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Subject:	Proposal for a Regulation of the European Parliament and of the Council on minimum requirements for water reuse
	- Analysis of the final compromise text with a view to agreement

Delegations will find in Annex the text for a Regulation on water reuse as it results from the third trilogue of 2 December 2019 and as it was agreed by the Committee of Permanent Representatives at its meeting on 18 December 2019.

DE and SI announced their intention to abstain when the text will be submitted for adoption by Council.

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,

Whereas:

- (1) The water resources of the Union are increasingly coming under pressure, leading to water scarcity and quality deterioration. In particular, climate change, unpredictable weather patterns and drought are contributing significantly to the strain on the availability of freshwater, arising from urban development and agriculture.

¹ OJ C , , p. .

² OJ C , , p. .

- (2) The Union's ability to respond to the increasing pressures on water resources could be enhanced by wider reuse of treated waste water, limiting extraction from water bodies and groundwater, reducing the impact of discharge of treated waste water into water bodies, and promoting water savings through the multiple use of urban waste water, while ensuring a high level of environmental protection. Directive 2000/60/EC of the European Parliament and of the Council³ mentions water reuse, in combination with the promotion of the use of water-efficient technologies in industry and water-saving irrigation techniques, 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 the need to create an instrument to regulate standards at Union level for water reuse, to remove the barriers to a widespread use of such an alternative water supply option, namely one that can help to reduce water scarcity and lessen the vulnerability of supply systems.
- (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.

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.

⁶ COM(2007) 414.

- (5) 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.
- (6) 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. The Commission should update its Action Plan and keep water resources as a priority area in which to intervene.
- (7) 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. Any such decision not to practise water reuse should be duly justified based on the criteria laid down in this regulation and reviewed regularly.
- (8) Reuse of appropriately treated waste water, for example from urban waste water treatment plants, is considered to have a lower environmental impact than other alternative water supply methods, such as water transfers or desalination. But such reuse, which could reduce water wastage and save water, only occurs to a limited extent in the Union. This appears to be partly due to the significant cost of waste water reuse system and the lack of common Union environmental and health standards for water reuse, and, as regards in particular agricultural products, the potential health and environmental risks and potential obstacles to the free movement of such products irrigated with reclaimed water.

⁷ 2008/2074 (INI)

⁸ COM(2015) 614.

- (9) Water reuse could contribute to the recovery of the nutrients contained in treated waste water, and the use of recovered water for irrigation purposes in agriculture or forestry could be a way of restoring nutrients, such as nitrogen, phosphorus and potassium, to natural biogeochemical cycles.
- (10) In view of ensuring an optimal reuse of urban waste water resources, end-users should be trained to ensure that the appropriate reclaimed water class is used. Where the same type of crop has unknown or multiple destinations, the highest class should be used, unless appropriate barriers are applied enabling the required quality to be achieved.
- (11) 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. The parameters are based on the technical report of the Commission Joint Research Center and reflect the international standards on water reuse.
- (12) 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 fertilizer. The end-users should be informed about the nutrient content of the reclaimed water.
- (13) 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.

- (14) The adherence to minimum requirements for water reuse should be consistent with Union water policy and 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 of water and safe water reuse globally with a view to contributing to achieving United Nations Sustainable Development Goal 12, on sustainable consumption and production. Furthermore, this Regulation seeks to ensure the application of Article 37 on environmental protection of the Charter of Fundamental Rights of the European Union.
- (15) The quality requirements for water intended for human consumption are laid down in Directive EU.../....of the European Parliament and the Council. Member States should take appropriate measures to ensure that water reuse activities do not lead to deterioration in drinking water quality. For this reason the risk management plan should pay special attention to the protection of bodies of water used for the abstraction of water intended for human consumption and/or relevant safeguards zones.
- (16) In some cases, the reclamation facility operators still transport and store the reclaimed water beyond the outlet of the reclamation facility, prior to delivering the reclaimed water to the next actors in the chain, such as the reclaimed water distribution operator, the reclaimed water storage operator, or the end-user. It is necessary to define the point of compliance to clarify where the responsibility of the reclamation facility operator ends and where the responsibility of the next actor in the chain starts.

- (17) 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 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.
- (18) Cooperation and interaction between the various parties involved in the water reclamation process should be a precondition for setting up reclamation treatment procedures in accordance with the requirements for specific uses and in order to be able to plan the supply of reclaimed water in line with demand from end-users.
- (19) In order to effectively protect the environment and human and animal health, reclamation facility operators should be primarily responsible for the quality of reclaimed water at the point of compliance. For the purposes of compliance with the minimum requirements and any additional conditions, set by the competent authority, reclamation facility operators should monitor the quality of reclaimed water in accordance with the minimum requirements and any additional conditions set by the competent authorities. 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/

- (20) 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 facility) 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 facility. 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.
- (21) 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 facility 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 facility 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 the multi-barrier approach.

- (22) It is necessary to ensure the safe use of reclaimed water, thereby encouraging water reuse at Union level and enhancing public confidence in it. Production and supply of reclaimed water for agricultural irrigation 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, 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 which should be adapted to take account of the requirements introduced by this Regulation. When designating the responsible party(ies) for the elaboration of the Water Reuse Risk Management Plan and the competent authority for the granting of the permit for production and supply of reclaimed water, Member States should ensure that there is no conflict of interests.
- (23) If a reclaimed water distribution operator and a reclaimed water storage operator are needed, it should be possible to make any such operator to be subject to a permit. If all requirements for the permit are met, the competent authority in the Member State should grant a permit that should contain all the necessary conditions and measures established in the risk Management Plan.

- (24) 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 facility 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 L 338 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).

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).

- (25) For the purposes of this Regulation, it should be possible for treatment operations and urban waste water reclamation operations to take place in the same physical location, using the same facility, or different, separate facilities. In addition, it should be possible for the same actor to be both the treatment plant operator and the reclamation facility operator.
- (26) 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 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.
- (27) There is a great potential for the recycling and reuse of treated waste water. With a view to promoting and encouraging the practice of water reuse, the indication of specific uses within this Regulation should not preclude Member States from allowing the use of reclaimed water for further purposes, including reuse for industrial, amenity-related and environmental purposes, as considered necessary in line with national circumstances and needs provided a high level of protection of human and animal health and the environment is secured.
- (28) In order to encourage confidence in water reuse, information should be provided to the public. Making available of clear, comprehensive and updated 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. In order to encourage water reuse, Member States should ensure that information and awareness-raising campaigns, adapted to the scale of water reuse, are developed, with a view to making stakeholders aware of the benefits of water reuse thereby promoting acceptance.

- (29) Education and training of the end-users are of primary importance as components of implementing and maintaining preventive measures. Specific human exposure preventive measures should be considered in the risk management plan, such as use of personal protective equipment, handwashing and personal hygiene.
- (30) 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.
- (31) 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).

- (32) In order to adapt the key elements of risk management 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-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.
- (33) 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 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.
- (34) 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 responsible party(ies) to take the necessary measures to ensure compliance. Supply of the reclaimed water should be suspended when non-compliance causes a significant risk to the environment or to human health.

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).

- (35) Competent authorities should cooperate with other relevant authorities, by exchanging information, in order to ensure compliance with relevant Union and national requirements.
- (36) 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.
- (37) 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. The evaluation should take into account scientific progress, in particular as regards the potential impact of substances of emerging concern.
- (38) The aim of this Regulation is, inter alia, to protect the environment and human and animal health. As the Court of Justice has held on numerous occasions, it would be incompatible with the binding effect which the third paragraph of Article 288 of the Treaty on the Functioning of the European Union ascribes to a Directive, to exclude, in principle, the possibility of an obligation imposed by a Directive from being relied on by persons concerned. That consideration also applies in respect of a Regulation which has as its objective to guarantee that reclaimed water is safe for agricultural irrigation.
- (39) 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.
- (40) Since the objectives of this Regulation, namely the protection of 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.

- (41) 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.
- (42) With a view to developing and promoting the reuse of properly treated waste water as much as possible, the European Union should support research and development in this area through the Horizon Europe programme in order to bring about a significant improvement in the reliability of properly treated waste water and in viable use methods.
- (43) 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.
- (44) This Regulation seeks to encourage the sustainable use of water. With that aim in view, the Commission should undertake to use Union programmes, including the LIFE Programme, to support local initiatives involving the reuse of properly treated waste water.

HAVE ADOPTED THIS REGULATION:

Article 1

Subject matter and purpose

1. This Regulation lays down minimum requirements for water quality and monitoring, as well as provisions for risk management, for the safe use of reclaimed water in the context of integrated water management.
2. The purpose of this Regulation is to guarantee that reclaimed water is safe for 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, contributing to the objectives of Directive 2000/60/EC by 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 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 water for agricultural irrigation in one or more of its river basin districts or parts thereof, taking into account the following criteria:
 - a) geographic and climatic conditions of the district or districts or parts thereof;
 - b) the pressures on and the status of other water resources, including the quantitative status of groundwater as referred to in Directive 2000/60;

- c) the pressures on and the status of the surface water bodies in which treated urban waste water is discharged;
- d) the environmental and resource costs of reclaimed water and of other water resources.

That decision shall be duly justified on the basis of the aforementioned criteria and submitted to the Commission. It shall be reviewed as necessary, in particular taking into account climate change projections and national climate change adaptation strategies, and at least every 6 years taking into account river basin management plans established pursuant to Directive 2000/60.

3. By way of derogation, research or pilot projects in relation to reclamation facilities do not need to comply with the provisions of this Regulation where the competent authority establishes that the following criteria are met:

- a) the research or pilot 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 or pilot 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 or pilot project exempted in accordance with this paragraph shall not be placed on the market.

4. 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 by 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 purpose 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 for production and/or supply of reclaimed water and the checking of the compliance, as well as regarding the granting of derogation for research or pilot projects;
2. *"end user"* means a natural or legal person, a public or private entity, who uses reclaimed water for agricultural irrigation;
3. *'urban waste water'* means urban waste water as defined in Article 2(1) of Directive 91/271/EEC;
4. *'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 facility in accordance with section 2 of Annex I of this Regulation;
5. *'reclamation facility'* means an urban waste water treatment plant or other facility 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;
6. *'reclamation facility operator'* means a natural or legal person, representing a private entity or a public authority, who operates or controls a reclamation facility;
7. *'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;

8. '*risk*' means the likelihood of identified hazards causing harm in a specified timeframe, including the severity of the consequences;
9. '*risk management*' is a systematic management that consistently ensures the safety of water reuse in a specific context;
10. '*preventive measure*' means appropriate action or activity that can be used to prevent or eliminate a health and environmental risk, or reduce it to an acceptable level;
11. '*point of compliance*' means the point where a reclamation facility operator delivers the reclaimed water to the next actor in the chain;
12. '*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;
13. '*permit*' means a written authorisation issued by the competent authority to produce and/or supply reclaimed water for agricultural irrigation in accordance with this Regulation;
14. '*responsible party(ies)*' means a party carrying out a role or activity in the water reuse system including the reclamation facility operator, the urban waste water treatment plant where different from the reclamation facility operator, the relevant authority(ies) other than the designated competent authority(ies), the reclaimed water distribution operator or the reclaimed water storage operator;
15. '*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, including distribution and storage infrastructure, where relevant.

Article 4

Obligations of the reclamation facility operators and obligations regarding reclaimed water quality

1. Reclamation facility operators shall ensure that reclaimed water destined for agricultural irrigation as specified in section 1 of Annex I, shall, at the 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 (c) and (d) of Article 6(3), as regards water quality.

After the point of compliance, the quality of the water shall no longer be the responsibility of the reclamation facility operator.

2. In order to ensure compliance with the requirements and conditions referred to in paragraph 1, the reclamation facility 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 (c) and (d) of Article 6(3), as regards monitoring.

Article 5

Risk management

1. For the purpose of producing, supplying and using reclaimed water, the competent authority shall ensure that a Water Reuse Risk Management Plan is established.
2. The Water Reuse Risk Management Plan shall be developed by the reclamation facility operator, other responsible party(ies), and end-users as appropriate. The responsible party(ies) preparing the Water Reuse Risk Management Plan shall consult all other relevant responsible party(ies) and the end-users, as appropriate.

3. The Water Reuse Risk Management Plan shall be based on all the key risk management elements set out in Annex II and identify the risk management responsibilities of the reclamation facility operator and other responsible party(ies). It may cover one or more water reuse systems.
4. The Water Reuse Risk Management Plan shall in particular:
 - a) set out any necessary requirements for the reclamation facility operator additional to those specified in Annex I in accordance with point (b) of Annex II to further mitigate any risks before the point of compliance;
 - b) identify hazards, risks and appropriate preventive and/or possible corrective measures in accordance with point (c) of Annex II;
 - c) identify additional barriers in the water reuse system, and set out any additional requirements after the point of compliance, necessary to ensure the safety of the water reuse system, including conditions related to distribution storage and use where relevant, and identify the party(ies) responsible for meeting those requirements.
5. The Commission is empowered to adopt, in accordance with Article 13, delegated acts amending this Regulation in order to adapt to technical and scientific progress the key elements of risk management set out in Annex II.

The Commission is also empowered to adopt, in accordance with Article 13, delegated acts supplementing this Regulation in order to lay down technical specifications of the key elements of risk management set out in Annex II.

Article 6

Obligations regarding reclaimed water permit

1. Any production and supply of reclaimed water destined for agriculture irrigation in section 1 of Annex I, shall be subject to a permit.
2. The responsible party(ies) in the water reuse system, including the end-user where relevant in accordance with national law, 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 facility operates or is planned to operate.
3. The permit shall set out the obligations of the reclamation facility operator and any other responsible party(ies), where relevant. It shall be based on the Water Reuse Risk Management Plan and shall include, inter alia, the following:
 - a) the quality class(es) of the reclaimed water and allowed agricultural use for which, according to Annex I, the reclaimed water is permitted, the place of use, the reclamation facility or facilities 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 additional requirements for the reclamation facility operator, if any, set out in the Water Reuse Risk Management Plan;
 - d) any other conditions necessary to eliminate any unacceptable risks to human and animal health or the environment to an acceptable level;
 - e) the validity period;
 - f) point of compliance.

4. For the purposes of assessing the application, the competent authority shall consult and exchange relevant information with other relevant authorities, in particular the water and health authorities, if different from the competent authority and any other party deemed relevant by the competent authority.
5. The competent authority shall decide without delay whether to grant a permit. Where the competent authority needs, due to the complexity of the application, more than 12 months from the receipt of the complete application, to take a decision, it shall communicate to the applicant the expected date of that decision.
6. The permit shall be regularly reconsidered and, where necessary, updated, at least in the following cases:
 - a) a substantial change of the capacity or when equipment is upgraded and when new equipment or processes are added;
 - b) changes in climatic or other conditions significantly affecting the ecological status of surface water bodies.
7. Member States may decide that storage, distribution and use of the reclaimed water shall be subject to a specific permit to apply the additional requirements and barriers identified in the water reuse risk management plan as referred to in Article 5(4).

Article 7

Compliance check

1. The competent authority shall verify compliance of the reclaimed water with the conditions set out in the permit. The compliance check shall be performed using all of the following means:
 - (a) on-spot checks;

- (b) use of monitoring data obtained in particular pursuant to this Regulation;
 - (c) any other adequate means.
2. In the event of non-compliance with the conditions set out in the permit, the competent authority shall require the reclamation facility operator and, if relevant, the other responsible party(ies) to take any necessary measures to restore compliance without delay and immediately inform the end-users affected.
 3. Where non-compliance with the conditions set out in the permit causes a significant risk to the environment or to human or animal health, the reclamation facility operator or any other responsible party(ies) shall immediately suspend any further supply of the reclaimed water, until the competent authority determines that compliance has been restored, following procedures defined in the Water Reuse Risk Management Plan, in accordance with Annex I, section 2, point 2.1, point a (para 1).
 4. If an incident affecting compliance with the conditions in the permit occurs, the reclamation facility operator or any other responsible party(ies) shall immediately inform the competent authority and other parties which may be potentially affected, and communicate to the competent authority the information necessary for assessing the impacts of such an incident.
 5. The competent authority shall regularly verify compliance by the responsible party(ies) with the measures and tasks set out in the Water Reuse Risk Management Plan.

Article 8

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, 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 9

Information and awareness raising

Savings of water resources as a result of water reuse shall be the subject of general awareness raising campaigns in Member States where reclaimed water is used for agricultural irrigation and which may include the promotion of the benefits of safe water reuse. Those Member States may also set up information campaigns for end-users to ensure an optimal and safe use of reclaimed water, ensuring thereby a high level of protection of human and animal health and the environment. Member States may adapt such information and awareness raising campaigns to the scale of water reuse.

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, provided that such data are available;
 - (c) permits granted or modified in accordance with this Regulation, including conditions set by competent authorities in accordance with Article 6(3);
 - (d) outcome of the compliance check performed in accordance with Article 7(1);
 - (e) contact points designated in accordance with Article 8(1).
2. The information referred to in paragraph 1 shall be updated every two years.
3. 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, 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 ... [six 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 7(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 7(1) and information about the measures taken in accordance with Article 7(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 14.

5. The Commission shall, in consultation with Member States, establish guidelines to support application in practice of this Regulation within two years after the date of entry into force of this Regulation.

Article 12

Evaluation and review

1. The Commission shall, by ...[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 set out in Annex II;
 - (c) the additional requirements set by competent authorities pursuant to point (b) and (c) of Article 6(3);
 - (d) the impacts of water reuse on the environment and human and animal health, including the impacts of substances of emerging concern.

3. As part of the evaluation referred to in paragraph 1, the Commission shall assess the feasibility of:
 - (a) extending the scope of this Regulation to reclaimed water intended for further specific uses, including reuse for industrial purposes;
 - (b) expanding the requirements of this Regulation to cover the indirect use of treated waste water.
4. 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.
5. Where appropriate, the Commission shall make legislative proposals for amendments in accordance with the Treaty.

Article 13

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 5(5) shall be conferred on the Commission for a period of 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 5(5) 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 5(5) 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 14

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 15

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 ...[four 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 16

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 ... [three 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.

USES AND MINIMUM REQUIREMENTS

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

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).

Without prejudice to the relevant Union law in the fields of environment and health, Member States may use reclaimed water for further uses such as industrial water reuse and for amenity-related and environmental purposes.

Section 2. Minimum requirements

2.1. Minimum requirements applicable to reclaimed water intended 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 5(4) (c) 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 7 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** or other irrigation method that avoids direct contact with the edible part of the crop
D	Industrial, energy, and seeded crops	All irrigation methods***

(*) If the same type of irrigated crop falls under multiple categories of Table 1, the requirements of the most stringent category shall apply.

(**) 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 Reclaimed water quality requirements for agricultural irrigation

Reclaimed water quality class	Indicative technology target	Quality requirements				
		<i>E. coli</i> (number/100 ml)	BOD ₅ (mg/l)	TSS (mg/l/g/l)	Turbidity (NTU)U	Other
A	Secondary treatment, filtration, and disinfection	≤10	≤10	≤10	≤5	<i>Legionella</i> spp.: <1,000 cfu/l where there is risk of aerosolization
B	Secondary treatment, and disinfection	≤100	According to Council Directive 91/271/EEC ¹	According to Directive 91/271/EEC (Annex I, Table 1)	-	Intestinal nematodes (helminth eggs): ≤1 egg/l for irrigation of pastures or forage
C	Secondary treatment, and disinfection	≤1,000	((Annex I, Table 1)		-	
D	Secondary treatment, and disinfection	≤10,000	¹ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40).		-	

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.

(b) Minimum requirements for monitoring

Reclamation facility 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.

The samples to be used to verify compliance with the microbiological parameters at the point of compliance shall be taken in accordance with standard EN ISO 19458 or in any other national or international standards which ensure equivalent quality.

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

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

Validation monitoring has to be performed before a new reclamation facility is put into operation.

Reclamation facilities 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 this validation monitoring obligation.

Validation monitoring has to be performed in all cases where equipment is upgraded, and when new equipment or processes are added.

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 point of compliance, considering the concentrations of the raw waste water 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 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 in accordance with EN ISO/IEC-17025 or other national or international standards which ensure an equivalent quality.

ANNEX II

(a) Key elements of risks management

Risk management shall 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. 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 facility, 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 volumes of reclaimed water to be supplied.
2. Identification of the parties involved in the water reuse system and identification of their responsibilities. The roles and responsibilities of all concerned parties shall be clearly specified and allocated.
3. 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.
4. Identification of the environments and populations at risk 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 environmental and health effects of the water reclamation operation have to be considered as well and supported by scientific evidence.

5. Assessment 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 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. The risk assessment could be based on review of available scientific studies and data.

The risk assessment shall consist of the following elements:

- (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/EEC²⁹;
- (b) the obligation for drinking water protected areas to meet the requirements of Council Directive 98/83/EC³⁰;
- (c) the requirement to meet the environmental objectives set out in Directive 2000/60/EC of the European Parliament and of the Council³¹;
- (d) the requirement to prevent groundwater pollution in accordance with Directive 2006/118/EC of the European Parliament and of the Council³²;
- (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 Council³³;
- (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;

²⁹ 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).

³⁰ 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).

³¹ 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)

³² 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).

³³ 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).

- (g) the requirement to meet the bathing water quality standards laid down in Directive 2006/7/EC of the European Parliament and of the Council³⁴;
- (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/EEC³⁵;
- (i) the requirements regarding hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council³⁶ 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 Council³⁷;
- (k) the requirement to comply with the relevant microbiological criteria set out in Commission Regulation (EC) No 2073/2005³⁸;
- (l) the requirements regarding maximum levels for certain contaminants in foodstuffs set out in Commission Regulation (EC) No 1881/2006³⁹;

³⁴ 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).

³⁵ 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).

³⁶ 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).

³⁷ 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).

³⁸ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L338 22.12.2005, p.1).

³⁹ 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).

- (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 Council⁴⁰;
 - (n) the requirements regarding animal health in Regulation (EC) 1069/2009 of the European Parliament and of the Council⁴¹ and Commission Regulation (EC) 142/2011 of the European Parliament and of the Council⁴².
- (b) Conditions relating to the additional requirements
6. 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 adequate protection of the environment, human and animal health, in particular when there is clear scientific evidence that the risks are originating from reclaimed water and not by other sources.

Depending on the outcome of the risk assessment referred to in point 5, such additional requirements may in particular concern:

- (a) heavy metals;
- (b) pesticides;

⁴⁰ 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).

⁴¹ 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).

⁴² 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).

- (c) disinfection by-products;
- (d) pharmaceuticals;
- (e) other substances of emerging concern, including micro pollutants and micro plastics;
- (f) anti-microbial resistance.

(c) Preventive measures

7. 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	- 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	- 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. 1.
C	- Prohibition of harvesting of wet irrigated or dropped produce. - Exclude grazing animals from pasture for five days after last irrigation. - Fodder has to be dried or ensiled before packaging. - Pigs must not be exposed to fodder irrigated with reclaimed water unless there is sufficient data to indicate that the risks for a specific case can be managed. 2.
D	- Prohibition of harvesting of wet irrigated or dropped produce.

- 8. Adequate quality control systems and procedures, including monitoring of the reclaimed water for relevant parameters, and adequate maintenance programmes for equipment.

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

- 9. Environmental monitoring systems to ensure that feedback from the monitoring is provided and that all processes and procedures are appropriately validated and documented.

10. Appropriate system to manage incidents and emergencies, including procedures to inform appropriately all relevant parties on such event, and regular update 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 guidelines⁴³ 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.

11. Ensure that coordination mechanisms are established amongst different actors to guarantee the safe production and use of reclaimed water.

⁴³ https://www.who.int/water_sanitation_health/publications/gsuweg2/en/;
https://www.who.int/water_sanitation_health/publications/ssp-manual/en/