives that may apply.

In order to comply with these EU directives, MS have to establish, on a case-by-case basis, minimum quality requirements for parameters included in the related EU directives to be complied with by the reclaimed water effluent and to be included for verification monitoring. The guidance documents produced by the Common Implementation Strategy (CIS) of the WFD to assist MS to implement the WFD are to be use as tools to characterize the existent quality status of the surface water, groundwater, and related ecosystems that may be affected by reclaimed water used for irrigation. Guidance documents are intended to provide an overall methodological approach, but these will need to be tailored to specific circumstances of each MS.

Environmental risks related to nutrients from agricultural irrigation with reclaimed water are in great part to be controlled and reduced by MS through codes of good agricultural practices and Action Programmes established under the Nitrates Directive (91/676/EEC). These must contain, at least, provisions covering the items mentioned in Annex II and Annex III of the Directive including measures concerning balanced fertilization. The prevention of nitrate pollution via run-off from agricultural irrigation needs to be ensured especially in the designated Nitrate Vulnerable Zones.

In addition to the parameters of the related EU directives, other microbiological and physico-chemical hazards may also affect surface water, groundwater and dependent ecosystems according to the wastewater effluent to be treated for reuse, and the site specific conditions. Therefore, MS have to establish, according to the outcome of an environmental risk assessment, minimum quality requirements for additional parameters not included in the related EU Directives to be complied with by the reclaimed water effluent and to be included in the reclaimed water quality criteria.

Furthermore, MS have to perform an environmental risk assessment to protect soils, and dependent ecosystems, including crops to be irrigated, on a case-by-case basis according to site specific conditions, and establish, according to the outcome of the risk assessment, minimum quality requirements to be complied with by the final reclaimed water effluent and to be included in the reclaimed water quality criteria. Guidance on environmental risk assessment to be performed by MS is given below.

Environmental risk assessment includes the following steps:

— **Hazard identification:** identification of hazards that might be present in wastewater and the associated adverse effects to the environment.

  Environmental hazards are to be considered according to the environmental matrices that may be exposed to reclaimed water, which are soil, groundwater, surface water, and related biota (e.g. plants).

  The physico-chemical hazards to be evaluated for preventing adverse effects on **surface water, groundwater, and related ecosystems** are additional to the parameters defined in the related EU Directives mentioned above. The physico-chemical hazards also to be evaluated are hazards for preventing adverse effects on **soils, and related ecosystems** including **crops** (agronomic parameters) that include salinity related parameters, metals, nutrients, and trace elements. Indicative agronomic parameters are included in different guidelines (FAO, 1985; WHO, 2006; USEPA, 2012; ISO 16075, 2015).

— **Estimate the likelihood of a hazardous event:** estimate the likelihood that an environmental endpoint will be exposed to the hazard in sufficient concentrations to cause a detrimental effect.

  Once the physico-chemical hazards concentrations are determined, it has to be established the likelihood that these concentrations will pose an adverse effect on the environmental matrices.

  The concentrations of the agronomic parameters evaluated have to be assess to establish if they can have adverse effects on soils, crops and dependent ecosystems. For this purpose, soils and crops have to be characterized. Soil characterization includes the determination of the agronomic parameters, including texture, hydraulic conductivity, water retention capacity, and organic matter content. The specific crop requirements and toxicity to the physico-chemical hazards found in reclaimed water has to be evaluated in order to avoid phytotoxicity. Data related to crops and soils tolerance according to site specific conditions has to be used. Examples of limit values for agronomic parameters to protect soils and crops are also included in international guidelines (FAO, 1985; NRMMC-EPHC-AHMC, 2006; WHO, 2006; ISO 16075, 2015). The Directive 86/78/EEC (Sludge Directive) on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture establishes limit values for heavy metals in soils, and the maximum limit values of heavy metals amounts which may be added annually to agricultural land based on a 10 year average (Annex I A and C of Directive 86/78/EEC). These values may be taken into account as a reference in order to do not damage the soil quality. However, since the adoption of the Directive 86/78/EEC, several MS have enacted and implemented stricter limit values for heavy metals and set requirements for other contaminants. The Sludge Directive is now under a revision process and any update should be considered accordingly.

— **Estimate the consequences of the hazardous event:** determine the consequences (or impacts) of exposure to a hazard by considering the specific conditions of the environmental endpoint.

  If additional hazards to the ones considered in the EU related Directives to prevent adverse effects on surface water, groundwater, and dependent ecosystems are defined, it is necessary to estimate the adverse impact that these hazards may pose. This has to be established based on scientific knowledge.

  The consequences of the adverse effects to be posed to crops and soils by the agronomic parameters evaluated has to be determined based on scientific knowledge.

— **Characterize the overall risk:** characterize the risk by integrating the data on hazards, hazardous events, likelihood and consequences, obtained through the steps described above.

  The characterization of the overall risk has to be determined by combining the hazards and hazardous events with their likelihood and consequences. This can be done using a risk assessment matrix that rates risks from "low" to "very high". An example of this procedure is found in the Australian guidelines (NRMMC-EPHC-AHMC, 2006).

  Based on the results obtained, MS have to establish water quality requirements to be included in the reclaimed water quality criteria, defining also possible preventive measures to be applied, as good agricultural practices.

4.2.4 Determination of preventive measures to limit risks

Safe use of reclaimed water requires the implementation of preventive measures (barriers) to reduce hazards and exposure to hazards by the following actions:

— Preventing hazards from entering reclaimed water.

— Removing them using treatment processes.

— Reducing exposure, either by using preventive measures at the site of use or by restricting uses.

Identification and implementation of preventive measures should be based on the multiple barrier principle. According to this principle, multiple preventive measures or barriers are used to control the risks posed by different hazards, thus making the process more reliable.

The strength of this principle is that a failure of one barrier may be compensated by effective operation of the remaining barriers, thus minimizing the likelihood of contaminants passing through the entire system and being present in sufficient amounts to cause any harm to human health or environmental matrices. Many control measures may contribute to control more than one hazard, whereas some hazards may require more than one control measure (WHO, 2011).

Water treatment processes prevent or reduce the concentration of hazards in the reclaimed water effluent and are the most important barrier to eliminate or minimize health and environmental risks of water reuse practices.

On-site controls are additional preventive measures that can prevent or minimise public exposure to hazards and can also minimise the impact on receiving environments.

The preventive measures that MS have to consider in order to reduce potential adverse effects on health and the environment, according to site specific conditions, are the following:

— **Wastewater treatment technologies**: treatment technologies are an essential barrier to prevent health and environmental risks. Untreated raw wastewater and secondary treated wastewater effluents (complying with UWWTD) are forbidden to be used directly for irrigation purposes. Therefore, an additional treatment is always needed in order to use urban wastewater for agricultural irrigation.

— **Crops characteristics**: the characteristics of crops (i.e. crops eaten raw, processed, with inedible skin) are taken into account as a barrier to reduce health risks to consumers. Selection of crops has to be made according to crop tolerance (e.g. salt and specific ion tolerance), reclaimed water quality and soil properties to produce satisfactory yields.

— **Irrigation method**: the different irrigation methods considered reflect the reduction in exposure to health hazards that specific irrigation methods present (i.e. drip irrigation) and the greater risks that other irrigation methods pose due to aerosols formation (i.e. sprinkler irrigation).

— **Drinking water sources protection**: the vulnerability of existing drinking water sources to the use of reclaimed water for irrigation has to be assessed. Article 7 of the WFD requires that MS shall ensure the necessary protection for waters used for the abstraction of drinking water, or intended for such use, with the aim of avoiding deterioration in their quality, establishing safeguard zones for those bodies of water, if necessary.

— **Control of the storage and distribution system**: within the distribution system, that may include storage (open and closed reservoirs), reclaimed water for irrigation may suffer changes that affect its chemical and biological quality (e.g. microbial regrowth, nitrification, algae growth, natural decay of microorganisms). Thus, management strategies, including monitoring, have to be undertaken in order to prevent the deterioration of reclaimed water quality. Maintaining good water quality in the distribution system will depend on the design and operation of the system and on maintenance and survey procedures to prevent contamination. Control of short-circuiting and prevention of stagnation in both storage and distribution, including use of backflow prevention devices, maintaining positive pressure throughout the system and implementation of efficient maintenance procedures are strategies to maintain the quality of reclaimed water within the storage and distribution system. Reclaimed water can be mixed with water from natural sources to correct for certain parameters.

— **Irrigation schedule**: reclaimed water application rates need to be controlled so that irrigation is consistent in providing maximum benefit, while minimising impacts on receiving environments (including soils, groundwater and surface water). Irrigation systems should be installed and operated to minimise surface ponding and to control surface run-off.

— **Access control, buffer zones (security distances) and withholding periods**: these measures should be established as necessary to minimize exposure to health hazards to humans and animals. It is needed to consider access control for on-site workers, general public, and animals, and define specific withholding periods for livestock to be fed with irrigated pastures or fodder.

  The establishment of access control, buffer zones (security distances) and withholding periods has to be evaluated considering the reclaimed water quality used, the irrigation method, and the site specific conditions (e.g. windy situations). On-site workers access should ensure compliance with related occupational health and safety regulations in place.

— **Education and training**: education and training of on-site workers and managers involved in agricultural irrigation are of principal importance as components of implementing and maintaining preventive measures. Personnel should be kept fully informed on the use of reclaimed water. Agricultural workers are especially vulnerable, and a range of human exposure measures (e.g. personal protective equipment, handwashing and personal hygiene) are also to be implemented.

Occupational health related EU Directives and national regulations from MS should apply.

— **Signage**: accidental exposure to reclaimed water can be reduced through the use of measures such as signage at irrigation sites, indicating that reclaimed water is being used and is not suitable for drinking.

Recommendations for the assessment and implementation of these preventive measures in water reuse schemes for agricultural irrigation are included in the ISO guidelines (ISO 16075, 2015) and other water reuse guidelines (NRMMC-EPHC-AHMC, 2006; WHO, 2006; USEPA, 2012). However, MS must always consider site specific conditions for selection and implementation of preventive measures.

The selection of common preventive measures (barriers) already considered by this document to develop the common minimum quality requirements in Section 4.3 have been the wastewater treatment technology, the crops characteristics, the irrigation method and the withholding periods and access control for livestock.

4.2.5 Development of operational procedures

MS have to assure the appropriate performance of the water reuse system to deliver the requested level of reclaimed water quality. It is necessary to develop an operational monitoring protocol to define operational procedures for all activities and process applied within the **whole water reuse system** to ensure that all preventive measures implemented to control hazards are functioning effectively.

MS have to develop an operational monitoring protocol to assess and confirm that the performance of preventive measures of the water reuse system ensures reclaimed water of an appropriate quality to be consistently provided. A water reuse system in Section 2 of this document is defined as follow:

— Raw wastewater entering the wastewater treatment plant (WWTP).

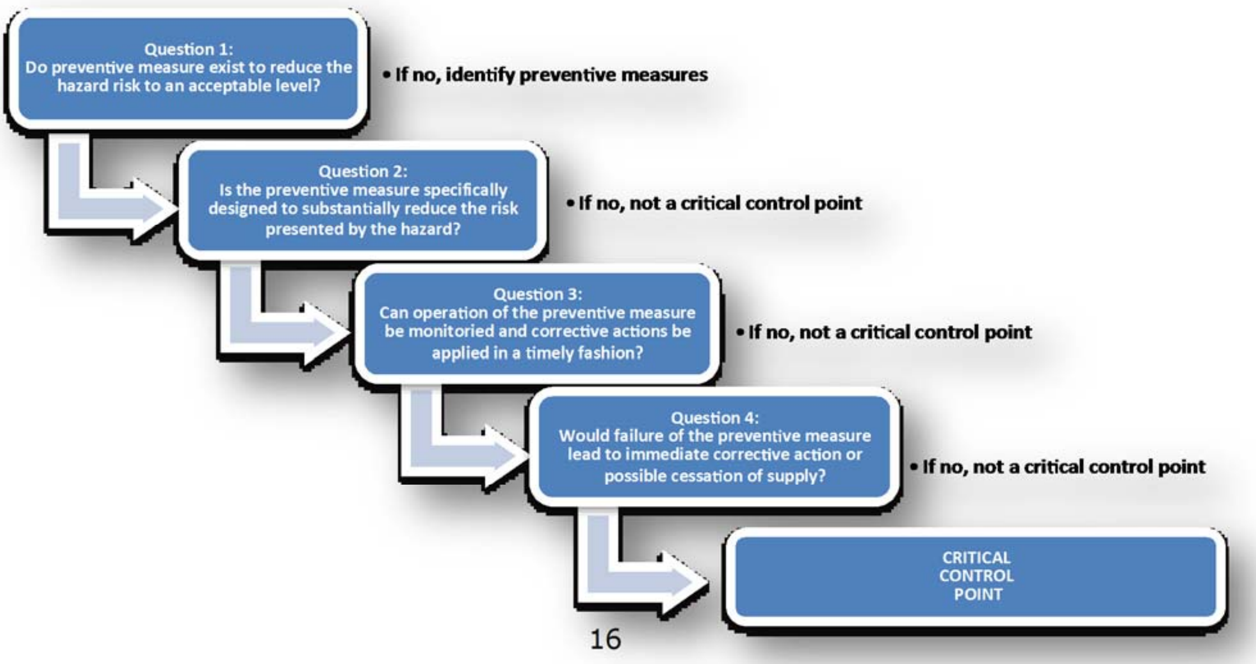
— The wastewater treatments included in the WWTP.

— The additional treatments to produce reclaimed water of the required quality for reuse.

— The storage and distribution systems.

— The irrigation system.

Figure 1. Decision support tree to identify critical control points in a water reuse system.



Source: JRC, 2014.

Critical control points of the water reuse system have to be determined as they are the focus of the operational monitoring. The identification of critical control points is system specific and it can be done by applying a decision tree shown in Figure 1.

The operational monitoring protocol has to include parameters that can be readily measured and provide an immediate indication of performance of the preventive measures to enable a rapid response (e.g. disinfectant residuals and other disinfection-related parameters). On-line monitoring with real-time data reporting is strongly recommended when technologically feasible (see informative Annex). Operational parameters have to be associated with target limits and critical limits to define effectiveness and detect variations in performance. Observational manual checking of preventive measures is also part of the operational monitoring.

Operational monitoring protocol has also to include procedures for corrective actions to be implemented when operational parameters are deviated from the critical limit. Operational monitoring protocols are described in several guidelines (NRMMC-EPHC-AHMC, 2006; WHO, 2006).

Examples of operational monitoring requirements for the preventive measure of wastewater treatment processes are shown in Table 1.

Table 1. Examples of operational monitoring for several treatment processes.

Treatment process	Operational monitoring	Indicative frequency
Secondary treatment (activated sludge)	Flow rate Nitrate, nitrites BOD_5 Suspended solids, solids retention time Dissolved oxygen Hydraulic retention time	Continuous (on-line) for flow rate, dissolved oxygen Weekly for other parameters
Low-rate biological systems (stabilization ponds)	Flow rate BOD_5, (facultative and maturation ponds) Algal levels	Continuous (on-line) for flow rate Weekly for other parameters
Soil-aquifer treatment	Flow rate Total Organic Carbon (TOC) Total Nitrogen, nitrates, nitrites	Continuous (on-line) Weekly for other parameters
Media filtration system	Flow rate Turbidity	Continuous (on-line)
Membrane bioreactor (MBR)	pH Turbidity Suspended solids, solids retention time Dissolved oxygen Hydraulic retention time Transmembrane pressure	Continuous (on-line) for parameters such as pH, turbidity, dissolved oxygen, transmembrane pressure Weekly for other parameters
Membrane filtration technology	Transmembrane pressure Turbidity Electrical conductivity	Continuous (on-line)

Treatment process	Operational monitoring	Indicative frequency
Ultraviolet light disinfection (UV)	Flow rate Turbidity upstream UV intensity and/or calculated dose UV transmissivity	Continuous (on-line)
Ozone / Biological Activated Carbon	Ozone dose Temperature	Continuous (on-line)
Chlorination	Free chlorine residual, Ct* pH Temperature	Continuous (on-line)

(*) Ct means the product of residual disinfectant content (mg/l) and disinfectant contact time (min).

Source: WHO, 2006; NRMMC-EPHC-AHMC, 2006; USEPA, 2012.

4.2.6 Verification of water quality and receiving environments

This element comprises verification of the overall performance of the water reuse treatment system, the ultimate quality of reclaimed water being supplied, and the quality of the receiving environment. Verification monitoring is the use of methods, procedures or tests, in addition to those used in operational monitoring, to assess the overall performance of the treatment system, the compliance with regulatory requirements of the ultimate quality of the reclaimed water being supplied, and the quality of the receiving environment.

MS have to perform a routine monitoring to verify that the reclaimed water effluent is complying with the requested quality criteria included in Section 4.3 and the additional quality requirements that MS decide to include as quality criteria derived from EU related Directives and risk assessment outcomes according to site specific conditions.

MS have to implement monitoring programs of the environmental matrices at risk to control the effect of reclaimed water irrigation as part of the verification monitoring. A monitoring program for soils, crops, groundwater and surface water, and dependent ecosystems has to be established, on a case-by-case basis, according to the identified risks. Recommendations for monitoring programs of environmental matrices when reclaimed water is used for agricultural irrigation are described in the ISO guidelines (ISO 16075, 2015).

Analytical methods used for monitoring shall comply with the requirements included in the related Directives (i.e. WFD (2000/60/EC), DWD (98/83/EC), GWD (2006/118/EC) to conform to the quality control principles, including, if relevant, ISO/CEN or national standardized methods, to ensure the provision of data of an equivalent scientific quality and comparability.

4.2.7 Validation of processes and procedures

Validation aims to ensure that processes and procedures control hazards effectively and that the water reuse system is capable of meeting its design requirements. One of the objectives of validation monitoring is to prove that the water reuse system can deliver the expected water quality specified for the intended use. Therefore, validation monitoring includes also operational and verification monitoring parameters, discussed above.

Validation monitoring has to be conducted when a reclamation system is established (commissioned) and put in operation, when equipment is upgraded or new equipment or processes are added. Once the setup of the whole water reuse system has been validated, it is generally sufficient with the operational and verification monitoring.

MS have to perform, as part of the validation monitoring, the requested performance targets defined in Table 5.

4.2.8 Management of incidents and emergencies

This element deals with responses to incidents or emergencies that can compromise the quality of reclaimed water. MS have to establish incident and emergency protocols, and to develop and document response plans. Such responses protect public and environmental health, and help to maintain user confidence in reclaimed water.

Following the aforementioned key principles for a risk management framework, minimum reclaimed water quality criteria and preventive measures to manage human and animal health risks from consuming crops irrigated with reclaimed water have been derived to be implemented to all water reuse projects at EU level. The justification for this selected requirements is presented in Section 4.4.

4.3 Minimum reclaimed water quality criteria and preventive measures

Following the aforementioned key principles for a risk management framework, minimum reclaimed water quality criteria and preventive measures to manage human and animal health risks from consuming crops irrigated with reclaimed water have been derived to be implemented to all water reuse projects at EU level. The justification for this selected requirements is presented in Section 4.4.

The reclaimed water quality criteria are defined in Table 2. The classes of reclaimed water quality, and the associated use according to the barriers considered is shown in Table 3. The frequencies for monitoring the final reclaimed water effluent are defined in Table 4.

Table 2. Reclaimed water quality criteria for agricultural irrigation.

Reclaimed water quality class	Indicative technology target	Quality criteria				
		E. coli (cfu/100 ml)	BOD_5 (mg/l)	TSS (mg/l)	Turbidity (NTU)	Additional criteria
Class A	Secondary treatment, filtration, and disinfection (advanced water treatments)	≤10 or below detection limit	≤10	≤10	≤5	*Legionella* spp.: ≤1,000 cfu/l when there is risk of aerosolization. Intestinal nematodes (helminth eggs): ≤1 egg/l when irrigation of pastures or fodder for livestock.
Class B	Secondary treatment, and disinfection	≤100	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-	
Class C	Secondary treatment, and disinfection	≤1,000	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-	
Class D	Secondary treatment, and disinfection	≤10,000	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-	

Source: JRC analysis.

Table 3. Classes of reclaimed water quality, and the associated agricultural use and irrigation method considered.

Crop category	Minimum reclaimed water quality class	Irrigation method
All food crops, including root crops consumed raw and food crops where the edible portion is in direct contact with reclaimed water	Class A	All irrigation methods allowed
Food crops consumed raw where the edible portion is produced above ground and is not in direct contact with reclaimed water	Class B	All irrigation methods allowed
	Class C	Drip irrigation only
Processed food crops	Class B	All irrigation methods allowed
	Class C	Drip irrigation only
Non-food crops including crops to feed milk- or meat-producing animals	Class B	All irrigation methods allowed
	Class C	Drip irrigation only
Industrial, energy, and seeded crops	Class D	All irrigation methods allowed

Source: JRC analysis.

Table 4. Minimum frequencies for reclaimed water monitoring for agricultural irrigation.

	Minimum monitoring frequencies					
Reclaimed water quality classes	***E. coli***	**BOD_5**	**TSS**	**Turbidity**	***Legionella* spp. (when applicable)**	**Intestinal nematodes (when applicable)**
Class A	Once a week	Once a week	Once a week	Continuous	Once a week	Twice a month or frequency determined according to the number of eggs in wastewater.
Class B	Once a week	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-		
Class C	Twice a month	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-		
Class D	Twice a month	According to Directive 91/271/EEC	According to Directive 91/271/EEC	-		

Source: JRC analysis.

The reclaimed water quality criteria will be considered compliant with the requirements shown in Table 2 if the analytical controls meet all of the following criteria:

— Values for criteria of *E. coli* and *Legionella* and intestinal nematodes (Table 2) must be conformed at 90% of the samples. Samples cannot exceed the maximum deviation limit of 1 log unit from the indicated value for *E. coli* and *Legionella*, and 100% of the indicated value for intestinal nematodes.

— Values for criteria of BOD_5, TSS, and turbidity in Class A (Table 2) must be conformed at 90% of the samples. Samples cannot exceed the maximum deviation limit of twice the value defined in Table 2.

Reclaimed water must comply with the quality criteria at the outlet of the treatment plant. The reclaimed water has to follow the same procedures as for any other irrigation water source once the water is delivered to the final user. The European Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene is a guidance document to be considered (Notice 2017/C 163/01).

MS have to perform a routine monitoring to verify that the reclaimed water effluent is complying with the requested quality criteria and to be included in the verification procedures of the water reuse system.

Validation monitoring is mandatory for MS for the most stringent reclaimed water quality class, Class A, which relies only on the treatment technologies in place to meet the minimum quality requirements. The Class A allows irrigation of food crops eaten raw even when the reclaimed water is in contact with the edible parts of the crop and root crops eaten raw. Validation for Class A is required to assess that the performance targets (log_{10} reduction) are complied with by the water reuse system. Validation monitoring entails the monitoring of the indicator microorganisms associated to each group of pathogens (bacteria, virus and protozoa). The indicator microorganisms selected are *E. coli* for pathogenic bacteria, F-specific coliphages, somatic coliphages or coliphages for pathogenic viruses, and *Clostridium perfringens* spores or spore-forming sulfate-reducing bacteria for protozoa. Performance targets and monitoring frequencies required are shown in Table 5.

It has to be notice that the **reference pathogens** used to define the log removals (see section 4.4.4), *Campylobacter*, rotavirus and *Cryptosporidium*, can always be used for monitoring purposes instead of the proposed indicators.

Performance targets (log_{10} reduction targets) for the selected indicator microorganisms are to be met considering the concentrations of the raw wastewater effluent entering the UWWTP as the initial point, and the concentrations of the final reclaimed water effluent at the outlet of the additional treatment processes as the final point.

Validation monitoring has to be performed before the reuse scheme is put into place, when equipment is upgraded, and when new equipment or processes are added.

Table 5. Validation monitoring of the treatment performance for agricultural irrigation.

Reclaimed water quality class	Indicator microorganisms	Performance targets for the treatment train (log_{10} reduction)
Class A	*E. coli*	≥ 5.0
	Total coliphages/F-specific coliphages/ somatic coliphages*	≥ 6.0
	Clostridium perfringens spores/spore-forming sulphite-reducing bacteria**	≥ 5.0

(*)Total coliphages is selected as the most appropriate viral indicator. However, if analysis of total coliphages is not feasible, at least one of them (F-specific or somatic coliphages) has to be analyzed.

(**)*Clostridium perfringens* spores is selected as the most appropriate protozoa indicator. However, spore-forming sulfate-reducing bacteria is an alternative if the concentration of *Clostridium perfringens* spores does not allow to validate the requested log_{10} removal.

Source: JRC analysis.

Analytical methods used for monitoring shall comply with the requirements included in the related Directives (i.e. WFD (2000/60/EC), DWD (98/83/EC), GWD (2006/118/EC) to conform to the quality control principles, including, if relevant, ISO/CEN or national standardized methods, to ensure the provision of data of an equivalent scientific quality and comparability.

MS have to comply with common specific preventive measures for any water reuse project regardless of the site specific conditions (Table 6).

Table 6. Specific additional preventive measures for health protection to be complied with by MS for any site specific condition.

Reclaimed water quality class	Specific additional preventive measures to be complied with by MS
Class A	- Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate the risks for a specific case can be managed.
Class B	- Prohibition of harvesting of wet irrigated or dropped produce. - Exclude lactating dairy cattle from pasture until pasture is dry. - Fodder has to be dried or ensiled before packaging. - Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate the risks for a specific case can be managed.
Class C	- Prohibition of harvesting of wet irrigated or dropped produce. - Exclude grazing animals from pasture for five days after last irrigation. - Fodder has to be dried or ensiled before packaging. - Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate the risks for a specific case can be managed.
Class D	- Prohibition of harvesting of wet irrigated or dropped produce.

Source: JRC analysis.

The reclaimed water quality requirements and preventive measures are an integral part of the risk management framework for water reuse in agriculture. It is clearly emerging that the more "site-specific" risks, which are mostly related to environmental issues, are handled either under the umbrella of the Water Framework Directive and its Daughter Directives or subject to the development of specific risk assessments considering local conditions.

4.4 Justification for the selected quality requirements

The quality requirements have been established following the risk management approach. This framework is recommended by the WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater (WHO, 2006) and it has been applied and further detailed in the Australian Guidelines for Water Recycling (NRMMC–EPHC–AHMC, 2006).

There was no specific risk assessment with European data performed for the present document to evaluate water reuse schemes for agricultural irrigation. The selection of the minimum quality requirements established is based on existing water reuse guidelines and MS regulations, and on the health and environmental risks considered by them.

The health and environmental risks related to water reuse in agricultural irrigation are associated to the potential presence of pathogens and physico-chemical constituents that may pose a risk to human and animal health, and to environmental matrices.

4.4.1 Health and environmental risks considered for agricultural irrigation

Health risks considered in this document are established based on the exposure scenarios recommended by WHO guidelines (WHO, 2006), which are the following:

— Ingestion of irrigated crops by consumers.

— Ingestion of droplets (produced by sprinkler irrigation) by workers, bystanders and residents in nearby communities.

— Inhalation of aerosols (produced by sprinkler irrigation) by workers, bystanders and residents in nearby communities.

— Dermal exposure by workers, bystanders and residents in nearby communities.

— Ingestion of soil particles by workers, bystanders and residents in nearby communities.

— Ingestion of pastures and fodder by milk- or meat-producing animals (human and animal health).

— Contamination of drinking water sources.

The environmental risks considered are based on the principle of no adverse effects to be caused to environmental matrices, according to their present status, in compliance with the related EU directives for environmental protection mentioned above. In complementarity, specific environmental risks assessments related to water reuse for agricultural irrigation established in different guidelines for the environmental matrices (soil, groundwater, surface water, plants, and dependent ecosystems) (WHO, 2006; NRMMC–EPHC–AHMC, 2006) have been also considered. These guidelines include risks of salinization, eutrophication, toxicity, and soil structure decline, among others.

4.4.2 Tolerable risk for human health

The definition of a tolerable risk as a health-outcome target is required by the risk management framework to develop the other health-based targets (performance targets and water quality targets).

Although the management of health risks is context specific, the WHO guidelines consider that the overall levels of health protection should be comparable for different water-related exposures (i.e. drinking water, reclaimed water irrigation of foods).

The WHO Guidelines for Drinking Water Quality (WHO, 2004 and 2011) establish the tolerable burden of disease (caused by either a chemical or an infectious agent) as an upper limit of 10^{-6} Disability Adjusted Life Years (DALYs) per person per year (pppy). This upper limit DALY is approximately equivalent to a 10^{-5} excess lifetime risk of cancer (i.e. 1 excess case of cancer per 100 000 people ingesting drinking-water at the water quality target daily over a lifetime that is used in the guidelines to determine guideline values for the maximum concentration of genotoxic carcinogens in drinking water), or an annual diarrhoeal risk of disease of 10^{-3} (i.e. one illness per 1000 people or 1 in 10 lifetime risk). These figures correspond closely to the 70-year lifetime waterborne cancer risk of 10^{-5} per person accepted by the USEPA (Mara, 2011). The tolerable burden of disease of 10^{-6} DALYs corresponds approximately to an infection risk of 10^{-3} ppy for rotavirus or *Cryptosporidium* and 10^{-4} ppy for *Campylobacter* (WHO, 2006; Mara, 2008).

In the context of reclaimed water use, since food crops irrigated with reclaimed water, specially those eaten uncooked, are also expected to be as safe as drinking water by those who eat them, the WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater (WHO, 2006) also recommend the same tolerable level of risk of 10^{-6} DALYs. The tolerable risk adopted in the Australian Guidelines for Water Recycling (NRMMC–EPHC–AHMC, 2006) is the same as the one selected by the WHO guidelines (WHO, 2006).

The 10^{-6} DALYs tolerable risk has been also selected for the Directive (98/83/EC) of water for human consumption (Drinking Water Directive (DWTD)) that considers as tolerable health risk a 10^{-5} excess lifetime risk of cancer, as recommended by the WHO.

The other often referred benchmark level of acceptable risk is the one defined by the USEPA that considers one infection per 10000 individuals in a given year ($\leq 10^{-4}$ pppy) as a reasonable level of safety for drinking water and also reclaimed water use (USEPA, 1989 and 2012). This number was derived in 1987 by determining the waterborne disease burden already tolerated in the United States. The USEPA does not use the DALYs metric, and the tolerable risk of infection selected can be considered similar to the WHO guidelines tolerable risk, although comparisons are difficult due to the assumptions applied to derive them.

It is important to notice that the current tolerable risk levels of WHO and USEPA guidelines have been questioned and they have been considered too stringent (Haas, 1996; Mara, 2011). Haas (1996) has said that it became apparent that some key factors used for computing of the 1:10,000 level of acceptable risk in USEPA guidelines may not be accurate thus considering that the current benchmark may be far too stringent. The computation of the currently used risk level from the late 1980s appears to have risen partly because, at that time, the perceived waterborne disease rate was 1 case per 10,000 people per year. But more recent assessments show that the actual burden of waterborne disease associated with water treatment practices appear to be much higher (Haas, 1996; Colford *et al.*, 2006). This would suggest that an annual risk of infection of 1 in 1,000, or even a less strict risk level, is more appropriate than the current approach. Mara (2011) states that the current maximal additional burden of disease (10^{-6} DALYs pppy) should be lowered to 10^{-4} DALYs pppy, based on a critical analysis of the basis from which the current benchmark is derived, the 70-lifetime waterborne cancer risk of 10^{-5} per person per year.

Therefore, in view of these considerations, the tolerable risk of **10^{-6} DALYs pppy** used in this document is considered safe enough to be applied at EU level.

4.4.3 Reference pathogens

Reference pathogens have been selected to be able to determine the performance targets ($\log_{10}$ reductions). It is impractical, and there are insufficient data, to set performance targets for all waterborne pathogens potentially present in wastewater, particularly since this would require information on concentrations, dose-response relationships, and disease burdens that is often not available. A more practical approach is to identify reference pathogens that represent groups of pathogens taking into account variations in characteristics, behaviours and susceptibilities of each group to different treatment processes. Typically, different reference pathogens will be identified to represent bacteria, viruses, protozoa and helminths (NRMMC-EPHC-AMHC, 2006; WHO, 2006; USEPA, 2012). It is to note that controlling reference pathogens implies controlling all pathogen risks that are covered by the reference pathogen.

The reference pathogens selected are the ones recommended by the WHO guidelines for water reuse and drinking water, which are *Campylobacter* for bacteria, rotavirus for viruses and *Cryptosporidium* for protozoa (WHO, 2006 and 2011). These are also the reference pathogens used by the DWD.

Campylobacter compared with other bacterial pathogens, has the infective dose relatively low and is relatively common, and waterborne outbreaks have been recorded. This selection is in agreement with the bacterial reference pathogens recommended by Australian guidelines for water reuse and drinking water (NRMMC–EPHC–AHMC, 2006; NHMRC-NRMMC, 2011).

Rotavirus is used as reference pathogen for pathogenic enteric viruses because they represent a major risk of viral gastroenteritis, they have a relatively high infectivity compared with other waterborne viruses and a dose-response model has been established (Havelaar and Melse, 2003). Adenoviruses have been detected in very high numbers in raw wastewater, and they appear to be the most resistant to water treatment technologies. Data gathered on rotavirus, norovirus and adenovirus indicated that prevalence in raw wastewater of these three viruses could be similar (NRMMC–EPHC–AHMC, 2006). Due to these considerations, the reference pathogen for pathogenic viruses selected by the Australian guidelines is an amalgam of rotavirus and adenovirus, using dose-response data for rotavirus and occurrence data for adenovirus.

Nevertheless, the use of rotavirus has been complicated by the development and use of a rotavirus vaccine that over time will change the incidence and severity of disease outcomes from this pathogen (Gibney *et al.*, 2014). On this basis, norovirus seems that it would be selected instead of rotavirus in the future potable reuse WHO guidelines and the future new revision of the Australian guidelines as reference pathogen. A dose response model has been published for norovirus (Teunis *et al.*, 2008) and a disease burden has been determined (Gibney *et al.*, 2014). However, these risk assessments are not published yet and there is no evidence that these considerations would change the final log_{10} reduction requested for viruses applied by the Australian guidelines.

Cryptosporidium is reasonably infective (Teunis *et al.*, 2002), is resistant to chlorination and is one of the most important waterborne human pathogens in developed countries (NRMMC–EPHC–AHMC, 2016). Although *Giardia* may be another candidate, as it is typically present in raw wastewater at some 10–100 times the concentration of *Cryptosporidium* (Yates and Gerba, 1998), and may be marginally more infective (Rose *et al.*, 1991), it is more readily removed by treatment processes and is more sensitive to most types of disinfection than *Cryptosporidium* (NRMMC–EPHC–AHMC, 2016). Therefore, *Cryptosporidium* is preferred as the reference pathogen for protozoa. This selection is also in agreement with the reference pathogens selected by the Australian guidelines for water reuse and drinking water (NRMMC–EPHC–AHMC, 2006; NHMRC-NRMMC, 2011).

It has not been selected a reference pathogen for helminths, since helminth infections are not endemic in EU countries, there is limited information on occurrence in water and there is no human dose-response model. However, for protection of human health, the protozoan reference pathogen can be used as a reference for helminths. Helminths are likely to be present in lower numbers than protozoa in sources of reclaimed water, and they will be removed more readily by physical treatment processes such as filtration and stabilization ponds as they are larger than protozoa (NRMMC–EPHC–AHMC, 2006).

4.4.4 Performance targets

No risk assessment has been performed specifically for this work, therefore, the performance targets have been established following the approach used by the Australian guidelines for water reuse practices (NRMMC–EPHC–AHMC, 2006) to establish performance and water quality targets. This approach consist on the translation of a tolerable risk level to performance targets. The Australian guidelines have been selected as the most appropriate scientific-based document to be used. They apply the tolerable risk of 10^{-6} DALYs pppy recommended by the WHO guidelines and considered safe enough for the development of the minimum quality requirements at EU level, and they also deploy the risk assessment carried out to derived the performance targets (log_{10} reductions) for human health risks control. Although there are some similarities with the log_{10} reductions defined by the WHO guidelines, it is considered that assumptions made by Australian guidelines reflect more accurately the situation in MS, also considering the fact that the WHO guidelines include assumptions from developing countries in the development of the risk assessment.

Pathogen concentration in raw wastewater can vary over a wide range, *Campylobacter* concentration can vary from 10^2 to 10^5 cfu/l, rotavirus can also vary from 10^2 to 10^5 pfu/l, and *Cryptosporidium* may vary between 0 and 10^4 oocysts/l according to several sources cited in Australian guidelines (NRMMC–EPHC–AHMC, 2006) which are in line with concentrations reported in WHO and EPA guidelines (WHO, 2006; EPA, 2012). Due to these variations, 95th percentiles are therefore used in determining the performance targets. The 95th percentiles of organisms per litre in raw wastewater used for the reference pathogens were 7000 for *Campylobacter*, 8000 for rotavirus and 2000 for *Cryptosporidium*. These concentrations are consistent with international data, according to Australian guidelines. The assumptions made to apply the risk assessment model (e.g. exposure per event, dose-response constants, ratio of desease/infection ratios, susceptibility fraction) are further detailed in Appendix 2 of the Australian guidelines (NRMMC–EPHC–AHMC, 2006).

The $\log_{10}$ reductions established have been calculated considering the worst-case scenario of the irrigation of lettuce when edible parts are in contact with reclaimed water (i.e. sprinkler irrigation) and the only barrier to reduce risk to a tolerable level is the wastewater treatment (secondary treatment, filtration and disinfection). The $\log_{10}$ defined reductions are the following:

— *Campylobacter*: 5 $\log_{10}$ reduction

— Rotavirus: 6 $\log_{10}$ reduction

— *Cryptosporidum*: 5 $\log_{10}$ reduction

These results are consistent with the higher disease risk for viruses relative to other enteric pathogens generally obtained when a Quantitative Microbial Risk Assessment (QMRA) is performed for different classes of pathogens (De Keuckelarre *et al.*, 2015).

According to the multiple-barrier approach included in the risk management framework, these $\log_{10}$ reductions can be obtained using several water treatment options alone or in combination with other non-treatment options (e.g. type of crop to be irrigated, irrigation method, post-harvest processing).

These $\log_{10}$ reductions are then applied as $\log_{10}$ reductions of the microbiological indicators selected for each reference pathogen (*E. coli*, F-specific bacteriophages and *Clostridium perfringens* spores) for monitoring purposes. The justification for the selection of these indicators is in Section 4.4.5.

4.4.5 Microbiological parameters for monitoring

The justification for the microbiological parameters selected for monitoring purposes is presented below, for each group of microorganisms (bacteria, viruses and protozoa):

Bacteria: *Escherichia coli* (*E. coli*) and *Legionella* spp.

E. coli is the most suitable indicator of faecal contamination, and it is a traditional bacterial indicator for monitoring purposes in water treatment. Although some guidelines and regulations utilize thermotolerant (faecal) or total coliforms as bacterial indicators for agricultural irrigation (WHO, 2006; USEPA, 2012; CDPH, 2014), *E. coli* is considered more specific of fecal contamination and reflects better the behaviour of the pathogenic enteric bacteria (Ashbolt *et al.*, 2001; NRMMC–EPHC–AHMC, 2006). *E. coli* is the first organism of choice in monitoring programmes including surveillance of drinking-water quality (WHO, 2011), as well as the most commonly used bacterial indicator in national water reuse legislations of MS (JRC, 2014). In addition, *E. coli* is considered an appropriate indicator for the presence/absence of *Campylobacter* in drinking water systems (WHO, 2016). The ISO guidelines establish that *E. coli* and thermotolerant coliforms can be both used for water quality monitoring as the difference in values is not considered significant (ISO 16075, 2015).

Legionella spp. is selected as bacterial parameter following the ISO recommendations (ISO 16075, 2015). *Legionella pneumophila* is a non-conventional opportunistic waterborne pathogen, as it is not transmitted orally. Transmission is through mechanical means, which generate aerosols including sprinklers. *Legionella pneumophila* is on the USEPA Candidate Contaminant List for drinking water purposes as an important pathogen. It is commonly encountered in freshwater environments and in wastewater and there is a potential of growth in distribution systems of reclaimed water in warm climates where suitable temperatures and conditions for their multiplication may be provided (Jjemba *et al.*, 2015). No legionellosis outbreak has been linked to reclaimed water yet, but it is recommended as a reference pathogen for pathogens able to grow in water distribution systems in the revision of Annex I of the Directive 98/83/EC on the quality of water intended for human consumption performed by the WHO (WHO, 2016), although no recommendations for monitoring are made. The ISO guidelines recommend monitoring of *Legionella* spp. only for green houses irrigation with risk of aerosolization (ISO 16075, 2015). *Legionella* spp. is only recommended for monitoring of agricultural irrigation practices in the Spanish regulations, and only when there is risk of aerosolization.

Viruses: Total coliphages/F-specific coliphages/somatic coliphages

Generally, viruses are more resistant to environmental conditions and treatment technologies, including filtration and disinfection, than bacteria (WHO, 2011). Therefore, due to the limitations of bacterial indicators, there has been significant research into determining a viral indicator that may be adopted for water quality monitoring. Two groups of bacteriophages that infect *E. coli*, somatic coliphages and F-specific coliphages, are the major groups that have been used as viral indicators of pathogenic viruses for many years, as they share many properties with human viruses, notably composition, morphology, structure and mode of replication (AWPRC, 1991; Armon et Kott, 1996; Grabow, 2001, Jofre, 2007). Furthermore, regulatory authorities in different parts of the world are beginning to consider coliphages as viral indicators concerning reclaimed water (QEPA, 2005; NCDENC, 2011), biosolids used in agriculture (DEC, 2011) and groundwater (USEPA, 2006).

However, issues such as their potential replication in natural water environments, the cumbersome detection and enumeration methods, a lack of definition concerning which of the two groups should be included in future regulations, and the lack of a clear correlation between coliphages and human viruses and health risks in different water settings remain controversial. Jofre *et al.* (2016) is a recent review article that attempts to shed some light on these contentious issues.

The conclusions of this review article are that: supposing that they can replicate in some natural water settings, the contribution of coliphages replicated outside the gut will not affect the numbers contributed by fecal pollution and detected by strains recommended for standardized methods; there are easy, fast, and cost-effective methods that can be used in routine laboratories after a little training (Méndez *et al.*, 2002); the low correlation of coliphages with human viruses and health risks is no worse than the correlation between different human viruses; perhaps the best option is to determine both groups in a single step. A general conclusion is that coliphages are likely to be better indicators of viruses than the current bacterial indicators (i.e. *E. coli* and enterococci).

In general, somatic coliphages outnumber F-specific coliphages. However, regarding reclaimed water, F-specific coliphages have been observed to be more resistant than somatic coliphages to UV radiation, thus F-specific coliphages surpassing numbers of somatic coliphages. This trend is also observed in clayey sediments, and groundwater from certain aquifers (Jofre *et al.*, 2016).

Coliphages (i.e. somatic coliphages) are recommended for monitoring of high-exposure water reuse schemes in the Australian guidelines, and the WHO guidelines stay that, under certain circumstances, bacteriophages may be included for monitoring to overcome *E. coli* limitations as indicator (NRMMC–EPHC–AHMC, 2006; WHO, 2006).

The USEPA guidelines recognize that alternative indicators to *E. coli* may be adopted in the future for water quality monitoring (e.g. bacteriophages), but they do not include any specific viral indicator in their recommendations (USEPA, 2012). However, regarding indirect potable reuse for surface spreading or direct injection, the USEPA guidelines state that $\log_{10}$ removal credits for viruses can be based on challenge tests (spiking) or the sum of log_{10} removal credits allowed for individual treatment processes, although monitoring for viruses is not required.

California regulations include F-specific bacteriophages as a performance target (99.999% removal/inactivation from raw wastewater) for food crops irrigation (CDPH, 2014). In addition, US state regulations of North Carolina adopt coliphages as water quality target for irrigation of food crops not processed (USEPA, 2012).

MS regulations for agricultural irrigation do not include coliphages, or any viral indicator, for monitoring, with the exception of the French regulation that includes F-RNA coliphages as performance target for validation monitoring in agricultural irrigation (JRC, 2014).

Due to the different characteristics and behaviour of F-specific coliphages and somatic coliphages, it is recommended the use of total coliphages as viral indicators. However, if this is not feasible, at least one of them must be analyzed.

Protozoa: *Clostridium perfringens* spores/spore-forming sulfate-reducing bacteria

Giardia cysts and *Cryptosporidium* oocysts have been found in reclaimed water (Huffman *et al.*, 2006; USEPA, 2012). This triggered considerable concern regarding the occurrence and significance of *Giardia* and *Cryptosporidium* in water reuse schemes.

E. coli is more readily removed by disinfection methods than protozoa, which are mainly removed by filtration systems. Protozoa also survive longer than bacteria in groundwater. *Clostridium perfringens* spores and spore-forming sulfate-reducing bacteria have been suggested as indicators of protozoan removal and effectiveness of filtration processes. *Clostridium perfringens* spores have an exceptional resistance to disinfection processes and other unfavourable environmental conditions, its spores are smaller than protozoan (oo) cysts, and hence more difficult to remove by physical processes (NRMMC–EPHC–AHMC, 2006; WHO, 2006; WHO, 2011).

Protozoan indicators (i.e. *Clostridium perfringens* spores) are recommended for monitoring of high-exposure water reuse schemes in the Australian guidelines, and the WHO guidelines state that, under certain circumstances, additional indicators *to E. coli* may be included for monitoring (NRMMC–EPHC–AHMC, 2006; WHO, 2006). The DWD and also the draft from the WHO on the revision of Annex I of the DWD include *Clostridium perfringens* spores monitoring for treatment control for disinfection-resistant pathogens such as *Cryptosporidium* (WHO, 2016).

The USEPA guidelines do not include any specific protozoan indicator in their recommendations (USEPA, 2012). As regards of aquifer recharge for potable uses (indirect potable reuse) using surface spreading or direct injection, the USEPA guidelines state that log_{10} removal credits for *Giardia* and *Cryptosporidium* can be based on challenge tests (spiking) or the sum of log_{10} removal credits allowed for individual treatment processes, although monitoring for these pathogens is not required (USEPA, 2012).

State regulations of North Carolina have specific water quality limits for *Clostridium* for non-processed food crops, and Florida requires monitoring of *Giardia* and *Cryptosporidium* for food crops irrigation (USEPA, 2012).

MS regulations for agricultural irrigation do not include protozoan indicator for monitoring, with the exception of the French regulation that requests monitoring of spores of sulphite-reducing bacteria as performance target for validation in agricultural irrigation, but this indicator was selected because it was more abundant in wastewater than spores of *Clostridium* (JRC, 2014).

It is recommended to use *Clostridium perfringens* spores as indicator, although spore-forming sulfate-reducing bacteria may be an alternative if the concentration of *Clostridium perfringens* spores does not allow to validate the requested log_{10} removal.

Helminth eggs, intestinal nematodes specifically, are selected to be monitored when reclaimed water is used to irrigate crops to feed livestock in order to control animal health risks. These pathogens are included in Table 2, and the associated justification is shown in Section 4.4.6.

4.4.6 Water quality criteria

The *E. coli* concentrations to be complied with by the reclaimed water effluent for monitoring (Table 2) are established considering the concentration of *E. coli* present in raw wastewater and the log_{10} reduction to be achieved by the microbiological indicator, taking into account the log_{10} reductions to be achieved by the treatment train and by the type of crop to be irrigated, and the reduction achieved by applying different irrigation systems and withholding periods (Table 2). The log_{10} reductions effectiveness of this barriers is established by several guidelines (NRMMC–EPHC–AHMC, 2006; WHO, 2006; USEPA, 2012; ISO 16075, 2015).

Class A has been defined to be able to be applied on the highest health risks which consist on irrigation of crops eaten raw when reclaimed water comes into direct contact with edible parts of the crop, and irrigation of root crops (WHO, 2006). This worst-case scenario only considers the treatment technologies in place as a preventive measure (barrier). Thus, the natural pathogen die-off on crop surfaces that may be from 0.5 to 2 log_{10} unit reduction per day (NRMMC–EPHC–AHMC, 2006; WHO, 2006) is not considered, as this reduction depends on several variables like type of pathogen, climate conditions (i.e. temperature, sunlight intensity, humidity), time interval, and type of crop.

The reduction of 1 log_{10} unit that may be achieved when crops are washed with clean water has not been taken into account to define the water quality targets in this document as this is a process that cannot be controlled by the responsible managers.

Class B, C and D consider the characteristics of the type of crop to be irrigated as a barrier, and also the possibility of using irrigation methods that provide exposure reductions, thus allowing the use of less stringent water quality targets.

The irrigation of pastures and fodder crops with reclaimed water may potentially pose a risk to the health of both livestock and humans through the consumption of animal products. The "species barrier" means that many human pathogens, including human enteric viruses, are not of significant concern for livestock health and, in addition, reduction of bacteria, viruses and protozoa includes also reduction of pathogens for livestock. However, pathogens like helminth parasites eggs such as those of *Taenia saginata* and *Taenia solium* may be present in raw wastewater, especially if slaughterhouses wastewater is present in the urban wastewater treatment plant, although this type of wastewater usually undergoes a treatment before arriving to a WWTP.

A limitation in approaching the livestock health risks associated with reclaimed water is that virtually no dose-response models are available for infection in animals, therefore, water quality targets cannot be derived using a QMRA. Therefore, a practical approach has been proposed following recommendations from the Australian guidelines (NRMMC–EPHC–AHMC, 2006).

The control of *Taenia saginata* in reclaimed water that is to be used in contact with livestock has previously been prescribed through either 25 days of hydraulic retention time in waste stabilization ponds or equivalent treatment (NHMRC and ARMCANZ, 2000). This has been effective management of the risk posed by *T. saginata*. However, there is no guidance on what constitutes an "equivalent treatment". Using the empirical model described by Ayres *et al.* (1992), relating the percentage removal of helminth eggs with detention time in days, a mean hydraulic retention time of 25 days is equal to approximately 4 log_{10} reduction of helminth eggs. This is the target that alternative treatment processes to stabilization ponds should meet if *Taenia saginata* requires specific management. The concentration of helminth eggs in raw wastewater is in a range of 0 to 10^4 eggs per litre, therefore a limit values of 1 egg/l is selected to be achieved when reclaimed water is used to irrigate pastures or fodder crops. This limit value is also recommended by the WHO to protect human health, considering epidemiological data as there is not sufficient data available to perform a QMRA. In addition, when health risks for livestock were evaluated in a recent study, using reclaimed water for irrigation that complied with the WHO recommendations for water quality none of the animals showed signs of infection or of disease (Bevilacqua *et al.*, 2014). There was also no evidence to suggest any resulting health risk to humans from the consumption of milk from animals fed with reclaimed-water-irrigated forage crops.

This limit value is similar to the value recommended by the ISO standards and is in agreement with the Spanish regulation that includes the same limit values for *Taenia saginata* and *Taenia solium* when milk- or meat-producing animals are to be fed with pastures irrigated with reclaimed water.

Taenia solium ova can infect pigs, causing cysticercus, which may result in human infection with the pig tapeworm if undercooked meat is consumed. *T. solium* infection can cause a severe neurological disease in humans (neurocysticercosis), therefore it has been recommended in Australian guidelines a prohibition of use of reclaimed water for pig fodder due to the severity of the disease, unless there is sufficient data to indicate the risks for a specific case can be managed (NRMMC–EPHC–AHMC, 2006).

The use of reclaimed water can potentially contaminate milk and pose risk to human health when used for dairy cattle. Therefore, a withholding period should be implemented for lactating dairy cattle when pastures are irrigated with reclaimed water (NRMMC–EPHC–AHMC, 2006).

Dermal exposure to microorganisms is also possible, but there is a lack of evidence of health impacts through this route and it is considered unlikely to cause significant levels of infection or illness in the normal population (NRMMC–EPHC–AHMC, 2006). Accidental ingestion of soil particles by agricultural workers or children is a route of exposure that has been considered to be under the tolerable risk applying the WHO limit values recommended, thus for a more stringent values the risk should be also defined as tolerable (WHO, 2006; Mara *et al.*, 2007).

The limit values for *E. coli* are in line with the values established by the ISO guidelines for water reuse in irrigation, which are based on the WHO and USEPA guidelines (ISO 16075, 2015). MS regulations present differences regarding the *E. coli* limit value, and only the Spanish regulation is similar.

Validation monitoring (Table 5) is required only for the most stringent reclaimed water quality criteria, Class A, as this class allows irrigation of food crops consumed raw with edible parts in contact with reclaimed water (using sprinkler irrigation), and without relying on the pathogen die-off due to time interval between last irrigation and harvesting, which is the highest exposure risk scenario. The California regulations also include a $\log_{10}$ reduction to be complied with by F-specific coliphages for irrigation of food crops eaten raw when reclaimed water comes into contact with edible parts of the crop (CDPH, 2014).

The frequencies for water quality criteria monitoring are based on the monitoring frequencies for similar quality classes recommended by Australian guidelines and are also in line with the monitoring frequencies recommended by the ISO guidelines. However, it has to be noted that the ISO guidelines recommend a range of frequencies, stating that the monitoring programme should be adapted to local conditions. MS regulations that apply similar requirements have similar monitoring frequencies (e.g. Spain).

Health outcome targets are based on a defined tolerable burden of disease or level of risk that is considered acceptable. Disability Adjusted Life Years (DALYs) are a measure of burden of disease that is used mainly for microbiological hazards. For chemical hazards, the health outcome target is based on no-observed-adverse-effect levels derived from international chemical risk assessments. Although the application of DALYs to chemical parameters is likely to expand, however, unlike pathogens, there are insufficient data to develop DALYs for most chemical hazards, thus expressing health-based targets for chemical hazards using the DALYs approach has been limited in practice (WHO, 2011).

Regarding chemical compounds in wastewater, the document considers that wastewater from UWWTP that comply with the Directive 91/271/EEC. Therefore, wastewater from industries not included in the UWWTD are not considered. This limits the potential concentration of toxic chemicals in reclaimed water. The evidence of direct health impacts from chemical compounds associated with water reuse in agriculture is very limited (WHO, 2006) probably due to the nature of chemical toxicity. The concentrations of most chemicals in reclaimed water or reclaimed water irrigated products will almost never be high enough to result in acute health effects. Chronic health effects that may be associated with exposure to chemicals (e.g. cancer) usually occur only after many years of exposure and may also result from a variety of other exposures not related to the agricultural use of reclaimed water (WHO, 2006). The use of reclaimed water for irrigation may introduce toxic chemical compounds into soils, and pollutants accumulated in the soils may subsequently be uptaken by crops and pose health risks to humans and animals. A major health concern is due to metals as they can be found in any municipal wastewater effluent. Many of them are biologically beneficial in small quantities but become harmful at high levels of exposure. Plant uptake of heavy metals is highly dependent on soil conditions. Cobalt, copper, and zinc are not likely to be absorbed by irrigated crops in sufficient quantities to prove harmful to consumers and are toxic to plants far before reaching a content that is toxic to humans. However, there WHO guidelines recommend a maximum concentration limit for hexavalent chromium, because it is rapidly reduced to trivalent chromium, which forms a less soluble solid phase in wastewater or soils. Cadmium is the metal that causes the largest risk. Its uptake can increase with time, depending on soil concentration, and is toxic to humans and animals in doses much lower than those that visibly affect plants (WHO, 2006).

Specific considerations on health risks from compounds of emerging concern (CECs) are shown in Section 6.

4.4.7 Physico-chemical parameters for monitoring

The justification for the physico-chemical parameters selected for monitoring purposes is presented below:

Biochemical Oxygen Demand (BOD_5): this parameter acts as an indication of biological treatment effectiveness and indirect potential for bacterial regrowth in distribution systems. BOD_5 can be considered a surrogate for performance related to pathogen reduction (NRMMC–EPHC–AHMC, 2006).

BOD_5 appears in the Australian and USEPA guidelines for agricultural irrigation, as well as in other guidelines (NRMMC–EPHC–AHMC, 2006; USEPA, 2012; ISO 16075, 2015). Some MS include BOD_5 in their water reuse legislations for agricultural irrigation (Cyprus, Greece and Italy).

Total suspended solids (TSS): this parameter indicates effectiveness of sedimentation and it is also related with filtration and disinfection efficacy. The removal of suspended matter is linked to pathogen removal, as many pathogens are particulate-associated, and both bacteria and viruses can be shielded from disinfectants such as chlorine and UV. Furthermore, materials in suspension are listed as pollutants which input has to be limited in Annex VIII of the WFD.

TSS is included in the USEPA guidelines for monitoring of processed food crops and non-food crops irrigation (USEPA, 2012). The Australian guidelines follow a similar pattern (NRMMC–EPHC–AHMC, 2006). The ISO guidelines include TSS for agricultural irrigation monitoring (ISO 16075, 2015).

MS regulations include TSS for agricultural irrigation (JRC, 2014).

Turbidity: it is a traditionally used parameter to indicate filtration effectiveness and suitability for disinfection, and can be a surrogate for protozoa removal, and viruses. Turbidity is an important factor both as parameter reflecting the potential of breakthrough of small particles, including pathogens, and because particulate matter in water may shield pathogens from disinfectants, rendering disinfection less effective.

Turbidity appears in the USEPA guidelines for food crops eaten raw and aquifer recharge, similarly to the Australian guidelines (NRMMC–EPHC–AHMC, 2006; USEPA, 2012). The ISO guidelines include turbidity for irrigation of food crops eaten raw (ISO 16075, 2015). Turbidity is included in the Greek and Spanish water reuse legislations for specific categories of use for agricultural irrigation.

Monitoring of these parameters is compulsory in order to control environmental risks to soils, plants, surface waters and groundwaters associated with reclaimed water use for agricultural irrigation (e.g. salinity, phytoxicity).

Agronomic parameters are included in all guidelines for water reuse (WHO, 2006; NRMMC–EPHC–AHMC, 2006; USEPA, 2012; ISO 16075, 2015) and also in water reuse regulations from MS. The specific agronomic parameters and the associated limit values comprised in guidelines and regulations are adapted from the recommendations made by the Food and Agriculture Organization of the United Nations (FAO) (FAO, 1985). The FAO recommendations are a worldwide reference document that provides a guide to making an initial assessment of agronomic parameters for application of reclaimed water in agriculture. They emphasize the long-term influence of water quality on crop production, soil properties and farm management.

However, almost all water reuse guidelines and regulations have applied some modifications to the FAO recommendations due to their basic assumptions and comments and the number of variables that are site specific when establishing agronomic parameters and values (e.g. soil characteristics, climate conditions, crop variety, cultivation practices like the irrigation method and the hydraulic loading).

MS have to specify minimum quality requirements on a case-by-case basis taking into account site specific conditions, to be complied with by reclaimed water effluent and to be included for monitoring.

Physico-chemical parameters from related EU Directives, some of them included also in the FAO guidelines, are to be complied with by the reclaimed water effluent. As regards MS legislations, the Spanish water reuse legislation states that the use of reclaimed water for agricultural irrigation must respect the EQSD, and the Italian legislation includes some organic contaminants for monitoring in reclaimed water. The Greek regulation for water reuse includes a list of the priority substances from the EQSD, with some modifications, that has to be complied with for reclaimed water quality for all categories of use.

According to the qualitative and quantitative environmental risk assessments described in several guidelines (FAO, 1985; NRMMC–EPHC–AHMC, 2006; WHO, 2006; USEPA, 2012; ISO 16075, 2015), and the experience gathered by MS on agricultural irrigation with reclaimed water, there are key environmental hazards associated to environmental risks that are identified (mostly agronomic adverse impacts), which are salinization, sodicity, toxicity, and nutrient imbalance.

Salinization of soils irrigated with reclaimed water is one of the most important risks. The presence of soluble salts in reclaimed water may lead to accumulation of salts in soils (especially in dry climates), the release of cadmium from soils due to increased chlorine content, reduced rates of plant growth and productivity, water stress due to plants' susceptibility to osmotic effects, changes in native vegetation, groundwater salinization affecting dependent ecosystems, and increased salinity in surface water aquatic systems.

A high proportion of sodium (Na^+) ions relative to calcium (Ca^{2+}) and magnesium (Mg^{2+}) ions in soil or water (sodicity) could degrade soil structure by breaking down clay aggregates, which makes the soil more erodible, causing surface sealing and preventing the movement of water (permeability) and air (anoxia) through the soil, thus reducing plant growth.

The effect of specific toxicity of certain ions to plants (e.g. chloride, boron, sodium, and some trace elements) may lead to reduced crop yields. Some ions may prejudice the microbial activity of the soil, and aquatic biota. In addition, heavy metals and other toxic compounds present in reclaimed water can accumulate in soils or/and in crops, and may reach groundwater or surface water bodies causing their deterioration.

Unbalanced supply of nutrients may result in crop deficiencies and toxicities. Macronutrients like nitrogen, phosphorus and potassium in reclaimed water may be higher than the needs of the crop, or not supplied at an optimal rate for the crop. Excess of nutrients may lead to groundwater deterioration, and surface waters eutrophication.

The limit values for BOD_5, TSS and turbidity established for Class A are based on the ISO guidelines as the most stringent class. This is in line with the water reuse guidelines and MS regulations that apply BOD_5 and TSS values usually in the range of the requirements of the UWWTD, with more stringent requirements only for some uses, like irrigation of food crops eaten raw (NRMMC-EPHC-AHMC, 2006; USEPA, 2012; JRC, 2014). Frequencies defined for all classes are based on Australian and ISO guidelines recommendations.

5 Management of health and environmental risks for water reuse in aquifer recharge

This section includes the definition of the requirements to manage health and environmental risks when reclaimed water is used IN aquifer recharge, following a risk management approach, and the associated justification.

Regarding the source of wastewater to be reclaimed, as a minimum requirement, it has to be stressed that, as for agricultural irrigation, the Directive 91/271/EEC (UWWTD) that concerns the collection, treatment and discharge of urban wastewater, establishes quality requirements that have to be satisfied by discharges from urban wastewater treatment plants (UWWTP) including also specific requirements for discharges in sensitive areas (Annex I of UWWTD). Water from wastewater treatment plants destined for reuse is considered a discharge under the UWWTD at the point where it leaves the water treatment plant (after treatment) (EC, 2016). Therefore, as the only source of wastewater considered in this document is the wastewater covered by the UWWTD, all treated wastewater potentially considered for reclamation and reuse (i.e. wastewater coming from an UWWTP) has to comply, **at least**, with the quality requirements specified in the UWWTD Annex I, table 1 and, when applicable, with the requirements from Annex I, table 2 for sensitive areas.

In order to assure that wastewater that enter a UWWTP is included in the Annex III of the Directive 91/271/EEC, thus, it is necessary to establish source control programs and oversight of industrial and commercial discharges to the sewer systems connected to a wastewater treatment plant.

5.1 Aquifer recharge uses

Aquifer recharge refers, in the present document, to managed aquifer recharge, leaving incidental aquifer recharge out of the scope of this document.

There is no definition at EU level of managed aquifer recharge (MAR), thus, a common definition of MAR at EU level is needed. In this regard, the definition considered is the one included in the Australian Guidelines for Water Recycling: Managed Aquifer Recharge (NRMMC–EPHC–NHMRC 2009). Managed aquifer recharge (MAR) is defined as the intentional recharge of water (reclaimed water in this document) to aquifers for subsequent recovery or environmental benefit.

Although the WFD provides a definition for "aquifer" that applies to this document, the difficulties in physically delimiting an aquifer, especially in the case of fractured karstic subsoil should be acknowledged.

The purposes for managed aquifer recharge considered in this document are the following:

— Establish saltwater intrusion barriers in coastal aquifers.

— Provide storage for the recharged water for subsequent retrieval and reuse.

— Maintain groundwater dependent terrestrial and aquatic ecosystems.

— Dilute saline or polluted aquifers.

— Control or prevent ground subsidence.

All types of aquifers are contemplated in this document for potentially being recharged with reclaimed water. This document considers that all freshwater aquifers are potentially exploitable as potable water source. Furthermore, different aquifers may be connected, especially in karstic areas. Therefore, the present document doesn't differentiate quality requirements according to the present or future use of the aquifer but only according to its present quality and environmental objective under the WFD.

It is to be noted that the present document includes indirect potable reuse as a potential use of managed aquifer recharge. However, this document does not intend to promote water reuse for direct drinking water purposes.

All existing recharge methods for managed aquifer recharge are allowed when using reclaimed water. Recharge methods can be grouped in two main categories: surface spreading and direct injection (NRMMC-EPHC–NHMRC, 2009; USEPA, 2012; CDPH, 2014). MS water reuse regulations that include aquifer recharge with reclaimed water apply this distinction between surface spreading and direct injection (JRC, 2014).

Surface spreading is a method of recharge whereby the water moves from the land surface to the aquifer by infiltration and percolation through the vadose zone (Regnery *et al.*, 2013). Direct injection recharge is achieved when water is pumped directly into the groundwater zone (i.e. saturated zone), usually into a well-confined aquifer (USEPA, 2012).

Article 11.3(j) of the WFD includes a 'prohibition of direct discharges of pollutants into groundwater' as a basic measure. Water reuse schemes, therefore, should be designed so as not to allow direct discharges of pollutants into groundwater. This prohibition should be seen as complementary to the above mentioned controls imposed by Article 11.3(f) and the requirements of Article 6 of the Groundwater Directive. It follows that reuse of treated wastewater for recharge of aquifers can contribute to the achievement of WFD objectives, as long as the water is of sufficient quality. It follows that neither the WFD nor the GWD excludes, in principle, a direct injection of treated wastewater for managed aquifer recharge which is permitted in accordance with Article 11.3(f) of the WFD.

5.2 Risk management framework for managed aquifer recharge

MS have to apply the elements of a risk management framework described in Section 4.2 to manage health and environmental risks derived from the use of reclaimed water for managed aquifer recharge.

The required reclaimed water quality criteria for managed aquifer recharge has to be defined on a case-by-case basis because it is considered site specific. As stated above, quality requirements, for managed aquifer recharge are only differentiated, in this document, according to the existing groundwater quality and the environmental objectives under the WFD. Therefore, a site-by-site approach is necessary. In addition, due to the range of aquifer characteristics that come into play, it is difficult to use performance at one aquifer recharge site to predict performance at another.

Groundwater protection is the overarching aspect when aquifer recharge is performed. In this regard, the Directive 2006/118/EC amended by Directive 2014/80/EU (Groundwater Directive (GWD)) complements the WFD and the objective of the GWD is to protect groundwater against pollution and deterioration through the establishment of specific measures to prevent and control groundwater pollution. MS must assure that the quality of reclaimed water for managed aquifer recharge does not compromise the objectives of the GWD and related Directives. MS have to establish, if necessary, minimum quality requirements for the parameters included in the related EU directives on a case-by-case basis to be complied with by the reclaimed water effluent and to be included for reclaimed water criteria in the verification monitoring.

An aquifer characterization has to be performed following the requirements established in the GWD in accordance with Article 5 of the WFD. Advanced modelling tools are advised to be used. Guidance documents and technical reports have been produced by the Common Implementation Strategy (CIS) of the WFD to assist MS to implement the WFD, and some of them are tools to support aquifer characterisation as they provide guidance on, for instance, establishing groundwater monitoring programmes for status and trend assessment (EC, 2007a; EC, 2007b; EC, 2009). Guidance documents are intended to provide an overall methodological approach, but these will need to be tailored to specific conditions of each case. Furthermore, the Environmental Impact Assessment Directive (2014/52/EU) (amending Directive 2011/92/EU) requires that managed aquifer recharge schemes where the annual volume of water recharged is equivalent to or exceeds 10 million m^3 have to undergo an environmental impact assessment.

Considering the risks from chemical substances, the GWD (Article 6) demands establishment of measures to prevent or limit inputs of pollutants into groundwater. These measures have to prevent inputs of any hazardous substances, in particular taking into account hazardous substances belonging to the families or groups of pollutants referred to in points 1 to 9 of Annex VIII of the WFD, where these are considered to be hazardous (including priority hazardous substances of the EQSD). The measures also have to limit inputs of pollutants from Annex VIII of the WFD which are not considered hazardous and any other non-hazardous substances not listed in Annex VIII considered to present an existing or potential risk of pollution, so as to ensure that such inputs do not cause deterioration or significant and sustained upward trend in the concentration of pollutants in groundwater. According to the GWD (amended by Directive 2014/80/EU) MS have to establish threshold values for groundwater pollutants and indicators of pollution on a national, river basin district or other appropriate level having regard dependent ecosystems and regional or even local conditions.

Besides the parameters of the GWD, additional hazards may also affect groundwater, and dependent ecosystems according to the potential hazards of the wastewater effluent to be treated for reuse and site specific conditions. In addition, when surface spreading is used as a recharge method, MS have to avoid adverse effects to the soil and related dependent ecosystems where reclaimed water is spread. Therefore, following an environmental risk assessment, MS have to establish, if necessary, minimum quality requirements for additional parameters not included in the GWD to be complied with by the reclaimed water effluent and to be included in the reclaimed water quality criteria in order to avoid adverse effects on groundwater and soils and related dependent ecosystems.

MS have to implement monitoring programs of the environmental matrices at risk to control the effect of managed aquifer recharge with reclaimed water irrigation as part of the verification monitoring. A monitoring program has to be established, on a case-by-case basis, according to the identified risks.

Considering risks from health hazards (i.e. pathogens) these have to be prevented or limited from entering the aquifer considering the existing groundwater quality following the principle of no deterioration. No additional treatment has to be applied to the recovered water to comply with the water quality required for the intended use compare to the groundwater quality before recharge. Since the indirect potable use is always to be considered, a Quantitative Microbial Risk Assessment (QMRA) is always needed.

When establishing reclaimed water quality parameters for managed aquifer recharge, it has to be considered the recharge method. Managed aquifer recharge by surface spreading will provide added benefits to reclaimed water quality that direct injection is unable to, due to the natural attenuation capacity of the **vadose zone**. Surface spreading makes reclaimed water to pass through the vadose zone (i.e. unsaturated zone), hence allowing mechanisms that may result in attenuation or degradation of substances and microorganisms content, as filtration, adsorption, precipitation, volatilisation, biodegradation, and microbial assimilation to take place (Van Houtte and Verbauwhede, 2008, NRMMC-EPHC–NHMRC, 2009). The GWD states that processes in the vadose zone that result in attenuation or degradation of substances may be taken into account when considering measures to prevent or limit input into groundwater. It also indicates that the natural attenuation capacity of the unsaturated zone may be taken into account when defining measures for both the *preventing* and *limiting* objective. For *limiting* even processes taking place in the saturated zone may be considered.

MS must assess the removal capacity of the vadose zone, on a case-by-case basis, in order to establish less stringent reclaimed water quality requirements for managed aquifer recharge by surface spreading, if applicable. However, as stated above, the adverse effects on soils and dependent ecosystems over the time have to be assess.

Removals in aquifers are primarily related to the residence time of the recharge water, the activity of the indigenous groundwater microorganisms, the redox state of the aquifer, and the temperature. Residence time in the aquifer induce an attenuation of human pathogens and selected organic chemicals. MS have to evaluate the variables that may contribute to the removal of hazards. However, there are considerable challenges in validating and continually demonstrating the attenuation of pathogens in aquifers. The scientific literature demonstrating the removal of pathogens in managed aquifer recharge is limited, only a few pathogens have been studied, and in many cases these are not the worst-case target pathogen (NRMMC-EPHC–NHMRC, 2009; USEPA, 2012).

Reclaimed water must comply with the quality criteria established by MS at the outlet of the treatment plant.

Analytical methods used for monitoring shall comply with the requirements included in the related Directives (i.e. WFD (2000/60/EC), DWD (98/83/EC), GWD (2006/118/EC) to conform to the quality control principles, including, if relevant, ISO/CEN or national standardized methods, to ensure the provision of data of an equivalent scientific quality and comparability.

MS may use the Australian guidelines for managed aquifer recharge (NRMMC-EPHC–NHMRC, 2009) as a guidance to assess and manage environmental risks for managed aquifer recharge, as the risk management framework is applied in that guidelines.

Following the same approach as for agricultural irrigation, MS have to develop an operational monitoring protocol to assess and confirm that the performance of preventive measures of the water reuse system ensures reclaimed water of an appropriate quality to be consistently provided. Examples of operational monitoring requirements for the preventive measure of wastewater treatment processes are shown in Table 1 and are described in the Australian guidelines for managed aquifer recharge (NRMMC-EPHC–NHMRC, 2009).

5.3 Justification for the selected requirements

The case-by case approach selected for managed aquifer recharge quality requirements is recommended by the Australian guidelines for managed aquifer recharge (NRMMC-EPHC–NHMRC, 2009), the USEPA guidelines (USEPA, 2012) and the California regulations (CDPH, 2014). The USEPA guidelines and the California regulations establish specific quality requirements for indirect potable reuse through managed aquifer recharge, similar to drinking water quality requirements, as they differentiate between potable and non-potable aquifers.

The GWD is the EU Directive most directly related to managed aquifer recharge. Considering the hazards potentially present in wastewater, microbiological and chemical hazards, a risk assessment is to be performed to assess additional hazards not contemplated in the GWD that may represent a health or environmental risk. This is also in line with guidelines and regulations that include managed aquifer recharge with reclaimed water as site specific for managing risks (NRMMC-EPHC–NHMRC, 2009; USEPA, 2012; CDPH, 2014).

This situation of a highly site-specific framework of boundary conditions to be considered for aquifers makes it very challenging to establish EU-wide parametric values to be implemented.

6 Compounds of emerging concern

This section addresses the subject of the compounds of emerging concern related to the use of reclaimed water for agricultural irrigation and aquifer recharge.

6.1 Knowledge and gaps

With the advance of analytical techniques a number of chemical compounds, which are not commonly regulated, have been detected in drinking water, wastewater, or the aquatic environment, generally at very low levels. This broad and growing group of chemicals is termed Compounds of Emerging Concern (CECs) (or sometimes in a misleading way emerging pollutants). The concern is due to either a knowledge gap about the relationship of the substances' concentrations and possible (eco)toxicological effects – usually due to chronic exposure, or the lack of understanding how such substances interact as chemical mixture. CECs are not necessarily new compounds and might have been present in the environment for a longer time, while their presence and significance are only recognised now. While the Water Framework Directive addresses the issue through a process of structured prioritization, no precises relationship is established between the occurrences and levels of CECs in (treated) wastewater and the acceptable level in the aquatic environment.

CECs include groups of compounds categorized usually by end use (e.g. pharmaceuticals, non-prescription drugs, personal care products, household chemicals, food additives, flame retardants, plasticizers, disinfection-by-products, and biocides), by environmental and human health effects (e.g. hormonally active agents, endocrine disrupting compounds [EDCs]), or by type of compound (e.g. chemical vs. microbiological, antibiotic resistance gens, phenolic vs. polycyclic aromatic hydrocarbons), as well as transformation products resulting from various biotic and abiotic processes, and mixtures of chemicals (WHO, 2011; USEPA, 2012).

It is commonly accepted that today a frequent monitoring for every potential chemical substance is neither feasible nor plausible. Research is focusing on the development of a science-based framework to guide the identification of CECs that should be monitored or otherwise regulated, including the context of reclaimed water use, especially for potable use (Drewes *et al.*, 2013). A sound selection framework is needed that can provide a short list of meaningful indicator measurements that can address both human health relevance and assurance of proper performance of water treatment processes in addition to routine monitoring for compliance with guidelines and/or regulations.

As presented by Paranychianakis *et al.* (2014) in a review paper, a few studies have shown that the uptake, translocation and the accumulation of a wide range of emerging chemicals in crop tissues is in overall low and does not pose significant risks for public health. Moreover, plants possess metabolic pathways that might transform and degrade organic pollutants further decreasing the potential risks.The health risks resulting from the ingestion of food exposed to 22 chemicals revealed a safety margin greater than 100 for all the substances identified in the irrigation water, except gemfibrozil. The risks related to the direct use of pesticides applied to crops appear to be of greater importance. Paranychianakis *et al.*, 2014 continues hence that the concern regarding CECs focuses on potable reuse applications. Considering the wide diversity of organic chemical structure, some are relatively easy to attenuate, while others are more recalcitrant (Paranychianakis *et al.*, 2014). Aquifer recharge through infiltration can be highly effective in the removal of many contaminants, though some can persist into the underlying groundwater (Laws *et al.*, 2011).

While a broad range of publications have investigated the occurrence of CECs, the role of CECs in agricultural systems is poor, reason for which the Organisation for Economic Cooperation and Development (OECD) investigated the issue through a high-level expert team (OECD, 2012). The report carefully assesses the state-of-the-art and identifies and suggests measures for risk mitigation. It is noteworthy that the report does not identify or mention the use of treated wastewater for agricultural irrigation as a significant entry pathway. However, it also states that it is possible that important pathways would have been overlooked and identifies a list of priority actions to fill knowledge gaps.

Among, these the lack of long-term exposure data to trace organics constrains the accurate quantification of the health risks (Paranychianakis *et al.*, 2014). The available data show great temporal and spatial variations in the concentration of organics as a result of the source concentrations and treatment processes.

It should be noted that the existing data are not sufficient to set ecological limits for most organics. Critical information is required for many disciplines to obtain a better understanding of the ecological impacts of water reuse on aquatic organisms of CECs and their mixtures on biodiversity, biogeochemical cycles of nutrients, ecosystems functions and services, and their resilience to environmental stressors (Paranychianakis *et al.*, 2014).

Most of the scientific literature regarding the assessment of CECs' uptake by plants is focused on experiments on plant uptake and bioavailability in artificially amended soils or contaminated growing media and biosolids (Fatta-Kassinos *et al.*, 2016). The same authors conclude that the agricultural use of biosolids is a significantly greater reservoir for plant uptake of CECs than irrigation with treated wastewater.

Prosser and Sibley (2015) carried out an assessment that indicates that the majority of individual pharmaceuticals and personal care products (PPCPs) in the edible tissue of plants due to biosolids or manure amendment or wastewater irrigation represent a *de minimis* risk to human health. Assuming additivity, the mixture of PPCPs could potentially present a hazard. Further work needs to be done to assess the risk of the mixture of PPCPs that may be present in edible tissue of plants grown under these three amendment practices (Prosser and Sibley, 2015).

6.2 Anti-microbial resistances

Among the CECs the issue of antimicrobial resistance (AMR) is of growing concern. AMR threatens the effective prevention and treatment of an ever-increasing range of infections caused by bacteria, parasites, viruses and fungi. In 2014, WHO has published a first global assessment on the current status of surveillance and information on AMR, in particular antibacterial resistance (ABR), at country level worldwide (WHO, 2014). In a joint report, the European Food Safety Authority and the European Centre for Disease Prevention and Control (EFSA and ECDC, 2015) looked into the antimicrobial resistance data on zoonotic and indicator bacteria in 2013, submitted by 28 EU MS. Resistance in zoonotic *Salmonella* and *Campylobacter* species from humans, animals and food, and resistance in indicator *Escherichia coli* and enterococci, as well as data on meticillin-resistant *Staphylococcus aureus*, in animals and food were addressed. Although mentioning that the bacterial resistance to antimicrobials occurring in food-producing animals can spread to people not only via food-borne routes, but also by routes such as water or environmental contamination (e.g. at slaughter) no further information is provided on the relevance of treated wastewater use as a possible pathway.

However, the spreading of antibiotic resistance genes (ARG) due to water reuse practices such as irrigation of crops and landscapes, and augmentation, conservation or restoration of surface water bodies has being received particular concern in the last years. Since the discovery of antibiotics and their wide spread use in medicine, stockbreeding and aquaculture, the occurrence of ARG in the environment has been increasing. Thanner *et al.* (2016) looked more specifically into the issue of AMR in agriculture and clearly state that a proper risk analyses regarding ARB "*require comparable data across different biomes: soil, plant, animal, humans, water*". A conclusive risk assessment is currently virtually impossible, a situation which according to the same authors has created great differences within the scientific community.

It appears also that more information is required to obtain a clear picture of the risks associated with water reuse applications. The adoption of (meta)genomic approaches which provide information on the whole microbial community and not only to the culturable portion of microorganisms will improve our understanding on the mechanisms responsible for the induction of ARG, their spreading and how they differ among the different taxa.

On the other hand, no difference in the abundance of ARG among fresh and recycled water irrigated soils was detected in a study carried out in Israel (Negreanu *et al.*, 2012) suggesting that the majority of resistant to antibiotics bacteria entering the soils cannot survive. The high abundance of ARGs in the soil reported often is probably indicative of native antibiotic resistance associated with the soil microbiome (Negreanu *et al.*, 2012). This argument finds confirmation in other findings emphasizing the importance of natural environment in antibiotic resistance (Wellington *et al.* 2013, Paranychianakis *et al.*, 2014).

Although a great deal of information, amongst others compiled by the COST NEREUS action, indicate that domestic wastewater is amongst a likely major environmental reservoirs, the issue of antimicrobial resistance (AMR) has to be addressed in a general context of wastewater sanitation rather than specifically for reuse schemes. Evidence seems actually to indicate that a reuse for irrigation leads to a removal of AMR, since most of the resistant bacteria cannot survive in the receiving soils. A respective minimum requirement for AMR is hence neither justified, nor feasible to the lack of inconclusive and comparable data.

6.3 Measurements and testing

Although great progress has been made in developing novel tools and approaches to "grasp" better CECs including AMR through their (eco) toxicological effects, these tools remain at a pre-market level or have not even reached such a maturity. This vicious circle of "not-being-measured", "no limit value" and "not-inclusion in legislation" can only be broken by further targeted research.

The EU Technical Report on aquatic effect-based monitoring tools (EC, 2014b) presents, in the context of the WFD, a range of effect-based tools (e.g. biomarkers, bioassays) that could be used in the context of different monitoring programmes, and that might be able to take account of the presence of several known and unknown compounds with similar effects.

Effect-based tools could be used as a screening and prioritisation tool for subsequent chemical analysis. Nevertheless, there is still significant uncertainty regarding the role of effect-based tools in a regulatory context and developments in bioanalytical science should be examined to identify validated bioassay candidates.

Similar considerations apply for AMR/ARG dimension, where the scientific community is far from having reached a consensus on reference and indicator resistances and a (commercially viable) way to quantify them.

7 Conclusions

Water is a limited resource and hydric stress an increasing challenge at EU and global level. Linked with growing needs of the population and regionally aggravated by climate change, water scarcity is fast becoming a concern across the EU. Existing water resources in Europe are not always managed efficiently. Treated water from urban wastewater treatment plants can provide a source for a reliable water supply Water reuse needs to be considered as a measure within the context of the water policy hierarchy.

Although the use of reclaimed water is an accepted practice in several EU countries, the uptake of water reuse solutions remains limited in comparison with their potential. One of the main barriers identified is the lack of harmonization in the regulatory framework to manage health and environmental risks related to water reuse at the EU level, and thus a lack of confidence in the health and environmental safety of water reuse practices. The development of minimum quality requirements for water reuse for agricultural irrigation and aquifer recharge at EU level have the aim of helping to overcome this barrier.

A risk management framework has been selected for the establishment of the minimum quality requirements. This framework is recommended by the WHO as the most suitable approach to control health and environmental risks of water reuse practices. The key principles of the risk management framework are defined and minimum quality requirements are settled for agricultural irrigation and aquifer recharge. Monitoring recommendations are also included.

For agricultural irrigation, different crop categories are established, and microbiological and physico-chemical parameters are selected. According to the multiple barrier approach, and the health risk assessments developed in international guidelines, specific limit values are defined according to the tolerable risk (burden of disease) of 10^{-6} DALYs pppy. Environmental risks are recommended to be considered on a case-by-case basis taking into consideration site-specific characteristics. The national regulations and guidelines on water reuse already issued by some Member States where also taken into consideration.

For aquifer recharge, the Groundwater Directive is the overarching document to be complied with for groundwater protection. In addition, MS have to apply a risk assessment to control health and additional environmental risks that may arise from the use of reclaimed water.

It is of paramount importance to develop further guidance on the health and environmental risk assessment and the establishment of a risk management framework in general.

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List of abbreviations and definitions

ABR	Antibacterial Resistance
AHMC	Australian Health Ministers' Conference
AMR	Antimicrobial Resistance
ANZECC	Australian and New Zealand Environment and Conservation Council (Note: in 2001, the functions of ARMCANZ and ANZECC were taken up by the Environment Protection and Heritage Council and the Natural Resource Management Ministerial Council)
APHA	American Public Health Association
Aquifer	A subsurface layer or layers of rock or other geological strata of sufficient porosity and permeability to allow either a significant flow of groundwater or the abstraction of significant quantities of groundwater (according to Directive 2000/60/EC).
ARG	Antibiotic Resistance Genes
ARMCANZ	Agricultural and Resource Management Council of Australia and New Zealand (Note: in 2001, the functions of ARMCANZ and ANZECC were taken up by the Environment Protection and Heritage Council and the Natural Resource Management Ministerial Council)
bdl	Below Detection Limit
BOD_5	5 day Biochemical Oxygen Demand
CAC	Codex Alimentarius Commission
CCR	California Code of Regulations
CDPH	California Department of Public Health
CECs	Compounds of Emerging Concern
CEN	European Committee for Standardization
cfu	colony forming unit
CIS	Common Implementation Strategy
COD	Chemical Oxygen Demand
COM	Communication from the Commission
Critical limit	A prescribed tolerance that distinguishes acceptable from unacceptable performance.

Ct	The product of residual disinfectant concentration (C) in milligrams per litre and the corresponding disinfectant contact time (t) in minutes.
DALYs	Disability Adjusted Life Years
DG ENV	Directorate General Environment (European Commission)
Domestic wastewater	Wastewater from residential settlements and services which originates predominantly from the human metabolism and from household activities (according to Directive 91/271/EEC).
Dose–response	The quantitative relationship between the dose of an agent and an effect caused by the agent.
DWD	Drinking Water Directive
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
EDC	Endocrine Disrupting Compound
EDCs	Endocrine Disrupting Compounds
EEA	European Environment Agency
EFSA	European Food Safety Authority
EPHC	Environment Protection and Heritage Council
EQSD	Environmental Quality Standards Directive
EU	European Union
Exposure assessment	The estimation (qualitative or quantitative) of the magnitude, frequency, duration, route and extent of exposure to one or more contaminated media.
FAO	Food and Agriculture Organization
Further treatment	Treatment processes, beyond secondary or biological processes, which further improve effluent quality, such as filtration and disinfection processes.
GWD	Groundwater Directive
HACCP	Hazard Analysis and Critical Control Points
Hazard	A biological, chemical, physical or radiological agent that has the potential to cause harm to people, animals, crops or plants, other terrestrial biota, aquatic biota, soils or the general environment.
Hazardous event	An incident or situation that can lead to the presence of a hazard.

Indirect potable reuse	Discharge of reclaimed water directly into a suitable environmental buffer (groundwater or surface water) with the intent of augmenting drinking water supplies, thus preceding drinking water treatment.
Industrial wastewater	Any wastewater which is discharged from premises used for carrying on any trade or industry, other than domestic wastewater and run-off rain water (according to Directive 91/271/EEC).
ISO	International Organization for Standardization
JRC	Joint Research Centre (European Commission)
Log_{10} removal	Used in reference to the physical-chemical treatment of water to remove, kill, or inactivate microorganisms such as bacteria, protozoa and viruses (1 log_{10} removal = 90% reduction in density of the target organism, 2 log_{10} removal = 99% reduction, 3 log_{10} removal = 99.9% reduction, etc).
Managed aquifer recharge	The intentional recharge of water (reclaimed water in this document) to aquifers for subsequent recovery or environmental benefit (according to NRMMC–EPHC–NHMRC, 2009).
MAR	Managed Aquifer Recharge
More stringent treatment	Includes treatment beyond secondary treatment processes (N- and/or P removal) for discharges from urban waste water treatment plants to sensitive areas which are subject to eutrophication. One or both parameters may be applied depending on the local situation (according to Directive 91/271/EEC).
MS	Member States
NHMRC	National Health and Medical Research Council
no	Number
NRC	National Research Council
NRMMC	Natural Resource Management Ministerial Council
NTU	Nefelometric Turbidity Unit
NWRI	National Water Research Institute of the United States
OECD	Organisation for Economic Cooperation and Development
PDT	Pressure Decay Test
pfu	plaque forming unit
Population	The organic biodegradable load having a five-day biochemical oxygen

equivalent	demand (BOD_5) of 60 g of oxygen per day.
PPCs	Pharmaceuticals and personal care products
pppy	per person per year
Preventive measure	Any action and activity that can be used to prevent or eliminate a health and environmental hazard, or reduce it to an acceptable level.
Primary treatment	Treatment of urban wastewater by a physical and/or chemical process involving settlement of suspended solids or other processes in which the BOD_5 of the incoming wastewater is reduced by at least 20% before discharge and the total suspended solids of the incoming wastewater are reduced by at least 50% (according to Directive 91/271/EEC).
QMRA	Quantitative Microbial Risk Assessment
Raw wastewater	Wastewater that has not undergone any treatment, or the wastewater entering the first treatment process of a wastewater treatment plant.
Reclaimed water	Urban wastewater that has been treated to meet specific water quality criteria with the intent of being used for a range of purposes. Synonymous with recycled or reused water.
Risk	The likelihood of identified hazards causing harm in a specified timeframe, including the severity of the consequences.
SAR	Sodium Adsorption Ratio
SCHEER	Scientific Committee on Health, Environmental and Emerging Risks
Secondary treatment	Treatment of urban wastewater by a process generally involving biological with a secondary settlement or other process in which the requirements established in Table 1 of Annex I of Directive 91/271/EEC are respected.
SSP	Sanitation Safety Planning
Target criteria	Performance goals to provide early warning that a critical limit is being approached.
TOC	Total Organic Carbon
TSS	Total Suspended Solids
Urban wastewater	Domestic wastewater or the mixture of domestic wastewater with industrial wastewater and/or run-off rain water (according to Directive 91/271/EEC).
USEPA	United States Environmental Protection Agency
UV	Ultraviolet

UWWTD	Urban Wastewater Treatment Directive
Water reuse	Use of treated wastewater for beneficial use. Synonymous with water reclamation and water recycling.
WFD	Water Framework Directive
WHO	World Health Organization
WSP	Water Safety Plans
WWTP	Wastewater Treatment Plant

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Annex

Informative Annex

The Continuous[1] Water Quality Monitoring (CWQM) approach

Research and innovation on continuous physico-chemical and microbiological monitoring is rapidly advancing, often funded by EU innovation programmes. Nowadays, the water quality parameters recommended for the verification of reclaimed water can be continuously monitored for most chemical and physical parameters. Turbidity and TSS are already available with commercial probes. The continuous monitoring of bacterial indicators, as *E. coli*, has been recently demonstrated[2], and BOD_5 related monitoring devices are almost ready to market (applying direct or indirect measurement methods).

Regarding the CWQM technologies for microbiological parameters, there are available devices with two different approaches: detection and measuring. Detection devices are suitable for applications where just the simple presence of microorganisms represents an early warning (drinking water applications, process water for food industry). However, in reclaimed water use for irrigation and aquifer recharge, concentrations of microorganisms below a threshold are allowed for some practices. Thus, in several applications, simple detection will not be suitable if not combined with other measures, and measuring the concentration will be required.

The traditional approach, based on manual sampling and standardized analytical methods, defined for verification monitoring provides the results after 1 to 4 days, depending on the target parameter. Such delay makes the obtained results not suitable for early warning purposes, neither for process control and optimization (operational monitoring). When reclaimed water is reused to irrigate crops, it will be distributed and utilized far before analysis results will be available. In case of a pollution event, the microbial contamination will have spread along the irrigation infrastructure, and the crops could be not anymore suitable for the market. The availability of proven CWQM devices, providing the results in shorter timeframes, will definitely help to close the gap between operational needs and verification monitoring.

In this sense, the CEN/SABE ENV Team (Environmental Monitoring Strategy Team) is preparing a Strategic Position Paper on "Standardization needs in continuous water quality monitoring", to be delivered by the end of 2017[3]. The paper analyses the added-value of CWQM devices, the barriers to their adoption, and the measures to encourage a more rapid uptake of the innovations, as the ISO/CEN standardization. Additionally in 2014 SABE adopted a position paper[4] on water reuse which identified recommendations on water reuse and implications for future standardization. However, standardization might become a long process for potentially excellent CWQM technologies that may find difficulty penetrating the market.

In order to provide independent verification of the performance of environmental technologies that cannot be fully assessed through certification or labels, and to improve the penetration of these technologies into the EU and global markets, the EC launched the EU Environmental Technologies Verification[5] pilot programme (ETV) in December 2011. The ETV is a suitable, faster and more affordable process to assess performance of CWQM devices compared to the traditional methods and make results available for the whole EU. "This opens up the water directives for scientifically validated technologies, either lab-based or online, and eliminates the need to address requirements for monitoring technologies in the directive itself, with the risk of being outdated shortly after each revision"[6]. Summing up, the CWQM sector is fast moving at the pace of new technologies, therefore whatever standardization or regulation need to be open enough to do not block ongoing innovation.

[1] The 'continuous' concept refers to real time, but also to semi-continuous or near real time, providing measurements at a given frequency.

[2] http://r3water.eu/wp-content/uploads/2014/04/R3Water-Final-Brochure-2017_online.pdf

[3] https://www.cencenelec.eu/News/Brief_News/Pages/TN-2017-006.aspx

[4] https://www.cencenelec.eu/news/policy_opinions/PolicyOpinions/ReplyWasteWater2014Nov.pdf

[5] https://ec.europa.eu/environment/ecoap/etv_en

[6] https://www.eipwater.eu/sites/default/files/AG100%20RTWQM%20water%20legislation_whitepaper_v2_150714_def.pdf (Sections 3.3, 3.4 and 4)

With courtesy of EIP Water – Action Group (AG100) Real Time Water Quality Monitoring (RTWQM).

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