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NOTE

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Subject:	Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse - General approach

I. INTRODUCTION

1. On 28 May 2018, the Commission adopted its legislative proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse¹, the so-called Regulation on water reuse.
2. The overarching objective of the proposal is to address water scarcity across the EU through use of reclaimed water for agricultural irrigation. As a result, water reuse contributes to the circular economy and climate change adaptation. At the same time, the proposal protects human and animal health and the environment by setting minimum requirements for both the quality of reclaimed water and for monitoring compliance, in combination with harmonisation of key elements of risk management.

¹ 9498/18 + ADD 1 to ADD 6.

3. The Economic and Social Committee adopted its opinion on the proposal on 12 December 2018². The Committee of the Regions adopted its opinion on 6 December 2018³.
4. The European Parliament adopted its first reading position on the Commission proposal on 12 February 2019 (with 588 votes in favour, 23 votes against and 66 abstentions).

II. WORK AT THE COUNCIL

5. The Commission presented its legislative proposal and the accompanying impact assessment to the Working Party on the Environment (WPE) on 14 June 2018. The WPE examined the impact assessment and started analyzing the proposal.
6. During the Romanian Presidency substantial progress was made at expert level to converge views on the scope and application of the Regulation, the procedures for permitting water reuse and risk management as well as on Annex I on uses and minimum requirements and Annex II, on key elements of risk management.
7. On 12 June 2019, the Presidency submitted to the Permanent Representative Committee an overall compromise text on the Regulation on water reuse (9909/19) for discussion.

² NAT/723-EESC-2018-02925

³ ENVE-VI/034

8. The Presidency considers that the compromise text submitted to Coreper strikes a delicate balance between the different interests. The main elements concern the following:
- Member States which do not intend to practice water reuse have the possibility to decide themselves whether and when they consider it appropriate to start doing so. As a result of such decision, these Member States can refrain from the obligation to establish the administrative framework for enabling water reuse. Such decision must be communicated to the Commission and made available to the public.
 - The minimum requirements for the quality of reclaimed water set out in Annex I preserve the Commission proposal. These requirements are the outcome of discussions amongst Member States' experts over a period of 3 years and are based on a report of the Joint Research Centre that draws on the internationally recognised water reuse standards and practices. The technical experts consider these minimum requirements to provide sufficient protection of human and animal health and the environment. Moreover, the compromise text provides for a review by the Commission of the minimum requirements.
 - Water reuse is permitted only on the basis of a permit or authorization granted by the competent authorities of the Member States. The system for permitting the production and supply of reclaimed water provides for general harmonised obligations while offering sufficient flexibility for Member States to determine the details of the procedures for granting permits or authorizations at national level.

- The Water Reuse Risk Management Plan constitutes the basis for permitting of production and supply of reclaimed water. The risk management approach identifies and manages possible risks in relation to reclaimed water in a proactive way in order to ensure sufficient protection of human and animal health and the environment.
- The obligation to inform the public about water reuse, as well as the obligation to inform the Commission on monitoring of implementation is maintained for the Member States where reclaimed water is used for agricultural irrigation.
- Entry into application of the Regulation is set at 5 years after entry into force. As a result, Member States have sufficient time to take up the obligations of the Regulation.

9. Discussions at Coreper on 12 June 2019 showed that there was wide support for reaching a general approach at the Environment Council on 26 June 2019. However, few delegations still maintained the view that the minimum requirements in Annex I should be stricter and that the provisions on risk management should be strengthened. In light of the discussions, the Presidency has put forward during Coreper new amendments to further fine tune the compromise text:

- Clarification of the link between the general evaluation provision of the Regulation and the review of the minimum requirements for the quality of reclaimed water. The amended compromise text provides that the Commission must have carried out the evaluation 8 years after entry into force of the Regulation. Moreover, based on the results of this evaluation, or whenever new technical and scientific knowledge so requires, the Commission may examine the need to review the minimum requirements and, where appropriate, shall make legislative proposals for amendments in accordance with the Treaty. These amendments are reflected in Article 13 and recital (15bis) and in deletion of Article 13bis.

- Specification of the procedure for cooperation between Member States in relation to cross-border reuse of treated urban waste water in Article 9.
- Enhanced legal clarity about the application of stricter requirements in case the assessment shows a risk by deleting the paragraph at the end of point a) in Section 2 of Annex 1.

The compromise text resulting from Coreper discussions is set out in the Annex to this note. Amendments to the Commission proposal are indicated in **bold** and ~~striketrough~~ for deletions.

III. CONCLUSION

9. The Council is invited to examine the compromise text as set out in the Annex to this note with a view to reaching agreement on a general approach.

The General approach will constitute the Council's mandate for future negotiations with the European Parliament.

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 Committee¹,

Having regard to the opinion of the Committee of the Regions²,

Acting in accordance with the ordinary legislative procedure,

¹ OJ C , , p. .

² OJ C , , p. .

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 Council³ 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/EEC⁴ 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"⁵ pointed to water reuse for irrigation or industrial purposes as an alternative water supply option requiring Union attention.

³ 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).

⁴ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).

⁵ COM (2012) 673

- 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"⁶ 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.
- 4a) **The European Parliament in its Resolution of 9 October 2008 on addressing the challenge of water scarcity and droughts in the European Union⁷, recalls that a demand-side approach should be preferred when managing water resources and considers, however, that the EU should adopt a holistic approach when managing water resources, combining measures of demand management, measures to optimise existing resources within the water cycle, and measures to create new resources, and that the approach needs to integrate environmental, social and economic considerations.**
- 5) In its Action Plan for the Circular Economy⁸ 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 COM(2007) 414

⁷ **2008/2074 (INI)**

⁸ COM(2015) 614

- 5a) **The purpose of this legal instrument on water reuse is to facilitate the uptake of water reuse whenever it is appropriate and cost-efficient, thereby creating an enabling framework for those Member States who wish or need to practice water reuse. Water reuse is a promising option for many Member States, but currently only a small part of them practice water reuse and adopted national legislation or standards in this regard. This legal instrument should be flexible enough to allow the continuation of water reuse and at the same time to ensure the possibility for other Member States to apply these rules when they decide to introduce this practice at a later stage.**
- 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.

- 7a) Water reuse for agricultural irrigation can also contribute to the promotion of the circular economy by recovering nutrients from the reclaimed water and applying them to crops, by means of fertigation techniques. Thus, water reuse could potentially reduce the need for supplemental applications of mineral fertiliser.**
- 7b) The high investments needed for the upgrading of urban waste water treatment plants and the lack of financial incentives for implementing water reuse in agriculture have been identified among the reasons for low uptake of water reuse in Europe. These issues can be addressed by promoting innovative schemes and economic incentives to appropriately account for the costs and the socio-economic and environmental benefits of 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.
- 8a) There is a great potential for recycling and reusing of treated waste water. In order to encourage the recycling and reuse at national level, the treated waste water can be used for other purposes than those established by this Regulation, as considered necessary in line with the national characteristics and needs. To this end, national provisions on water reuse could be adopted in order to ensure the protection of the environment and human health from such uses.**

- 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 **elements of risk management tasks** and should identify any additional water quality requirements necessary to ensure sufficient protection of the environment, human and animal health. **For this purpose, the water reuse risk management plans should ensure that reclaimed water is safely used and managed and there are no risks to human and animal health and the environment. In order to develop these risk management plans, existing international guidance or standards such as ISO 20426:2018 Guidelines for health risk assessment and management for non-potable water reuse, ISO 16075:2015 Guidelines for treated waste water use for irrigation projects or WHO guidelines⁹ could be used. Special attention should be given to the protection of bodies of water used for the abstraction of water intended for human consumption and/or relevant safeguards zones.**
- 10) In order to effectively protect ~~the environment and~~ human **and animal health and the environment**, reclamation plant operators should be primarily responsible for the quality of reclaimed water **up to the point of compliance**.

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.

⁹ https://www.who.int/water_sanitation_health/publications/gsuweg2/en/

- 10a) Reclaimed water covered by the requirements of this Regulation is obtained from waste water that has been collected in collecting systems and that has been treated in urban waste water treatment plants in accordance with Directive 91/271/EEC and that follows further treatment (either in the urban waste water treatment plant or in a reclamation plant) to meet the parameters set out in Annex I of this Regulation. In accordance with Article 3(1) of Directive 91/271/EEC, agglomerations of less than 2000 population equivalent (p.e.) do not have the obligation to be provided with a collecting system. However, urban waste water from agglomerations of less than 2000 p.e. entering a collecting systems should be subject to appropriate treatment before this waste water is discharged to fresh water and estuaries, in accordance with Article 7 of Directive 91/271/EEC. In this context, waste water from agglomerations of less than 2000 p.e. would fall under the scope of this Regulation only when it enters a collecting system and is subject to treatment in an urban waste water treatment plant. In a similar way, this Regulation does not regard biodegradable industrial waste water from plants belonging to the industrial sectors listed in Annex III of Directive 91/271/EEC, unless the waste water from these plants enters a collecting system and is subject to treatment in an urban waste water treatment plant.**
- 10b) The reuse of treated urban waste water for agricultural irrigations is a market driven action, based on demands and needs of the agricultural sector, in particular in certain Member States facing water resource shortages. The reclamation plant operators and the end users should cooperate to ensure that reclaimed water quality produced in accordance with the minimum requirements established by this Regulation meet the needs of the end users regarding crop categories. In cases where the water quality classes produced by the reclamation plant operators are not compatible with the crop category and irrigation method already in place in the served area (e.g. in a collective supply system), water quality requirements could be obtained using at a subsequent stage several water treatment options alone or in combination with other non-treatment options of the reclaimed water, in line with multi-barrier approach.**

- 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~~ **Production and supply of reclaimed water for particular uses agricultural irrigation** should therefore only be permitted on the basis of a permit **or authorisation**, 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 **or authorisation** should be laid down at the Union level. However, the details of the procedures for granting permits **or authorisations, such as the competent authorities and deadlines**, should be determined by Member States. Member States should be able to apply existing procedures for granting permits **or authorisations** which should be adapted to take account of the requirements introduced by this Regulation. **When designating the responsible party(ies) or authority(ies) for the elaboration of the Water Reuse Risk Management Plan and the competent authority for the granting of the permit or authorisation for production and supply of reclaimed water, Member States should ensure that there is no conflict of interests.**

- 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/EEC¹⁰ and 98/83/EC¹¹, Directives 91/271/EEC and 2000/60/EC, Regulations (EC) No 178/2002¹², (EC) No 852/2004¹³, (EC) No 183/2005¹⁴, (EC) No 396/2005¹⁵ and (EC) 1069/2009¹⁶ of the European Parliament and of the Council, Directives 2006/7/EC¹⁷, 2006/118/EC¹⁸, 2008/105/EC¹⁹ and 2011/92/EU²⁰ of the European Parliament and of the Council, Commission Regulations (EC) No 2073/2005²¹, (EC) No 1881/2006²² and (EC) 142/2011²³.

¹⁰ 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).

¹¹ 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).

¹² 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).

¹³ 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).

¹⁴ 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).

¹⁵ 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)

¹⁶ 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)

¹⁷ 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)

¹⁸ 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).

¹⁹ 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 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).

²⁰ 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).

²¹ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338 22.12.2005, p.1)

²² 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)

- 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~~ **minimum requirements** 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.

²³ 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)

15) Directive 2003/4/EC of the European Parliament and of the Council²⁴ 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 Matters²⁵ (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 Council²⁶, 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.

15bis) The minimum requirements for the safe reuse of treated urban waste water reflect available scientific knowledge and internationally recognised water reuse standards and practices and guarantee that such water can be safely used for agricultural irrigations, thereby ensuring a high level of protection of human and animal health and the environment. In light of the results of the evaluation of this Regulation or whenever new scientific developments and technical progress so requires, the Commission could examine the need to review the minimum requirements set out in section 2 of Annex I and, where appropriate, should make legislative proposals for amendments in accordance with the Treaty.

²⁴ 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).

²⁵ OJ L 124, 17.5.2005, p. 4.

²⁶ 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 **elements of 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 **elements of 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-Making²⁷. 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 Council²⁸.

²⁷ OJ L 123, 12.5.2016, p. 1.

²⁸ 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).

- 18) Competent authorities should verify compliance of the reclaimed water with the conditions set out in the permit **or authorisation**. In cases of non-compliance, they should require the ~~reclamation plant operator~~ **responsible party(ies) or authority(ies)** to take the necessary measures to ensure compliance. ~~The operators of reclamation plants should immediately suspend any~~ Supply of the reclaimed water **should be suspended** 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.~~
- 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 **and animal health and the environment**, 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.
- 25a) Directive 2000/60/EC provides Member States with the necessary flexibility to include supplementary measures in the programmes of measures adopted to support their efforts to achieve the water quality objectives as established by this Directive. The non-exclusive list of supplementary measures provided for in Annex VI Part B of Directive 2000/60/EEC contains, among others, water reuse measures. In this context and in line with the hierarchy of measures that could be considered by the Member States in managing water scarcity and droughts and that encourages with priority measures from water saving to water pricing policy and alternative solutions, and taking due account of the cost-benefit dimension, the minimum requirements for water reuse, as established by this Regulation, should be applicable whenever treated urban waste water from urban waste water treatment plants is reused, in accordance with Article 12(1) of the Directive 91/271/EEC of 21 May 1991 concerning urban waste-water treatment, for agricultural irrigation.**

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~~ **specific** 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~~ **agricultural irrigation**, thereby ensuring a high level of protection of human and animal health and the environment, **promoting the circular economy and supporting adaptation to climate change**, 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

1. This Regulation shall apply to ~~reclaimed water destined for a use~~ **whenever treated urban waste water is reused, in accordance with Article 12(1) of Directive 91/271/EC, for agricultural irrigation** as specified in section 1 of Annex I.
2. **A Member State may decide that it is not appropriate to reuse treated urban waste water for agricultural irrigation in parts of or in its whole territory, taking into account its geographic and climatic conditions, including the quantitative status of groundwater as referred to in the Directive 2000/60/EC, the surface water, the social, environmental and economic effects of reuse and other appropriate solutions to deal with water scarcity and drought.**

This decision shall be based on one or more of the criteria referred to in the first subparagraph and shall be communicated to the Commission.

Member State shall review this decision as necessary, in particular taking into account the need to adapt to climate change.

2a. By way of derogation, research projects in relation to reclamation plants need not comply with the provisions of this Regulation where the competent authority establishes that the following criteria are met:

a) the research project will not be carried out within a body of water used for the abstraction of water intended for human consumption and/or relevant safeguard zones designated pursuant to Directive 2000/60;

b) the research project will be subject to appropriate monitoring.

Any decision taken pursuant to this paragraph shall be limited to a maximum period of 5 years. All crops resulting from a research project exempted in accordance with this paragraph shall not be placed on the market.

3. This Regulation shall apply without prejudice to Regulation 852/2004 and does not preclude food business operators from obtaining the water quality required to comply with Regulation 852/2004 applying at a subsequent stage several water treatment options alone or in combination with other non-treatment options or from using other alternative water sources for agricultural irrigation.

Article 3

Definitions

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

1. '*competent authority(ies)*' means an authority(ies) or body(ies) designated by a Member State to carry out obligations arising from this Regulation **regarding the granting of the permit or authorisation for production and/or supply of reclaimed water and the checking of the compliance, as well as regarding the granting of derogation for research projects;**
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 **in accordance with section 2 of Annex I of this Regulation;**
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;
12. ***'point of compliance'* means the outlet of the reclamation plant unless defined by the competent authority at a later point where the reclaimed water is delivered by the reclamation plant operator to the next actor in the chain;**
13. ***'barrier'* is any mean, including physical or process steps or conditions of use, that reduces or prevents the risk of human infection by preventing contact of the reclaimed water with the ingested produce and the directly exposed persons, or other mean that, for example, reduces the concentration of microorganisms in the reclaimed water or prevents their survival on the ingested produce;**
14. ***'permit or authorisation'* means a written approval issued by the competent authority to produce and/or supply reclaimed water for agricultural irrigation in accordance with this Regulation;**
15. ***'responsible party(ies) or authority(ies)'* means a party(ies) or authority(ies), different from competent authority(ies), that carry out obligations arising from this Regulation;**
16. ***'water reuse system'* means the group of infrastructures and other technical elements necessary for producing, supplying and using reclaimed water. It comprises all the elements from the inlet of the wastewater treatment plant to the point(s) where reclaimed water is applied for agricultural irrigation.**

Article 4

*Obligations of ~~reclamation plant operators~~ as regards **reclaimed** water quality*

1. Reclamation plant operators shall ensure that reclaimed water destined for ~~a use~~ **agricultural irrigation as** 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 **or authorisation** pursuant to points (~~b c~~) and (~~e d~~) of Article 7 **6(3)**, as regards water quality.

The reclamation plant operator shall not be responsible for the quality of reclaimed water after the point of compliance.

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 **or authorisation** pursuant to points (~~b c~~) and (~~e d~~) of Article 7 **6(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.~~
3. **The quality requirements laid down in section 2 of Annex I may be accompanied by additional barriers in the water reuse system to guarantee that water meets the quality requirements at the point of end-use in accordance with Regulation 852/2004.**

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);~~
 - e) ~~any other party deemed relevant by the reclamation plant operator.~~
2. ~~The reclamation plant operator shall draw up~~ **For the purpose of producing, supplying and using reclaimed water, the competent authority shall ensure that** a Water Reuse Risk Management Plan **is established**, based on the key **elements of risk management tasks** set out in Annex II. **The Water Reuse Risk Management Plan may cover one or more water reuse systems.**

The Water Reuse Risk Management Plan **shall identify the risk management responsibilities, shall identify potential risks and hazards and their appropriate preventive and/or possible corrective measures and** 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 before the point of compliance.~~

3. **The Water Reuse Risk Management Plan may further identify any additional requirements to those specified in Annex I after the point of compliance and the party(ies) responsible for carrying them out.**

The Water Reuse Risk Management Plan may also identify the additional barriers as referred to in Article 4 (3), including conditions related to storage, distribution and use.

4. 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 **elements of 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.~~

5. **The Commission shall, in consultation with Member States, establish guidelines to support the elaboration of the Water Reuse Risk Management Plans within two years after the date of entry into force of this Regulation.**

Article 6

Application for a permit to supply **Obligations regarding reclaimed water permit or authorisation**

1. ~~Any supply of~~ **Any production and supply of** reclaimed water destined for a use **agricultural irrigation** as specified in section 1 of Annex I, shall be subject to a permit **or authorisation**.
2. ~~An operator~~ **The responsible party(ies) or authority(ies) for reclaimed water** shall ~~submit an application~~ **apply** for the permit **or authorisation** referred to in paragraph 1, or for a modification of an existing permit **or authorisation** to the competent authority of the Member State in which the reclamation plant operates or is planned to operate.
3. ~~The application~~ **permit or authorisation shall be based on the Water Reuse Risk Management Plan and** shall include, **inter alia**, 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;~~

- ~~e) a description of how the reclamation plant operator will comply with the additional requirements proposed in the Water Reuse Risk Management Plan.~~
- a) **the quality class(es) of the reclaimed water and allowed agricultural use or uses for which, according to Annex I, the reclaimed water is permitted or authorized, the place of use, the reclamation plant or plants and the estimated yearly volume of the reclaimed water to be produced;**
- b) **conditions in relation to the minimum requirements for water quality and monitoring set out in section 2 of Annex I;**
- c) **conditions in relation to the additional requirements proposed in the Water Reuse Risk Management Plan;**
- d) **any other conditions necessary to further mitigate any unacceptable risks to human and animal health or the environment;**
- e) **the validity period.**

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;~~
 - ~~e) any other conditions necessary to further mitigate any unacceptable risks to the human and animal health or the environment.~~
4. The permit **or authorisation** shall be reviewed regularly and ~~at least every five years and~~, if necessary, modified, **in particular in case of a substantial change of the capacity or the technological process of the reclamation plant.**
5. **Member States may decide that storage, distribution and use of the reclaimed water shall be subject to a specific permit or authorisation to apply the additional requirements and barriers identified in the Water Reuse Risk Management Plan, as referred to in Article 5 (3).**

Article 8

Compliance check

1. The competent authority shall verify compliance of the reclaimed water with the conditions set out in the permit **or authorisation**, 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 **in particular** pursuant to this Regulation and, **if necessary**, Directives 91/271/EEC and 2000/60/EC;
 - c) **or** any other adequate means.
2. In the event of non-compliance **with conditions set out in the permit or authorisation**, the competent authority shall require the ~~reclamation plant operator~~ **responsible party(ies) or authority(ies)** 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~~ **responsible party(ies) or authority(ies)** shall ~~immediately~~ suspend ~~any further supply~~ **the use** of the reclaimed water until the competent authority determines that compliance has been restored.
4. If an incident affecting compliance with the conditions in the permit **or authorisation** occurs, the ~~reclamation plant operator~~ **responsible party(ies) or authority(ies)** shall ~~immediately~~ inform the competent authority and ~~the end-user(s)~~ **other parties** 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. **Where water reuse is of cross-border relevance**, Member States shall designate a contact point **or shall use existing structures stemming from international agreements** to cooperate as appropriate with other Member States' contact points and competent authorities. The role of contact points **or existing structures** shall be to provide assistance upon request and coordinate communication between competent authorities. **Competent authorities shall exchange information on the conditions set out in Article 6(3) before granting the permit or authorization, with the contact point in the Member State in which reclaimed water is intended to be used.** 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 **where reclaimed water is used for the agricultural irrigation as specified in section 1 of Annex I of this Regulation** shall ensure that adequate and up-to-date information on reuse of water is available online **or by other means** 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;~~

- e b) permits **or authorisations** granted or modified in accordance with this Regulation, including conditions set by competent authorities in accordance with Article 7 ~~6~~(3);
 - e c) outcome of the compliance check performed in accordance with Article 8(1);
 - e d) contact points designated in accordance with Article 9(1).
2. The information referred to in paragraph 1 shall be updated ~~at least once a~~ **every two** years.
 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.~~

Member States shall ensure that the decision made in accordance with Article 2(2) is made available to the public online or by other means.

Article 11

Information on monitoring of implementation

1. Without prejudice to Directives 2003/4/EC and 2007/2/EC, ~~each~~ Member States **where reclaimed water is used for the agricultural irrigation as specified in section 1 of Annex I of this Regulation**, assisted by the European Environment Agency, shall:
 - a) set up and publish by ... [~~three~~ **eight** 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 **or authorisation**, 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, **in consultation with Member States**, 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.
 1. ~~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).~~
 2. ~~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 and review

1. The Commission shall, by ... [~~6~~ **8** 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 **or other international guidance or ISO standards**.

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 **elements of** 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 6(3);
 - d) the impacts of water reuse on the environment and human **and animal** health.
3. **Based on the results of the evaluation referred to in paragraph 1 or whenever new technical and scientific knowledge so requires, the Commission may examine the need to review the minimum requirements set out in section 2 of Annex I and, where appropriate, shall make legislative proposals for amendments in accordance with the Treaty.**

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~~ 4) shall be conferred on the Commission for ~~an indeterminate~~ a period of ~~time~~ **five years** from the date of entry into force of this Regulation. **The Commission shall draw up a report in respect of the delegation of power not later than nine months before the end of the five-year period. The delegation of power shall be tacitly extended for periods of an identical duration, unless the European Parliament or the Council opposes such extension not later than three months before the end of each period.**
3. The delegation of power referred to in ~~Article 4(3)~~ and Article 5(~~3~~ 4) 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 4) 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.

Where the Committee delivers no opinion, the Commission shall not adopt the draft implementing act and the third subparagraph of Article 5(4) 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~~ **five** 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~~ **five** years 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

ANNEX I

USES AND MINIMUM REQUIREMENTS

Section 1. Uses of reclaimed water as referred to in Article 2

a) Agricultural irrigation

Agricultural irrigation means irrigation of the following types of crops:

- food crops consumed raw, meaning crops which are intended for human consumption to be eaten raw or unprocessed;
- processed food crops, meaning 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, meaning crops which are not intended for human consumption (e.g. pastures, forage, fiber, ornamental, seed, energy and turf crops).

Section 2. Minimum requirements

2.1. Minimum requirements applicable to reclaimed water destined to be used for agricultural irrigation

The classes of reclaimed water quality and the allowed uses and irrigation methods for each class are set out in Table 1. The minimum requirements for water quality are set out in point (a), Table 2. The minimum frequencies and performance targets for monitoring the reclaimed water are set out in point (b), Table 3 (routine monitoring) and Table 4 (validation monitoring).

The crop categories shall be irrigated with reclaimed water of the corresponding minimum reclaimed water quality class as set out in Table 1 below, unless appropriate additional barriers as referred to in Article 4(3) are applied, resulting in achieving the quality requirements set out in Table 2. Such additional barriers may be based on the indicative list of preventive measures mentioned in point 6 of Annex II or in any other equivalent national or international standards, e.g. the standard ISO 16075-2.

Table 1 Classes of reclaimed water quality and allowed agricultural use and irrigation method

Minimum reclaimed water quality class	Crop category	Irrigation method
A	All food crops, including root crops, consumed raw and food crops where the edible part is in direct contact with reclaimed water	All irrigation methods
B	Food crops consumed raw where the edible part is produced above ground and is not in direct contact with reclaimed water, processed food crops and non-food crops including crops to feed milk- or meat-producing animals	All irrigation methods
C	Food crops consumed raw where the edible part is produced above ground and is not in direct contact with reclaimed water, processed food crops and non-food crops including crops to feed milk- or meat-producing animals	Drip irrigation* only or other irrigation method that avoids direct contact with the edible part of the crop
D	Industrial, energy, and seeded crops	All irrigation methods**

(*) Drip irrigation (also called trickle irrigation) is a micro-irrigation system capable of delivering water drops or tiny streams to the plants and involves dripping water onto the soil or directly under its surface at very low rates (2-20 litres/hour) from a system of small diameter plastic pipes fitted with outlets called emitters or drippers.

(**) **In cases of irrigation methods which imitate rain, special attention should be paid to the protection of the health of workers or bystanders. For this purpose appropriate preventive measures should be applied.**

a) Minimum requirements for water quality

Table 2 Minimum requirements for reclaimed water quality requirements for agricultural irrigation

Reclaimed water quality class	Indicative technology target	Quality requirements				
		<i>E. coli</i> (cfu number/ 100 ml) or below detection limit	BOD ₅ (mg/l)	TSS (mg/l)	Turbidity (NTU)	Other
A	Secondary treatment, filtration, and disinfection	≤10 or below detection limit	≤10	≤10	≤5	<i>Legionella</i> spp.: <1,000 cfu/l where there is risk of aerosolization in greenhouses Intestinal nematodes (helminth eggs): ≤1 egg/l for irrigation of pastures or forage
B	Secondary treatment, and disinfection	≤100	According to Council Directive 91/271/EEC ²⁹ (Annex I, Table 1)	According to Directive 91/271/EEC (Annex I, Table 1)	-	
C	Secondary treatment, and disinfection	≤1,000			-	
D	Secondary treatment, and disinfection	≤10,000			-	

The reclaimed water will be considered compliant with the requirements set out in Table 2 if the measurements meet all of the following criteria:

- The indicated values for *E. coli*, *Legionella spp* and Intestinal nematodes are met in 90% or more of the samples. None of the values of the samples can 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.
- The indicated values for BOD₅, TSS, and turbidity in Class A are met in 90% or more of the samples. None of the values of the samples can exceed the maximum deviation limit of 100% of the indicated value.

²⁹ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).

b) Minimum requirements for monitoring

Reclamation plant operators shall perform routine monitoring to verify that the reclaimed water is complying with the minimum water quality requirements set out in point (a). The routine monitoring shall be included in the verification procedures of the water reuse system.

Table 3 Minimum frequencies for routine monitoring of reclaimed water for agricultural irrigation

Minimum monitoring frequencies						
Reclaimed water quality class	<i>E. coli</i>	BOD ₅	TSS	Turbidity	<i>Legionella</i> spp. <i>(when applicable)</i>	Intestinal nematodes <i>(when applicable)</i>
A	Once a week	Once a week	Once a week	Continuous	Once a week Twice a month	Twice a month or frequency determined by the reclamation plant operator according to the number of eggs in waste water entering the reclamation plant
B	Once a week	According to Directive 91/271/EEC (Annex I, Section D)	According to Directive 91/271/EEC (Annex I, Section D)	-	Twice a month	
C	Twice a month			-		
D	Twice a month			-		

Validation monitoring has to be performed before ~~the~~ a new reclamation plant is put into operation, when equipment is upgraded, and when new equipment or processes are added. **Reclamation plants that are already in operation and meeting the reclaimed water quality requirements set out in Annex I table 2 at the date of entry into force of this Regulation, shall be exempted from the validation monitoring obligations.**

Validation monitoring shall be performed for the most stringent reclaimed water quality class, Class A, to assess that the performance targets (\log_{10} reduction) are complied with. 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 (\log_{10} reduction) for the validation monitoring for the selected indicator microorganisms are set out in Table 4 and shall be met at the ~~outlet of the reclamation plant~~ (point of compliance), considering the concentrations of the raw waste water effluent entering the urban waste water treatment plant. **At least 90% of validation samples shall reach or exceed the performance targets.**

If a biological indicator is not present in sufficient quantity in raw waste water effluent to achieve the \log_{10} reduction, the absence of such biological indicator in reclaimed water shall mean that the validation requirements are complied with. The performance with the compliance target may be established by analytical control, by addition of the performance granted to individual treatment steps based on scientific evidence for standard well-established processes, such as published data of testing reports, case studies etc., or tested in laboratory under controlled conditions for innovative treatment.

Table 4 Validation monitoring of reclaimed water for agricultural irrigation

Reclaimed water quality class	Indicator microorganisms (*)	Performance targets for the treatment chain (log ₁₀ reduction)
A	<i>E. coli</i>	≥ 5.0
	Total coliphages/ F-specific coliphages/somatic coliphages/coliphages(**)	≥ 6.0
	<i>Clostridium perfringens</i> spores/spore-forming sulfate-reducing bacteria(***)	≥ 4.0 (in case of <i>Clostridium perfringens</i> spores) ≥ 5.0 (in case of spore-forming sulfate-reducing bacteria)

(*) The reference pathogens *Campylobacter*, Rotavirus and *Cryptosporidium* can also be used for validation monitoring purposes instead of the proposed indicator microorganisms. The following log₁₀ reduction performance targets should then apply: *Campylobacter* (≥ 5.0), Rotavirus (≥ 6.0) and *Cryptosporidium* (≥ 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 sporeforming sulfate-reducing bacteria is an alternative if the concentration of *Clostridium perfringens* spores does not allow to validate the requested log₁₀ removal.

Methods of analysis for monitoring shall be validated and documented by the operator in accordance with EN ISO/IEC-17025 or other national or international standards which ensure an equivalent quality.

ANNEX II

KEY ELEMENTS OF RISKS MANAGERMENTS TASKS

Risk management should comprise identifying and managing risks in a proactive way to ensure that reclaimed water is safely used and managed and there are no risks to human and animal health and the environment. For this purpose, a Water Reuse Risk Management Plan is established based on the following elements:

1. ~~Describe~~ **Description of the entire water reuse system**, from the waste water entering the urban waste water treatment plant to the point of use, including the sources of waste water, the treatment steps and technologies at the reclamation plant, the supply, **distribution** and storage infrastructure, the intended use, the place **and period** of use (**e.g. temporary or ad-hoc use**), **the irrigation methods, the crop type, other water sources if mix is foreseen** and the ~~quantities~~ **volumes** of reclaimed water to be supplied. ~~The aim of this task is to provide a detailed description of the entire water reuse system.~~
- 1a. **Identification of the parties involved in the water reuse system and identification of their responsibilities. The roles and responsibilities of all concerned parties should be clearly specified and allocated.**
2. ~~Identify~~ **Identification of potential hazards**, in particular the presence of pollutants and pathogens, **and the potential for hazardous events** such as treatment failures, accidental leakages or contamination in the described water reuse system.
3. ~~Identify~~ **Identification of the environments and populations and individuals at risk of direct or indirect and the exposure routes** to the identified potential hazards, taking into account specific environmental factors such as local hydrogeology, topology, soil type and ecology, and factors related to the type of crops and farming **and irrigation** practices. Possible irreversible or long-term negative effects of the water reclamation operation have to be considered as well **and supported by scientific evidence.**

4. ~~Conduct a risk a~~ **Assessment covering both of environmental risks and risks to human and animal health**, taking into account the nature of the identified potential hazards, **the duration of the intended uses**, the identified environments **and** populations ~~and individuals~~ at risk of exposure to those hazards and the severity of possible effects of the hazards **considering the precautionary principle**, as well as all relevant Union and national legislation, guidance documents and minimum requirements in relation to food and feed and worker safety. ~~Scientific uncertainty in risk characterisation shall be addressed in accordance with the precautionary principle.~~ **The risk assessment could be based on review of available scientific studies and data.**

The risk assessment shall consist of the following elements **as appropriate**:

- a) an assessment of **environmental risks**, including all of the following:
 - i) confirmation of the nature of the hazards, including, where relevant, the predicted no-effect level;
 - ii) assessment of the potential range of exposure;
 - iii) characterisation of the risk.
- b) an assessment of **risks to human and animal health**, including all of the following:
 - i) confirmation of the nature of the hazards, including, where relevant, the dose-response relationship;
 - ii) assessment of the potential range of dose or exposure;
 - iii) characterisation of the risk.

The risk assessment may be carried out using qualitative or semi-quantitative risk assessment. Quantitative risk assessment will be used when there is sufficient supporting data or in projects having a potential high risk for the environment or the public health.

The following requirements and obligations shall, as a minimum, be taken into account in the risk assessment:

- a) the requirement to reduce and prevent water pollution from nitrates in accordance with Council Directive 91/676/EEC³⁰;
- b) the obligation for drinking water protected areas to meet the requirements of Council Directive 98/83/EC³¹;
- c) the requirement to meet the environmental objectives set out in Directive 2000/60/EC of the European Parliament and of the Council³²;
- d) the requirement to prevent groundwater pollution in accordance with Directive 2006/118/EC of the European Parliament and of the Council³³;
- e) the requirement to meet the environmental quality standards for priority substances and certain other pollutants laid down in Directive 2008/105/EC of the European Parliament and of the Council³⁴;

³⁰ 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).

³¹ 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).

³² 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).

³³ 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).

³⁴ 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 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).

- f) the requirement to meet the environmental quality standards for pollutants of national concern (i.e. river basin specific pollutants) laid down in Directive 2000/60/EC;
- g) the requirement to meet the bathing water quality standards laid down in Directive 2006/7/EC of the European Parliament and of the Council³⁵;
- h) the requirements concerning the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture under Council Directive 86/278/EEC³⁶;
- i) the requirements regarding hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council³⁷ and the guidance provided in the Commission Notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene;
- j) the requirements for feed hygiene laid down in Regulation (EC) No 183/2005 of the European Parliament and the Council³⁸.
- k) the requirement to comply with the relevant microbiological criteria set out in Commission Regulation (EC) No 2073/2005³⁹;

³⁵ 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).

³⁶ Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6).

³⁷ 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).

³⁸ 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).

³⁹ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338 22.12.2005, p.1)

- l) the requirements regarding maximum levels for certain contaminants in foodstuffs set out in Commission Regulation (EC) No 1881/2006⁴⁰;
- m) the requirements regarding maximum residue levels of pesticides in or on food and feed set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council⁴¹;
- n) the requirements regarding animal health in Regulation (EC) 1069/2009 of the European Parliament and of the Council⁴² and Commission Regulation (EC) 142/2011 of the European Parliament and of the Council⁴³.

5. **Consideration of requirements for water quality and monitoring that are additional to and/or stricter than those specified in Annex I**, when necessary and appropriate to ensure sufficient protection of the environment, ~~and~~ human **and animal** health, **specify requirements for water quality and monitoring that are additional to and/or stricter than those specified in Annex I**, in particular when there is clear scientific evidence that the risks are originating from reclaimed water and not by other sources.

⁴⁰ 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)

⁴¹ 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)

⁴² 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)

⁴³ 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)

Depending on the outcome of the risk assessment referred to in point 4, such additional requirements may in particular concern:

- a) heavy metals;
- b) pesticides;
- c) disinfection by-products;
- d) pharmaceuticals;
- e) other substances of emerging concern;
- f) anti-microbial resistance.

6. **Identify Identification of preventive measures** that are already in place or that should be taken to limit risks so that all identified risks can be adequately managed. **Special attention should be paid to bodies of water used for the abstraction of water intended for human consumption and relevant safeguard zones.**

Such preventive measures may include:

- a) access control;
- b) additional disinfection or pollutants removal measures;
- c) specific irrigation technology mitigating the risk of aerosol formation (e.g. drip irrigation);
- d) **specific requirements for sprinkler irrigation (e.g. maximum wind speed, distances between sprinkler and sensitive areas);**

- e) **specific requirements for agricultural fields (e.g. slope inclination, field water saturation, karstic areas);**
- f) pathogen die-off support before harvest;
- g) **establishment of minimum safety distances (e.g. from surface water, including sources for livestock, or activities such as aquaculture, fish farming, shellfish aquaculture, swimming and other aquatic activities);**
- h) **signage at irrigation sites, indicating that reclaimed water is being used and is not suitable for drinking.**

Specific preventive measures that may be relevant are set out in Table 1.

Table 1: Specific preventive measures

Reclaimed water quality class	Specific preventive measures
A	<ul style="list-style-type: none"> - Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate that the risks for a specific case can be managed.
B	<ul style="list-style-type: none"> - 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 that the risks for a specific case can be managed.
C	<ul style="list-style-type: none"> - 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 that the risks for a specific case can be managed.
D	<ul style="list-style-type: none"> - Prohibition of harvesting of wet irrigated or dropped produce.

7. ~~Ensure that Adequate quality control systems and procedures are in place~~, including monitoring of the reclaimed water for relevant parameters, and ~~that adequate maintenance programmes for equipment are established~~.

It is recommended that the reclamation plant operator set up and maintain a quality management system certified under ISO 9001 or equivalent.

8. ~~Ensure that Environmental monitoring systems are in place that will detect any negative effects of the water reuse, as well as to ensure that feedback from the monitoring is provided and that all processes and procedures are appropriately validated and documented.~~

~~It is recommended that the reclamation plant operator set up and maintain a quality management system certified under ISO 9001 or equivalent.~~

9. ~~Ensure that an Appropriate system is in place to manage incidents and emergencies,~~ including procedures to inform **appropriately** all relevant parties ~~appropriately~~ **on** such event, and ~~keep a regularly updated~~ **of** emergency response plan.

Member States could use existing international guidance or standards such as ISO 20426:2018 Guidelines for health risk assessment and management for non-potable water reuse, ISO 16075:2015 Guidelines for treated waste water use for irrigation projects or other equivalent standards accepted at international level or WHO guidelines⁴⁴ as instruments for the systematic identification of hazards, the evaluation and the management of risks, based on a priority approach applied to the whole chain (from the treatment of urban waste water for reuse, to the distribution and the utilization for agricultural irrigation, to the control of the effects) and on site specific risk assessment.

⁴⁴ https://www.who.int/water_sanitation_health/publications/gsuweg2/en/;
https://www.who.int/water_sanitation_health/publications/ssp-manual/en/