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Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
on minimum requirements for water reuse

(Text with EEA relevance)

{SEC(2018) 249 final} - {SWD(2018) 249 final} - {SWD(2018) 250 final}

EXPLANATORY MEMORANDUM

1. CONTEXT OF THE PROPOSAL

• Reasons for and objectives of the proposal

Water is a limited resource in the EU, with one third of the EU territory experiencing water stress. The growing needs of populations and climate change will make the availability of water in sufficient quantity and quality even more of a challenge in Europe in the future. Water over-abstraction, in particular for agricultural irrigation¹ but also for industrial use and urban development is one of the main threats to the EU water environment, while availability of water of appropriate quality is a critical condition to growth in water-dependent economic sectors and society in general. The overall impacts on the economy due to the 2003 drought have been estimated at a minimum of EUR 8.7 billion (mainly concerning Mediterranean countries, France and the UK), measured as the estimated losses directly resulting from the drought (EC, 2007). Immediate effects of droughts, such as damage to agriculture and infrastructure, as well as more indirect effects, such as a reluctance to invest in an area at risk, can also have a serious economic impact.

As an effect of climate change, the frequency and intensity of droughts and their environmental and economic damages have drastically increased over the past thirty years: between 1976 and 2006 the number of areas and people affected by droughts went up by almost 20% and the total costs of droughts amounted to EUR 100 billion (EC, 2012). The droughts of the summer of 2017 may further illustrate the dimensions of economic loss; the Italian farming sector alone was predicting losses of EUR 2 billion². This trend is expected to continue with water scarcity no longer confined to a few corners of Europe, but already a concern across the EU with significant environmental and economic consequences. This may in turn affect competitiveness and the efficient functioning of the internal market. To respond to this problem, Europe's water resources should be managed more efficiently. The Communication from the Commission to the European Parliament and the Council on Water Scarcity and Droughts³ sets out the hierarchy of measures that Member States should consider in managing water scarcity and droughts, highlighting that water saving must become the priority and all possibilities to improve water efficiency should be explored. As part of an integrated water management approach, in addition to water savings, treated waste water from urban waste water treatment plants provides a reliable alternative water supply for various purposes. Of these, agricultural irrigation has the highest potential for an increased uptake of water reuse and a contribution to the alleviation of water scarcity in Europe. Reuse of treated waste water generally has a lower environmental impact than for example water transfers or desalination, and offers a range of environmental, economic and social benefits. Furthermore, it extends the water life cycle, thereby helping to preserve water resources and in full compliance with the circular economy objectives. Today, whilst water reuse in the EU could obviously never by itself solve water scarcity problems, the uptake of water re-use practices falls far below its full potential, with practices diverging widely across Member States.

The general objective is to contribute to alleviating water scarcity across the EU, in the context of adaptation to climate change, notably by increasing the uptake of water reuse, in particular for agricultural irrigation wherever this is relevant and cost-effective while ensuring

¹ Overall accounting for around a quarter of total freshwater abstracted. Abstraction for irrigation accounts for about 60% of total freshwater abstraction in Southern and South Eastern Europe, and up to 80% in certain River basin districts (RBDs).

² <http://www.bbc.com/news/world-europe-40803619>

³ COM (2007)414

the maintenance of a high level of public health and environmental protection. Setting harmonised minimum requirements (notably key parameters on reference pathogens) on the quality of reclaimed water and monitoring together with harmonised risk management tasks would ensure a level playing field for those engaged in water reuse and those affected, prevent potential obstacles to the free movement of agricultural products irrigated with reclaimed water, ensure health and the environment are protected and thereby also increase confidence in the practice of water reuse. It is estimated that the proposed instrument could lead to water reuse in agricultural irrigation in the magnitude of 6,6 billion m³ per year, as compared to 1,7 billion m³ per year in the absence of any EU legal framework. Reusing more than 50% of the total water volume theoretically available for irrigation from waste water treatment plants in the EU would avoid more than 5% of direct abstraction from water bodies and groundwater, resulting in a more than 5% reduction of water stress overall. Acting now would contribute to alleviating water stress where it is already a reality today in the EU and also prepare operators and farmers to be ready to act also in those parts of the EU which will experience increasing water stress in the coming years and decades.

The need to address the problem at EU level has been acknowledged in the 2012 Commission Communication "**A Blueprint to Safeguard Europe's Water Resources**" (COM(2012) 673). A **Fitness check of EU Freshwater policy** (SWD(2012) 393) published in November 2012 as a building block of the Blueprint, concluded that "**alternative water supply options with low environmental impact need to be further relied upon**" in order to address **water scarcity**. A number of actions to promote water reuse were included in the Communication from the Commission "Closing the loop – An EU action plan for the circular economy" (COM(2015) 614), including an action to prepare a legislative proposal on minimum requirements for water reuse for irrigation and groundwater recharge. This proposal has been included in the European Commission's Work Programme of 2017 and 2018 as it contributes to the political priorities set by the Commission to promote a more circular economy. In addition, it may complement the planned future modernisation of the Common Agricultural Policy.⁴ Finally, the proposed Regulation contributes to the EU's implementation of the Sustainable Development Goals (SDGs) and in particular SDG 6 on Clean Water and Sanitation, which sets a target of substantially increasing recycling and safe water reuse globally by 2030.

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

- **Consistency with existing policy provisions in the policy area**

At present, water reuse is already identified and encouraged in provisions of two existing EU instruments, which however **do not specify conditions** for the reuse:

- **The Water Framework Directive** (2000/60/EC, WFD): its Annex VI, part B mentions water reuse as one of the possible supplementary measures;

⁴ To note in this context that reference to water reuse is made in a Commission Staff Working Document on Agriculture and Sustainable Water Management in the EU (SWD(2017) 153final as one of a number of measures that has the potential to reduce negative impacts associated with over-abstraction.

- **The Urban Waste Water Treatment Directive** (91/271/EEC, UWWTD): its Article 12 stipulates, as part of the condition on wastewater discharges that *"treated waste water shall be reused whenever appropriate. Disposal routes shall minimize the adverse effects on the environment."*

In the Water Framework Directive, dealing with water scarcity is one of the key aspects of water management. This legislation sets inter alia a central goal of attaining good status for Europe's waters by 2015. It requires Member States to characterise the situation of their water in terms of pressures from human activities and set 'programmes of measures' to achieve the good status objective. Those programmes are part of River Basins Management Plans, to be reviewed and reported to the European Commission every 6 years. In 2007, the EU policy on water scarcity and droughts (COM(2007) 414) elaborated on the integration of water scarcity planning into River Basins Management Plans, including the use of appropriate water pricing and ecological requirements for river flows. It spelled out the hierarchy of measures Member States should consider in managing water scarcity and droughts, with priority for water saving and efficiency measures, and with additional water supply infrastructures only to be considered as an option when other options have been exhausted. The proposed Regulation on water reuse is to be considered within such an integrated water management approach. Furthermore, the proposed Regulation will complement the Urban Waste Water Treatment Directive.

A proposal for a Regulation would complement and be coherent whilst not lowering the applicable levels of environmental protection with the existing EU legislative framework on water, notably:

- The Water Framework Directive, the Groundwater Directive, the Environmental Quality Standards Directive, the Urban Waste Water Treatment Directive, the Sewage Sludge Directive, Waste Framework Directive, Regulation concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals and the Nitrates Directive.
- Food safety, notably the Regulation on the Hygiene of Foodstuffs.

- **Consistency with other Union policies**

The general objective of the proposal is fully in accordance with the 7th Environmental Action Programme⁵ and, at the global level, the United Nations' 2030 Agenda for sustainable

⁵ General Union Environment Action Programme to 2020 (Decision No 1386/2013/EU), and more especially its following objectives:

- *"To protect, conserve and enhance the Union's natural capital"*, with actions ensuring that by 2020:
 - (b) *the impact of pressures on transitional, coastal and fresh waters (including surface and ground waters) is significantly reduced to achieve, maintain or enhance good status, as defined by the Water Framework Directive;*
 - (f) *the nutrient cycle (nitrogen and phosphorus) is managed in a more sustainable and resource-efficient way;*
- *"To turn the Union into a resource-efficient, green and competitive low-carbon economy"* with actions ensuring that by 2020:
 - (b) *the overall environmental impact of all major sectors of the Union economy is significantly reduced, resource efficiency has increased, and benchmarking and measurement methodologies are in place. Market and policy incentives that foster business investments in resource efficiency are in place, while green growth is stimulated through measures to foster innovation;*

development and the achievement of the sustainable development goal n°6 "Ensure access to water and sanitation for all", in particular as regards the two following targets:

- By 2030, improve water quality by reducing pollution, eliminating dumping and minimizing release of hazardous chemicals and materials, halving the proportion of untreated wastewater and substantially increasing recycling and safe reuse globally;
- By 2030, substantially increase water-use efficiency across all sectors and ensure sustainable withdrawals and supply of freshwater to address water scarcity and substantially reduce the number of people suffering from water scarcity.

The proposal would contribute to the implementation of several other EU policies, in particular the EU climate change adaptation and disaster prevention policies and the resource-efficient Europe flagship initiative under the Europe 2020 Strategy.

2. LEGAL BASIS, SUBSIDIARITY AND PROPORTIONALITY

• Legal basis

The proposal is based on Article 192(1) of the Treaty on the Functioning of the European Union (ex-Article 175 of the Treaty establishing the European Community), as the main objective is to preserve, protect and improve the quality of the environment; protect human health, contribute to the prudent and rational utilisation of natural resources and promoting measures at international level to deal with regional or worldwide environmental problems, and in particular combating climate change. The proposal is also expected to contribute to the functioning of the internal market.

• Subsidiarity (for non-exclusive competence)

The EU has shared competence with Member States to regulate environment and health in the field of water. This means that the EU can only legislate as far as the Treaties allow it, and with due consideration for the principles of necessity, subsidiarity and proportionality.

The objectives of this Regulation, namely the protection of environment and human health from the adverse effects of any contamination of reclaimed water will be achieved by setting minimum requirements for water quality, monitoring and preventive measures and the key tasks of a risk management at Union level.

Concerning environmental protection, EU-level action on water management is also justified because 60% of EU river basins are international, shared by between 2 and 19 countries (Danube); action taken by a single or few Member State is therefore not sufficient, for instance in relation to quantitative aspects of water management and cross border water pollution. Moreover, if Member States act alone, the technical barriers to water reuse and associated costs are likely to be unnecessarily high.

EU intervention on water reuse for agricultural irrigation is justified to prevent that different requirements in individual jurisdictions negatively affect the level playing field (e.g. between farmers and growers) and cause obstacles to the internal market, especially for primary agricultural products. Additionally, different requirements may also be used as an argument to restrict the import of food products from Member States suspected of having lower

(c) structural changes in production, technology and innovation, as well as consumption patterns and lifestyles have reduced the overall environmental impact of production and consumption, in particular in the food, housing and mobility sectors;

requirements, as exemplified in the E. Coli outbreak of 2011⁶. The current situation does not guarantee a level playing field between food producers of different countries; the current EU regulatory framework does not yet address the specific modalities of agricultural products irrigated with treated waste water. Addressing such barriers is an appropriate EU level response, taking into account EU food safety, health, agriculture, climate and energy policies.

EU action is further justified because different and changing requirements in individual jurisdictions are a barrier to the creation of a level playing field for investments in innovation and for water reuse. It is unlikely that national regulators can coordinate a harmonisation of their regulatory requirements as the number of Member States involved is too large and increasing.

- **Proportionality**

The proposed Regulation on minimum requirements for water reuse, in particular in agricultural irrigation, in combination with other non-regulatory actions as outlined in the Action Plan on Circular Economy is a proportionate response to the objective of fostering the development of safe reuse of treated waste water. It does not go beyond what is necessary to achieve this objective. Important Member States' prerogative on the extent to which water reuse will be encouraged remains untouched.

Treated waste water may be used for a wide variety of purposes. In the 2015 Communication 'Closing the loop – An EU action plan for the Circular Economy' (COM/2015/614) and in the Impact Assessment, agricultural irrigation was identified as the main potential source of demand for reused water by having the greatest potential in terms of its higher uptake, scarcity alleviation and EU relevance.

- **Choice of the instrument**

The impact assessment for this proposal has considered the full array of legal instruments, namely amending one of the existing Directives, a new Directive or Regulation, or Guidance.

When considering new legislation on water reuse, a possible option was to amend an existing framework where water reuse is already mentioned, notably the Urban Waste Water Treatment Directive. However, an amended or new Directive would require transposition in national legislation by all Member States. While water reuse is certainly a promising option for many Member States, it needs to be considered that at present only 6 Member States (Cyprus, Greece, Spain, France, Italy and Portugal) have requirements on water reuse in place (in legislation or in national non-regulatory standards). An amended or a new Directive would imply transposition for all Member States and necessarily leave flexibility in transposition of the requirements. While this would accommodate for differences across the EU, this would pose a serious limitation in meeting the objectives, in particular as regards the minimum harmonisation of the requirements for reclaimed water and the methodology to undertake the risk management, as well as setting a common level playing field. This limitation was already identified in the impact assessment of the 'Blueprint to Safeguard Europe's Water Resources'

⁶ The case of the E.coli outbreaks which affected 16 countries in Europe and North America in 2011, with more than 4000 reported cases and 53 deaths in Germany, is an example of this situation. The outbreak was blamed on cucumbers irrigated with treated waste water, imported from Spain, and several Member States, including Austria, Belgium, the Czech Republic, Denmark, Germany and the UK blocked or restricted the import of Spanish products over concerns that these would have been contaminated during irrigation. It was subsequently proven that the source of the E.coli contamination was not the cucumbers but rather sprouted seeds from a German farm, and the fenugreek seeds involved were sourced from Egypt. It was estimated that this event cost Spain EUR 200 million per week as orders were cancelled and contributed to cut agricultural income from the Murcia region by 11.3% for the 2010-2011 growing season. This has been deterring investment in processing food products irrigated with reused water.

in which a regulation was eventually the only regulatory policy option assessed in detail. Flexibility for adaptation to local contexts, which seems to be the main argument for a Directive or an amendment of a Directive, can be achieved with other tools, notably the proposed introduction of a common risk management.

Concerning the form of the legal instrument, the impact assessment considers that both a Directive and a Regulation could be suitable, each with certain advantages and disadvantages. A Regulation would cater better for the enabling nature of the initiative, in particular for those Member States where water reuse is considered useful or where strong business interests to develop water reuse technologies exist. A Directive may allow for easier flexibility in terms of setting more stringent national requirements, while imposing a higher transposition burden on all Member States, although water reuse is not relevant in all of them at present.

The Regulation has been finally selected as the most appropriate legal instrument to achieve the objectives for the following reasons:

- It would be directly applicable to business operators (next to Member States), thus stimulating market uptake, potentially even in those Member States that are currently not facing the issue of water scarcity, but where good "green" technologies are being produced. This could have a positive impact on research and innovation, as well as the emergence of best technologies and new business opportunities in the internal market.
- A Regulation would come into force much faster than any potential future amendment to the Urban Waste Water Treatment Directive (for which the ongoing evaluation is scheduled to be completed in 2019; any subsequent legislative proposal for amendment would only be possible following an impact assessment process), thus delivering faster on the main objective of addressing water scarcity.

3. RESULTS OF EX-POST EVALUATIONS, STAKEHOLDER CONSULTATIONS AND IMPACT ASSESSMENTS

- **Ex-post evaluations/fitness checks of existing legislation**

The need to address the problem at EU level has been acknowledged in the 2012 Commission Communication "**A Blueprint to Safeguard Europe's Water Resources**" (COM(2012) 673). A **Fitness check of EU Freshwater policy** (SWD(2012) 393) published in November 2012, as a building block of the Blueprint, assessed the performance of the measures taken, both in environment and in other policy areas, in achieving the objectives already agreed in the context of water policy. It also identified the major gaps to be filled in order to deliver environmental objectives more efficiently. In relation to wastewater reuse, the Fitness check concluded that "**alternative water supply options with low environmental impact need to be further relied upon**" in order to address water scarcity.

- **Stakeholder consultations**

The consultation process for a possible new EU initiative on water reuse began in 2012 and continued until July 2017 in various forms, both organised and ad hoc. The implementation of the consultation strategy involved collecting and analysing input from a wide range of stakeholders as well as two online public consultations.

A [first internet-based public consultation ran from 30 July to 7 November 2014](#) and received 506 contributions. A [second internet-based public consultation ran from 28 October 2016 to 27 January 2017](#) and focused on the more detailed policy options to set minimum requirements for reused water for irrigation and groundwater recharge. In total, 344

contributions were received. In the online public consultations in 2016 and 2014, 60% to 80% of all respondents were in favour of an EU regulatory framework. In addition, more than 80% of respondents to the online public consultation held in 2014 considered legally binding EU minimum standards as effective to ensure the environmental and health safety of water reuse practices. The respondents which are mostly in favour of the instrument of an EU regulation, in both cases, are representatives from private companies, from the sanitation, drinking water, food industry and environment sectors, and/or from Southern EU Member States.

There is a wide perception among respondents of the benefits of reusing water for irrigation or aquifer recharge purposes with regards to the availability of water resources, in the context of water stress or scarcity, unsustainable water abstractions and climate change (perception from more than 70% of respondents across and within different categories of respondents). The potential contribution of water reuse to the quality of water bodies, through preserving groundwater from salinization is perceived by a large number of respondents as well. Furthermore, water reuse is also perceived by a number of respondents as a means to increase resource efficiency, foster innovation and contribute to soil fertilisation, although these benefits were considered more moderate compared to the former ones.

On the other hand, respondents are much less inclined to perceive cost savings for authorities, increased revenues, or energy and carbon savings as benefits of water reuse. The analysis per category of respondents shows in particular that countries regularly exposed to water stress and Southern EU Member States perceive significantly more and higher benefits than other categories of respondents. Large consensus is found about these benefits among the respondents from the sanitation, drinking water, environment and economics sectors.

There is an overall consensus amongst respondents about the safety of reused water compared to water from rivers, as nearly 70% of respondents consider reused water as at least as safe. Respondents from Southern EU Member States and countries facing regular water stress are significantly more inclined to consider reused water for both irrigation and aquifer recharge as being at least as safe as alternative sources (rivers or groundwater) than respondents from Eastern and Northern EU Member States, which tend to consider reused water as less safe in the same proportions. Respondents from private companies show by far the most positive perception of reused water safety compared to other types of organisations, keeping in mind that they are involved at 68% in drinking and sanitation sectors.

The various contributions from targeted stakeholders received⁷ are summarized in Annex II – Synopsis report on consultation activities of the Impact Assessment Report. The received input and findings have been used in the preparation of the impact assessment and the updating of the scientific basis for the current proposal (the JRC report in Annex 7 of the Impact Assessment Report) and were further used to inform the decision-making process in view of a proposal for a Regulation on water reuse at EU level.

Consultation of experts in Member States and stakeholder organisations

Consultation took place in the framework of the Common Implementation Strategy (CIS) for the implementation of the Water Framework Directive (WFD). Water reuse was discussed in 6 meetings of the former Working Group on the Programmes of Measures (September and November 2013, March and October 2014, March and October 2015). A dedicated activity on water reuse and an Ad-hoc Task Group was included in the CIS work programme for 2016-2018 to accompany the development of related actions and has met regularly.⁸

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<http://ec.europa.eu/environment/water/reuse.htm>

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Information on the status of water reuse in EU Member States was collected and participants were invited to give feedback on draft versions of the IA support studies elaborated by consultants. A technical

- **Collection and use of expertise**

The legal proposal, as well as the Impact Assessment, is based on a vast body of underpinning evidence, as referenced in the Impact Assessment Staff Working Document. The main information sources for the Impact Assessment of the proposed Regulation were the Blueprint Impact Assessment from 2012 and subsequent supporting studies as well as the scientific basis developed by JRC (minimum quality requirements), together with a hydro-modelling by JRC. Moreover, specific aspects have been assessed, namely the impacts on innovation and territorial impacts.

For the purposes of developing the current proposal, the JRC carried out as a first step a review of the available scientific, technical and legal knowledge on water reuse in agricultural irrigation and aquifer recharge. The documents that have been the basis to establish the proposal for minimum quality requirements included:

- 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;
- world-wide reference guidelines and regulations on water reuse;
- additional scientific references considered relevant for the topic.

During the development of the scientific basis for this proposal a tiered approach for consultation was applied by the JRC. In the first tier, the JRC asked a group of selected experts from academia, the water sector and WHO to provide input and comment on the drafting work. In a second tier, Member States were formally informed through the Ad-hoc Group on Water Reuse, where JRC presented at three occasions the respective versions. Comments received in writing from the Member States were documented and replies from JRC were disseminated. In addition, the JRC presented at several public events as well as scientific meetings the progress of work. These presentations included amongst others the Water Group of the European Parliament, the EIP Water Action Group on Water Reuse, 11th IWA International Conference on Water Reclamation and Reuse as well as the COST NEREUS Action on New and Emerging Challenges and Opportunities in Wastewater Reuse. Considering the sensitivity of the health and environmental issue and public confidence in water reuse practice, in the third tier, the scientific opinions of the independent Scientific Committee on Health, Environmental and Emerging Risks (SCHEER) and the European Food Safety Authority (EFSA) have been requested and taken into consideration in the finalisation of the document or, if not, a justification has been provided. The experts, whose contributions are gratefully acknowledged, have been consulted to provide comments and input through critical discussion on the document along the process.

All underlying studies and the technical report of JRC are available on <http://ec.europa.eu/environment/water/reuse.htm>.

workshop on possible minimum quality requirements on water reuse at EU level was organised by DG ENV and JRC in June 2015. Meetings were held in March 2016, October 2016 and June 2017 to specifically discuss draft versions of the JRC technical report. Draft elements of the impact assessment were also presented in order to collect feedback and gather additional information. Expert Groups on the Groundwater Directive, the EQS Directive, the UWWTD and on the Drinking Water Directive were also consulted.

- **Impact assessment**

The proposal is based on an Impact Assessment, for which a positive opinion with reservations⁹ was received from the Regulatory Scrutiny Board on 19 January 2018 (previously, a negative opinion was received on 27 October 2017). The issues raised by the Regulatory Scrutiny Board were addressed in the revised version of the Impact Assessment Staff Working Document, in which a specific chapter details the changes made following the Regulatory Scrutiny Board's opinion (Annex 1 to the Impact Assessment report – Procedural information).

Based on the Blueprint to Safeguard Europe's Water Resources, the Fitness Check of EU Freshwater policy, supporting studies and the stakeholder consultations, a number of policy options were developed to address the identified problem and its underlying causes. The Impact Assessment assessed the options in light of their potential and effectiveness to achieve the overarching objective of the Regulation of addressing water scarcity through water reuse while ensuring the protection of environment and human health. For aquifer recharge, the analysis carried out in the impact assessment showed that EU regulatory action is not found proportionate, due to a strong local dimension. Details on the outcome of these analyses are provided in the Impact Assessment Study and the Impact Assessment Staff Working Document.

The three assessed policy options contain (1) **Legal instrument** ensuring safety of agricultural products with a "**one-size-fits-all**" approach (the most stringent minimum requirements set regardless of the food crop category and irrigation technique) and protection of local public health and of the environment (the key risk management tasks), (2) **Legal instrument** ensuring safety of agricultural products with a "**fit-for-purpose**" approach (minimum requirements set depending on the food crop category and irrigation technique) and protection of local public health and of the environment (the key risk management tasks) and (3) **Guidance** document on safety of agricultural products with a "**fit-for-purpose**" approach (minimum requirements set depending on the food crop category and irrigation technique) and protection of local public health and of the environment (the key risk management tasks). For options (1) and (2), the legal instrument would be accompanied by Guidance on the implementation of the key risk management tasks, to be elaborated together with Member States.

Agricultural irrigation by far is the largest application of reused water worldwide and in Europe and a significant use of water in Europe, overall accounting for around a quarter of total freshwater abstracted. Abstraction for irrigation accounts for about 60% of total freshwater abstraction in Southern and South Eastern Europe, and up to 80% in certain river basin districts. Water reuse in agriculture therefore has the highest potential for an increased uptake of water reuse, thus contributing to the alleviation of water scarcity in Europe. The analyses and the consequent ranking of the options led to the conclusion that the preferred option for agricultural irrigation is **a Legal instrument with a "fit for purpose" approach** as it is able to provide a higher volume of treated waste water at lower cost than the other options. For agricultural irrigation, an EU Regulation with a "fit-for-purpose" approach and risk management would entail the most environmental, economic and social benefits as compared to other options. It would in particular contribute to alleviating water stress through an increased uptake of water reuse at affordable prices reaching a magnitude of about 6.6 billion m3 per year as compared to the baseline of 1.7 billion m3. In addition, it would create

⁹ Board opinion SEC(2018)249, Impact Assessment SWD(2018)249, Executive summary SWD(2018)250

a level playing field for investors and provide certainty for the distribution of the relevant products in the internal market, thereby also contributing to increased public confidence in water reuse for irrigation.

Administrative costs to national authorities were assessed to be negligible or diminishing compared to the baseline. An EU Regulation with a "fit-for-purpose" approach is expected to require investments to treat the available volumes of water of EUR 38 /m3/day while under a "one-size-fits-all" approach these rise to EUR 271 /m3/day. An investment of less than EUR 700 million would allow treating more than 6,6 billion m3 yearly below the same cost threshold under the "fit-for-purpose" approach with a total cost of reclaimed water below EUR 0.5 /m3.

- **Regulatory fitness and simplification**

The proposed Regulation is new and was therefore not covered by the recent Fitness Check of Reporting and Monitoring of EU environmental policy¹⁰. However, the outcome, lessons learnt and recommendations from this Fitness Check and the related action plan¹¹ have been considered in the preparation of the monitoring and reporting obligations under this proposal with the view to minimising administrative burden (by using modern ICT tools and focussing on indicator-based reports) and ensuring transparency and accountability vis-à-vis citizens. Moreover, the approach also considers the need to ensure the appropriate evidence base is available for the evaluation of the Regulation in line with the Better Regulation Guidelines (section V on monitoring). The streamlined approach for monitoring of implementation has been applied first in the recent Commission proposal on the revision of the Drinking Water Directive¹². This current proposal has used these provisions as a starting point, and adapted them, where necessary. The approach will therefore also ensure coherence which is another important factor for regulatory fitness.

- **Fundamental rights**

This proposal would contribute to the application of Article 37 on environmental protection of the Charter of Fundamental Rights of the European Union.

4. BUDGETARY IMPLICATIONS

The proposal is mostly for regulatory measures without immediate impact on operational expenditure. During the concrete implementation, which is expected to start in 2021 only, a limited impact on the resources for the European Environment Agency (EEA) may occur. However, this will be in any case covered by the financial envelope and the staff allocation for the EEA under the next MFF post 2020.

5. OTHER ELEMENTS

- **Implementation plans and monitoring, evaluation and reporting arrangements**

Transparency and access to information is a critical aspect for promoting trust among users and also the general public as regards the safety of reclaimed water. Thus emphasis has been made on providing information to the public instead of traditional reporting obligations. The monitoring requirements will primarily be imposed to the operators of the reclamation plants

¹⁰ SWD(2017) 230

¹¹ COM(2017) 312

¹² COM(2017) 753

and the Member States shall ensure that the information is made available online to the public.

The proposed Regulation includes additional monitoring requirements on the quality of reclaimed water. Member States shall verify compliance with the permit conditions based on monitoring data obtained pursuant to this proposed Regulation, the Water Framework Directive and the Urban Waste Water Treatment Directive and other relevant information. The Member States shall publish the outcome of the compliance check and ensure that the Commission has access to relevant data.

The Commission will lay down detailed rules regarding the format and presentation of the information which should be available online to the public. The requirements will be developed in consultation with experts in Member States taking into account the conclusion of the Fitness Check of Reporting and Monitoring of EU environmental policy and follow-up actions, in particular as regards the use of advanced information and communication technologies (ICT).

Given the expected evolution both in knowledge and in the policy framework as regards contaminants of emerging concern, the proposal includes a clause to adapt annexes to technical and scientific progress, as well as a requirement for evaluation.

- **Detailed explanation of the specific provisions of the proposal**

Article 1 – Subject matter and purpose

This Article specifies the objectives of the proposal, namely to lay down minimum requirements for water quality and monitoring and to set out key risk management tasks in order to guarantee that the reuse of treated waste water is safe, addresses the issue of water scarcity and contributes to the efficient functioning of the internal market.

Article 2 – Scope

This Article specifies the application of the proposed Regulation to reclaimed water intended for specific uses set out in section 1 of Annex I, which is agricultural irrigation.

Article 3 – Definitions

This Article lists the definitions used in the proposed Regulation.

Article 4 – Obligations of reclamation plant operators as regards water quality

This Article defines the minimum requirements that have to be complied with before the reclaimed water could be used for agricultural irrigation. Reference is made to Annex I that specifies the minimum requirements for reclaimed water quality and monitoring and additional requirements as referred to in Article 7, based on the application of the risk management, as defined by Article 5.

Article 5 – Risk management

This Article defines the process of risk management that should be carried out by the operator of a reclamation plant in cooperation with relevant parties (the end-user of the reclaimed water, the urban waste water treatment plant supplying water to the reclamation plant, etc.). The reclamation plant operator shall elaborate a Water Reuse Risk Management Plan identifying additional requirements to further mitigate risks, which would be part of a permit issued by the competent authority. The Water Reuse Risk Management Plan must be based on the key risk management principles, as defined by Annex II of the proposal. A delegated act is envisaged in order to lay down technical specifications which can supplement the key risk management tasks, as defined in Annex II.

Article 6 – Application for a permit to supply reclaimed water

This Article specifies the application process for a permit to supply reclaimed water, including the list of documents to be provided by the applicant.

Article 7 – Granting of the permit

This Article specifies the obligations of relevant actors in the permitting procedure. Furthermore, it defines the conditions to be included in the permit and the requirement to review the permit at least every 5 year.

Article 8 – Compliance check

This Article defines the obligation of the competent authorities to verify the compliance of the reclaimed water with the conditions set out in the permit. This Article further specifies rules to follow in case of non-compliance or incidents resulting in non-compliance with the proposed Regulation.

Article 9 – Cooperation between Member States

This Article provides the modalities for information exchange between competent authorities of Member States, when relevant, before a permit for water reuse is issued.

Article 10 – Information to the public

In accordance with the conclusions of the Fitness Check on Reporting, this Article stipulates the information to be provided by Member States to the public. The intention is to increase transparency that would result in improved consumers' confidence in water reuse and understanding of impacts of this Regulation on the higher uptake of water reuse. An implementing act is envisaged in order to lay down detailed rules regarding the format and presentation of the information to be provided.

Article 11 – Information on monitoring of implementation

In accordance with the conclusions of the Fitness Check on Reporting, this Article specifies the procedure for gathering relevant data on the implementation of the proposed Regulation, aiming at minimising administrative burden (by using modern ICT tools and focussing on indicator-based reports) and ensuring transparency and accountability vis-à-vis citizens. This Article foresees that Member States should put in place data sets containing information on water reuse, using as much as feasible data from current reporting streams under the Urban Waste Water Treatment Directive and Water Framework Directive. The data sets should be set up in compliance with the INSPIRE Directive. To that end, the support of the European Environmental Agency is foreseen, whose role will also be to regularly access the data and provide the Commission with overviews of the Regulation's implementation at Union level, to be used also in the context of future evaluations of the Regulation (Article 13). An implementing act is envisaged in order to lay down detailed rules regarding the format and presentation of the information to be provided.

Article 12 – Access to justice

This Article is in line in line with Article 47 of the Charter of Fundamental Rights and implements the Aarhus Convention with regard to access to justice. It should be possible for citizens and NGOs to legally review the decisions taken by Member States under this Regulation.

Article 13 – Evaluation

This Article sets the frame for future evaluations (in the sense of the Commission's Better Regulation guidelines) of the Regulation. The first evaluation is foreseen 6 years after the entry into force of the Regulation.

Article 14 – Exercise of the delegation

This is a standard Article for the adoption of delegated acts.

Article 15 – Committee procedure

This is a standard Article for the adoption of implementing acts.

Article 16 – Penalties

This is a standard Article on penalties.

Article 17 – Entry into force and application

This Article sets the date of entry into force and the date of application, i.e. one year after the date of entry into force in order to provide sufficient time to the Member States to adapt to the Regulation, as well as to elaborate an implementing act ensuring the uniform application of the risk management.

Annex I – Uses and minimum requirements

Section 1 – Uses of reclaimed water

This section specifies the uses of reclaimed water, namely agricultural irrigation.

Section 2 – Minimum requirements

This part specifies classes of reclaimed water quality and the associated agricultural use (Table 1). Part (a) specifies minimum requirements for water quality as defined by the JRC based on the Member States and international practice (Table 2).

Part (b) specifies the monitoring requirements for reclaimed water (Table 3) and the validation monitoring for the most stringent class A (Table 4).

Annex II – Key risk management tasks

This Annex sets out the details for the tasks to be followed by the reclamation plant operator in order to develop a Water Reuse Risk Management Plan, to identify additional requirements to be included in the permit, as well as for the implementation of the water reuse system.

Proposal for a

REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

on minimum requirements for water reuse

(Text with EEA relevance)

THE EUROPEAN PARLIAMENT AND THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty on the Functioning of the European Union, and in particular Article 192(1) thereof,

Having regard to the proposal from the European Commission,

After transmission of the draft legislative act to the national parliaments,

Having regard to the opinion of the European Economic and Social Committee¹³,

Having regard to the opinion of the Committee of the Regions¹⁴,

Acting in accordance with the ordinary legislative procedure,

Whereas:

- (1) The water resources of the Union are increasingly coming under pressure, leading to water scarcity and quality deterioration. In particular, climate change and drought are contributing significantly to the strain on the availability of freshwater, arising from urban development and agriculture.
- (2) The Union's ability to respond to the increasing pressure on water resources could be enhanced by wider reuse of treated waste water. Directive 2000/60/EC of the European Parliament and of the Council¹⁵ mentions the reuse of water as one of the supplementary measures Member States may choose to apply to achieve the Directive's objectives of good qualitative and quantitative water status for surface waters and groundwaters. Council Directive 91/271/EEC¹⁶ requires that treated waste water be reused whenever appropriate.
- (3) The Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions on "A Blueprint to Safeguard Europe's Water Resources"¹⁷ pointed to water reuse for

¹³ OJ C , , p. .

¹⁴ OJ C , , p. .

¹⁵ Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1).

¹⁶ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).

¹⁷ COM (2012) 673

irrigation or industrial purposes as an alternative water supply option requiring Union attention.

- (4) The Communication from the Commission to the European Parliament and the Council "Addressing the challenge of water scarcity and droughts in the European Union"¹⁸ sets out the hierarchy of measures that Member States should consider in managing water scarcity and droughts. It states that in regions where all preventive measures have been implemented according to the water hierarchy and where demand for water still exceeds availability, additional water supply infrastructure can, in some circumstances and taking into account of the cost benefit dimension, serve as an alternative approach to mitigate the impacts of severe drought.
- (5) In its Action Plan for the Circular Economy¹⁹ the Commission committed to taking a series of actions to promote the reuse of treated waste water, including the development of a legislative proposal on minimum requirements for water reuse.
- (6) Reuse of appropriately treated waste water, for example from urban waste water treatment plants or industrial installations, is considered to have a lower environmental impact than other alternative water supply methods, such as water transfers or desalination, but such reuse only occurs to a limited extent in the Union. This appears to be partly due to the lack of common Union environmental or health standards for water reuse, and, as regards in particular agricultural products, the potential obstacles to the free movement of such products irrigated with reclaimed water.
- (7) Health standards in relation to food hygiene for agricultural products irrigated with reclaimed water can be achieved only if quality requirements for reclaimed water destined for agricultural irrigation do not differ significantly in Member States. Harmonisation of requirements will also contribute to the efficient functioning of the internal market in relation to such products. It is therefore appropriate to introduce minimum harmonisation by setting minimum requirements for water quality and monitoring. Those minimum requirements should consist of minimum parameters for reclaimed water and other stricter or additional quality requirements imposed, if necessary, by competent authorities together with any relevant preventive measures. In order to identify stricter or additional requirements for water quality, the reclamation plant operators should perform key risk management tasks. The parameters are based on the technical report of the Commission Joint Research Center and reflect the international standards on water reuse.
- (8) The adherence to minimum requirements for water reuse should help support the achievement of the Sustainable Development Goals of the United Nations 2030 Agenda for Sustainable Development, in particular Goal 6, to ensure the availability and sustainable management of water and sanitation for all as well as a substantial increase in recycling and safe reuse of water globally. Furthermore, this Regulation seeks to ensure the application of Article 37 on environmental protection of the Charter of Fundamental Rights of the European Union.
- (9) Risk management should comprise identifying and managing risks in a proactive way and incorporate the concept of producing reclaimed water of a quality required for particular uses. The risk assessment should be based on key risk management tasks and should identify any additional water quality requirements necessary to ensure sufficient protection of the environment, human and animal health.

¹⁸ COM (2007)414

¹⁹ COM (2015)614

- (10) In order to effectively protect the environment and human health, reclamation plant operators should be primarily responsible for the quality of reclaimed water. For the purposes of compliance with the minimum requirements and any additional conditions, set by the competent authority, reclamation plant operators should monitor the quality of reclaimed water. It is therefore appropriate to establish the minimum requirements for monitoring, consisting of the frequencies of the routine monitoring and the timing and performance targets for validation monitoring. Certain requirements for routine monitoring are specified in accordance with Directive 91/271/EEC.
- (11) It is necessary to ensure the safe use of reclaimed water, thereby encouraging water reuse at Union level and enhancing public confidence in it. Supply of reclaimed water for particular uses should therefore only be permitted on the basis of a permit, granted by competent authorities of Member States. In order to ensure harmonised approach at Union level, traceability and transparency, the substantive rules for that permit should be laid down at the Union level. However, the details of the procedures for granting permits should be determined by Member States. Member States should be able to apply existing procedures for granting permits which should be adapted to take account of the requirements introduced by this Regulation.
- (12) The provisions of this Regulation are complementary to the requirements of other Union legislation, in particular with regard to possible health and environmental risks. In order to ensure a holistic approach to addressing possible human and animal health, and environmental risks, the reclamation plant operators and the competent authorities should therefore take into account the requirements laid down in other relevant Union legislation, in particular Council Directives 86/278/EEC, 91/676/EEC²⁰ and 98/83/EC²¹, Directives 91/271/EEC and 2000/60/EC, Regulations (EC) No 178/2002²², (EC) No 852/2004²³, (EC) No 183/2005²⁴, (EC) No 396/2005²⁵ and (EC) 1069/2009²⁶ of the European Parliament and of the Council, Directives 2006/7/EC²⁷, 2006/118/EC²⁸, 2008/105/EC²⁹ and 2011/92/EU³⁰ of the European Parliament and of

²⁰ Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1-8).

²¹ Council Directive 98/83/EC of 3 November 1998 on the quality of water intended for human consumption (OJ L 330, 5.12.1998, p. 32).

²² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety (OJ L 31, 1.2.2002, p. 1).

²³ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

²⁴ Regulation (EC) 183/2005 of the European Parliament and the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1).

²⁵ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1)

²⁶ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (Animal by-products Regulation) (OJ L 300, 14.11.2009, p. 1)

²⁷ Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC (OJ L 64, 4.3.2006, p. 37)

²⁸ Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19).

²⁹ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing

the Council, Commission Regulations (EC) No 2073/2005³¹, (EC) No 1881/2006³² and (EC) 142/2011³³.

- (13) Regulation (EC) 852/2004 lays down general rules for food business operators and covers the production, processing, distribution and placing on the market of food intended for human consumption. That Regulation addresses the health quality of food and one of its main principles is that the primary responsibility for food safety is borne by the food business operator. That Regulation is also subject to detailed guidance, of particular relevance being the Commission Notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (2017/C 163/01). The performance targets for reclaimed water laid down in this Regulation do not preclude food business operators from obtaining the water quality required to comply with Regulation 852/2004 using at a subsequent stage several water treatment options alone or in combination with other non-treatment options.
- (14) In order to encourage confidence in water reuse, information should be provided to the public. Making available of information on water reuse should allow for increased transparency and traceability and could also be of particular interest to other relevant authorities for whom the specific water reuse has implications.
- (15) Directive 2003/4/EC of the European Parliament and of the Council³⁴ aims at guaranteeing the right of access to environmental information in the Member States in line with the Convention on Access to Information, Public Participation in Decision-making and Access to Justice in Environmental Matters³⁵ (Aarhus Convention). Directive 2003/4/EC lays down extensive obligations related both to making environmental information available upon request and actively disseminating such information. Directive 2007/2/EC of the European Parliament and of the Council³⁶, covers the sharing of spatial information, including data-sets on different environmental topics. It is important that provisions of this Regulation related to access to information and data-sharing arrangements complement those Directives and do not create a separate legal regime. Therefore, the provisions of this Regulation on information to the public and on information about monitoring of implementation should be without prejudice to Directives 2003/4/EC and 2007/2/EC.

³⁰ Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84).

³⁰ Directive 2011/92/EU of the European Parliament and of the Council of 13 December 2011 on the assessment of the effects of certain public and private projects on the environment (OJ L 26, 28.1.2012, p. 1).

³¹ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338 22.12.2005, p.1)

³² Commission Regulation (EC) No 1881/2006 of 19 December 2006 setting maximum levels for certain contaminants in foodstuffs (OJ L 364, 20.12.2006, p. 5)

³³ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive Text with EEA relevance (OJ L 54, 26.2.2011, p. 1)

³⁴ Directive 2003/4/EC of the European Parliament and of the Council of 28 January 2003 on public access to environmental information and repealing Council Directive 90/313/EEC (OJ L 41, 14.2.2003, p. 26).

³⁵ OJ L 124, 17.5.2005, p. 4.

³⁶ Directive 2007/2/EC of the European Parliament and of the Council of 14 March 2007 establishing an Infrastructure for Spatial Information in the European Community (INSPIRE) (OJ L 108, 25.4.2007, p. 1).

- (16) In order to adapt the existing minimum requirements and the key risk management tasks to scientific and technical progress, the power to adopt acts in accordance with Article 290 of the Treaty on the Functioning of the European Union should be delegated to the Commission to amend the minimum requirements and the key risk management tasks. Moreover, in order to ensure a high level of protection of the environment and human health, the Commission should also be able to adopt delegated acts supplementing the key risk management tasks by laying down technical specifications. It is of particular importance that the Commission carries out appropriate consultations during its preparatory work, including at expert level, and that those consultations be conducted in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making³⁷. In particular, to ensure equal participation in the preparation of delegated acts, the European Parliament and the Council receive all documents at the same time as Member States' experts, and their experts systematically have access to meetings of Commission expert groups dealing with the preparation of delegated acts.
- (17) In order to ensure uniform conditions for the implementation of this Regulation, implementing powers should be conferred on the Commission for the adoption of detailed rules regarding the format and presentation of the information to be provided to the public by Member States, regarding the format and presentation of the information on monitoring of the implementation of this Regulation to be provided by the Member States and regarding the format and presentation of the information as regards the Union-wide overview drawn up by the European Environmental Agency. Those powers should be exercised in accordance with Regulation (EU) No 182/2011 of the European Parliament and of the Council³⁸.
- (18) Competent authorities should verify compliance of the reclaimed water with the conditions set out in the permit. In cases of non-compliance, they should require the reclamation plant operator to take the necessary measures to ensure compliance. The operators of reclamation plants should immediately suspend any supply of the reclaimed water when non-compliance causes a significant risk to the environment or to human health.
- (19) Competent authorities should cooperate with other relevant authorities, by exchanging information, in order to ensure compliance with relevant Union and national requirements.
- (20) Data provided by Member States is essential to enable the Commission to monitor and assess the performance of the legislation against the objectives it pursues.
- (21) Pursuant to paragraph 22 of the Interinstitutional Agreement of 13 April 2016 on Better Law-Making, the Commission should carry out an evaluation of this Regulation. The evaluation should be based on the five criteria of efficiency, effectiveness, relevance, coherence and EU value added and should provide the basis for impact assessments of possible further measures.
- (22) In accordance with the Aarhus Convention members of the public concerned should have access to justice in order to contribute to the protection of the right to live in an environment which is adequate for health and well-being of individuals.

³⁷ OJ L 123, 12.5.2016, p. 1.

³⁸ Regulation (EU) No 182/2011 of the European Parliament and of the Council of 16 February 2011 laying down the rules and general principles concerning mechanisms for control by the Member States of the Commission's exercise of implementing powers (OJ L 55, 28.2.2011, p. 13).

- (23) Member States should lay down rules on penalties applicable to infringements of the provisions of this Regulation and ensure that they are implemented. The penalties should be effective, proportionate and dissuasive.
- (24) Since the objectives of this Regulation, namely the protection of environment and human health, cannot be sufficiently achieved by the Member States, but can rather, by reason of the scale and effects of the action, be better achieved at Union level, the Union may adopt measures in accordance with the principle of subsidiarity as set out in Article 5 of the Treaty on the European Union. In accordance with the principle of proportionality, as set out in that Article, this Regulation does not go beyond what is necessary in order to achieve those objectives.
- (25) It is necessary to provide for sufficient time for Member States to set up the administrative infrastructure necessary for the application of this Regulation as well as for operators to prepare for the application of the new rules,

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and purpose

1. This Regulation lays down minimum requirements for water quality and monitoring and the obligation to carry out specified key risk management tasks, for the safe reuse of treated urban waste water in the context of integrated water management.
2. The purpose of this Regulation is to guarantee that reclaimed water is safe for its intended use, thereby ensuring a high level of protection of human and animal health and the environment, addressing water scarcity and the resulting pressure on water resources in a coordinated way throughout the Union, thus also contributing to the efficient functioning of the internal market.

Article 2

Scope

This Regulation shall apply to reclaimed water destined for a use specified in section 1 of Annex I.

Article 3

Definitions

For the purposes of this Regulation, the following definitions apply:

1. 'competent authority' means an authority or body designated by a Member State to carry out obligations arising from this Regulation;

2. *'water authority'* means an authority or authorities identified in accordance with Article 3(2) or (3) of Directive 2000/60/EC;
3. *'end-user'* means a natural or legal person who uses reclaimed water;
4. *'urban waste water'* means urban waste water as defined in Article 2(1) of Directive 91/271/EEC;
5. *'reclaimed water'* means urban waste water that has been treated in compliance with the requirements set out in Directive 91/271/EEC and which results from further treatment in a reclamation plant;
6. *'reclamation plant'* means an urban waste water treatment plant or other plant that further treats urban waste water complying with the requirements set out in Directive 91/271/EEC in order to produce water that is fit for a use specified in section 1 of Annex I to this Regulation;
7. *'reclamation plant operator'* means a natural or legal person who operates or controls a reclamation plant;
8. *'hazard'* means 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;
9. *'risk'* means the likelihood of identified hazards causing harm in a specified timeframe, including the severity of the consequences;
10. *'risk management'* is a systematic management that consistently ensures the safety of water reuse in a specific context;
11. *'preventive measure'* means any action or activity that can be used to prevent or eliminate a health and environmental risk, or reduce it to an acceptable level.

Article 4

Obligations of reclamation plant operators as regards water quality

1. Reclamation plant operators shall ensure that reclaimed water destined for a use specified in section 1 of Annex I, shall, at the outlet of the reclamation plant (point of compliance), comply with the following:
 - (a) the minimum requirements for water quality laid down in Section 2 of Annex I;
 - (b) any additional conditions set by the competent authority in the relevant permit pursuant to points (b) and (c) of Article 7(3), as regards water quality.
2. In order to ensure compliance with the requirements and conditions referred to in paragraph 1, the reclamation plant operator shall monitor water quality in accordance with the following:
 - (a) section 2 of Annex I;
 - (b) any additional conditions set by the competent authority in the relevant permit pursuant to points (b) and (c) of Article 7(3), as regards monitoring.
3. The Commission is empowered to adopt delegated acts amending this Regulation in accordance with Article 14 in order to adapt to technical and scientific progress the minimum requirements set out in Section 2 of Annex I.

Article 5

Risk management

1. For the purposes of producing and supplying reclaimed water risk management shall be undertaken by the reclamation plant operator in consultation with the following actors:
 - (a) the operator of the urban waste water treatment plant(s) supplying a reclamation plant with water, if different from the reclamation plant operator;
 - (b) end-user(s);
 - (c) any other party deemed relevant by the reclamation plant operator.
2. The reclamation plant operator shall draw-up a Water Reuse Risk Management Plan based on the key risk management tasks set out in Annex II. The Water Reuse Risk Management Plan shall propose any additional requirements to those specified in Annex I necessary to further mitigate any risks, and shall, inter alia, identify hazards, risks and appropriate preventive measures.
3. The Commission is empowered to adopt, in accordance with Article 14, delegated acts amending this Regulation in order to adapt to technical and scientific progress the key risk management tasks set out in Annex II.

The Commission is also empowered to adopt, in accordance with Article 14, delegated acts supplementing this Regulation in order to lay down technical specifications of the key risk management tasks set out in Annex II.

Article 6

Application for a permit to supply reclaimed water

1. Any supply of reclaimed water destined for a use specified in section 1 of Annex I, shall be subject to a permit.
2. An operator shall submit an application for the permit referred to in paragraph 1, or for a modification of an existing permit to the competent authority of the Member State in which the reclamation plant operates or is planned to operate.
3. The application shall include the following:
 - (a) a Water Reuse Risk Management Plan drawn up in accordance with Article 5(2);
 - (b) a description of how the reclamation plant operator will comply with the minimum requirements for water quality and monitoring set out in section 2 of Annex I;
 - (c) a description of how the reclamation plant operator will comply with the additional requirements proposed in the Water Reuse Risk Management Plan.

Article 7

Granting of the permit

1. For the purposes of assessing the application, the competent authority shall, if appropriate consult and exchange relevant information with the following:
 - (a) other relevant authorities of the same Member State, in particular the water authority, if different than the competent authority;
 - (b) contact points in potentially affected Member State(s) designated in accordance with Article 9(1).
2. The competent authority shall decide within 3 months from the receipt of the complete application as referred to in point (a) of Article 6(3) whether to grant the permit. Where the competent authority needs more time due to the complexity of the application, it shall inform the applicant thereof, indicate the expected date of granting the permit and provide reasons for the extension.
3. Where the competent authority decides to grant a permit, it shall determine the conditions applicable, which shall include the following, as applicable:
 - (a) conditions in relation to the minimum requirements for water quality and monitoring set out in section 2 of Annex I;
 - (b) conditions in relation to the additional requirements proposed in the Water Reuse Risk Management Plan;
 - (c) any other conditions necessary to further mitigate any unacceptable risks to the human and animal health or the environment.
4. The permit shall be reviewed regularly and at least every five years and, if necessary, modified.

Article 8

Compliance check

1. The competent authority shall verify compliance of the reclaimed water with the conditions set out in the permit, at the point of compliance. The compliance check shall be performed using the following means:
 - (a) on-spot checks;
 - (b) use of monitoring data obtained pursuant to this Regulation and Directives 91/271/EEC and 2000/60/EC;
 - (c) any other adequate means.
2. In the event of non-compliance, the competent authority shall require the reclamation plant operator to take any necessary measures to restore compliance without delay.
3. Where non-compliance causes a significant risk to the environment or to human health, the reclamation plant operator shall immediately suspend any further supply of the reclaimed water until the competent authority determines that compliance has been restored.
4. If an incident affecting compliance with the permit's conditions occurs, the reclamation plant operator shall immediately inform the competent authority and the

end-user(s) which may be potentially affected, and communicate to the competent authority the information necessary for assessing the impacts of such an incident.

Article 9

Cooperation between Member States

1. Member States shall designate a contact point to cooperate as appropriate with other Member States' contact points and competent authorities. The role of contact points shall be to provide assistance upon request and coordinate communication between competent authorities. The contact points shall, in particular, receive and transmit requests for assistance.
2. Member States shall respond to requests for assistance without undue delay.

Article 10

Information to the public

1. Without prejudice to Directives 2003/4/EC and 2007/2/EC, Member States shall ensure that adequate and up-to-date information on reuse of water is available online to the public. That information shall include the following:
 - (a) the quantity and the quality of the reclaimed water supplied in accordance with this Regulation;
 - (b) the percentage of the reclaimed water in the Member State supplied in accordance with this Regulation compared to the total amount of treated urban waste water;
 - (c) permits granted or modified in accordance with this Regulation, including conditions set by competent authorities in accordance with Article 7(3);
 - (d) outcome of the compliance check performed in accordance with Article 8(1);
 - (e) contact points designated in accordance with Article 9(1).
2. The information referred to in paragraph 1 shall be updated at least once a year.
3. The Commission may, by means of implementing acts, lay down detailed rules regarding the format and presentation of the information to be provided under paragraph 1. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15.

Article 11

Information on monitoring of implementation

1. Without prejudice to Directives 2003/4/EC and 2007/2/EC, each Member State, assisted by the European Environment Agency, shall:
 - (a) set up and publish by ... [three years after the date of entry into force of this Regulation], and update every 6 years thereafter, a data set containing information on the outcome of the compliance check performed in accordance

with Article 8(1) and other information to be made available online to the public in accordance with Article 10;

- (b) set up, publish and update annually thereafter, a data set containing information on cases of non-compliance with the conditions set out in the permit, collected in accordance with Article 8(1) and information about the measures taken in accordance with Article 8(2) and (3).
- 2. Member States shall ensure that the Commission, the European Environment Agency and the European Centre for Disease Prevention and Control have access to the data sets referred to in paragraph 1.
- 3. On the basis of the data referred to in paragraph 1, the European Environment Agency shall draw up, publish and update, on a regular basis or following a request from the Commission, a Union-wide overview which shall include, as appropriate, indicators for outputs, results and impacts of this Regulation, maps, and Member State reports.
- 4. The Commission may, by means of implementing acts, lay down detailed rules regarding the format and presentation of the information to be provided in accordance with paragraph 1 as well as detailed rules regarding the format and presentation of the Union-wide overview referred to in paragraph 3. Those implementing acts shall be adopted in accordance with the examination procedure referred to in Article 15.

Article 12

Access to justice

- 1. Member States shall ensure that natural or legal persons or their associations, organisations or groups, in accordance with national legislation or practice, have access to a review procedure before a court of law or another independent and impartial body established by law to challenge the substantive or procedural legality of decisions, actions or omissions related to the implementation of Articles 4 to 8, when one of the following conditions is fulfilled:
 - (a) they have a sufficient interest;
 - (b) they maintain the impairment of a right, where the administrative procedural law of the relevant Member State requires this as a precondition.
- 2. Member States shall determine at what stage decisions, acts or omissions may be challenged.
- 3. What constitutes a sufficient interest and impairment of a right shall be determined by Member States, consistently with the objective of giving the public concerned wide access to justice.

To that end, the interest of any non-governmental organisation promoting environmental protection and meeting the requirements under national law shall be deemed sufficient for the purposes of paragraph 1(a).

Such organisations shall also be deemed to have rights capable of being impaired for the purposes of paragraph 1(b).
- 4. Paragraphs 1, 2 and 3 shall not exclude the possibility of a preliminary review procedure before an administrative authority and shall not affect the requirement of

exhaustion of administrative review procedures prior to recourse to judicial review procedures, where such a requirement exists under national law.

5. Any review procedure referred to in paragraphs 1 and 4 shall be fair, equitable, timely and not prohibitively expensive.
6. Member States shall ensure that information is made available to the public on access to administrative and judicial review procedures.

Article 13

Evaluation

1. The Commission shall, by ... [6 years after the date of entry into force of this Regulation], carry out an evaluation of this Regulation. The evaluation shall be based at least on the following elements:
 - (a) the experience gathered from the implementation of this Regulation;
 - (b) the data sets set up by Member States in accordance with Article 11(1) and the Union-wide overview drawn up by the European Environment Agency in accordance with Article 11(3);
 - (c) relevant scientific, analytical and epidemiological data;
 - (d) technical and scientific knowledge;
 - (e) World Health Organisation recommendations, where available.
2. In the context of the evaluation referred to in paragraph 1, the Commission shall pay particular regard to the following aspects:
 - (a) the minimum requirements set out in Annex I;
 - (b) the key risk management tasks set out in Annex II;
 - (c) the additional requirements set by competent authorities pursuant to point (b) and (c) of Article 7(3);
 - (d) the impacts of water reuse on the environment and human health.

Article 14

Exercise of the delegation

1. The power to adopt delegated acts is conferred on the Commission subject to the conditions laid down in this Article.
2. The power to adopt delegated acts referred to in Article 4(3) and Article 5(3) shall be conferred on the Commission for an indeterminate period of time from the date of entry into force of this Regulation.
3. The delegation of power referred to in Article 4(3) and Article 5(3) may be revoked at any time by the European Parliament or by the Council. A decision to revoke shall put an end to the delegation of the power specified in that decision. It shall take effect the day following the publication of the decision in the *Official Journal of the*

European Union or at a later date specified therein. It shall not affect the validity of any delegated acts already in force.

4. Before adopting a delegated act, the Commission shall consult experts designated by each Member State in accordance with the principles laid down in the Interinstitutional Agreement of 13 April 2016 on Better Law-Making.
5. As soon as it adopts a delegated act, the Commission shall notify it simultaneously to the European Parliament and to the Council.
6. A delegated act adopted pursuant to Article 4(3) and Article 5(3) shall enter into force only if no objection has been expressed either by the European Parliament or by the Council within a period of two months of notification of that act to the European Parliament and the Council or if, before the expiry of that period, the European Parliament and the Council have both informed the Commission that they will not object. That period shall be extended by two months at the initiative of the European Parliament or of the Council.

Article 15

Committee procedure

1. The Commission shall be assisted by the Committee established by Directive 2000/60/EC. That committee shall be a committee within the meaning of Regulation (EU) No 182/2011.
2. Where reference is made to this paragraph, Article 5 of Regulation (EU) No 182/2011 shall apply.

Article 16

Penalties

Member States shall lay down the rules on penalties applicable to infringements of this Regulation and shall take all measures necessary to ensure that they are implemented. The penalties provided for shall be effective, proportionate and dissuasive. Member States shall, by ... [three years after the date of entry into force of this Regulation], notify the Commission of those rules and of those measures and shall notify it of any subsequent amendment affecting them.

Article 17

Entry into force and application

This Regulation shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.

It shall apply from ... [one year after the date of entry into force of this Regulation].

This Regulation shall be binding in its entirety and directly applicable in all Member States.

Done at Brussels,

For the European Parliament
The President

For the Council
The President