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COMMISSION NOTICE

Guidelines to support the application of Regulation 2020/741 on minimum requirements for water reuse

(2022/C 298/01)

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1. Introduction

The EU's water resources are increasingly coming under pressure. This is leading to water stress, when water resources are insufficient to meet the needs, and to a deterioration in water quality. In addition, climate change, unpredictable weather patterns and drought are contributing significantly to the strain on the availability of freshwater. Reusing reclaimed water is widely recognised as a practice that helps manage water resources more efficiently and helps adapt our systems to climate change, in line with the EU's strategy set out in the European Green Deal ([1]).

Regulation (EU) 2020/741 of the European Parliament and of the Council on minimum requirements for water reuse (the Water Reuse Regulation) ([2]) seeks to facilitate and encourage the practice of reusing water for irrigation in agriculture, a sector that can be particularly vulnerable to scarce or intermittent water resources, making the EU food system more sustainable and resilient ([3]), while protecting public health and the environment.

The Water Reuse Regulation, applicable from 26 June 2023, sets uniform minimum water quality requirements for the safe reuse of treated urban waste water in agricultural irrigation. Harmonised minimum requirements will also ensure the single market for agricultural produce works properly and should boost consumer confidence.

Under this Regulation, urban waste water treated in line with the requirements of Directive 91/271/EEC governing urban waste water treatment (the Urban Waste Water Treatment Directive) ([4]), must undergo further treatment to meet the new minimum quality parameters and become suitable for use in agriculture.

In addition to the uniform minimum requirements for water quality, the Regulation also sets out uniform minimum monitoring requirements, risk management rules to assess and address potential additional health risks and environmental risks, permitting obligations, and rules on transparency, under which key information on all water reuse projects must be made publicly available.

Article 11(5) of the Water Reuse Regulation requires the Commission, in consultation with Member States, to draw up guidelines for applying the Regulation. This Notice sets out the guidelines. It has been prepared in close cooperation with the Working Group on Water Reuse ([5]) - established under the Strategic Coordination Group for Water Policy ([6]) - whose membership includes Member States authorities and stakeholder organisations. The Working Group on Water Reuse thoroughly discussed the document at two meetings on 21-22 October 2021 and 18 February 2022 and provided written comments.

Section 2 of these guidelines covers the general and administrative obligations set by the Regulation, including its scope. Section 3 covers the more technical aspects.

2. General and administrative obligations

This Section covers the following aspects: the scope of the Regulation, and in particular the application of Article 2(2); the competent authority(ies); the contact points and cross-border cooperation; the responsibilities of different actors; permits; compliance checks; penalties; awareness raising and information sharing.

([1]) Both the Circular Economy Action Plan (COM/2020/98 final) and the EU's new climate adaptation strategy (COM/2021/82 final) refer to water reuse, as the EU's ability to respond to the increasing pressures on water resources could be improved by wider reuse of treated waste water. In addition to irrigation, water reuse can also be usefully applied in the industrial sector, contributing to the goals set in the Commission's proposal for a revised Industrial Emissions Directive (COM(2022) 156 final/2).

([2]) OJ L 177, 5.6.2020, p. 32.

([3]) Water reuse could contribute to the goal of reducing the environmental and climate footprint of the EU food system, set out in the Farm to Fork Strategy (COM/2020/381 final).

([4]) OJ L 135, 30.5.1991, p. 40, the Urban Waste Water Treatment Directive requires that treated waste water be reused whenever appropriate. This Directive is currently under review, but the planned future legislative set up is expected to reinforce the link to the practice of water reuse. Thus, any reference to this Directive in this Notice will in future refer to the planned revised legislation on the treatment of urban waste water.

([5]) Formerly called Ad Hoc Task Group on Water Reuse, set up as a permanent Working Group in 2022.

([6]) For more information on this group: https://circabc.europa.eu/ui/group/9ab5926d-bed4-4322-9aa7-9964bbe8312d/library/3644e20b-f5c5-46de-9d2f-3d9efb965fac?p=1&n=10&sort=modified_DESC

2.1. ***Scope***

The Regulation applies whenever treated urban waste water is reused for agricultural irrigation. However, according to Article 2(2), Member States may decide it is not appropriate to reuse water for agricultural irrigation in one or more of their river basin districts or in parts of them.

Article 2(2) decisions effectively ban water reuse in (part of) a territory and as a result, the Regulation does not apply in those areas. In other words, if a Member State considers the reuse of water inappropriate in only part of its territory, the Regulation would still apply in full in remaining areas where water can be reused.

Some of the more general obligations in the Regulation could still be applicable even if water reuse is banned throughout a Member State. For instance:

— Article 2(3) on exemptions for research projects: if a Member State allows such projects, it should designate the relevant competent authorities responsible for checking compliance with the criteria set out in Article 2(3);

— Article 8 on designating a contact point to cooperate with other Member States;

— Article 10(1) on informing the public about the contact point;

— Article 15 on penalties to ensure that, if a decision is taken not to allow water reuse, it is complied with, i.e. water is not reused and any exempt research projects meet the applicable conditions.

In the absence of an Article 2(2) decision, by the date the Regulation starts applying (26 June 2023), any responsible party in a water reuse system must be able to apply for a permit.

In other words, the default situation (in the absence of a national decision stating otherwise) is that water reuse is allowed subject to a permit granted under the Regulation. This means that the risk management plan must cover all possible risks and the project must be in full compliance with all EU health and environmental legislation.

2.1.1. *Criteria*

Many different circumstances and climatic characteristics in the Member States can influence a decision as to whether water reuse has a role to play in integrated water management.

It may be that certain Member States' climatic conditions may render water reuse unnecessary and/or uneconomical, due to the abundance of rainfall. However, even Member States that face water shortages and recurring droughts may also have circumstances that mean that water reuse generally intended to address water scarcity may not be an appropriate practice.

This may be the case, for instance, if certain areas suffer long and prolonged droughts, and surface water bodies are dependent for their ecological flow and good water status on discharges of treated waste water. If treated waste water were to be redirected to a reclamation plant and subsequently to agriculture, this could deprive a surface water course of essential water volumes to guarantee minimum ecological flow.

In these cases, it is also necessary to assess the impact of using alternative sources, i.e. abstraction from (other) surface and/or groundwater bodies, as these may also have an impact on water quantity/quality. Pressure such as water abstraction might impact the quantitative status of groundwater bodies, in which case water reuse might offer an alternative water source. There may also be situations where there is no pressure from abstraction and the cost of reusing water might not be competitive with other water sources.

Any decision should therefore carefully weigh up the advantages and disadvantages of water reuse. All these considerations should feed into any decision not to reuse water in a given area as part of integrated water management.

Article 2(2) of the Regulation sets out the criteria that Member States must take into account to determine whether water reuse is not appropriate in certain river basin districts (or part(s) of them).

Member States taking any such decision under Article 2(2) of the Regulation must duly justify the decision and submit it to the Commission. If the ban is the result of pressure on the quality of surface water bodies that are dependent on the discharged waste water for their flow and ecological status, the decision would be duly justified providing it mentions:

— which bodies are affected;

— their current status:

— what other cost/effective measures have been taken and may be taken to close the gap to good status and/or avoid deterioration;

— the alternative sources of water for agricultural irrigation; and

— whether these other sources could result in over-abstraction from other surface or groundwater bodies, possibly affecting their quantitative or qualitative status.

If the decision is based on the criteria for cost effectiveness, it is important to take all costs into account, both environmental and resource costs (of the reclaimed water, and of the alternative source(s) that the Member State considered more appropriate). The economic analysis carried out under Article 5 of and Annex III to Directive 2000/60/EC Directive may provide useful background information.

2.1.2. *Submitting and reviewing the decision*

Any duly justified and clearly argued decision, based on the criteria set out in Article 2(2) of the Regulation, must be submitted to the Commission in writing, via the regular communication channels (e.g. via the Member State's Permanent Representation to the EU). The Member State must also make any such decision available to the public, in accordance with Article 10(3).

Article 2(2) of the Regulation specifies that any such decision must be reviewed whenever necessary, to reflect changing circumstances. In particular, these decisions must be reviewed to take into account climate change projections and national climate change adaptation strategies (updated on a bi-annual basis) ([7]), and at least every six years, taking into account river basin management plans drawn up under Directive 2000/60/EC.

Any decision to ban water reuse should be therefore justified in the broader context of integrated water management. It should be fully compatible with the management approach set out in the relevant river basin management plans, as well as with climate mitigation and adaptation policies.

This means that the decision to ban water reuse must be based on information on water status, pressure and on the impacts and measures collected and set out in those plans. This would also entail making an assessment of the environmental and resource costs of reclaimed water and other water resources, also taking into account the economic analysis made under Article 5 of Directive 2000/60/EC.

2.2. ***Competent authority***

Competent authorities referred to in Article 3(1) are responsible for:

— granting permits to produce and supply reclaimed water, including ensuring that a water reuse risk management plan is established;

— establishing whether the criteria for exempting research or pilot projects from the Regulation are met (where applicable);

— verifying compliance with the conditions set out in the permits and taking follow-up action in the event of breaches.

These responsibilities may entail, for example: reviewing the water reuse risk management plan and ensuring it covers all aspects; regularly verifying compliance with the measures and tasks in the plans; facilitating communication between different actors in a water reuse scheme; coordinating the exchange of information with other authorities. Depending on their administrative set-up, for example the structures used to manage river basins, Member States may decide to designate more than one competent authority.

([7]) Article 5(4) of Regulation (EU) 2021/1119 establishing the framework for achieving climate neutrality and amending Regulations (EC) No 401/2009 and (EU) 2018/1999, OJ L 243, 9.7.2021, p. 1, Article 19(1) of Regulation (EU) 2018/1999 on the Governance of the Energy Union and Climate Action (OJ L 328, 21.12.2018, p. 1).

If a Member State decides that it is not appropriate to produce and reuse reclaimed water for agricultural irrigation in any river basin district (effectively on its entire territory), in accordance with Article 2, setting up a competent authority would only be necessary if research and pilot projects on water reuse for agricultural irrigation were conducted. Similarly, if a Member State authorises the production of reclaimed water but not its use, a competent authority would also be required to manage permits for production.

2.3. *Contact points*

Article 8 of the Regulation requires Member States to designate a contact point for cooperation with other Member States' contact points.

The role of the contact points is to: (a) receive and send requests for assistance; (b) provide assistance upon request; and (c) coordinate communication between competent authorities in different Member States. For example, before granting a permit to produce or supply reclaimed water, competent authorities must exchange information on the conditions set out in the related permit and risk management plans with the contact point in the Member State where reclaimed water is intended to be used. The contact points should respond to requests for assistance without undue delay.

It may not be necessary to create contact points if a Member State decides, on the basis of Article 2(2), that it is not appropriate to use reclaimed water for agricultural irrigation in any river basin district (effectively on its entire territory).

However, if a Member State does not authorise reclaimed water to be used on its territory, but exports reclaimed water to a neighbouring country, it must still have a contact point. Similarly, a contact point is needed in Member States that do not produce reclaimed water on their territory, but wish to import it, for use in irrigation, from a neighbouring country.

In addition, projects carried out in a neighbouring Member State may in some way affect a shared water catchment area and therefore require consultation between Member State competent authorities via the contact points.

2.4. *Responsible parties*

The Regulation identifies a series of 'responsible parties', i.e. actors carrying out a role or activity in a water reuse system. The water reuse system, as defined in Article 3(15), comprises the infrastructure and other technical parts, from the point of entry into the urban waste water treatment plant to the point where reclaimed water is used for agricultural irrigation, including distribution and storage infrastructure, where relevant.

Article 3(14) specifies that the responsible parties include:

— the reclamation facility operator;

— the urban waste water treatment plant operator, if this is different from the reclamation facility operator;

— the relevant authorities, other than the designated competent authority; and

— the reclaimed water distribution operator or the reclaimed water storage operator, where relevant.

The Regulation describes the minimum responsibilities for the reclamation facility operator (see Section 2.4.1).

The permit issued by the competent authority will set out the responsibilities for the other responsible parties, taking into account the responsibilities identified in the risk management plan.

The roles of other authorities, different from the competent authority, could include reviewing the risk management plans to verify compliance with the applicable regulations (e.g. on health, the environment, agriculture), setting specific requirements in their domain of expertise and issuing an opinion on the risk management plan.

The Member States may, where relevant, and in accordance with national laws, further define roles and responsibilities, provided they comply with the minimum rules.

2.4.1. *Responsibility of the reclamation facility operator for water quality*

The reclamation facility operator operates or manages a reclamation facility and it may be a private or a public body. It may be a different entity to the operator of the urban waste water treatment plant under the Urban Waste Water Treatment Directive.

Article 4(1) of the Regulation clarifies that the reclamation facility operator is responsible for the quality of the reclaimed water at the point of compliance.

The point of compliance is, as defined in Article 3(11), the point where the reclamation facility operator delivers the reclaimed water to the next actor in the chain. Depending on the specific set-up of a water reuse system in a Member State, the next actor may be the end user, or, if water is transported, distributed or stored for future use, it could be other actors.

At the point of compliance, which will be specified in the permit for producing and supplying reclaimed water (see Section 2.5 on permits), the reclamation facility operator must ensure that the reclaimed water meets the minimum requirements set out in Annex I as well as any other additional relevant condition set by the competent authority in the related permit, and as described in the risk management plan.

2.4.2. *Responsibility of other actors*

After the point of compliance, responsibility for water quality passes to the next actor in the chain, either the end user or any intermediate actor in charge of distribution or storage.

The risk management plan must set out the conditions related to distribution, storage and use, where relevant, and identify which parties in the water reuse system are responsible for meeting those requirements.

Where the risk management plan sets conditions of use for the end user, these must comply with EU food (and feed) hygiene legislation and related documents, in particular those mentioned in the Water Reuse Regulation. These include:

— Regulation (EC) No 178/2002 ([8]): the 'General food law', which lays down (in Article 17) the primary responsibility of all food business operators (including primary producers, i.e. farmers).

— Regulation (EC) No 852/2004 ([9]) on food hygiene: Article 4(1) repeats the responsibility of primary producers to comply with general hygiene provisions (good hygiene practices) laid down in Annex I to that Regulation. Annex I, Part A, II 5(c) states that food business operators producing or harvesting plant products must take adequate measures, and use potable water, or clean water, as appropriate, whenever necessary to prevent contamination.

— Regulation (EC) 2073/2005 ([10]) laying down microbiological criteria for foodstuffs, which includes *E. coli* criteria in certain food of non-animal origin (post-harvest).

— Regulation (EU) 2017/625 ([11]) (replacing Regulation (EC) No 882/2004) providing a legal framework for official controls on food and food safety at any stage of production, processing and distribution. Competent authorities must enforce and verify that the food business operator meets the food safety requirements.

— Commission Notice issuing guidance on addressing microbiological risks in fresh fruit and vegetables at primary production through food hygiene ([12]).

([8]) Regulation (EC) No 178/2002 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).

([9]) Regulation (EC) No 852/2004 on the hygiene of foodstuffs (OJ L 139, 30.4.2004, p. 1).

([10]) Commission Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1).

([11]) Regulation (EU) 2017/625 on official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products (OJ L 95, 7.4.2017, p. 1).

([12]) Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (OJ C 163, 23.5.2017, p. 1).

The Water Reuse Regulation, which defines water quality for a specific water source at a stage before primary production (before it is used for irrigation), complements the food hygiene rules. The food (and feed) hygiene rules apply from the stage of primary production, including irrigation, and cover all aspects of irrigation, for all sources of water.

2.5. ***Permits***

Article 6(1) of the Regulation requires that the production and supply of reclaimed water for agricultural irrigation be subject to a permit. All permits must be based on the water reuse risk management plan and must set out the obligations of the reclamation facility operator and, where relevant, of any other responsible parties, in accordance with Article 6(3).

The Regulation describes the information that permits must cover, but it is up to the Member States to specify the details of the procedures for granting permits, such as the designation of the competent authorities and deadlines.

Therefore this Section does not cover issues related to the procedure, except to say that the Regulation explicitly allows Member States to apply existing procedures for granting permits, provided these are adapted to meet the requirements laid down in the Regulation.

2.5.1. *Authorities granting the permit*

Water reuse permits can only be granted by the competent authorities designated by the Member States. There should be no conflict of interest between the parties responsible for drawing up the draft water reuse risk management plan and the permit application, and the authority that grants the permit to produce and supply reclaimed water.

For the purpose of assessing an application, the competent authority must consult and exchange information with any other relevant authorities, in particular the water and health authorities (if different from the competent authority) and any other party the competent authority deems relevant.

Examples

Several different set-ups are possible at national level, as illustrated by the examples below.

Example 1 – If the reclamation plant, and thus its operator, is the same as the urban waste water treatment plant, the competent authority could be the urban waste water treatment permitting authority, and thus might be different from the water or health authorities.

In these cases, close cooperation between the different authorities is needed to ensure (i) the applicable water standards are complied with and maximum levels are not exceeded when reduced volumes of water are discharged into a surface water body, and (ii) the health standards are complied with when the water is used for irrigation.

In these cases, the water or health authorities can provide input into the process of preparing the risk management plan and the permit application, since there would be no conflict of interest with the authority granting the permit.

Example 2 – If the reclamation plant, and thus its operator, is different from the urban waste water treatment plant, the competent authority for the water reuse permit might be different from the permitting authority for the urban waste water treatment plant.

It could, for example, be the water or health authorities. In that case, these authorities cannot be involved in drafting the application for the permit or the risk management plan, since this would be a conflict of interest between the permitting authority and the parties drafting the permit application and risk management plan.

Nevertheless, these authorities could be asked to provide data or other information as input to the process, such as water resource monitoring data or other environmental data, providing guidance on the procedures to be followed or similar.

Example 3 – If the reclamation plant is owned by the competent authority, procedures should be in place to avoid conflicts of interest, ensure that the permit application and risk management plan are prepared by all responsible parties as appropriate, and that there is no interference with the person or division in charge of granting the permit.

If all requirements for the permit are met, the competent authority in the Member State should (in accordance with Article 6(5)) grant a permit containing all the necessary conditions and measures set out in the water reuse risk management plan, and without undue delay. This is to ensure regulatory certainty for all parties involved.

If, due to the complexity of an application, the competent authority needs more than 12 months from the date it received a complete application to decide whether to grant a permit, it must communicate the expected date of its decision to the applicant(s).

2.5.2. *Permit application*

Under Article 6(2), any responsible party in the water reuse system, including the end user where relevant in accordance with national law, can apply for a permit, or for changes to an existing permit. They must submit their application to the competent authority of the Member State in which the reclamation facility operates or is planned to operate.

In some water reuse projects, the reclamation plant operator transfers the reclaimed water directly to the end user. In other projects, however, other parties come into play and there may be a need for a reclaimed water distribution operator and a reclaimed water storage operator.

In these cases, Member States may choose to require such operators and end users to have a specific permit, in accordance with Article 6(7). These specific permits must then set out the obligations, including any additional requirements and barriers identified in the water reuse risk management plan developed for that scheme, as referred to in Article 5(4).

2.5.3. *Content of the permit*

As set out in Article 6(3), the permit – or permits, where responsible parties other than the reclamation plant operator are required to have a specific permit (Article 6(7)) – must be based on the water reuse risk management plan.

The water reuse risk management plan must be drawn up in line with Annex II to the Regulation. It must set out the conditions to meet to ensure compliance with the water quality, use and monitoring requirements in Annex I to the Regulation.

The permit must specify:

— The reclaimed water quality class(es) and the agricultural use for which the reclaimed water is permitted.

— The place or places where use is authorised.

— The reclamation facilities, including for example the location of the facility(ies), contact details of the operator, and the estimated yearly volume of reclaimed water to be produced.

— Conditions on the minimum requirements for water quality and monitoring set out in Section 2 of Annex I, which could include specifications about the type of treatment.

— Any conditions in relation to additional requirements for the reclamation facility operator, as set out in the water reuse risk management plan.

— Any other conditions necessary to eliminate any unacceptable risks to the environment or to human and animal health. These could include information on the exact role, tasks, activities and responsibilities of the other responsible parties in the system; or obligations related to environmental monitoring systems, depending on the outcomes of the risk management plan, and follow-up procedures if negative environmental consequences arise.

— The validity period of the permit.

— The point of compliance where checks will be carried out to verify that the operator has met its obligations as regards the quality of the reclaimed water.

As set out in Article 6(6), permits must be regularly reviewed and updated whenever necessary. Permits must be reviewed and updated at least when the following changes arise:

— a substantial change in the plant's capacity;

— equipment is upgraded or new equipment or processes added, resulting in the need for validation monitoring before operation (for class A water);

— changes in climatic or other conditions that have a significant effect on the ecological status of surface water bodies.

2.5.4. *Exemptions for research and pilot projects*

Under Article 2(1), the Regulation applies whenever reclaimed water is used for agricultural irrigation. However, under Article 2(3) research or pilot projects can be exempted from this rule, if certain conditions are met. The competent authority must ascertain that the following criteria are met in order to grant this exemption:

— the research or pilot project will not be carried out within a water body used for the abstraction of water intended for human consumption or inside a safeguard zone designated under Directive 2000/60/EC;

— the research or pilot project will be subject to appropriate monitoring.

It is for the competent authority to set the monitoring conditions and frequencies, on a case-by-case basis, needed to ensure compliance with the Water Framework Directive and other applicable legislation.

Exemptions may not last longer than five years. In addition, no crops grown in a research or pilot project exempted from this Regulation can be placed on the market.

2.6. ***Compliance checks***

Compliance checks need to be performed by the competent authorities to ensure that the requirements set out in the permits are met by the different parties to the water reuse system.

These requirements may be for the reclamation plant operator, at the point of compliance, or for any other responsible parties or end users, according to the water reuse risk management plan.

If these players operate in different Member States – for example in a cross-border project as described in Section 2.3 – the competent authorities with jurisdiction for the relevant players need to perform these checks.

2.7. ***Penalties***

In accordance with Article 15, Member States have to lay down the rules on penalties applicable to infringements of this Regulation and should take all measures necessary to ensure that they are implemented. The penalties should be effective, proportionate and dissuasive.

The following criteria could be taken into account when setting penalties:

a) the nature, gravity, extent and duration of the infringement;

b) the intentional or negligent character of the infringement;

c) the areas affected by the infringement, in particular sensitive areas;

d) the benefits derived from the infringement by those responsible (to ensure that those responsible are deprived of those benefits);

e) the repetitive character of the infringement (to discourage further offences of the same kind).

Member States should put in place compliance assurance measures to prevent and detect infringements and apply the penalties. Compliance assurance includes all the ways in which public authorities intervene to ensure that businesses and others ('duty-holders') comply with their environmental obligations including, for example, inspections and enforcement measures.

Broadly three categories of action could be considered:

— **compliance monitoring:**

this means analysis, assessments, surveillance, inspections, investigations, audits or other checks and interventions carried out by, on behalf of, or under the supervision of a competent authority, to examine whether duty-holders are complying with enforceable obligations;

— **follow-up and enforcement:**

this means action by a competent authority under administrative, civil or criminal law in response to non-compliance or suspected non-compliance with an enforceable obligation; and

— **compliance promotion and prevention of non-compliance:**

this means action to encourage compliance with enforceable obligations other than by means of compliance monitoring or follow-up and enforcement.

This rule applies to all aspects of the Regulation, including the rules that Member States may decide to introduce regarding areas of their territories where water reuse is not considered appropriate or regarding scientific or pilot research projects.

2.8. ***Awareness raising and information sharing***

According to Article 9, Member States who practice water reuse for agricultural irrigation are required to organise general awareness-raising campaigns, which could include promoting the benefits of safe water reuse.

Member States are free to adapt the extent and tone of such campaigns to their specific circumstances, including to the scale of water reuse. They may also set up specific information campaigns for end users, to encourage, where appropriate, the use of reclaimed water as a safe and sustainable alternative for irrigation and ensure its optimal and safe use, giving a high level of protection to the environment and human and animal health.

Such information campaigns can be useful for addressing possible public concerns about water reuse and can help ensure broad support for setting up a water reuse scheme. In this context, to create trust and acceptance, it is recommended to involve stakeholders early and carefully tailor messages, tapping into personal experiences and addressing location-specific challenges.

Good practice suggests that multiple levels of public and stakeholder participation can be effective in reaching a wide audience, ranging from targeted awareness-raising campaigns through to consultation and higher levels of stakeholder involvement in planning and decision-making.

As a general indication, the 2016 'CIS Guidelines on integrating water reuse into water planning and management in the context of the Water Framework Directive' ([13]) suggest gathering the following information as input to information and awareness campaigns:

— the justification of the need for water reuse, e.g. the context of water scarcity, including under future climate conditions;

— the costs of installing treatment and distribution systems;

— the environmental benefits and drawbacks/risks;

— the social and economic benefits and drawbacks/risks: transparency about exposure risks to the public, how these will be addressed and the applicable standards of treatment.

It is also important to take into account the cost of crop losses due to the lack of water for irrigation, which could be minimised by using a reliable and more predictable water source, such as reclaimed water.

Article 10 and 11 of the Regulation set out rules regarding information to be made available to the public and information on how the rules are implemented. This information must be accessible to the European Commission, the European Environment Agency and the European Centre for Diseases Prevention and Control.

Information that has to be made regularly available to the public includes:

— the quantity and quality of reclaimed water supplied;

— the percentage of the total amount of treated urban waste water that the reclaimed water represents, where this data is available;

— the results of compliance checks;

([13]) https://ec.europa.eu/environment/water/pdf/Guidelines_on_water_reuse.pdf

— the designated contact points; and

— any Article 2(2) decision.

Furthermore, Member States will have to publish datasets with additional information on the outcome of compliance checks, as well as additional information on cases of non-compliance, including on measures taken to restore compliance.

Member States may choose the most appropriate format and means of sharing Article 10 information with the public, adapted to their own specific circumstances.

Regarding Article 11, which details the information on implementation that the Member States have to make available, the format and presentation of this data may be set out in implementing acts that the Commission may develop, assisted by the Committee established by Directive 2000/60/EC and in accordance with the procedure detailed in Article 14.

3. Technical aspects

This Section addresses: all aspects related to risk management; types of crops and reclaimed water classes; and validation monitoring.

3.1. *Risk management*

As set out in Article 5(1) of the Regulation, the competent authority is ultimately responsible for making sure that a risk management plan is established that addresses all possible aspects of a water reuse project, including the production, supply and use of reclaimed water, and which assigns responsibility for each aspect of the management of a reuse project.

While the competent authority is responsible for making sure a risk management plan is established, the parties who must actually draw up the plan are the reclamation facility operator, other responsible parties and end users, as appropriate.

The person/persons/entity who actually develop and draft the risk management plan can be any of the 'responsible parties' involved in a water reuse system or the end user, in accordance with national legislation. For the purpose of correctly implementing the Regulation it does not matter who is actually preparing or compiling the plan, as long as all relevant responsible parties and end users are consulted as appropriate and required by the nature, location and characteristics of the water reuse scheme.

The risk management plan can cover one or more water reuse systems, provided it specifically addresses all aspects required by the Regulation. This could lead to a system in which a number of standard basic elements are established - for example in cases with similar crops and irrigation practices in the area served or in a code of good practice – that can form the basis of a more tailored risk management plan for specific water reuse systems.

The aspects that the risk management plan has to address (as required by the Regulation) consist of any additional requirements for the plant operator, to be met before the water is delivered to the next actor in the chain. And appropriate preventive/corrective measures and barriers, monitoring or any other requirement to be applied in the water reuse system, to ensure its safety, after the point of compliance, by other players in the system.

The risk management plan describes the tasks and requirements, and clearly identifies the responsibilities of the relevant actors in the scheme.

There may be cases where a specific end user has not yet been identified. In such cases the risk management plan could be developed on the basis of the intended use of reclaimed water in the specific area (e.g. based on most common agriculture practices and crops).

When a new end user is identified after the risk management plan is finalised, an evaluation should be carried out to establish whether adaptations to the plan are necessary: for example, the new end user's irrigation practice and crops might differ from those already served by the reclamation facility plant (requiring, for example, a higher class of water quality).

In this case, the risk management plan might require any risks, preventive measures or barriers for the new uses to be reassessed. This might require some adaptations in the water reuse scheme (as well as adaptations to the permit, which is based on the risk management plan, where relevant). This re-assessment could be done by any of the responsible parties or the end user, as appropriate.

3.1.1. *Key risk management elements*

The risk management plan must be based on the elements of risk management listed in Annex II of the Regulation. It must follow a systematic approach that includes carrying out a structured analysis of the water reuse system, identifying potential hazards and hazardous events (along with the populations and environments at risk and the related exposure routes), and planning, where appropriate, possible preventive measures and barriers to manage and mitigate the assessed risks.

It should also include provisions for communication and cooperation among the parties involved, to ensure that corrective action is taken and notified where required. The key elements of the risk management plan (KRMs) are the basis for ensuring that the reclaimed water is used and managed safely to protect human and animal health and the environment.

Annex II of the Regulation identifies 11 key elements (KRMs), divided into Parts A, B and C and constituting the basis of the suggested overall approach for a risk management plan.

These are:

Part (A) – Key elements of risk management

1. **System description (KRM1) –** describe the entire water reuse system, from the entry point to the urban waste water treatment plant, to the point of use.

2. **Actors and roles (KRM2) –** identify all the parties involved in the water reuse system, along with their roles and responsibilities.

3. **Hazard identification (KRM3) –** identify potential hazards (pathogens and pollutants) and hazardous events (e. g. treatment failures) associated with the water reuse system.

4. **Environments and populations at risk and exposure routes (KRM4) -** identify populations and environments potentially exposed to each identified hazard.

5. **Environmental and health risk assessments (KRM5) –** for each previously identified hazard, identify potential associated risks for each receptor (people, animals, crops or plants, other terrestrial biota, aquatic biota, soils or the environment in general), for each exposure route.

Risk assessment may be conducted with qualitative and semi-quantitative methods; quantitative risk assessment would require sufficient supporting data. This risk assessment should also take into account any obligations and requirements set out by the EU legislation indicated in the Regulation, as well as any relevant national or local legislation.

Part (B) – Conditions relating to the additional requirements

6. **Additional requirements (KRM6) -** the outcomes of the risk assessment might identify additional or stricter water quality and monitoring requirements than those from Section 2 of Annex I of the Regulation.

If additional parameters or limits are included, this should be based on the outcomes of the risk assessment and supported by scientific evidence that they originate from the water reuse system and not from other sources.

These additional parameters may also include the following pollutants: heavy metals, pesticides, disinfection by-products, pharmaceuticals, substances of emerging concern, bacteria that exhibit anti-microbial resistance.

Part (C) - Preventive measures

7. **Preventive measures (KRM7) –** identify preventive measures or barriers (additional or already in place) that should be applied to parts of the water reuse system, to limit or mitigate any identified risk. For example, access control methods, additional water treatments or specific irrigation technologies or barriers.

8. **Quality control systems (KRM8) –** determine quality control measures, including protocols for monitoring the reclaimed water for the relevant parameters and maintenance programmes for the equipment, to ensure the effectiveness of the treatment chain and the preventive measures adopted.

9. **Environmental monitoring system (KRM9)** - set up an environmental monitoring system to control the release of the identified pollutants in the exposed environmental receptors (e.g. freshwater, groundwater, soil). The monitoring system could include documented procedures already in place to ensure ongoing environmental protection, where appropriate, or these could be further developed or tailored, depending on the results of the environmental risk assessment.

10. **Emergency management (KRM10)** - set up protocols to manage incidents and emergencies.

11. **Coordination (KRM11)** – determine coordination and communication mechanisms between the different actors involved in the water reuse system.

One possible structure to help organise the analysis of the KRM elements is described in the Joint Research Centre (JRC) technical report 'Technical Guidance – Water Reuse Risk Management for Agricultural Irrigation Schemes in Europe' ([14]). This JRC report proposes a modular structure (see Figure 1), whereby each module addresses a specific aspect of a risk management plan and includes several of the KRMs:

— Module I - Preparation (KRMs 1 and 2);

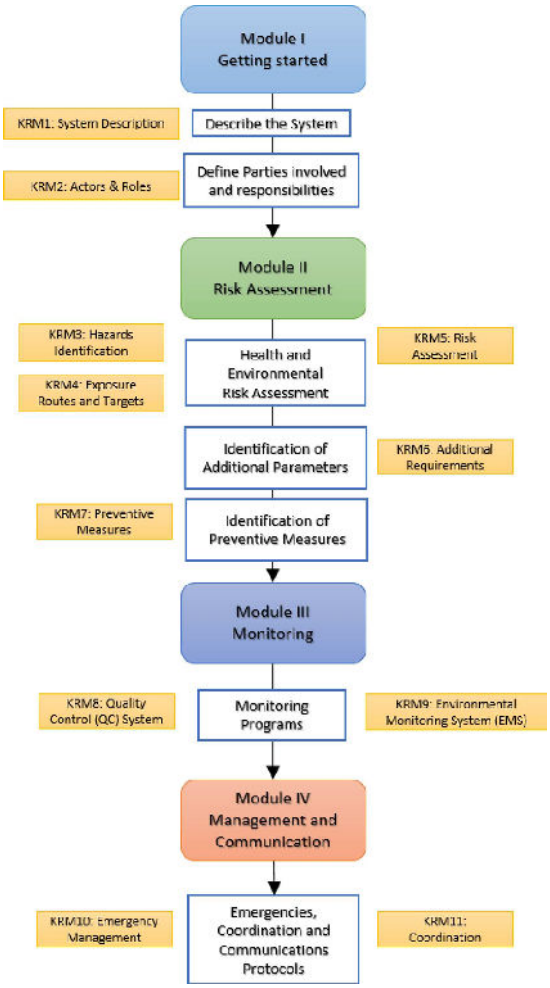
— Module II - Risk Assessment (KRMs 3, 4, 5 and 6);

— Module III - Monitoring (KRMs 6 and 9);

— Module IV - Governance, Management and Communication (KRMs 7, 8, 9, 10 and 11).

Figure 1

Water reuse key risk management elements (KRMs) organised into four modules, to aid the formulation of a risk management plan



([14]) R. Maffettone and B. M. Gawlik (2022), Technical Guidance: Water Reuse Risk Management for Agricultural Irrigation Schemes in Europe, European Commission, Luxembourg, JRC 129596.

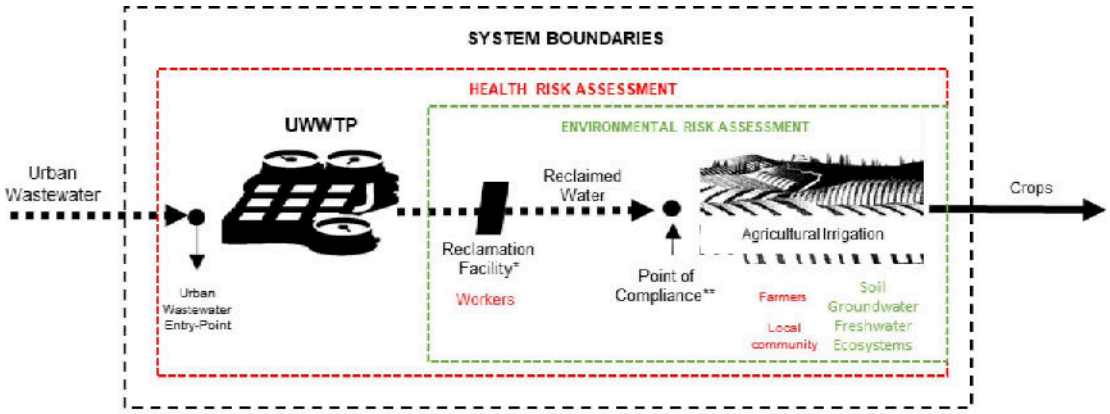
3.1.2. *System description*

A detailed description of the system **(KRM1)** is the starting point for completely characterising the entire water reuse system - from the inlet point for the raw waste water into the urban waste water treatment plant (UWWTP), to the final uses of reclaimed water. It should include a detailed description of the UWWTP and/or the reclamation facility, any infrastructure related to pumping, storage and distribution, irrigation systems, and final uses, within the identified system boundaries (see example in Figure 2).

To collect the data necessary for the risk assessment, the system description should also include a characterisation of the water quality for the sources of waste water entering the UWWTP, water volume data, any variability and weather events, and a description of the surrounding environmental matrices (soil, groundwater and surface water, ecosystems).

Figure 2

Main elements of a water reuse system, identifying receptors in the risk assessment



**Reclamation Facility*: it can be the urban waste water treatment plant or other facility that further treats urban waste water that is fit for a use specified in Section 1 of Annex I of the 741/2020 Regulation.
***Point of Compliance:* the point where a reclamation facility operator delivers reclaimed water to the next actor in the chain. In this image the reclaimed water is delivered directly to the end-users, but in other situations it may be delivered to a distribution operator or a storage operator.

3.1.3. *Actors and roles*

All the actors involved and their roles and responsibilities should be identified for each element of the water reuse system **(KRM2).**

This should include, the actors responsible for (i) operating the plants (UWWTP and reclamation facility operators), (ii) transport and storage, where relevant, and (iii) the irrigated fields (farmers). It should also include any relevant authorities or bodies (e.g. water authorities, public health authorities, environmental authorities), or other parties such as associations of farmers and consortia of irrigators.

3.1.4. *Hazard identification and environments and populations at risk*

Elements **KRM3** and **KRM4** include:

1. Identifying any potential hazards (pollutants and pathogens) or hazardous events (failure of treatments, accidental leakages, contamination) that originate from the water reuse system and might pose a risk to public health and/or the environment;

2. Characterising potential exposure routes for each hazard to the identified human, animal or environmental receptors (populations and environments exposed). These elements are needed to be able to subsequently assess the health and environmental risks **(KRM5)**.

The **identification of hazards (KRM3)** should include any pathogens and pollutants in the reclaimed water that might pose a risk to the human and animal health and the environment.

Microbial pathogens in reclaimed water (e.g. *E. coli* and other bacteria, viruses, parasites) used for agricultural irrigation could be responsible for water-borne disease outbreaks (e.g. gastroenteritis) and other acute effects ([15]).

Chemical pollutants that could be still present in reclaimed water might also pose a risk to human health. However, chemical contaminants are usually present at low concentrations in UWWTP effluents from domestic waste water, and generally require a longer exposure to cause illnesses or acute reactions, so overall the risk from these pollutants is lower than that posed by pathogens.

It is important to identify any industries located in the area served by the UWWTP whose discharges into the urban collection system might contribute to high concentrations of specific chemical pollutants in the urban waste water (e.g. pharmaceutical industries, galvanisation industries).

Uncontrolled concentrations of chemical hazards in UWWTP effluents might occur as a result of hazardous events, like accidental or inappropriate discharges. The likelihood of these can be minimised by appropriate preventive measures ([16]).

Full compliance of the reclaimed water with any legislation applicable to the water reuse system, regulating both microbiological and chemical pollutants, along with the requirements for agricultural irrigation set by the hygiene of feed and foodstuff legislations, would ensure the protection of the environment, as well as human and animal health.

The risk management system should ensure, therefore, that the use of reclaimed water does not lead to a harmful concentration of contaminants in a specific environmental matrix (e.g. groundwater) and that appropriate preventive measures are taken to prevent this (e.g. by appropriate treatments to reduce pollutants within set-up limits, by minimising any accidental release to the surroundings).

Along with the characterisation of the reclaimed water, an initial screening list of relevant hazards (pathogens and chemical pollutants) might be identified by also taking into account all the relevant EU, national and local legislation, as well as the requirements in the legislation (listed in Annex II point 5 of the Regulation) on protecting surface and groundwater resources. This legislation includes: the Water Framework Directive (WFD) 2000/60/EC, the Groundwater Directive (GWD) 2006/118/EC, the Environmental Quality Standards Directive (EQSD) 2008/105/EC, the Nitrates Directive (ND) Directive 91/676/EEC and, where applicable, the Bathing Water Directive (BWD) 2006/7/EC and Drinking Water Directive (DWD) 2020/2184.

The requirements that the reclaimed water should comply with will depend on the site-specific conditions for the water reuse system and the assessment of how the use of reclaimed water for agricultural irrigation may affect the surrounding environment through potential pathways (e.g. irrigational water run-off, infiltration into groundwater, etc.).

In particular, if reclaimed water were to migrate towards water bodies (surface or groundwater) in the area covered by the water reuse system, the assessment should consider whether the receiving water bodies would still meet the environmental objectives of Article 4 of the WFD (i.e. good surface water ecological and chemical status and good groundwater chemical status – with chemical status being further specified in the EQSD and GWD).

Good ecological and chemical status for surface water imply compliance with EU and national environmental quality standards (EQS). EU environmental quality standards are set under the EQS Directive, whereas national standards may address pollutants of national concern, namely River Basin Specific Pollutants, which are part of good surface ecological status.

([15]) Acute effects: health effects that usually occur rapidly, as a result of short-term exposure. Chronic effect: adverse health effect resulting from long-term exposure to a substance.

([16]) WHO Guidelines for the Safe Use of Wastewater, Excreta and Greywater (WHO, 2006).

The EQS Directive also provides for a 'Watch List' mechanism to collect monitoring data at EU-level on pollutants of emerging concern and substances that may pose a risk to or via the aquatic environment, and for which data on risk are insufficient to set an environmental quality standard.

The chemical status of freshwaters identified by Member States within their river basin management plans can be consulted via the WISE system ([17]).

Further information on environmental quality standards for priority substances can be consulted via the ECHA database ([18]).

Relevant information on emissions of specific pollutants can be found in the European Pollutant Release and Transfer Register (applicable to UWWTP with a capacity of 100 000 P.E.) ([19]).

Other site-specific conditions for protecting surface water and groundwater may also apply: for example, if the water reuse system and the irrigated areas are located near a Nitrate Vulnerable Zone designated under the Nitrates Directive.

Although water reuse in agriculture could be a way of recovering nutrients for irrigation, careful consideration should be given to avoiding nitrates pollution in water resources, by reducing the nitrate content in the reclaimed water below harmful levels.

Similarly, if the reclaimed water is likely to migrate to water bodies classified as Drinking Water Protected Areas (DWPAs), it is important to (i) identify any risks of contamination for drinking water sources from regulated pollutants present in the reclaimed water and (ii) plan any treatments needed to reduce them to acceptable levels.

Furthermore, if reclaimed water runs off to surface waters used for recreational bathing activities, additional requirements for pathogens, deriving from the Bathing Water Directive, may be included. These laws aim to protect the environment and human health by setting standards and/or monitoring obligations for pathogens or chemicals, including heavy metals, disinfection by-products, pharmaceuticals and other substances classified as priority pollutants.

Because reclaimed water is used for agricultural irrigation, the Regulation identifies additional legislation in Annex II point 5 that protects food and feed, soil, crops, and animals. The relevance of the requirements in this legislation to a specific water reuse system will depend on the types of cultivation (e.g. production of foodstuff or feedstuff) and practices (e.g. use of pesticides, use of sewage sludge) on the agricultural field irrigated with reclaimed water.

These requirements include: requirements on the hygiene of foodstuff (Regulation (EC) No 852/2004), feed hygiene (Regulation (EC) No 183/2005), microbiological criteria (Regulation (EC) No 2073/200), maximum contaminants in foodstuff (Regulation (EC) No 1881/2006), levels of pesticides in food and feed (Regulation (EC) No 396/2005), use of sewage sludge (Directive 86/278/EEC), and the protection of animal health (Regulations (EC) No 1069/2009 and (EU) No 142/2011).

Figure 3 shows a graphical example of how to determine which directive or regulation applies to a water reuse system, assuming potential pathways of the reclaimed water to the environmental matrices (freshwater resources) due to accidental leakages or via run-off from the irrigated field.

The figure also illustrates the regulations and directive listed at point 5 of Annex II that might apply, depending on the agricultural practices. A table identifying the applicability of these requirements to a water reuse system is also presented in Annex 2 to this Notice.

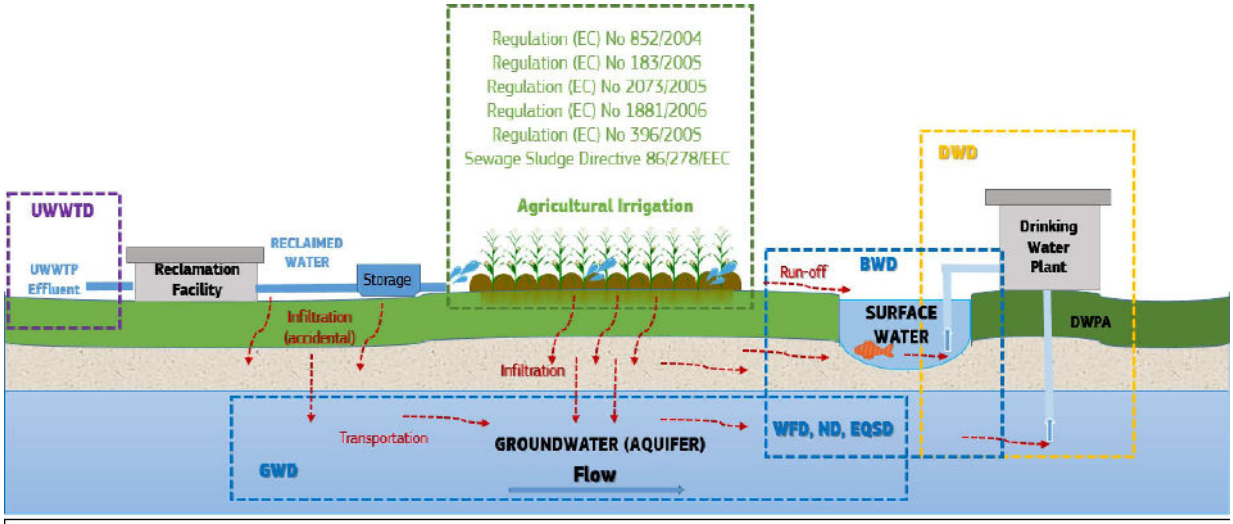
([17]) WISE Freshwater resource catalogue - https://water.europa.eu/freshwater/data-maps-and-tools/metadata#surface-water-bodies-priority-substances-2nd-rbmp-overview-chart

([18]) Environmental Quality Standards – ECHA - https://echa.europa.eu/environmental-quality-standards

([19]) The European Pollutant Release and Transfer Register – https://ec.europa.eu/environment/industry/stationary/e-prtr/legislation.htm

Figure 3

Example of (i) how to identify applicable directives and regulations in a water reuse system, based on potential pathways taken by reclaimed water to the surrounding environments (surface water and groundwater) and (ii) regulations and directives that could apply to agricultural irrigation, depending on specific agricultural practices



UWWTPD: Urban Wastewater Treatment Directive; DWD: Drinking Water Directive (if surface or groundwater are classified drinking water protected area (DWPAs); BWD: Bathing Water Directive (if surface water is used for bathing activities); GWD: Groundwater Directive; WFD: Water Framework Directive; EQSD: Environmental Quality Standard Directive; ND: Nitrate Directive (if water reuse scheme falls into Nitrate Vulnerable Zone (NVZ))

Other specific aspects linked to the effect of reclaimed water quality parameters on agronomic characteristics, including hazards on soil and crops/plants, should also be considered. According to ISO 16075-1:2020, agronomic hazards from reclaimed water that could damage soil and irrigated crops are: (i) chemical substances, such as salinity, boron, specific ion toxicity; (ii) other chemical elements; and (iii) nutrients.

Pathogens that could cause disease to plants or crops are not usually found in reclaimed water from UWWTP effluents. However, their presence in reclaimed water could be assessed in site-specific conditions (e.g. run-off of irrigation water infected with plant pathogens).

Annex 2 of this Notice contains informative examples and tables for pathogens and pollutants typically present in UWWTP effluents and regulated by some of the above-mentioned directives and regulations, as well as examples of agronomic hazards that could affect soils, crops, freshwater and groundwater during agricultural irrigation.

It also contains examples of hazardous events and exposure routes for health and environmental risk assessment, and examples of populations and environments at risk.

Note, however, that the lists of resources in the Annex are **not to be considered exhaustive** and are proposed purely for information. **The hazards should be accurately identified for each specific water reuse system**, considering the characterisation of the reclaimed water and any applicable requirements.

Some other pollutants that are not yet regulated and cannot be found in the listed directives and regulations (e.g. micro-plastics or some compounds of emerging concern) could be added to the list of hazards, if the risk to human and animal health or the environment is supported by scientific evidence and it is proven that these contaminants originate from the water reuse system and not from other sources. The risk assessment could also identify the source of these contaminants, e.g. due to the presence of particular industries, and plan any preventive measures.

3.1.5. *Environmental and health risk assessments methods*

Environmental and health risk assessment **(KRM5)** should be conducted by taking into account previously identified hazards (individually or in groups) and hazardous events, potential routes of exposure and the receptors identified within the water reuse system.

Risk assessment may be conducted by qualitative or semi-quantitative methods. Qualitative risk assessment is suggested as the most appropriate and economically-feasible methodology. Quantitative risk assessment could be used for projects with high risk and when enough supporting data are available for their implementation.

As regards methodologies, qualitative, semi-quantitative and quantitative methodologies can be used for these assessments. The health risk assessment evaluates any risk to human and animal health, whereas the environmental risk assessment aims to determine if the identified contaminants in the reclaimed water affect the quality status of environmental matrices.

Qualitative and semi-quantitative risk assessments can be developed through several approaches, such as event trees, matrices or indicators. A usual methodology is the one based on a combined evaluation of the likelihood and magnitude/severity of the impact of a hazard on the exposed receptor.

Likelihood analysis can be performed through historical data review or assessment of human error, fault trees and event trees. The analysis of the impacts is usually done through a classification into categories, with increasing levels of severity for the impact.

There are several methods on qualitative and semi-quantitative risk assessment available in published guidelines and standards that can be followed (e.g. WHO Guidelines, 2006; ISO 20426 (2018); FAO and WHO, 2019) ([20]).

Annex 3 of this Notice illustrates qualitative and semi-quantitative methods for assessing the health risk by using matrices to identify likelihood and severity of impact. It also illustrates a semi-quantitative methodology applicable to water resources. The JRC Technical Report ([21]) also provides further practical examples.

Quantitative risk assessments can provide a numerical estimation of the risk – for example the impact of specific microbial infection in one year under a specific scenario.

This characterisation of the risks to human and animal health is usually based on dose-response relationships to identify if a hazard or hazardous event might have an effect on health.

A health risk assessment by microbial hazard can be done using a quantitative microbial risk assessment (QMRA), based on evaluating dose-response relationships between the concentration of hazards and the effect it may cause on receptors. The outputs from this method represent the probability values for adverse health effects and are expressed by probability of infection or by the disability-adjusted life years (DALY) indicator.

This approach can answer specific questions that apply to a certain point. Therefore, to cover the whole project and increase the level of security, it can be combined with qualitative or semi-quantitative methods.

Methodologies and criteria for QMRA and DALY can be consulted in the WHO Guidelines (2006) and the WHO Guidelines on QMRA (2016) ([22]).

A quantitative approach for assessing the environmental risk (Quantitative Chemical Risk Assessment, QCRA) is usually based on:

— the ratio of the predicted environmental concentration, calculated with complex models for fate and transfers of a specific pollutant to environmental compartments; and

— the predicted no-effect concentrations, or the maximum allowable concentration of the pollutant, as set by the applicable legislation (e.g. environmental quality standards applicable to water bodies according to their quality status).

This type of approach requires a significant volume of monitoring data from the water reuse projects and detailed characterisations of the surrounding environment. This means it is applicable only for projects where sufficient data is available and assumptions are supported by scientific evidence.

([20]) FAO and WHO, 2019. Safety and Quality of Water Used in Food Production and Processing – Meeting report. Microbiological Risk Assessment Series No 33 Rome – https://www.fao.org/3/ca6062en/CA6062EN.pdf

([21]) R. Maffettone and B. M. Gawlik (2022), Technical Guidance: Water Reuse Risk Management for Agricultural Irrigation Schemes in Europe, European Commission, Luxembourg, JRC 129596

([22]) WHO, 2016. Quantitative Microbial Risk Assessment: Application for Water Safety Management. World Health Organisation, Geneva, Switzerland – https://apps.who.int/iris/handle/10665/246195

3.1.6. *Conditions relating to the additional requirements*

The outcome of the health and environmental risk assessment will help establish if any **specific additional requirements (KRM6)** for parameters (additional to or stricter than those specified in Section 2 of Annex I) should be added for water quality and monitoring.

This could include additional pathogens or pollutants identified by the health and environmental risk assessment, taking into account the site-specific conditions, as well as the applicable directives and regulations as described before.

For example, the risk assessment could identify that a specific pollutant in reclaimed water (e.g. nitrates) could negatively affect a nearby water body (e.g. by eutrophication), if present in the reclaimed water at higher concentration than the predicted maximum allowable.

Therefore, a limit based on the maximum allowable concentration, resulting from the risk assessment, could be established for the reclaimed water quality, and this parameter could be included among those to be monitored.

The maximum allowable concentrations could also be equal to the required limits, for example, for the specific quality class (e.g. environmental quality standards, EQS) of the exposed water body. A list of additional parameters, along with the identified limits, could be added for water quality and monitoring, if it is clear that they originate from the water reuse system and the reference values for them are supported by the risk assessment and by a sufficient degree of scientific knowledge.

3.1.7. *Preventive measures*

KRM7 should include the identification of **preventive measures and barriers** applicable to the water reuse system, to remove or reduce to an acceptable level the identified hazards that might lead to a risk.

Preventive measures are any treatments, actions or procedures, whether already implemented or identified during the risk assessment that can be applied at different parts of the water reuse system. For example: (i) at the UWWTP (i.e. by evaluating the process in place and/or by identifying additional treatments); (ii) at the reclamation facility (e.g. considering adding advanced treatments); (ii) at the irrigated fields (e.g. by considering alternative irrigation methods that minimise risks to exposure, providing buffer zones, etc.), protecting workers and farmers (e.g. identifying specific PPE or hygiene protocols, in addition to possible measures already taken to comply with rules on health and safety at work).

The identification of barriers or modifications to the existing irrigation system could be based on the evaluation of existing methods, type of crops and class of water, and should be decided in consultation with the farmers, and other actors in the water reuse system. Please refer to Annex 4 of this document for examples of preventive measures and barriers.

3.1.8. *Quality control and environmental monitoring systems*

KRM8 and KRM9 elements include all the monitoring activities planned for the water reuse system: identification of procedures and protocols for the quality control of the system and for the environmental monitoring system (EMS).

Operational and environmental monitoring programmes provide assurances to workers, the public and authorities of adequate system performance. They should include protocols, programmes (e.g. location, parameters, frequency) and procedures for at least the requirements on routine monitoring and any additional parameters and limits identified as additional requirements by the risk assessment (KRM6).

A quality management system, developed according to ISO 9001 standards or equivalent, may also be prepared by the plant operators whenever appropriate.

The EMS protocols should be based on the results of the environmental risk assessment, to ensure continued protection of the environment when using reclaimed water. Protocols should be in line with existing legislation, e.g. water resources monitoring should comply with Directive 90/2009/EC ([23]) to ensure the results are comparable with those obtained through monitoring under the Water Framework Directive.

3.1.9. *Emergency management and coordination*

KRM10 and KRM11 include management, emergencies and communication protocols linked to the elements KRM10 (Emergency Management), and KRM11 (Coordination).

These programmes constitute the basis for effective communication between the party(ies) responsible for a risk management plan and the actors involved.

KRM11 should include protocols on how the information will be communicated between actors, formats and procedure for reporting accidents and emergencies, notification procedures, sources of information and consultation processes.

Annex 5 of this Notice can be consulted for examples of (i) protocols for managing incidents and emergencies and (ii) communication protocols.

3.2. ***Types of crops and reclaimed water classes***

For the safe use of reclaimed water, Table 1 - Annex I of the Regulation sets out permitted classes of reclaimed water quality (Class A, B, C, D) that must be used for irrigating a given category of crops, based on the irrigation method chosen.

The minimum water quality requirements for each class in Table 2 - Annex I differ mainly by concentration of *E. coli*, as well as other aggregate parameters.

With the combination of crop types and the number and type of accredited barriers, such as irrigation methods, risks can be minimised by avoiding any contact between the reclaimed water and the edible parts of irrigated produce (see Annex 4 to this Notice for examples).

To do so, it is important to first establish whether the edible part of the crops will likely be in contact with the reclaimed water. The risk of contact should be assessed for each specific water reuse system, by evaluating the presumed distance of the edible part of the crops to the irrigated soil and the potential pathways of reclaimed water when sprayed, delivered in drops or by flooding.

If the crops undergo additional treatments (e.g. cooking or industrial processes) that reduce potential contamination, these should also be considered.

According to the Regulation, reclaimed water can be used for the agricultural irrigation of:

— **Food crops consumed raw:** crops cultivated for human consumption, which will not undergo additional processes. Based on the distance ([24]) of the edible part of the crop from the ground, further classification includes:

  — **Root crops:** that grow below ground in the soil and the root portion is edible (e.g. carrots, onions, beetroots)

  — **Above-ground low-growing crops**: that grow above ground in partial contact with soil. These crops can be further divided into crops which grow on the soil surface, such a leafy crops (e.g. lettuce) and crops that grow above ground with the edible portion at <25 cm above the soil surface (e.g. tomato, pepper)

  — **Above-ground high-growing crops**: that grow above ground and with the edible portions at >50 cm above the soil surface, which therefore do not normally touch the soil (e.g. fruit trees)

— **Processed food crops**: crops cultivated for human consumption that will undergo additional processes (i.e. cooked or industrially processed) and will not be eaten raw (e.g. rice, wheat)

— **Non-food crops (fodder):** crops cultivated not for human consumption but for pastures and forage or in other sectors (industrial, energy and seeded crops)

([23]) Directive 2009/90/EC of 31 July 2009 laying down, pursuant to Directive 2000/60/EC, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36).

([24]) Please see Annex 4 for examples on distances between edible parts of the crops and irrigated ground.

Irrigation methods can be generally classified into:

— **Open or gravity-flow irrigation systems:** water is applied directly to the soil surface and is not subject to pressure. This includes flood and furrow irrigation.

— **Sprinkler irrigation systems:** water is sprayed into the air and falls on the soil surface like rainfall.

— **Micro irrigation systems:** water is applied locally with drip or trickle systems (surface or sub-surface) or by micro-spray irrigation.

Irrigation methods should be assessed as pathways that potentially allow contaminants to reach the crops. For example, with sprayed systems, above-ground high-growing crops (e.g. fruit trees) could be exposed to contamination by falling drops, so a higher quality of water should generally be selected.

Localised systems (e.g. drip irrigation) are associated with a lower contamination risk, since water is directed to the inedible part of crops. Additional appropriate and accredited barriers might be applied to achieve the required water quality class (see Section 3.2.2 and Annex 4).

Any risk to the health of workers or people living near the irrigated area should also be assessed. For example, aerosols from sprinkler irrigation systems could reach receptors living near irrigated areas. Aerosol-related risks depend especially on the irrigation water quality and wind velocity (responsible for disseminating aerosols around the irrigated area).

Note that the irrigation methods and preventive measures or barriers indicated in the following section are examples of a suggested approach on how to interpret Table 1- Annex I. They are not intended to be an exhaustive list.

The irrigation systems and preventive measures or barriers already in place or planned should be assessed in order to identify whether additional requirements (e.g. additional treatments or barriers, changes to the irrigation system) could be needed, to minimise potential crop contamination, depending on the class of reclaimed water.

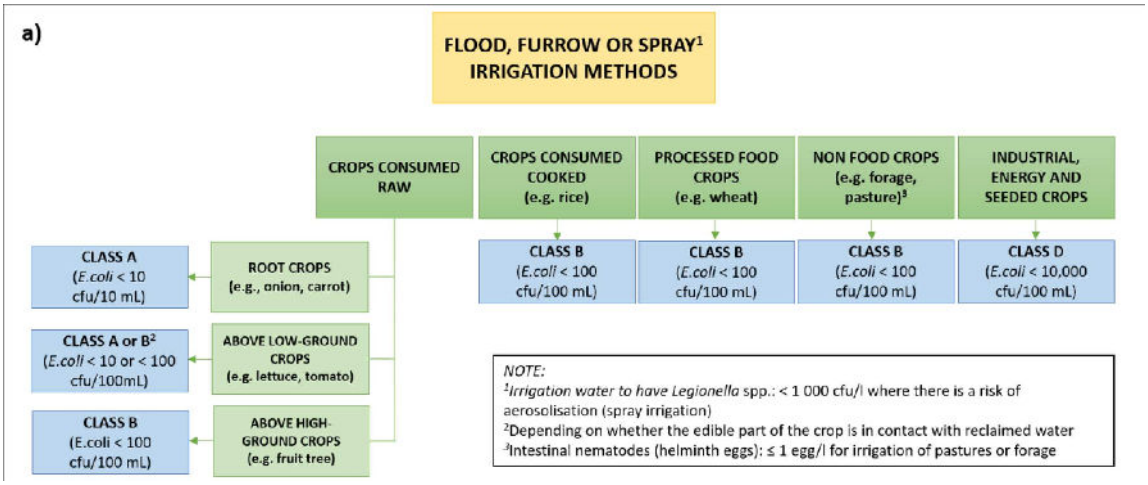
3.2.1. *Examples of irrigation methods and crop types*

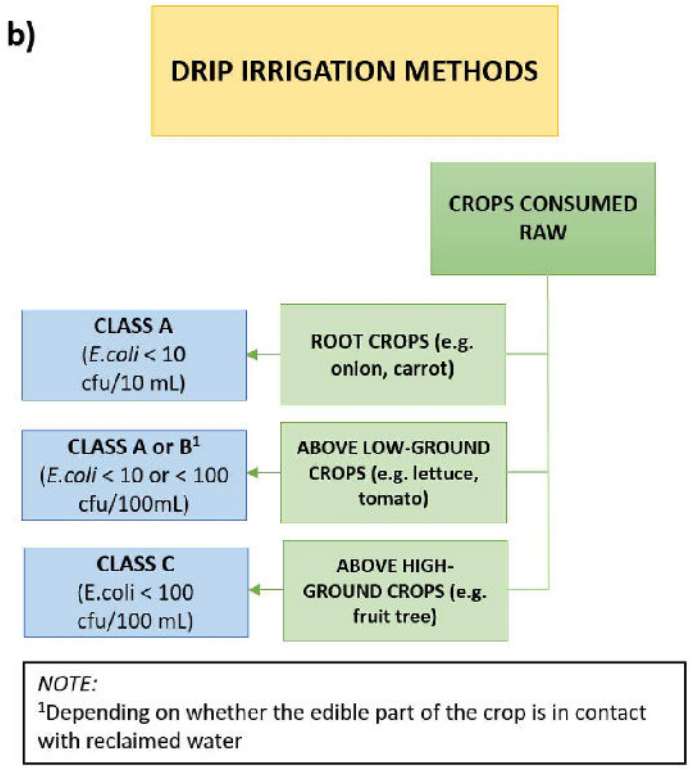
Figure 4 shows two examples of schematics that could help identify the classes of reclaimed water that provide sufficient protection for consumers and workers against *E.coli* when irrigating by (a) gravity-flow or pressurised methods or (b) localised systems.

Regardless of the class of water, the schematics take into account additional microbial requirements when reclaimed water is used to irrigate pastures or forages (intestinal nematodes, Note 3 of Figure 4) and where there is risk of aerosols (Legionella *spp*, Note 1 of Figure 4).

Figure 4

Examples of schematics for selecting the class of reclaimed water (according to the Regulation) for (a) open irrigation methods or (b) localised irrigation methods





The following example from the WHO Safety Plan Guidelines (*Worked Example: SSP in Newtown* - hypothetical) has been adapted to the requirements of the Regulation, to show how the above schematics could be applied in practice.

Only the elements of this example that are allowed by the Regulation were considered. Reclaimed water was used to grow several types of crops, using different irrigation methods (Table 1).

Table 1

Crop types and irrigation methods used in the example

Crops categories	Irrigation methods	Destination of crops (*)
— Root crops consumed raw (onions, carrot) — Low-ground leaf crops consumed raw (lettuce, peppers) — High-ground crops consumed raw (fruits)	— Flood — Open furrows — Manual applications (e.g. scoops, watering cans) — Spray irrigation	— Consumed by farmers and their families — Sold to local community for consumption — Sold to nearby cities for consumption

(*) Without prejudice to the current legislation and guidance documents already in place for food safety and hygiene. Note that, according to the boundaries of Figure 2, the risk assessment will end at the point at which the crop is produced.

In this case, according to Tables 1 and 2 of Annex I of the Regulation, considering the potential pathways by which the reclaimed water could reach the crops, the following classes should be selected:

— For root crops and leafy crops consumed raw, when flood, furrow or spray irrigation is applied **Class A** (*E. coli* ≤ 10 number/100 mL)

— For food crops that grow low above-ground, consumed raw (e.g. pepper): when flood, furrow or spray irrigation is applied **Class A** (*E. coli* ≤ 10 number/100 mL); when drip or sub-surface irrigation systems are used **Class B** (*E. coli* ≤100 number/100 mL).

— For food crops grown high above-ground and not in direct contact with reclaimed water (i.e. fruit trees) only when furrow or flood irrigation is applied **Class B** (*E. coli* ≤100 number/100 mL).

Based on further risk evaluation, in presence of fruits with edible skin, **Class A** might be required when spray irrigation is used, to avoid potential contamination of the fruits from the sprayed water. For fruits with inedible skin, Class B could be appropriate, but the final selection of water quality should be based on the risk assessment.

3.2.2. *Examples of applying barriers to achieve the required water quality class*

Article 2(4) of the Regulation specifies that food business operators can achieve the water quality required to comply with Regulation 852/2004 by using after the point of compliance several water treatment options, either alone or in combination with non-treatment options.

According to the multi-barrier approach, the log reductions to obtain the required water quality class can indeed be achieved by different treatment and non-treatment measures in combination (barriers).

According to Article 3(12) of the Regulation, when reclaimed water is used for irrigation, a barrier is defined as:

— any means, including physical or process-related steps or conditions of use, that reduces or prevents a risk of human infection by preventing contact between reclaimed water and (i) produce that will be ingested, or (ii) and directly exposed persons, or

— other means that, for example, reduce the concentration of microorganisms in the reclaimed water or prevent their survival on the produce that will be ingested.

In other words, and in line with Annex I Section 2 of the Regulation, a barrier should be seen as a means for minimising the risks to levels equivalent to those of the required water quality class for the selected crops.

Different barriers might achieve different log reductions and a combination of them can be applied to the reclaimed water to achieve the required overall log reduction necessary to minimise any risks, based on the selected water quality class.

Table 2 suggests the number of barriers that should be applied to the reclaimed water quality class to obtain the required equivalent level of higher class, based on the type of crop.

Table 3 suggests types of accredited barriers, as well as their related log reduction.

Annex 4 to this Notice contains examples of how to determine the type and number of barriers, based on type of crop and water quality class.

Table 2

Suggested number of barriers needed for irrigation with reclaimed water, according to their quality (adapted from Table 3 of ISO 16075:2020)

NB - changes to the ISO table were made solely to exclude from this table water quality classes and types of crop that are not addressed in the Water Reuse Regulation. See below the table for further explanation on how to interpret this table in relation to the Water Reuse Regulation.

Category[1]	Irrigation of vegetables consumed raw[2]	Irrigation of vegetables after processing and pastures[3]	Irrigation of food crops other than vegetables (orchards, vineyards) and horticulture[4]	Irrigation of fodder and seeded crops[5]	Irrigation of industrial and energy crops[6]
A	0	0	0	0	0
B	1	0	0	0	0
C	3	1	1	0	0
D	forbidden	forbidden	3	1[*]	0

The following definitions for each column in the table are in line with Table 1 of Annex 1 to the Water Reuse Regulation and are intended to help the reader find the crop category that broadly corresponds to the ISO categorisation, and thus identify which additional barriers may be needed:

(1) Minimum reclaimed water quality class.

(2) Food crops consumed raw where the edible part is in direct contact with reclaimed water and root crops consumed raw.

(3) Processed food crops and non-food crops, including crops used to feed milk- or meat- producing animals.

(4) Food crops consumed raw, where the edible part is produced above ground and it is not in direct contact with reclaimed water.

(5) 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 used to feed milk- or meat- producing animals (in both cases, when drip irrigation or another irrigation method is used that avoids direct contact with the edible part of the crop). NB. The seeded crops mentioned here can be seeds for human consumption or for use as animal fodder.

(6) Industrial, energy crops, and seeded crops (intended to produce seeds for sowing).

(*) Note from ISO 16075:2020: Edible seeds or seeds for sowing which have been irrigated for less than 30 days prior to harvesting. If the period before harvesting is equal to or higher than 30 days, then class D can be directly applicable without restrictions (i.e. without the need for additional barriers).

Table 3

Types of accredited barriers and respective pathogen log reductions (adapted from Table 2 of ISO 16075:2020)

Changes were made solely to exclude from this table water quality classes and types of crop that are not addressed in the Water Reuse Regulation.

Type of barrier	Application	Pathogen log reduction	Number of barriers
IRRIGATION OF FOOD CROPS			
Drip irrigation	Drip irrigation of low-growing crops such as 25 cm or more above the ground	2	1
	Drip irrigation of high-growing crops such as 50 cm or more above the ground	4	2
	Sub-surface drip irrigation where water does not ascend by capillary action to the ground surface	6	3
Spray and sprinkle- irrigation	Sprinkler and micro-sprinkler irrigation of low-growing crops such as 25 cm or more from the water jet	2	1
	Sprinkler and micro-sprinkler irrigation of fruit trees such as 50 cm or more from the water jet	4	2
Additional disinfection in field	Low level disinfection (<1 mg/L of total chlorine, after 30 min. of chlorination)	2	1
	High level disinfection (≥1 mg/L of total chlorine, after 30 min. of chlorination)	4	2
Sun resistant cover sheet	In drip irrigation, where the sheet separates the irrigation from the vegetables	2 to 4	1
Pathogen die-off	Die-off support through irrigation cessation or interruption before harvest	0,5 to 2 per day	1 to 2
Produce washing before selling to the customers	Washing salad crops, vegetables, and fruits with drinking water	1	1

Produce disinfection before selling to the customers	Washing salad crops, vegetables and fruits with a weak disinfectant solution and rinsing with drinking water	1	1
Produce peeling	Peeling of fruits and root crops	2	1
IRRIGATION OF FODDER AND SEEDED CROPS			
Access control	Restricting entry into the irrigated field for 24 h and more after irrigation, for example, animal entering pastures or workers entering fields	0,5 to 2	1
	Restricting entry into the irrigated field five days and more after irrigation	2 to 4	2
Sun drying of fodder crops	Fodder crops and other crops that are sun-dried and harvested before consumption	2 to 4	2

Note: barriers could already be in place at the irrigation field; crop restrictions and irrigation methods as barriers are already included in the Regulation when selecting reclaimed water quality class and type of crop.

3.3. ***Validation monitoring***

3.3.1. *General principles*

Validation monitoring is necessary to demonstrate that the design of new water reuse systems or any changes in existing treatment lines will reliably and consistently achieve certain inactivation levels of microbial indicators for Class A of reclaimed water quality (Table 4 – Annex I of the Regulation). Inactivation of microbial indicators is expressed in $\log_{10}$ reduction ([25]).

Validation monitoring is different from the regular routine monitoring that is performed by the operator (Table 3 - Annex I of the Regulation) to make sure the treatment process is reaching the requirements of the Regulation. It should be seen as an intense, short-term activity to be performed before commissioning or during the start-up phase of new treatment trains or processes, or when they are upgraded.

Changes in the water reuse system that entail process updates might be due, for example, to structural variations in:

1. waste water flow and/or quality due to new discharged permits in the sewage system;
2. population equivalents (P.E.) served by the Urban Waste Water Treatment Plant (UWWTP);
3. climatic conditions (increase in seasonal rainfall or drought events);
4. other conditions not addressed by the risk management plan, which require an update in the technology/ processes used.

Because any substantial changes in the capacity of a UWWTP or upgrades in the treatment line of the reuse system will require an existing permit to be reviewed or updated (Article 6(6)), it is recommended to conclude validation monitoring before an authorisation procedure commences.

In any case, during validation activities, reclaimed water might not be delivered for its end-use until monitoring is completed. During this time, reclaimed water could be sent back either to the inlet of the UWWTP or to an identified point of discharge, until the validation's microbial quality requirements are met.

Once validation monitoring confirms that the new system or technologies meet the requirements for microbial indicators, it will be sufficient to continue with the requirements of routine monitoring.

([25]) 1-log removal = 90 % reduction in density of the target organism, 2-log removal = 99 % reduction, 3-log removal = 99,9 % reduction, etc.

To support the validation activities, a report illustrating validation monitoring approach, experimental design, and analysis of inlet and outlet samples for the required microbial indicators can be prepared. The report should be prepared by a qualified waste water professional.

Reclamation facilities that were already in operation and continue to meet the reclaimed water quality requirements set out in Table 2 (a) on 25 June 2020 have no obligation to perform validation monitoring.

3.3.2. *Validation monitoring protocols*

Table 4 - Annex I of the Regulation specifies the $\log_{10}$ reductions to be complied with through validation monitoring on the treatment chain (i.e. between the inlet point for raw waste water into the UWWTP and the point of compliance) for bacteria, viruses and protozoa indicators (*E. coli*, *Campylobacter*, total coliphages/F-specific coliphages/somatic coliphages/coliphages, rotavirus, *Clostridium perfringens* spores/spore-forming sulfate-reducing bacteria and *Cryptosporidium*).

Because in any given reclamation facility the required $\log_{10}$ reduction could be met by combining different processes, no single, harmonised validation monitoring protocol can be identified. Instead, this should be defined and implemented for each specific case by waste water professionals.

When establishing a validation protocol for a water reuse system, the difference between the concentrations in raw waste water and in the target water quality class will determine the needed number and level of treatments (Figure 5).

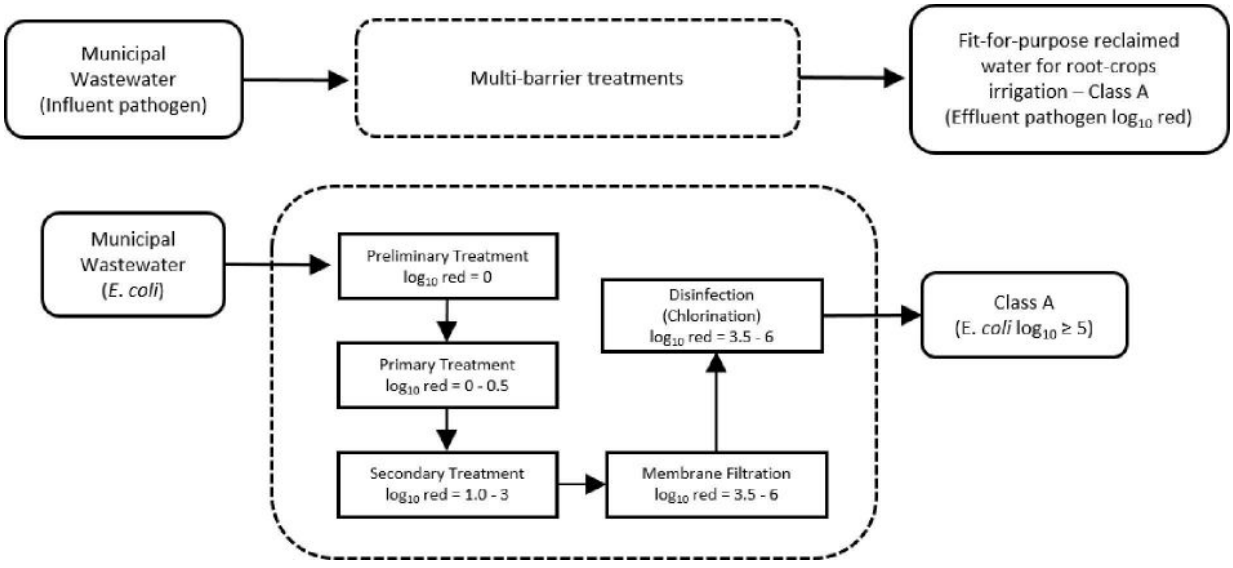
For well-established treatment processes, default values of $\log_{10}$ removal are often available from technical guidelines, textbooks and published data; for innovative processes, a testing protocol should be designed to gather $\log_{10}$ reduction data.

Figure 5 shows an example how the target $\log_{10}$ reduction of *E. coli* can be achieved by the sum of multiple treatments. It is worth noting that, although primary and secondary treatments might reduce the pathogenic bacteria of some logs, disinfection and tertiary treatments are those associated with the highest log reduction and should be carefully characterised.

When a system comprises multiple treatments, log removal values could be determined by technical values or by conducting on-site or off-site pre-testing protocols. On-site validation analysis could then be conducted at the facility(ies), on inlet and outlet samples. Guidelines or standards may be developed at national or other level, to standardise validation monitoring.

Figure 5

Evaluation of an arbitrary multi-barrier water reuse system to reduce E.coli to required $\log_{10}$ reduction for Class A of irrigation ($\log_{10}$ reduction ranges are assumed in Table 3.4 of the Australian Guidelines – see Section 3.3.4)



Once the treatments at the reclamation facility has been identified, there are several strategies for performing validation monitoring, mainly conducting either off-site tests or on-site preliminary tests. Any of these approaches can be used for validation. However, should off-site tests not be enough, on-site testing can complement them. To comply with the validation requirements of the Regulation, it would then be sufficient to test inlet and outlet effluent samples.

The following steps show how to conduct a pre-testing protocol:

— Available performance data on treatments against microbial indicators could first be gathered by consulting technical data sheets from suppliers, published scientific and technical literature, guidelines from legislative authorities or professional bodies, and historical data. This would determine if any process is well-established or pre-testing is necessary.

— If enough technical data is available to prove that the treatments will meet the validation requirements, a pre-testing protocol might not be necessary.

However, it will still be necessary to conduct the analysis required by Table 4 of Annex I to the Regulation, for validation monitoring during the start-up phase in the inlet and outlet effluent, to prove that microbial $\log_{10}$ reductions are achieved.

Preliminary tests could be performed for the specific process/technology on the most challenging organisms for each group of microbial indicators (bacteria, virus, and protozoa), and then validated for all the groups.

Laboratory tests (off-site) or pilot tests (off-site or on-site) might be implemented for innovative technologies, to collect specific design parameters or when there is a lack of data on the performance of the technology.

Experimental design can be developed based on available information and the expertise of waste water professionals. Laboratory tests could be performed on real waste water or, if this is not possible, a solution can be prepared with spiked target organisms. Samples could then be further analysed on-site to confirm laboratory observations.

— For on-site tests, the reclamation facility operators could perform validation monitoring, after having established the protocol. Where needed, they could also be supported by independent and qualified professionals, to oversee the activities. Analysis of validation monitoring should be performed by an independent and certified laboratory.

— For microbial monitoring, it is important to perform analysis on a number of samples that is statistically valid – so at least three samples at each sample point to allow the calculation of averages and standard deviations.

It is suggested that standard deviation should be less than 1 $\log_{10}$ among the samples. At least 90 % of samples should meet the performance targets. The frequency and duration of validation monitoring should be established on the basis of the protocol developed for the specific case.

— If there is no biological indicator in the reclaimed water, the validation requirements are not needed. In particular, if the microbial indicator is not present in the raw waste water, or it is present at a low concentration, it is considered that validation monitoring has approved that indicator.

3.3.3. *Validation monitoring examples*

The following case was selected from the Australian Guidelines as an example of how a validation monitoring protocol might be performed under the requirements of the Regulation.

In this case, spray irrigation of salad crops with reclaimed water from a UWWTP was planned. Validation monitoring was required during the commissioning of the new plant and before the approval of the water reuse system (in the terms of the Regulation, before granting a permit).

In this example, the system was not designed on the basis of available technical standards, thus default values for log reduction were not available. Therefore, a testing plan at lab and pilot scale was necessary to obtain performance data on the inactivation of selected microbes.

The treatment chain for the water reuse system included: secondary treatment, lagoon, coagulation, dissolved air flotation and filtration, and chlorination. Table 2 reports the initial and final concentrations from the performed analysis. For reference, the last column reports the minimum requirements under the Regulation.

Table 2

Validation monitoring results according to an example available in the Australian Guidelines

Indicator microorganisms (*)	Initial concentration in raw waste water	Concentration in treated waste water	Total log reduction	Performance target from Regulation (Table 4 of Annex I)
Cryptosporidium	2 000/litre	<1/50 litres	5 log	≥5 log
Giardia	20 000/litre	<1/50 litres	NA	NA
Adenoviruses, reoviruses, enteroviruses, hepatitis A	8 000/litre	<1/50 litres	5,5 log	NA
E. coli	NA	<1 CFU/100 mL	>6 log	≥5 log

(*) detected using cell culture except in the case of hepatitis A, which was detected using the polymerase chain reaction

3.3.4. *Additional resources*

Because a validation monitoring procedure should be designed to cover specific treatments, some external resources are reported here for consideration by waste water practitioners, to help them implement a specific protocol.

Validation aspect	Reference
Typical $\log_{10}$ reduction ranges for microbial indicators in conventional waste water treatment processes ([26])	— Table 3.4, Chapter 3, Australian Guidelines for Water recycling: Managing Health and Environmental Risks, 2006. — Table 1 - Global water pathogen project part four. Management of risk from excreta and waste water pathogen reduction and survival in complete treatment works, 2019 — Metcalf & Eddy Inc., et al. Waste Water Engineering: Treatment and Resource Recovery. 5th ed., McGraw-Hill Professional, 2013.
Validation protocols for disinfection systems	— ISO 20468-4 Guidelines for performance evaluation of treatment technologies for water reuse systems - Part-4: UV Disinfection — USEPA. 2006. Ultraviolet Disinfection Guidance Manual for the Final Long Term 2 Enhanced Surface Water Treatment Rule. EPA 815-R-06-007. U.S. Environmental Protection Agency, Office of Water, Washington, DC. U.S. Environmental Protection Agency, Office of Water, Washington, DC.USEPA, 2005. Membrane Filtration Guidance Manual. EPA 815-R-06-009. U.S. Environmental Protection Agency, Office of Water, Washington, DC. — Metcalf & Eddy Inc., et al. Waste Water Engineering: Treatment and Resource Recovery. 5th ed., McGraw-Hill Professional, 2013.W

([26]) Reduction rates depend on specific operating conditions, such as retention times, contact times and concentrations of chemicals used, pore size, filter depths, pre-treatment, and other factors. Ranges given should not be used as a basis for design or regulation – they are meant to show relative comparisons during the design of the validation monitoring protocol.

ANNEX 1

Glossary

The following terms are frequently used in this document and are to be understood as explained below. These are not legal definitions, with the exception of those referred to under Article 3 of Regulation 2020/741 on water reuse, or under Article 2 of Directive 91/271/EEC on urban wastewater treatment.

— **Acute toxicity:** rapid adverse effect (e.g. death) caused by a substance in a living organism. It can be used to define either the exposure or the response to an exposure (effect) [NRMMC–EPHC–AHMC, 2006].

— **Barrier:** any means, including physical or process-related steps or conditions of use, that reduces or prevents a risk of human infection by preventing contact of reclaimed water with produce to be ingested and directly exposed persons, or other means that, for example, reduces the concentration of microorganisms in the reclaimed water or prevents their survival on the produce to be ingested [Article 3 (12), Regulation (EU) 2020/741].

— **Competent authority:** an authority or a body designated by a Member State to carry out its obligations under this Regulation regarding the granting of permits for the production or supply of reclaimed water, regarding exemptions for research or pilot projects and regarding compliance checks [Article 3 (1), Regulation (EU) 2020/741].

— **Contaminant:** physical, chemical, biological or radiological substance or matter in water. The presence of contaminants does not necessarily indicate that the water poses a health risk [ISO 20670:2018].

— **Disability-Adjusted Life Years (DALY):** population metric of life years lost to disease, expressed as the number of years lost due to ill health, disability or early death. In the 2006 WHO Guidelines, the health-based target recommended is 10^{-6} DALY per person per year [WHO, 2006a].

— **Disinfection:** process that destroys, inactivates or removes microorganisms until an appropriate level is reached [ISO 20670:2018].

— **Dose–response assessment:** the determination of the relationship between the magnitude of exposure (dose) to a chemical, biological or physical agent and the severity and/or frequency of associated adverse health effects (response) [WHO, 2006a].

— **End-user**: a natural or legal person, whether a public or private entity, that uses reclaimed water for agricultural irrigation [Article 3 (2), Regulation (EU) 2020/741].

— **Environment:** surroundings in which a water reuse system operates, including air, water, land, natural resources, flora, fauna, humans, and their interrelationships [ISO 20670:2018].

— **Exposure**: contact of a chemical, physical or biological agent with the outer boundary of an organism (e.g. through inhalation, ingestion or dermal contact) [WHO, 2016a]

— **Exposure assessment**: the estimation (qualitative or quantitative) of the magnitude, frequency, duration, route and extent of exposure to one or more contaminated media [WHO, 2016a].

— **Fodder crops:** crops not for human consumption. Example: pastures and forage, fibre, ornamental, seed, forest crops and natural grasslands [ISO 20670:2018]

— **Food crops:** crops for human consumption. Food crops are often further classified according to whether the food crop is to be cooked, processed or consumed raw [ISO 20670:2018].

— **Hazard:** a biological, chemical, physical or radiological agent that has the potential to cause harm to people, animals, crops or plants, other terrestrial biota, aquatic biota, soils or the environment in general [Article 3 (7), Regulation (EU) 2020/741].

— **Hazardous event:** an event in which people are exposed to a hazard within the system. It may be an incident or a situation that introduces or releases the hazard to the environment in which humans are living or working; amplifies the concentration of a hazard; or fails to remove a hazard from the human environment [WHO, 2016a].

— **Health risk:** combination of the likelihood of occurrence of harm to health and the severity of that harm [ISO 20670:2018].

— **Health risk assessment:** use of available information to identify health hazards and to estimate health risk [ISO 20670:2018 (modified for the purposes of this Notice)].

— **Irrigation system:** assembly of pipes, components, and devices installed in the field for the purpose of irrigating a specific area [ISO 20670:2018].

— **Log-reduction:** organism reduction efficiencies: 1 log unit = 90 %; 2 log units = 99 %; 3 log units = 99,9 %; and so on [WHO, 2016a].

— **No-observed effect level or concentration**: greatest concentration or amount of a substance, found by observation or experiment, which causes no detectable effect [EEA Glossary, source: WHO, 2004)].

— **Pathogen:** disease-causing organisms (e.g. bacteria, helminths, protozoa or viruses) [WHO, 2016a].

— **Pollutant:** substance which either alone or in combination with other substances or through its products of degradation or emissions can have a harmful effect on human health or the environment [ISO 20670:2018].

— **Preventive measure:** an appropriate action or activity that can prevent or eliminate a health or environmental risk, or that can reduce such a risk to an acceptable level [Article 3 (10) of Regulation (EU) 2020/741].

— **Receptor:** defined entity that is vulnerable to the adverse effect(s) of a hazardous substance or agent. Example: human, animal, water, vegetation, building services [ISO 20670:2018].

— **Reclaimed water**: 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 to Regulation (EU) 2020/741 [Article 3(4) of Regulation (EU) 2020/741].

— **Reclamation facility**: 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 Regulation (EU) 2020/741 [Article 3(5) of Regulation (EU) 2020/741].

— **Reclamation facility operator:** a natural or legal person, representing a private entity or a public authority, that operates or controls a reclamation facility [Article 3(6) of Regulation (EU) 2020/741].

— **1 P.E. (population equivalent):** the organic biodegradable load having a five-day biochemical oxygen demand (BOD5) of 60 g of oxygen per day [Article 2(6), Directive 91/271/EEC].

— **Point of compliance**: the point where a reclamation facility operator delivers the reclaimed water to the next actor in the chain [Article 3(11), Regulation (EU) 2020/741].

— **Water reuse system**: the infrastructure and other technical elements necessary for producing, supplying and using reclaimed water; it comprises all the elements from the entry point of the urban waste water treatment plant to the point where reclaimed water is used for agricultural irrigation, including distribution and storage infrastructure, where relevant [Article 3(15), Regulation (EU) 2020/741].

— **Risk:** the likelihood of identified hazards causing harm in a specified timeframe, including the severity of the consequences [Article 3(8), Regulation (EU) 2020/741].

— **Risk assessment:** process to comprehend the nature of risk and to determine the level of risk [ISO 20670:2018].

— **Risk management:** systematic management that consistently ensures that water reuse is safe in a specific context [Article 3(9), Regulation (EU) 2020/741].

— **Stakeholder - interested party:** individuals, groups, organisations or agencies, with an interest in, involved in, and/or affected by water reuse activities, developments and/or decisions [ISO 20670:2018].

— **System boundary:** the boundary within which a risk management plan is conducted [WHO, 2016b (modified for the purposes of this Notice)].

— **Treatment process:** unit process designed to transform the water quality by physical, biological and/or chemical means [ISO 20670:2018].

— **Treatment system:** set of interrelated or interacting unit treatment processes [ISO 20670:2018].

— **Treatment technology:** wastewater treatment unit process or group of integrated unit processes designed to transform the water quality by physical, biological and/or chemical means [ISO 20670:2018].

— **Urban wastewater:** domestic waste water or the mixture of domestic waste water with industrial waste water and/or run-off rain water [Article 2(1), Directive 91/271/EEC].

— **Urban waste water treatment plant:** facility designed to treat urban wastewater by a combination of physical, chemical and biological processes, for the purpose of producing water that complies with the requirements set out in Directive 91/271/EEC [Regulation (EU) 2020/741].

— **Primary treatment:** treatment of urban waste water by a physical and/or chemical process involving settlement of suspended solids, or other processes in which the BOD_5 of the incoming waste water is reduced by at least 20 % before discharge and the total suspended solids of the incoming waste water are reduced by at least 50 % [Article 2 (7), Directive 91/271/EEC].

— **Secondary treatment:** treatment of urban waste water by a process generally involving biological treatment with a secondary settlement or other process in which the requirements established in Table 1 of Annex I to Directive 91/271/EEC are respected [Article 2(8), Directive 91/271/EEC].

— **Permit:** a written authorisation issued by a competent authority to produce or supply reclaimed water for agricultural irrigation in accordance with this Regulation [Article 3(13), Regulation (EU) 2020/741].

— **Responsible party**: a party carrying out a role or activity in the water reuse system, including the reclamation facility operator, the urban waste water treatment plant operator where different from the reclamation facility operator, the relevant authority other than the designated competent authority, the reclaimed water distribution operator or the reclaimed water storage operator [Article 3(14), Regulation (EU) 2020/741].

References:

WHO, 1994. Assessing human health risks of chemicals: derivation of guidance values for health-based exposure limits (Environmental health criteria 170). World Health Organization, Geneva, Switzerland.

WHO, 2016a. Quantitative Microbial Risk Assessment: Application for Water Safety Management. World Health Organization, Geneva, Switzerland.

WHO, 2016b. Sanitation safety planning: manual for safe use and disposal of wastewater, greywater and excreta. World Health Organization, Geneva, Switzerland.

ISO 20670, 2018. Water Reuse – Vocabulary. International Organization for Standardization, Geneva, Switzerland. Available for consultation.

Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse.

Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment.

NRMMC–EPHC–AHMC, 2006. Australian guidelines for water recycling: managing health and environmental risks (phase 1). National Water Quality Management Strategy. Natural Resource Management Ministerial Council, Environment Protection and Heritage Council, Australian Health Ministers' Conference. Canberra, Australia.

ANNEX 2

Example of health and environmental hazards and routes of exposure

This Annex provides examples of common hazards and hazardous events, routes of exposure and receptors that may be present in a system for water reuse in agricultural irrigation. It also provides a checklist to evaluate the applicability to a specific water reuse system of directives and regulations listed in the Regulation. These elements are selected from relevant EU directives and regulations, and published standards and guidelines (i.e. ISO 20426 (2018) ([1]), ISO 16075-1 (2020) ([2]), WHO Guidelines (2006) ([3]), WHO Sanitation Safety Planning Manual (2016) ([4]), Australian Guidelines (2006) ([5])). The aim is to propose examples to assist in the identification of these elements required for the development of a risk assessment. The elements reported here are mere examples: their correct identification and assessment must be based on the specific water reuse system.

Directives and regulations listed in point 5 of Annex II to the Regulation

Table 2.1

Directive and regulations listed in point 5 of Annex II and evaluation of their application on a water reuse system

Directive/Regulation	Requirements under Annex II, point 5	Applicability
NITRATES DIRECTIVE 91/676/EEC concerning the protection of waters against pollution caused by nitrates from agricultural sources.	To reduce and prevent water pollution from nitrates.	If the risk assessment identifies any surface water and ground water regulated under this Directive (e.g. identified as vulnerable zone to nitrates) and that would potentially be exposed by the reuse of reclaimed water for agricultural irrigation (e.g. via run-off or infiltration, respectively).
DRINKING WATER DIRECTIVE 2020/2184 on the quality of water intended for human consumption.	To meet the requirements for protected areas for water intended for human consumption, namely protected areas for drinking water production (DWPAs).	If the risk assessment identifies surface water and groundwater that are classified as DWPAs and that would potentially be exposed by the use of reclaimed water for agricultural irrigation (e. g. via run-off or infiltration, respectively).
WATER FRAMEWORK DIRECTIVE 2000/60/EC establishing a framework for Community action in the field of water policy.	To meet the environmental objectives on surface water and groundwater and the environmental quality standards for pollutants of national concern (river basin specific pollutants) for surface water	If the risk assessment identifies potential risks to surface water and groundwater (e.g. via run-off or infiltration, respectively) for which a chemical status was identified (*Good surface water chemical status* and *Good groundwater chemical status*).
GROUNDWATER DIRECTIVE 2006/118/EC on the protection of groundwater against pollution and deterioration	To prevent groundwater pollution.	If the risk assessment identifies groundwater resources regulated under this Directive that would potentially be exposed by the use of reclaimed water for agricultural irrigation.

([1]) ISO 20426:2018. Guidelines for health risk assessment and management for non-potable water reuse.
([2]) ISO 16075-1, 2020. Guidelines for treated wastewater use for irrigation projects. Part 1: the basis of a reuse project for irrigation.
([3]) WHO, 2006. WHO guidelines on the safe use of wastewater, excreta and greywater – Vol II: Wastewater in agriculture.
([4]) WHO, 2016. Sanitation safety planning: manual for safe use and disposal of wastewater, greywater and excreta.
([5]) NRMMC–EPHC–AHMC, 2006. Australian guidelines for water recycling: managing health and environmental risks (phase 1). National Water Quality Management Strategy.

ENVIRONMENTAL QUALITY STANDARDS DIRECTIVE 2008/105/EC on environmental quality standards in the field of water policy	To meet the environmental quality standards for priority substances and certain other pollutants.	If the risk assessment identifies surface waters (or sediment and biota) potentially exposed to the use of reclaimed water (e.g. via run-off) for which priority substances and environmental quality standards (EQS) are established within a river basin management plan (RBMP).
BATHING WATER DIRECTIVE 2006/7/EC concerning the management of bathing water quality	To meet the bathing water quality standards	If the risk assessment identifies water bodies used for bathing activities and that are potentially exposed to the use of reclaimed water (e.g. via run-off).
SEWAGE SLUDGE DIRECTIVE 86/278/EEC on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture	To protect the environment and the soil.	If sewage sludge is used in the agricultural field of the water reuse system.
Regulation (EC) No 852/2004 on the hygiene of foodstuffs	To address microbiological risks in fresh fruits and vegetables at primary production through good hygiene.	If the agricultural field irrigated with reclaimed water is used for the production of fresh fruits and vegetables.
Regulation (EC) No 183/2005 laying down requirements for feed hygiene	To meet the requirements of feed hygiene.	If the agricultural field irrigated with reclaimed water is used for the production of feed (e.g. non-food crops including crops used to feed milk- or meat-producing animals).
Regulation (EC) No 2073/2005 on microbiological criteria for foodstuffs	To meet the relevant microbiological criteria.	If the agricultural field irrigated with reclaimed water is used for the production of foodstuff.
Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in foodstuffs	To meet the requirements regarding maximum levels for certain contaminants in foodstuffs.	If the agricultural field irrigated with reclaimed water is used for the production of foodstuff.
Regulation (EC) No 396/2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin	To meet the requirements regarding maximum residue levels of pesticides in or on food and feed.	If the agricultural field irrigated with reclaimed water is used for the production of foodstuff and feed stuff to which pesticides are applied.
Regulations (EC) No 1069/2009 and (EU) No 142/2011 laying down animal health requirements	To meet the requirements regarding animal health	If the use of reclaimed water could affect the health of animals (feed or exposure in the field).

Hazardous events and routes of exposure

Hazardous events and routes of exposure for each potentially exposed receptor (human or environment at risk) should be identified at each step of a water reuse system. Hazardous events might happen during normal system operations (e.g. faulty infrastructure, system overloading, lack of maintenance, unsafe behaviour), due to a system failure or accident, or may be related to seasonal or climatic factors. Table 2.2 provides some examples of hazardous events along with potentially exposed receptors and routes of exposure. Further examples are described in the suggested standards and guidelines.

Table 2.2

Examples of hazardous events, potentially exposed receptors and route of exposures in a water reuse system (Source: Australian Guidelines (2006), ISO 20426, (2018))

Hazardous event	Exposed receptor	Route of exposure
— Treatment failures — Accidental or illegal discharges	— Workers (reclamation facility operators) — End-users (farmers) — Bystanders — Environment (freshwaters, marine water, soil and related biota) — Crops	— Direct contact with reclaimed water — Accidental ingestion — Absorption to crops
— Non-compliance of reclaimed water due to failure of treatment — Contamination of storage and distribution system	— Workers (reclamation facility operators) — End-users (farmers) — Environment (freshwaters, marine water, soil and related biota)	— Direct contact with reclaimed water — Accidental ingestion — Infiltration to groundwater — Run-off to surface water
— Accidental exposure to reclaimed water due to design and operational accidents: pipe burst or leaks, inadequate irrigation timing	— Workers (reclamation facility operators) — End-users (farmers) — Bystanders- Environment (freshwaters, marine water, soil and related biota)	— Direct contact with reclaimed water — Accidental ingestion
— Leaks from reclaimed water pipelines or distribution systems	— Environment (freshwaters, marine water, soil and related biota)	— Infiltration to groundwater — Run-off to surface water
— Accidental exposure to reclaimed water caused by end-use system failures	— End-users (farmers) — Bystanders — Crops	— Direct contact with reclaimed water — Accidental ingestion — Inhalation (aerosols)
— Human errors due to inadequate training and information about permitted use	— End-users (farmers) — Bystanders — Crops	— Direct contact with reclaimed water — Accidental ingestion — Contamination of crops

Health and environmental hazards in reclaimed water

Hazardous events might lead to the release of reclaimed water containing microbial and chemical substances that could be hazards to the exposed human and environmental receptors. The identification of hazards in reclaimed water should be based on the specific water reuse system, considering the urban waste water effluent characterisation and any applicable legal requirements in the context where the water reuse system is located (see Figure 3 of this Notice). A screening level phase could help identify hazards by matching the contaminants found in the specific reclaimed water with threshold values for these contaminants set out in the applicable directives, regulations and guidelines. The tables below provide examples of how to screen for potential hazards: the list of substances is purely indicative, and should not be considered exhaustive. It is the responsibility of the developers of the risk management plan to identify any hazards for the specific water reuse system.

Table 2.3 reports a list of microbial pathogens and their reference pathogens suggested for health risk assessment from relevant standards and guidelines, which may be relevant depending on the local context. Those hazards might be organised in groups and the risk assessment based on the reference pathogen. Other microbial requirements are set out in the applicable regulations on feed and food hygiene (Regulation (EC) No 852/2004, Regulation (EC) No 183/2005, Regulation (EC) No 2073/200, and Regulation (EC) No 1881/2006).

Table 2.3

List of microbial hazards usually detected in raw waste water and their effect on health and reference pathogens (Table A.1 of ISO 20426:2018) ([6])

Pathogen	Examples	Disease	Reference pathogen ([1])
Bacteria	*Shigella*	Shigellosis (bacillary dysentery)	*E. coli* O157:H7 *Campylobacter*
	Salmonella	Salmonellosis, gastroenteritis (diarrhoea, vomiting, fever), reactive arthritis, typhoid fever	
	Vibrio cholera	Cholera	
	Pathogenic *E.coli*	Gastroenteritis and septicaemia, haemolytic uremic syndrome	
	Campylobacter	Gastroenteritis, reactive arthritis, Guillain-Baré syndrome	
Protozoa	*Entamoeba*	Amoebiasis (amoebic dysentery)	*Cryptosporidium*
	Giardia	Giardiasis (gastroenteritis)	
	Cryptosporidium	Cryptosporidiosis, diarrhoea, fever	
Helminths	*Ascaris*	Ascariasis (roundworm infection)	Intestinal nematodes (helminth eggs)
	Ancylostoma	Ancylostomiasis (hookworm infection)	
	Necator	Necatoriasis (roundworm infection)	
	Trichuris	Trichuriasis (whipworm infection)	
Viruses	*Enteroviruses*	Gastroenteritis, heart anomalies, meningitis, respiratory illness, nervous disorders, others	*Rotavirus*
	Adenovirus	Respiratory disease, eye infection, gastroenteritis	
	Rotavirus	Gastroenteritis	

([1]) Source: Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge, JRC (2017)

The use of reclaimed water from urban waste water treatment plant effluents for agricultural use could affect the quality of waters for human use and the status of aquatic ecosystems (see Figure 3 of this Commission Notice). Quality objectives of water bodies are defined in EU legislation for the protection of human and animal health and of the environment. Quality standards are determined, for example, for coliform indicators in bathing water, for nutrients (nitrogen, phosphorus), biochemical oxygen demand (BOD) and chemical substances in the aquatic ecosystems, and for nitrates and chemicals in water sources used for drinking water production.

Table 2.4 gives an overview of microbial limits from the Bathing Water Directive. These parameters might be consulted if a risk assessment identifies a potential risk of contamination of a water body protected under this Directive.

([6]) JRC, 2017. Minimum quality requirements for water reuse in agricultural irrigation and aquifer recharge. JRC Science for Policy Report.

Table 2.4

Quality standards for intestinal enterococci and E. coli set in the Bathing Water Directive (2006/7/EC)

	Intestinal enterococci (CFU/100ml)		*E. coli* (CFU/100ml)	
Quality Class	Inland waters	Coastal and transitional waters	Inland waters	Coastal and transitional waters
Excellent	200 ([1])	100 ([1])	500 ([1])	250 ([1])
Good	400 ([1])	200 ([1])	1 000 ([1])	500 ([1])
Sufficient	330 ([2])	185 ([2])	900 ([2])	500 ([2])

([1]) 95th percentile of measured concentrations.
([2]) 90th percentile of measured concentrations.
Source: Directive 2006/7/EC; selected in JRC (2019) ([7])

If the water reuse system is located near protected areas for water intended for human consumption, a careful analysis of any risk due to infiltration and run-off must be performed. All measures necessary to meet the obligations of the Water Framework Directive and the requirements of the Drinking Water Directive 2020/2184 must also be taken. Management practices to protect drinking water sources can be found in ISO 16075–3, Section 6.6.

Table 2.5 presents a list of parameters selected from the Drinking Water Directive that could be present in effluent from urban waste water treatment plants. This is an indicative list of pollutants that could be used to screen for any potential hazards for drinking water resources, along with the characterisation of the waste water sources and, for example, the presence of industrial plants in the area. A similar approach could be used to screen for any other potential hazards present in the reclaimed water that could affect other environmental compartments. For example, the Environmental Quality Standards (EQS) Directive list of pollutants can also be consulted. An example of pollutants from the EQS Directive that could be found in effluents from urban waste water treatment plants is set out in Table 2.6.

Table 2.5

Examples of some chemical parameters listed in the Drinking Water Directive potentially present in urban waste water

Parameter	Value
Nitrate (NO_3)	50 mg/L
Copper	2,0 mg/L
Uranium	30 µg/L
Chromium	25 µg/L
Nickel	20 µg/L
Arsenic, Tri- and Tetrachloroethene	10 µg/L
Selenium	20 µg/L
Cadmium, Lead	5 µg/L
Antimony	10 µg/L
1, 2 - dichloroethane	3 µg/L
Mercury, Benzene	1,0 µg/L
Vinyl chloride	0,50 µg/L

([7]) JRC, 2019. Water quality in Europe: effects of the Urban Wastewater Treatment Directive. JRC Science for Policy Report.

PFAS Total (totality of per- and polyfluoroalkyl substances)	0,50 µg/L
Sum of PFAS (the sum of per- and polyfluoroalkyl substances considered a concern as regards water intended for human consumption)	0,10 µg/L
Acrylamide, polycyclic aromatic hydrocarbons (PAHs), Epichlorohydrin	0,10 µg/L
Benzo(a)pyrene	10 ng/L
Bisphenol A,	2,5 µg/L
Trihalomethanes Total	100 µg/L
Haloacetic acids (HAAs)	60 µg/L

Source: Annex I, Part B of Directive 2020/2184 (Minimum requirements for parametric values used to assess the quality of water intended for human consumption). Selected in JRC (2019) and adapted considering revisions of the new Drinking Water Directive and substances that could be found after disinfection.
Directive 2020/2184 provides a watch list mechanism to address compounds of emerging concern, such as endocrine-disrupting compounds, pharmaceuticals and microplastics. The Commission Implementing Decision of 19 January 2022 establishes, for the watch list of substances and compounds of concern for water intended for human consumption, the following endocrine-disrupting compounds:

— 17-beta-estradiol ≤ 1 ng/L
— nonylphenol: ≤ 300 ng/L

Table 2.6

Example of priority pollutants listed in the Environmental Quality Standard Directive potentially present in urban waste water ([1])

Parameter	Annual average (AA) value (µg/L)		Maximum allowable concentration (µg/L)		µg/kg wet weight
	Inland surface waters ([2])	Other surface waters	Inland surface waters ([2])	Other surface waters	Biota
Anthracene	0,1	0,1	0,1	0,1	-
Benzene	10	8	50	50	-
Brominated diphenyl-lethers (sum of the concentrations of congener numbers 28, 47, 99, 100, 153 and 154)	-	-	0,14	0,14	0,0085
Cadmium and its compounds (depending on water hardness classes)	0,08 to 0,25	0,2	0,45 to 1,5	0,45 to 1,5	-
C10-13 Chloro-alkanes (No indicative parameter is provided for this group of substances. The indicative parameter(s) must be defined through the analytical method)	0,4	0,4	1,4	1,4	-
1,2-Dichloroethane	10	10	not applicable	not applicable	-

Dichloromethane	20	20	not applicable	not applicable	-
Di(2- ethylhexyl)- phthalate (DEHP)	1,3	1,3	not applicable	not applicable	-
Fluoranthene	0,0063	0,0063	0,12	0,12	30
Hexachloro-benzene	-	-	0,05	0,05	10
Hexachloro-butadiene	-	-	0,6	0,6	55
Lead and its compounds	1,2 (bioavailable concentrations of the substances)	1,3	14	14	-
Mercury and its compounds	-	-	0,07	0,07	20
Naphthalene	2	2	130	130	-
Nickel and its compounds	4 (bioavailable concentrations of the substances)	8,6	34	34	-
Nonylphenols (4-Nonylphenol)	0,3	0,3	2,0	2,0	-
Octylphenols ((4-(1,1′,3,3′-tetramethylbutyl)-phenol))	0,1	0,01	not applicable	not applicable	-
Pentachloro-benzene	0,007	0,0007	not applicable	not applicable	-
PAH Benzo(a)pyrene ([3])	$1,7 \times 10^{-4}$	$1,7 \times 10^{-4}$	0,27	0,027	-
Tributyltin compounds (Tributyltin-cation)	0,0002	0,0002	0,0015	0,0015	-
Trichloro-benzenes	0,4	0,4	not applicable	not applicable	-
Trichloro-methane	2,5	2,5	not applicable	not applicable	-
Perfluorooctane sulfonic acid and its derivatives (PFOS)	$6,5 \times 10^{-4}$	$1,3 \times 10^{-4}$	36	7,2	9,1
Hexabromo-cyclododecanes (HBCDD)	0,0016	0,0008	0,5	0,05	167

([1]) Selected among the 45 priority substances set by the EQS Directive that includes pesticides, and household and industrial chemicals. *Source:* EQS Directive 2013/39/EU; selected in JRC, 2019.

([2]) Inland surface waters encompass rivers and lakes and related artificial or heavily modified water bodies

([3]) For the group of priority substances of polyaromatic hydrocarbons (PAH) (No 28), the biota EQS and corresponding AA-EQS in water refer to the concentration of benzo(a)pyrene, on the toxicity of which they are based. Benzo(a)pyrene can be considered as a marker for the other PAHs, hence only benzo(a)pyrene needs to be monitored for comparison with the biota EQS or the corresponding AA-EQS in water.

A hazard assessment could include the evaluation of the chemical quality status of groundwater and surface water, the designated Nitrate Vulnerable Zones, and the River Basin Specific Pollutants (RBSPs).

The resources reported in Table 2.7 could aid those responsible for the risk management plan in collecting information relevant to the specific water reuse system and local context.

Table 2.7

Online data sources

Source	Available information	Link
WISE Water Framework Directive (WFD) Protected Area Spatial Dataset	— Drinking water protected areas — Designated areas, such as Fish protected areas and Shellfish protected areas. — Nitrates vulnerable zones — Urban waste water sensitive areas — Bathing water protected areas	https://sdi.eea.europa.eu/catalogue/water/eng/catalog.search#/home
WISE EIONET Spatial Dataset	Information about European river basin districts, river basin district sub-units, surface water bodies, groundwater bodies and monitoring sites.	https://www.eea.europa.eu/data-and-maps/data/wise-eionet-spatial-3
WISE Water Framework Directive Quality Elements map	Information from the 2nd River Basin Management Plans (RBMPs) reported by EU Members States and Norway according to Article 13 of the Water Framework Directive (WFD). The map shows the ecological status or potential of surface water bodies based on their quality elements status value.	https://www.eea.europa.eu/data-and-maps/explore-interactive-maps/water-framework-directive-quality-elements
WISE Groundwater Chemical Status database	Information on groundwater chemical status (good, unknown, poor) per RBMP and country.	https://water.europa.eu/freshwater/data-maps-and-tools/water-framework-directive-groundwater-data-products/groundwater-chemical-status
WISE Freshwater Information System	Information and data on the state of Europe's rivers, lakes, groundwater, on the pressures affecting them, on the measures and actions taken to protect and conserve the aquatic environment.	https://water.europa.eu/freshwater
Knowledge Hub on Water and Agriculture	Water and Agriculture Information Tool: — Surface Water Quality — Groundwater Quality — Ecological Status of water bodies — Chemical Status of Water Bodies	https://water.jrc.ec.europa.eu/
European Chemical Agency (ECHA) database on Environmental Quality Standards	Environmental quality standards (EQS), including annual averages and maximum allowable concentrations, for priority substances and certain other pollutants, as provided for in Article 16 of Directive 2000/60/EC	https://echa.europa.eu/environmental-quality-standards

The European Pollutant Release and Transfer Register (E-PRTR)	Environmental data from industrial facilities in European Union Member States	https://ec.europa.eu/environment/industry/stationary/e-prtr/legislation.htm
European Food Safety Authority (EFSA) Chemical Hazards Database OpenFoodTox	Open source data for substances characterisation, background European legislation, and a summary of the critical toxicological endpoints and reference values.	https://www.efsa.europa.eu/en/data-report/chemical-hazards-database-openfoodtox

Agronomic hazards in reclaimed water

Table 2.8 illustrates some agronomic hazards potentially present in reclaimed water that could affect soil, freshwater resources and crops during irrigation. These hazards are associated with chemical substances in reclaimed water.

Table 2.8

Key environmental hazards, environmental receptors and potential negative effect of reclaimed water used for agricultural irrigation (source: Australian Guidelines, 2006, ISO 16075-1: 2020)

Hazard	Environmental receptor	Potential effect
Nitrogen	Soil Groundwater (leaching) Surface water (run-off) Crop	Nutrient imbalance in crops; eutrophication; toxic effect on terrestrial biota Contamination Eutrophication
Phosphorus	Soil Surface water	Eutrophication/toxic effect on biota Eutrophication
Chlorine disinfection residuals	Surface water Crop	Toxicity to aquatic biota Crop toxicity
Salinity (total dissolved solids, electrical conductivity)	Soil (salinisation) Surface water Groundwater	Soil damage; crop stress; crop uptake of cadmium Increase salinity
Boron	Soil (accumulation)	Crop toxicity
Chloride	Crop Soil Surface water Groundwater (leaching)	Crop toxicity (sprayed on leaves) Crop toxicity via roots uptake Toxicity to aquatic biota
Sodium	Crop Soil	Crop toxicity (sprayed on leaves) Soil damage (crop toxicity)
Inorganic adsorbable pollutants (e.g. heavy metals)	Soil accumulation	Crop toxicity

Reference values of these parameters depend on the local context (e.g. soil type, soil acidity, climate conditions, type of irrigated crops and their tolerance). Applicable legislation and reference standards could help to identify any maximum allowable concentration on the specific identified hazards. Examples of environmental and agronomic risks related to crops and soils can be found in ISO 16075-1 (2020). Annex B and C of ISO 16075-1 (2020) can be consulted for an indication of environmental hazards standards and risk management in agricultural irrigation using reclaimed water. Available information includes:

— Overview of soil-related risks (Table B.2) – e.g. mobilisation of inorganic adsorbable pollutants, salinisation of soil, slaking of upper soil layer, mobilisation of boron, accumulation and mobility of phosphorus.

— Examples of maximum levels of nutrients in treated waste water used for irrigation (Table C.1); example of maximum electrical conductivity of irrigation water, according to plant tolerance, when irrigated by overhead sprinkling (Table C.2); example of relative tolerance of selected crops to foliar injury from saline water applied by overhead sprinklers (Table C.3); combined effect of electrical conductivity of irrigation water and sodium adsorption ratio (SAR) on the likelihood of water infiltration (permeability) problems (Table C.4); example of maximum levels of salinity factors in treated wastewater used for irrigation according to crop sensitivity (Table C.5).

— Example of average value and maximum value of other chemical elements in treated waste water (Table C.6.): it reports suggested values in reclaimed water that would likely cause toxicity to the plants, excess absorption by the crops followed by accumulation of toxic levels of other chemical elements in plant tissues, and movement of other chemical elements into the groundwater.

ANNEX 3

Examples of risk assessment methodologies

Health and environmental risks can be assessed using different approaches with varying degrees of complexity and data requirements, depending on the specific water reuse system. By way of illustration, this Annex presents some qualitative and semi-quantitative risk assessment methods and tools selected among those proposed in published practices and standards: ISO 20426 (2018) ([1]), WHO Sanitation Safety Planning (SSP) ([2]) Manual (2016), ISO 16075-1 to 2 (2020) ([3]), and Australian Guidelines (2006) ([4]).

Best practices and examples from water reuse systems applied in several Member States are also available in the JRC Technical Report ([5]).

Health risk assessment

In a qualitative or semi-quantitative risk assessment, the level of risk for each identified hazard results from a combined evaluation of the likelihood level of an event happening and the level of its consequences or severity, as in the following expression:

Level of risk = Likelihood x Consequence (or Severity)

Likelihood indicates, in a certain timeframe, the probability of occurrence of a hazardous event with potential harmful effects. The probability of occurrence can be evaluated by reviewing available historical data or assessing human error, by using fault or event trees. In a water reuse system, such likelihood might derive from a combination of the probability of human exposure (e.g. via ingestion) to the reclaimed water containing a hazardous element (e.g. *E.coli*) and the probability of the presence of the hazard in reclaimed water (e.g. resulting from a hazardous event such as accidental release).

Consequence or Severity indicates a potential adverse health effect resulting from exposure to a hazard. Consequence levels can be determined by a qualitative evaluation based on a descriptive representation of the outcomes or by using other tools (e.g. decision trees) taking into account hazards and hazardous events.

In a qualitative and semi-quantitative risk assessment, hazard/hazardous events and the assignments of their likelihood and consequences levels are based on the risk assessment team's judgement and experiences. The level of risk can be expressed as *very low, low, moderate, high, or very high* by combining the levels of likelihood and consequences (Table 3.1).

Table 3.1

Example matrix for qualitative risk assessment (source: Table 4 ISO 20426: 2018)

LIKELIHOOD	CONSEQUENCES				
	1 – Insignificant	2 – Minor	3 – Moderate	4 – Major	5 – Catastrophic
A – Rare	Very low	Very low	Low	Low	Moderate
B – Unlikely	Very low	Low	Low	Moderate	High
C – Possible	Low	Low	Moderate	High	High
D – Likely	Low	Moderate	High	High	Very high
E – Almost certain	Moderate	High	High	Very high	Very high

([1]) ISO 20426: 2018. Guidelines for health risk assessment and management for non-potable water reuse.
([2]) WHO, 2016. Sanitation safety planning: manual for safe use and disposal of wastewater, greywater and excreta.
([3]) ISO 16075-1:2020 Guidelines for treated wastewater use for irrigation projects — Part 1: The basis of a reuse project for irrigation; ISO 16075-2:2020 Guidelines for treated wastewater use for irrigation projects — Part 2: Development of the project.
([4]) NRMMC–EPHC–AHMC, 2006. Australian guidelines for water recycling: managing health and environmental risks (phase 1). National Water Quality Management Strategy.
([5]) R. Maffettone and B. M. Gawlik (2022), Technical Guidance: Water Reuse Risk Management for Agricultural Irrigation Schemes in Europe, European Commission, Luxembourg, JRC 129596, 81 pages

An alternative risk matrix, proposed in the WHO Sanitation Safety Planning Manual (2016), is based on a semi-quantitative method for which a more rigorous approach is required (e.g. by using formulas) to assign, for each identified hazard or hazardous event, a specific numerical value for likelihood and severity, so as to arrive at a risk level or score (Table 3.2).

Table 3.2

Semi- quantitative risk assessment matrix (source: Tool 3.4 of WHO Sanitation Safety Planning Manual, 2016)

LIKELIHOOD	SEVERITY				
	1 – Insignificant	2 – Minor	4 – Moderate	8 Major	16 – Catastrophic
Rare (very unlikely) - 1	1	2	4	8	16
Unlikely – 2	2	4	8	16	32
Possible – 3	3	6	12	24	48
Likely – 4	4	8	16	32	64
Almost certain – 5	5	10	20	40	80
Risk Score R = L x S	<6	7-12		13-32	>32
Risk level	Low Risk	Medium Risk		High Risk	Very High Risk

In a semi-quantitative approach, it is necessary to define likelihood/probability levels, based on hazards or hazardous events, and consequence/severity levels, considering, for example, exceedances over protective thresholds of hazardous substances in reclaimed water and the magnitude of its associated health outcomes. These definitions should be developed on the basis of the specific water reuse system and local context and always consider the principle of public health protection and any applicable regulatory impacts. Table 3.3 and Table 3.4 provide some definitions taken from ISO 20426 (2018) and the WHO Sanitation Safety Planning Manual (2016).

Table 3.3

Suggested measures of consequence or severity of the impact (Table 2 of ISO 20426:2018; and Tool 3.3 of WHO, 2016)

CONSEQUENCES (OR SEVERITY)	
Level – Descriptor	Example description
1– INSIGNIFICANT	Hazard or hazardous event resulting in no or negligible health effects ([1]) compared to background levels.
2 – MINOR	Hazard or hazardous event potentially resulting in minor health effects ([2])
3 – MODERATE	Hazard or hazardous event potentially resulting in a self-limiting health effects or minor illness ([3]).
4 – MAJOR	Hazard or hazardous event potentially resulting in illness or injury ([4]); and/or may lead to legal complaint or concern.
5 – CATASTROPHIC	Hazard or hazardous event potentially resulting in serious illness or injury ([5]), or even loss of life; and/or will lead to major investigation by regulator with prosecution likely.

([1]) *No or negligible health effect*: not observed health effect.
([2]) *Minor health effect*: e.g. temporary symptoms like irritation, nausea and headache.
([3]) *Self-limiting health effects or minor illness*: e.g. acute diarrhoea, vomiting, upper respiratory tract infection, minor trauma.

([4]) *Illness or injury*: e.g. malaria, schistosomiasis, food-borne trematodiases, chronic diarrhoea, chronic respiratory problems, neurological disorders, bone fracture.
([5]) *Serious illness or injury*: e.g. severe poisoning, loss of extremities, severe burns, drowning.

Table 3.4

Suggested measures of likelihood that exposure events can happen (Table 3 of ISO 20426:2018, and Tool 3.3 of WHO, 2016)

LIKELIHOOD	
Level – Descriptor	Example description
A – RARE	Has not happened in the past and it is **highly improbable** it will happen in a reasonable period ([1]).
B – UNLIKELY	Has not happened in the past but **may occur in exceptional circumstances** in a reasonable period.
C – POSSIBLE	May have happened in the past and/or **may occur under regular circumstances** in the reasonable period.
D – LIKELY	Has been observed in the past and/or is **likely to occur under regular circumstances** in a reasonable period.
E – ALMOST CERTAIN	Has often been observed in the past and/or **will almost certainly occur** in most circumstances in a reasonable period.

([1]) Reasonable period depends on the level of risk and local jurisdiction.

The identified risk levels associated to hazard/hazardous events per route of exposure and receptor will determine priorities for risk management and any preventive measures that will reduce the risk(s). For example, if the level of risk is *medium* or higher, a preventive measure should lower the risk level. This evaluation could include the assessment of any preventive measures already in place and the identification of additional measures/actions for those hazards with no existing or no effective measures in place. If a preventive measure can sufficiently control the risk, then actions may require the setup of monitoring and other operational control methods to ensure its functionality. The multi-barrier approach, with multiple preventive measures and barriers in place, provides more reliable risk management than a single measure or barrier. The selected preventive measures and barriers should then be re-assessed to verify whether risk levels have decreased, as in the example in Table 3.5.

Table 3.5

Example of risk assessment and management for potential contact with pathogenic bacteria in reclaimed water at the end-use point, adapted from Table 5 of ISO 20426:2018

Hazard	Source of wastewater	Intended end-use	Hazardous event	Maximum risk			Preventive measure	Residual risk		
				Consequence	Likelihood	Risk		Consequence	Likelihood	Risk
Pathogenic bacteria (e.g. *E. coli*)	Urban wastewater	Agricultural use	Infection through contact or ingestion of reclaimed water (e.g. during irrigation practises)	Major	Likely	High (based on Table 3.1)	Source control	Major ([1])	Rare ([2])-([2])	Low
							Treatment control (e.g. disinfection)			
							End-use control (e.g. use of barriers and personal protective equipment)			

([1]) The consequence (severity) depends on the adverse health effect from the exposure of the receptor to the pathogenic bacteria and it does not change by applying a preventive measure.
([2]) The use of preventive measures (e.g. disinfection treatment, use of barriers and personal protective equipment) reduces the likelihood of the receptor to be exposed to the hazard.
NB - Examples of preventive measures and barriers are presented in Annex 4.

Environmental risk assessment on freshwater resources

While the health risk assessment focuses on human receptors, the environmental risk assessment evaluates any pressures on environmental compartments potentially affected by using reclaimed water for agricultural irrigation. This requires a detailed characterisation of the local geo-hydrogeological conditions where the water reuse system is located. The WISE EIONET spatial data set ([6]), which includes information about European river basin districts, river basin district sub-units, surface water bodies, groundwater bodies and monitoring sites can be consulted for this purpose. The procedure proposed here, developed in accordance with Section 6.3 of ISO 16075-1 (2020), and paragraph 4.2 of the Australian Guidelines (2006), aims to guide water practitioners to assess the impact of hazards present in reclaimed water on freshwater resources (surface water and groundwater).

Step 1 - Hazards screening

Comparing hazards in reclaimed water with known values from regulation, directives, standards and guidelines depending on the potentially affected environmental compartment (see Figure 3 of this Notice). This could include maximum allowable concentrations or environmental quality standards (EQS) for regulated contaminants in the potentially exposed environmental compartments whose compliance will, in most cases, ensure the protection of exposed environments. A worst-case scenario can be used, in which the 95th percentile or maximum-recorded concentration is compared with its lowest guidelines value (e.g. EQS). Hazardous events linked to the release of these hazards should also be identified (e.g. leaks from reclaimed water pipelines or distribution systems).

Step 2 - Probability of substances to reach the environmental receptor

Likelihood could be estimated by assessing if the hazards could reach the environmental receptor and considering any preventive measure and barrier in place. For groundwater and surface waters, the likelihood will depend on the hydrogeological conditions of the site (e.g. presence of an aquifer), the probability of the substance to move in the non-saturated zone for infiltration (e.g. soil type and hazard characteristics), and the type of irrigation conditions (e.g. agricultural practices, crop needs, soil type, probability of reclaimed water to overflow from drainage systems).

Step 3 - Consequence/severity of the damage

Consequence or severity levels of the damage will depend on the initial quality status of surface water or groundwater. The severity levels could define to what extent the hazard concentration will cause a detrimental effect on the environmental compartment. For example, the level of severity of damage will depend on the extent to which a hazard would contribute to the deterioration of the status of the water body being considered. Consequence levels could include other factors, for example if the water source is used for the production of drinking water.

Step 4 - assessment of risk levels

Once all the hazards and their likelihood and severity levels have been identified (either by assigning a qualitative level or a numerical value), then a qualitative or semi-quantitative matrix can be used to assess risk levels, as those proposed for the health risk assessment (Table 3.1 and 3.2).

The probability of a certain substance reaching a water body can be estimated by using the following tools from ISO 16075-1 (2020), which assess the vulnerability of groundwater and surface water to infiltration or run-off of reclaimed water, respectively. With this tool, surface water and groundwater are classified in four *sensitivity groups*, which are based on hydrogeological conditions for groundwater, and on the presence of drainage system to control run-off to surface water (Table 3.6).

([6]) Available at: https://www.eea.europa.eu/data-and-maps/data/wise-eionet-spatial-3

Table 3.6

Sensitivity groups definition for surface water and groundwater (source: Section 6.3.3 and Annex D of ISO 16075-1:2020)

Sensitivity group	Surface water	Groundwater
High (I)	Presence of surface run-off during irrigation or presence of surface accumulation, which is likely to wash out during rain events.	Presence of an unconfined acquirer beneath the irrigated area with clay content ([2]) < 5 % within the top 2 m of soil. Presence of an aquifer at a depth less than 5 m.
Medium (II)	Design and operation of irrigation system prevents surface run-off. Presence of a shallow underground drainage system (at a depth of 80 cm or less).	Presence of an aquifer at a depth of over 5 m from the surface with clay content of 15 to 40 % within the top 2m soil.
Low (III)	Design and operation of irrigation system prevents surface run-off. Presence of a deep drainage system (over 80 cm).	Presence of an aquifer at a depth of over 5 m with clay content > 40 % within the top 2 m soil.
(Zero) IV	Design and operation of irrigation system prevents surface run-off. Irrigation system does not include drainage ([1]).	No aquifer under the irrigated area and no hydrogeological continuity that will likely transfer the water to a nearby aquifer ([3])

([1]) The passage in the underground section provides filtration of contaminants. The existence of effective land drainage reduces the water content of the soil, but might lead to increased loads on surface water systems.
([2]) Clay content can be determined by sieve analysis.
([3]) Group to be selected only when a thorough hydrogeological analysis has been conducted. In the absence of clear knowledge of the underground geo-hydrogeology, the site should be regarded as if there was an aquifer beneath the irrigated area.

The combination of the sensitivity groups for groundwater and surface water with the level of infiltration to groundwater or surface run-off, respectively, can indicate a level of vulnerability of the water body (Table 3.7).

Table 3.7

Example of vulnerability ([1]) level of groundwater and surface water (source: Table D.1 ISO 16075-1:2020)

INFILTRATION RATE			No infiltration to groundwater	Low infiltration to groundwater	Medium infiltration to groundwater	High infiltration to groundwater
			I	II	III	IV
Sensitivity to groundwater	Shallow aquifer or no clay protection	I	1	2	3	3
	Deep aquifer with clay protection	II	1	2	2	3
	Deep aquifer with significant clay protection	III	1	1	2	2
	No aquifer with hydrological continuity to the area	IV	1	1	2	2
Sensitivity to surface water			3	3	2	1
			IV	III	II	I
			High surface run-off	Medium surface run-off	Low surface run-off	No surface run-off
			SURFACE RUN-OFF			

([1]) The term *vulnerability* is substituted for the original term *risk* used in Table C1 of ISO 16075-1 (2020), this is to avoid misinterpretation with the term *risk levels* used in this Notice to indicate the combination of likelihood with severity of damage in accordance with Table 3.1 and Table 3.2.

ANNEX 4

Preventive measures and barriers – illustrative examples

This Annex provides examples of preventive measures and barriers that could be deployed in a water reuse system, in accordance with Articles 5 and 6 and Annex I Section 2 of the Regulation. The examples aim to illustrate the type of analysis required to identify the type and number of preventive measures and barriers, depending on the type of crops and the water quality class, on the basis of international standards and practices. It should be noted that the analysis needs to be performed on a case-by-case basis, taking into account the specific context. Therefore, the examples presented below should not be understood as being automatically applicable to all cases and in every possible circumstance.

The examples have been developed on the basis of the requirements of the Regulation, and on existing international standards and practices: Australian Guidelines (2006), WHO Guidelines (2006) and ISO 16075-2:2020. Table 4.1 lists preventive measures that could be considered at different parts of a water reuse system.

Table 4.1

Examples of preventive measures for a water reuse system (list not exhaustive). Sources: Point 7 of Annex II of the Regulation, Box 2.6 and Appendix 3 of Australian Guidelines (2006) [1]**, WHO Guidelines (2006)** [2]

Type of preventive measure	Examples	Note
Protection of urban wastewater sources	— preventing or managing industrial discharges in urban waste water by ensuring any requirement under applicable EU and local legislation are met — protecting storm-water from animal and human waste — controlling type of water discharged into sewage system (e.g. setting limits)	-
Additional treatment of effluent from urban waste water treatment plants	— treatment processes to reduce microbiological and chemical pollutants in the effluent (e.g. additional disinfection or pollutants removal measures)	-
Protection and maintenance of storage system for reclaimed water	— use of buffer zones — avoid algal growth by minimising light (e.g. by covering the storage system) — maintaining drainage and sites (e.g. ground cover, nutrient balancing) — backflow prevention and cross-connection control on connected plumbing — chemical treatment to avoid clogging or bacterial regrowth	Refer to ISO 20419:2018 [1] for further examples
Control and maintenance of distribution systems and plumbing	— adoption of reclaimed water plumbing codes of practise (e.g. colour coding) — avoid connection of drinking water plumbing to reclaimed water plumbing (e.g. installing air gap or backflow prevention devices)	Refer to ISO 20419:2018 for further examples

[1] NRMMC–EPHC–AHMC, 2006. Australian guidelines for water recycling: managing health and environmental risks (phase 1). National Water Quality Management Strategy.

[2] WHO, 2006. WHO Guidelines for the safe use of wastewater, excreta and greywater. Volume II: Wastewater use in agriculture.

Specific requirements on irrigation systems (e.g. drip or subsurface, spray, micro-spray) and agricultural field	— establishment of minimum safety distances to reduce human and environmental exposure (e.g. from surface water, including sources for livestock, or activities such as aquaculture, fish farming, shellfish aquaculture, swimming and other aquatic activities) — control of slope inclination, field water saturation and karstic areas — control of clogging of emitters in drip irrigation systems — control of rate of application to minimise impact on receiving environments, including soils, groundwater and surface water (e.g. moisture sensors in soil, determination of water and nutrient balances, mechanisms to reduce impacts from salinity and sodicity) — control of time of application (e.g. limiting irrigation to only at night) — control of hydraulic loading and interception drains — specific requirements for sprinkler irrigation (e.g. maximum wind speed, distances between sprinkler and sensitive areas; install systems to minimise production of aerosols in spray and drip irrigation systems)	-
Specific requirements on irrigation of crops	— use of additional barriers*	*Refer to Table 4.2 of this Annex and Table 1 of Annex II to the Regulation.
Control of access and use of signage	— use of fences (e.g. simple railings, security mesh depending on the quality of reclaimed water) — use of signage indicating that water is not suitable for drinking (e.g. reclaimed water — do not drink) or other types of signage (e.g. reclaimed water being used – do not enter when irrigation is in progress) — access control: application methods, rates and times	
Protection of workers and farmers	— use of personal protective equipment (PPE) — education and training on hygiene (e.g. frequent hand-washing) — education and training on equipment control (e.g. on backflow prevention and cross-connection control, on correct installation of plumbing and appliances, best-practice management)	

([1]) ISO 20419:2018 Treated wastewater reuse for irrigation —Guidelines for the adaptation of irrigation systems and practices to treated wastewater.

In accordance with Annex I, Section 2 to the Regulation, a specific crop category is to be irrigated with the corresponding minimum water quality classes indicated in Table 1. A lower water quality class can be used if appropriate additional barriers are used, which result in achieving the quality requirements of the class for the given crop category. Table 4.2 gives examples on how to combine reclaimed water quality classes and accredited barriers for the irrigation of a specific class category in line with the recommendations of ISO 16075-2 (2020).

Table 4.2

Examples on how to calculate number and types of barriers based on type of crop and required reclaimed water quality classes as for Table 1 of Annex 1 to the Regulation, by considering Table 3 and Table 2 of ISO 16075-2:2020 (reported in this Notice as Table 2 and Table 3, respectively) and Table A.1 of ISO 16075-2:2020. The barriers are qualified provided that good practices are implemented

Crop category (Annex 1 Table 1 of the Regulation) (1)	Example crops (Table A.1 ISO 16075-2:2020) (2)	Reclaimed water quality class (Annex 1 Table 1 of the Regulation)[17]	Number of required barriers (Table 3 ISO 16075-2:2020 (3) = Table 2 of this Notice)	Possible accredited barriers (Table A.1 ISO 16075-2:2020 and Table 2 ISO 16075-2:2020 (4) = Table 3 of this Notice)	Number of barriers (Table 2 ISO 16075-2:20-20 = Table 3 of this Notice)	Note
All food crops consumed raw where the edible part is in direct contact with reclaimed water and root crops consumed raw	Leafy crops grown on the soil surface eaten raw (e.g. lettuce, spinach, Asian cabbage, cabbage, celery). Food crops ingested raw, which grow above ground and edible portion is <25 cm above soil surface (e.g. pepper, tomato, cucumber, courgettes, young beans).	A	0	-	0	-
		B	1	Sun-resistant cover sheet OR Additional disinfection in field (low level)	1	-
		C	3	High level disinfection + Sun resistant cover sheet	2+1	-
				Subsurface drip irrigation where water does not ascend by capillary action to the ground surface + Sun resistant cover sheet*	3 (+1)	*Sun-resistant cover sheet is an extra barrier to prevent contact by capillary action of drip irrigation. -
		D	Forbidden*	-	-	*In accordance with Table 3 ISO 16075:2020, and NOTE 3 of Table A.1: Effluents of medium quality (D) should not be used for the irrigation of vegetables.
	Food crops that can be ingested raw, which grow in the soil (e.g. carrot, radish, onion)	A	0	-	-	-
		B	1	Low level disinfection	1	-
		C	3	*No combination of accredited barriers seems to be possible*	-	-

		D	Forbidden*	-	-	*In accordance with Table 3 ISO 16075:2020, and NOTE 3 of Table A.1: Effluents of medium quality (D) should not be used for the irrigation of vegetables.
	Food crops ingested raw, which grow above ground and edible portion is >25 cm above soil surface* *with edible skin	A	0	-	-	-
		B	1	Sun-resistant cover sheet OR Additional disinfection in field (low-level)	1	-
		C	3	Low level disinfection + Drip irrigation of low-growing crops such as 25 cm or more above from the ground + Sun resistant cover sheet	1+1+1	-
		C	3	High level disinfection + Drip irrigation of low-growing crops such as 25 cm or more above from the ground	2+1	-
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 used to feed milk- or meat-producing animals	Food crops grown on the soil that can be eaten raw after peeling (e.g. watermelon, melon, pea)	A	0	-	-	-
		B	0	-	-	Inedible skin (or peeling) counts as one barrier
		C	2	Drip irrigation of low-growing crops such as 25 cm or more above from the ground OR Sprinkler and micro-sprinkler irrigation of low-growing crops such as 25 cm or more from the water jet + Sun-resistant cover sheet (in drip irrigation, where the sheet separates the irrigation from the vegetables)	1+1	-
				Low-level disinfection + Drip irrigation of low-growing crops such as 25 cm or more above from the ground	1+1	-

	Food crops grown above ground where edible portion is <25 cm above soil surface, eaten cooked or processed (e.g. aubergine, pumpkin, green beans, artichoke)	A	0	-	-	-
		B	0	-	-	-
		C	2	Low disinfection + Sun resistant cover sheet	1+1	-
				Subsurface drip irrigation where water does not ascend by capillary action to the ground surface + Sun-resistant cover sheet for extra protection)	3+1	-
	Food crops eaten cooked that grow in the soil (e.g. potato)	B	0	–	-	-
		C	2	High-level disinfection	2	-
	Food crops grown above ground that can be eaten after drying and cooking (dry beans, lentils)	B	0	–	-	-
		C	2	High-level disinfection OR Prolonged air drying*	2	*According to crops and weather conditions
	Food crops that grow above ground such as > 50 cm or more above the ground with edible skin (orchard for fruits with edible skin: apple, plum, pear, peach, apricot, persimmon, cherry, citrus fruits, dates; or orchard for fruits eaten after peeling: mango, avocado, papaya, pomegranate). Orchard for fruits eaten after processing (e.g. olives)	B	0	-	-	The natural distance from fruits (high- growing crops such as 50 cm or more above the ground) to irrigation system avoids direct contact with the edible part of the crop.
		C	0	-	-	
		D	3	Drip irrigation of high-growing crops such as 50 cm or more above the ground + Die-off support through irrigation cessation or interruption before harvest*	1 + 2	*Stop irrigation for more than 24h before the harvest.
	Orchard for nuts (e.g. almonds, pistachio)	C	1	Sun-dried crops*	2	*According to crops and weather conditions.
		D	3	Die-off support through irrigation cessation or interruption before harvest + Sun-dried crops*	1(2)*+2	*According to crops and weather conditions.

	Fodder crops for feed for milk- or meat-producing animals (e.g. alfalfa)	C	1	Die-off support through irrigation cessation or interruption* before the entrance of animals in the field	1	*Stop irrigation at least 24h before the entrance of animals. Animals must not be exposed to fodder irrigated with reclaimed water unless there are sufficient data to indicate that the risks for a specific case can be managed. Fodder has to be dried or ensiled before packaging.
		D	3	Die-off support through irrigation cessation or interruption before the entrance of animals in the field + Low-level disinfection	2+1	Exclude grazing animals from pasture for 5 days after last irrigation. Animals must not be exposed to fodder irrigated with reclaimed water unless there are sufficient data to indicate that the risks for a specific case can be managed. Fodder has to be dried or ensiled before packaging.

([1]) Table 1 – Classes of reclaimed water quality and permitted agricultural use and irrigation method. Annex I to Regulation 741/2020.
([2]) Table A.1 – Example of how to calculate the number and type of barriers. ISO 16075-2:2020.
([3]) Table 3 – Suggested number of barriers that are needed for irrigation with treated waste water according to their quality. ISO 16075-2:2020.
([4]) Table 2 – Suggested types and accredited number of barriers. ISO 16075-2:2020.

ANNEX 5

Management of emergencies and protocols – examples

This Annex provides examples of events and actions that can be addressed in emergency protocols. These protocols should be developed on the basis of the risk assessment for a specific water reuse system. Internal and external communications protocols should also be established with the involvement of relevant agencies (e.g. health, environment and other regulatory agencies), given that effective communication plays an important role when managing incidents and emergencies. Table 5.1 presents a list of events that can lead to emergencies, along with actions needed to deal with them.

Table 5.1

Examples of events that can lead to emergencies and actions that could be addressed in emergencies and communication protocols (source: Section 2.6. Australian Guidelines, 2006) [1]

Events	Actions to be addressed in protocols	Note
— Non-conformity with limits, guideline values and other requirements — Failure of treatment systems (e.g. system failure, incorrect dosage of chemicals, equipment breakdown, mechanical failure) — Accidental or illegal discharges (e.g. spills in catchments, illegal discharges into collection systems) — Prolonged power outages — Extreme weather events — Natural disasters (e.g. fire, earthquakes, lightning damage to electrical equipment) — Human actions (e.g. serious error, sabotage, strikes) — Outbreaks of illness leading to increased pathogen on treatment systems — Bio film or algae or microbial regrowth in storages or waterways — Killing of fish or other aquatic life — Crops damaged or destroyed by irrigation with reclaimed water (suspected)	— Define potential incidents and emergencies and document procedures and response plans with the involvement of relevant agencies — Define response actions, including increased monitoring — Define responsibilities and authorities among internal and external players — Identify alternative water supply in case of emergencies — Train employees and regularly test emergency response plans — Define a protocol to investigate any incidents or emergencies and revise them as necessary — Define communication protocols and strategies (including internal and external communication) — Include a contact list of key responsible parties and authorities with defined responsibilities, including emergency night and week-end shifts	— Employees should be trained in emergency response and incident protocols — Farmers and other stakeholders should be trained in good practices in the water reuse context, especially in emergency response and incident protocols — Regularly reviewing and practising emergency response plans including outside normal working hours (night and week-ends). Such activities improve preparedness and provide opportunities to improve the effectiveness of plans before an emergency occurs — Following any incident or emergency, an investigation should be undertaken and all involved staff should be debriefed, to discuss performance and address any issues or concerns to prevent new crises or reduce their effect

[1] NRMMC–EPHC–AHMC, 2006. Australian guidelines for water recycling: managing health and environmental risks: Phase 1. National Water Quality Management Strategy.