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COMMISSION DELEGATED REGULATION (EU) 2024/1261

of 11 March 2024

supplementing Regulation (EU) 2020/741 of the European Parliament and of the Council with regard to technical specifications of the key elements of risk management

(Text with EEA relevance)

THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Regulation (EU) 2020/741 of the European Parliament and of the Council of 25 May 2020 on minimum requirements for water reuse ⁽¹⁾, and in particular Article 5(5), second subparagraph, thereof,

Whereas:

- (1) Regulation (EU) 2020/741 sets out the minimum requirements for safe water reuse for agricultural irrigation. Article 6 of that Regulation requires that production and supply of reclaimed water is subject to a permit, and that such permit is to be based on a risk management plan. Article 5(3) of that Regulation requires in turn for the water reuse risk management plans to be based on the elements of risk management set out in Annex II to that Regulation.
- (2) Developing a water reuse risk management plan can be a complex exercise, requiring a multidisciplinary approach and the involvement of several actors in its preparation. For this reason, it is necessary to lay down technical specifications of the key elements of risk management set out in Annex II to Regulation (EU) 2020/741 to ensure that the water reuse risk management plans are robust, of high quality, and based on a systematic approach. The aim is to set out in more detail how the authors of the risk management plan and the risk assessors involved in its establishment should appropriately consider all the key elements through a structured and comprehensive analysis of the water reuse system. It should be possible to use existing risk assessment and management protocols to prepare a risk management plan, provided that the technical specifications set out in this Delegated Regulation are respected.
- (3) For the risk management plans to provide solid evidence to underpin the establishment of preventive measures and barriers and to ensure that irrigation with reclaimed water is safe for human and animal health and the environment, it should be supported by the most reliable scientific evidence available and other supporting sources, fully documented in the risk management plan.
- (4) Water reuse systems in place in Member States may differ in their set up and may serve a large number of end-users. Moreover a single risk management plan may cover more than one water reuse system, in accordance with Regulation (EU) 2020/741. The technical specifications of the key elements of risk management should be sufficiently flexible to accommodate these differences, while providing a comprehensive overview of the system and sufficient information to make it possible to identify all potential risks involved,

HAS ADOPTED THIS REGULATION:

Article 1

The technical specifications of the key elements of risk management laid out in Annex II to Regulation (EU) 2020/741 are set out in the Annex to this Regulation.

⁽¹⁾ OJ L 177, 5.6.2020, p. 32, ELI: <http://data.europa.eu/eli/reg/2020/741/oj>.

Article 2

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

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

Done at Brussels, 11 March 2024.

For the Commission
The President
Ursula VON DER LEYEN

ANNEX

Technical specifications of the key elements of risk management in water reuse**Description of the water reuse system**

In accordance with point 1 of Annex II to Regulation (EU) 2020/741, the description of a water reuse system shall detail all the different processes and stages involved from the start of the waste water treatment to the final reuse in agricultural fields, including all aspects relevant to the risk assessment. The description shall cover all the elements of the system, including all infrastructure and technical elements, relevant to the specific water reuse project, including information on the different points other than the point of compliance at which water is delivered to another actor in the chain.

If a single reclamation facility serves a high number of end-users, the risk management plan description may consider such users in general terms, based on different types of crops or standard irrigation practices in the served area, but it shall still provide an overview of the possible types of end-users and irrigated crops.

If a single risk management plan covers more than one water reuse system, in accordance with Article 5(1) of Regulation (EU) 2020/741, the system description may consist of basic elements that provide an overview of the potential risks involved and that are relevant to all systems covered by the plan. The description may refer to the types of crops most grown in the areas served, to standard irrigation practices, or to codes of good practice, detailing standard practices to safely use reclaimed water of a given quality class.

Depending on whether the reclamation facility is the same as the urban waste water treatment plant treating water in accordance with the standards required by Regulation (EU) 2020/741, or whether it is a separate facility, describing the water reuse system entails examining different stages in the treatment processes and analysing different points of the water reuse system.

The description of the water reuse system shall follow the technical specifications set out below and include information on the production of reclaimed water, storage (where relevant), distribution, irrigation methods, intended use and crop categories.

Production of reclaimed water

The description of the process to produce reclaimed water shall include:

- (1) the sources of the urban waste water that enters the urban waste water treatment plant that supplies water for reclamation. The sources of urban waste water shall be identified using the definitions set out in Council Directive 91/271/EEC ⁽¹⁾. Urban waste water may include a mixture of domestic waste water, industrial waste water and run-off, and thus discharges carrying various types of pollutants, pathogens or other substances;
- (2) the reference or name of the urban waste water treatment plant that supplies water for reclamation, and, if different from the reclamation facility, information on the types of treatments performed in the plant (primary, secondary, tertiary or quaternary).
- (3) the reference or name of the reclamation facility, if different from the urban waste water treatment plant, and information on the treatment processes and technologies used at the facility. Information shall also be provided on operating conditions and control parameters of processes which are relevant for the management of risks, including control parameters for processes that treat pathogens or pollutants that have been identified as hazards in accordance with point 3 of Annex II to Regulation (EU) 2020/741.
- (4) a characterisation of the quality of the urban waste water entering the urban waste water treatment plant, enabling the identification of the parameters that are relevant for the quality of reclaimed water and that may become hazards in the meaning of point 3 of Annex II to Regulation (EU) 2020/741. The characterisation may describe the water quality at different points of the water reuse system, addressing possible fluctuations due to hazardous events, system failures or seasonal variations.

⁽¹⁾ Council Directive 91/271/EEC of 21 May 1991 concerning urban waste water treatment (OJ L 135, 30.5.1991, p. 40, ELI: <http://data.europa.eu/eli/dir/1991/271/oj>).

These points may be:

- the inlet point for the treated waste water into the reclamation facility, if the reclamation facility is different from the urban waste water treatment plant;
- the outlet point of the treated waste water resulting from the secondary treatment stage, if the reclamation facility and the urban waste water treatment plant are the same;
- the outlet point of the resulting reclaimed water.

The characterisation of the quality of the water shall cover:

- parameters set out in Table 2 of Annex I to Regulation (EU) 2020/741;
 - parameters monitored in the effluent from the urban waste water treatment plant, treated in accordance with Directive 91/271/EEC and used to produce reclaimed water;
 - parameters derived from the requirements and obligations set out in point 5 of Annex II to Regulation (EU) 2020/741, and from any other legal requirement applicable in the area where the water reuse system is located that are relevant to the local conditions, including the status of affected water bodies and any relevant geographical, morphological, geological and hydrological conditions, and relevant for the identification of hazards referred to in point 3 of Annex II to Regulation (EU) 2020/741;
 - if applicable, parameters monitored in accordance with the European Pollutant Release and Transfer Register, as defined in Article 3 of Regulation (EC) No 166/2006 of the European Parliament and of the Council ⁽²⁾ (applicable to urban waste water treatment plants with a capacity of 100 000 population equivalent (p.e.)).
 - if available parameters reported in permits for discharging into the collection system served by the urban waste water treatment plant that might be relevant to identifying hazards, including, where relevant, pollutants reported in discharge permits of industrial plants, the release of which could affect the quality of reclaimed water.
- (5) the volume of water entering the urban waste water treatment plant and transiting through the water reuse system over 1 year (i.e. minimum, maximum and average flow) including any information on flow variability due to weather events or other events (tourist season) that could significantly affect the volume and quality of reclaimed water, where relevant. If only part of the treated urban waste water is used to produce reclaimed water, this information shall be limited to the volumes of water entering the reclamation facility or resulting from the secondary treatment stage and used to produce reclaimed water;
- (6) the identification of the point of compliance in the water reuse system.

Storage

Storage systems may be used to store reclaimed water before it is transported and delivered or after its delivery to the end user. If storage systems are used, the information to be provided shall include the following elements:

- (1) the types of storage systems (closed or open, including measures in place to avoid cross contamination with other sources of pollution, including run-off from industry and farming);
- (2) the operating mode of the system (operational or seasonal);
- (3) the average residence times;
- (4) the management strategies for controlling the physical, chemical and biological quality of reclaimed water, including bacterial regrowth or algal growth.

⁽²⁾ Regulation (EC) No 166/2006 of the European Parliament and of the Council of 18 January 2006 concerning the establishment of a European Pollutant Release and Transfer Register and amending Council Directives 91/689/EEC and 96/61/EC (OJ L 33, 4.2.2006, p. 1, ELI: <http://data.europa.eu/eli/reg/2006/166/oj>).

Distribution

The information on the distribution of reclaimed water to be provided shall include the following elements:

- (1) information on pumping systems;
- (2) the types of pipelines, channels or other distribution means used;
- (3) the management strategies for controlling the physical, chemical and biological quality of reclaimed water during supply;
- (4) measures to avoid cross-contamination with the drinking water system or with the sewage system or with any other source of pollution, including run-offs from industry or farming in case of open channels, where relevant.

Irrigation methods

The information on irrigation methods to be provided shall include:

- (1) a description of the irrigation methods within the served area, already in place or planned, taking into account that different methods may be used depending on the season or the availability of water. If end-users have not yet been identified or if a high number of them are served by a single reclamation facility, the information may consist of general information on the typical or more frequently used types of irrigation in the served area and include prescriptions on the irrigation method necessary to safely use a given reclaimed water quality class on certain types of crops.

Irrigation methods shall be classified into the below categories:

- surface (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. For this irrigation method, special attention shall be paid to the protection of the health of workers and by-standers that could be reached by drops of reclaimed water;
- micro-irrigation systems: water is applied locally with drip or trickle systems (surface or sub-surface) or by sprinkler. These irrigation methods are capable to deliver water in drops or tiny streams to the plants at low rates (2-20 litres/hour).

Further information, relevant for the identification of routes of exposure for the population or environment as referred to in point 4 of Annex II of Regulation (EU) 2020/741, to be provided if relevant to the type of irrigation method used, shall include, where applicable:

- the maximum radius of throw or maximum operating pressure;
- the prevailing local wind conditions, responsible for disseminating aerosols;
- the presence of preventive measures to contain sprayed drops or aerosol of reclaimed water during irrigation (including trees creating a hedge, wind breaking nets).

Intended use and crop categories

The information to be provided shall include:

- (1) the intended uses of reclaimed water (in accordance with the selected reclaimed water quality classes, crop categories and irrigation methods set out in Table 1 of Annex I to Regulation (EU) 2020/741), the points of use, as well as the prevailing planting and harvesting procedure, periods and frequency, and the prevailing crop husbandry method in the served area. If specific end-users or uses have not yet been identified or if a high number of users are served by a single reclamation facility, the information may be based on the intended use of reclaimed water in a specific area or on the most common agriculture practices and crops in this area. The information may also consist of prescriptions on how a given reclaimed water quality class can be safely used for certain crop types and under certain conditions.

The crop types, designated as categories in Table 1 of Annex I to the Regulation (EU) 2020/741, shall be described in accordance with the intended use of the crop:

- food crops consumed raw or unprocessed: crops cultivated for human consumption that will not undergo additional processing. The minimum reclaimed water quality class for these crops depends on whether the reclaimed water will be in contact with the edible part of the crops. Based on the distance from the edible part of the crops to the ground, these crops include:
 - root crops: crops that grow below ground in the soil and have an edible root portion. For this category, it is assumed that the reclaimed water will be in contact with the edible part of the crops;
 - above-ground low-growing crops: crops that grow above ground in partial contact with soil. These crops can be further divided into crops that grow on the soil surface, such as leafy crops, and crops that grow at 25 cm or more above the ground, whose edible portion may be found < 25 cm above the soil surface;
 - above-ground high-growing crops: crops that grow above the ground, 50 cm or more above the soil surface, and which, therefore, do not normally touch the soil.
 - processed food crops: crops cultivated for human consumption that will undergo additional processing, including cooking or industrial processing) and will not be eaten raw;
 - non-food crops: crops not cultivated for human consumption, including crops used for pastures and forage, and other non-food crops, including fibre, ornamental, industrial, energy and seeded crops (intended to produce seeds for sowing).
- (2) if relevant, information on additional treatments or appropriate barriers referred to in Article 5(4), point (c), of Regulation (EU) 2020/741, applied to the reclaimed water after the point of compliance, including, where relevant, at the distribution or storage infrastructure and at the irrigated fields, used to meet the quality requirements set out in Table 2 of Annex I to Regulation (EU) 2020/741.
 - (3) if relevant, information on other sources of water intended to be blended with reclaimed water, as well as on mixing points, quantity and quality characteristics and any variability relevant to assessing the risks, especially when blending is used as a barrier. If end-users have not yet been identified or if a high number of them are served by a single reclamation facility, the information may consist of general information on typical blending practices in the served area and include prescriptions to ensure the safety of this practice.
 - (4) the range of flows of reclaimed water expected to be supplied and any seasonal variability, and the period of use (temporary or ad-hoc), in accordance with the irrigation schedule.

Identification of all parties involved in the water reuse system and description of their roles and responsibilities

In accordance with point 2 of Annex II to Regulation (EU) 2020/741, the parties involved in each component of the water reuse system and their responsibilities shall be correctly identified for each part of the system.

This step shall identify for each party:

- the actions for which the party is responsible;
- the place or the step in the water reuse system where the actions need to be performed;
- the time of performing the actions.

Depending on the specific water reuse system set-up, the following parties may be involved in the water reuse system:

- (1) operators of the reclamation facility and of the urban waste water treatment plant, where different from the reclamation facility, including public or private water utility operators);
- (2) operators of facilities for storage and distribution of reclaimed water, where relevant;
- (3) operators that irrigate fields with reclaimed water, including farmers, associations of farmers, or consortia of irrigators;

- (4) relevant authorities, other than the designated competent authority, or bodies, including water authorities, public health authorities, environmental authorities;
- (5) other parties that could have responsibility in any part of the water reuse system or that are based in the local area.

Roles and responsibilities of parties involved in a water reuse system shall include:

Parties involved	Roles and responsibilities
Reclamation facility operator (and urban waste water treatment plant operator, if different)	Operate, manage, and maintain the reclamation facility (and the urban waste water treatment plant, if different) and ensure the proper operation of all treatments and processes. Ensure that at the point of compliance, the reclaimed water meets the minimum requirements for quality and monitoring set out in Annex I to Regulation (EU) 2020/741, in accordance with the reclaimed water quality classes and the permits. Ensure that at the point of compliance, the reclaimed water meets any additional relevant conditions for water quality and monitoring set out by the competent authority in the permit, in accordance with the risk management plan. Prepare or help prepare (with the other responsible parties and end users, as appropriate), review and update the risk management plan, in particular the parts relevant to the production and supply of reclaimed water. Take the necessary measures to manage the risks at the reclamation facility (or at the urban waste water treatment plant, if different) as set out in the risk management plan. Manage emergencies at the reclamation facility (or at the urban waste water treatment plant, if different) as set out in the risk management plan. Ensure proper communication with other parties, including during emergency situations.
Operators of storage and distribution facilities of reclaimed water	Prepare or help prepare, review, and update the part of the risk management plan relevant to storage and distribution of reclaimed water. Operate and maintain the reclaimed water storage and distribution systems, and any additional barriers in place, when applicable. Manage emergencies at the reclaimed water storage and distribution systems, as set out in the risk management plan. Take the necessary measures to manage the risks from the storage and distribution system, in accordance with the risk management plan. Ensure proper communication with other parties, including during emergency situations.
End-users	Irrigate crops with reclaimed water according to the reclaimed water quality classes. Operate and maintain irrigation systems and any preventive measures and barriers in place. Prepare or help prepare, review, and update the risk management plan for the irrigation of crops with reclaimed water. Take the necessary measures to manage the risks associated with the irrigation methods and barriers, in accordance with the risk management plan. Ensure proper communication with other parties, including during emergency situations.

Authorities (other than the designated competent authority)	Express an opinion, or help prepare, as appropriate, on the risk management plan and on threshold values for relevant parameters for the quality and monitoring of reclaimed water set out in the risk management plan. Share information with the designated competent authority.
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Identification of potential hazards and hazardous events

In accordance with point 3 of Annex II to Regulation (EU) 2020/741, any hazards or hazardous events arising from the water reuse system that may pose a risk to public health or the environment, shall be identified.

Hazards

Potential hazards present in the reclaimed water, including pollutants, pathogens or other substances, that could pose a risk to human and animal health, crops and the environment, including its flora and fauna, shall be identified on the basis of the qualitative characteristics of the waste water sources, as set out in the system description (point 1 of Annex II to Regulation (EU) 2020/741), by selecting those pathogens, pollutants or other substances that could pose a risk to health or the environment if not removed from the reclaimed water. These hazards may include:

- (1) pathogens (including bacteria, viruses, protozoa and helminth) responsible for water-borne disease outbreaks in humans and animals and other health effects, whenever justified, and pollutants that are generally present in urban waste water;
- (2) pathogens, pollutants or other substances associated with industrial discharges, or with urban run-off from contaminated surfaces into the urban collection system, where relevant, that may accumulate in high concentrations in the urban waste water and thus affect the use of reclaimed water;
- (3) pathogens, pollutants or other substances identified by taking into account the requirements listed in point 5 of Annex II to Regulation (EU) 2020/741, or other requirements set out in the relevant EU, national or local legislation, site-specific conditions and whether the reclaimed water can reach sensitive receptors. These requirements may include the following aspects:
 - protection of the environment, including water and soil. The relevance of that requirement may depend on whether the reclaimed water can reach the environmental matrices considered, through accidental leakages or run-off from the irrigated fields. It may also depend on the agricultural practices followed, such as use of pesticides or fertilisers, or use of sewage sludge or manure as soil improver, where there may be a combined effect of pollutants from different sources;
 - foodstuffs and feed hygiene, as well as animal health. The relevance of these requirements may depend, for example, on the crops grown, or on animal husbandry practices followed;
- (4) pathogens, pollutants or substances potentially present in reclaimed water that could damage soil and irrigated crops and are identified in accordance with the ISO 16075-1:2020 standard ^(?) or any guidelines for agricultural irrigation, including: (i) chemical substances, such as total soluble salts, sodium, chloride, boron, and ions with specific toxicity; (ii) other chemical elements and pathogens; and (iii) nutrients;
- (5) pollutants, that are not yet regulated (including micro-plastics or contaminants of emerging concern), identified in the reclaimed water and relevant to the specific context of the water reuse system.

^(?) ISO 16075-1:2020 Guidelines for treated wastewater use for irrigation projects – Part 1: The basis of a reuse project for irrigation.

Hazardous events

A hazardous event is a situation that can lead to the presence of a hazard or exacerbate a hazard's adverse impact.

A situation or an incident in a water reuse system can lead to a pathogen, pollutant or other substance identified as potentially harmful: (i) being introduced; (ii) being released; (iii) becoming more concentrated; or (iv) failing to be removed. As a minimum, the following hazardous events shall be considered:

- (1) failure of preventive measures at the reclamation facility (or at the urban waste water treatment plant, if different), in storage and distribution systems, or in the field. That can occur:
 - during normal operations of the water reuse system including due to faulty infrastructure, system overloading, lack of maintenance, unsafe behaviours of workers;
 - due to a system failure or accidents, including partial or full failure of treatments, power outage, equipment breakdown, errors of workers.
- (2) accidental or inappropriate (or illegal) discharges that could lead to uncontrolled concentrations of pathogens, pollutants or other substances in the sewage system and in the effluent from the urban waste water treatment plant, and that could affect the quality of the reclaimed water;
- (3) human errors caused by inadequate training or information on permitted uses;
- (4) seasonal changes or extreme weather conditions where relevant (including floods or droughts);
- (5) seismic occurrences;
- (6) acts of vandalism or terrorism (including cyber-attacks on infrastructure).

Identification of the environments and populations at risk, and the exposure routes to the identified potential hazards

In accordance with point 4 of Annex II to Regulation (EU) 2020/741, the environments and populations at risk and the exposure routes shall be identified for each hazard or group of hazards and hazardous events identified in the water reuse system, from the point of entry into the urban waste water treatment plant up to and including the point of use in the fields.

Populations

As a minimum, the following populations that could be exposed to the hazards present in the reclaimed water via potential exposure routes shall be considered:

- (1) operators and workers of the reclamation facility (or of the urban waste water treatment plant, if different), and of the storage and distribution facilities, if applicable;
- (2) end-users in the irrigated fields;
- (3) residents and workers from the local community or by-standers (including people incidentally located within or close to the water reuse system whose presence is unrelated to the system and who take no action to reduce exposure, workers or users of nearby activities) who could accidentally be exposed to reclaimed water (including by taking part in recreational activities on or near open channels that could receive reclaimed water, or by being exposed to drops of reclaimed water from sprinkler irrigation systems).

Environments

As a minimum, the following environmental compartments that could potentially be affected by the use of reclaimed water shall be considered:

- (1) surface waters, groundwater bodies or coastal waters and their aquatic ecosystems in the proximity of the water reuse system;
- (2) water resources used for the supply of drinking water, including water reservoirs for the supply of drinking water (i.e. drinking water protected areas), in the proximity of the water reuse system;

- (3) soil and crops of the irrigated field and of the surrounding fields;
- (4) ecosystems and/or protected areas (including those established under Directive 2000/60/EC of the European Parliament and of the Council ^(*) and other protected areas for nature conservation) and associated terrestrial and aquatic fauna and flora of the identified environmental compartments in the proximity of the water reuse system;
- (5) nutrient sensitive areas and nitrate vulnerable zones in the proximity of the water reuse system.

Exposure routes

Exposure routes shall be assessed considering the local context (including, if relevant, extension of the served area, location of urban areas or other agglomerations, geographic and topographic conditions), the irrigation methods, the hydrogeology, and the climatic and weather conditions of the site.

The following routes of exposure, which could be intentional or non-intentional (i.e. accidental), direct or indirect, and which could entail a health risk, shall be considered, where relevant:

- (1) ingestion of reclaimed water, directly or indirectly via crops, soil or objects that have been in contact with reclaimed water;
- (2) contact with reclaimed water (skin or eyes), directly or indirectly via crops, soil or objects that have been in contact with reclaimed water;
- (3) inhalation of reclaimed water (aerosol).

The following routes of exposure, which could be intentional or non-intentional, direct or indirect, and which could entail an environmental risk, shall be considered, where relevant:

- (1) infiltration of reclaimed water to groundwater via leaks (including from pipelines and storage systems), via irrigation or following heavy rain events;
- (2) run-off of reclaimed water to surface or coastal waters via leaks (including from pipelines and storage systems) or via irrigation;
- (3) run-off of reclaimed water to nutrient sensitive areas and nitrate vulnerable zones or protected areas (as identified above) via leaks (including from pipelines and storage systems) or via irrigation.

To identify the routes of exposure to environmental risks and the exposed groups the following site-specific conditions of the water reuse system shall be considered:

- (1) geological, hydrogeological and hydrological conditions in the area, including the presence of unconfined or a mixture of confined and unconfined aquifer and groundwater abstraction systems (including their main characteristics, for example the distance to irrigated areas, the type of system, the use of a pumping system or artesian well, water uses);
- (2) presence, characteristics and uses of surface waters, including required minimum flow rate, seasonal flow variations, contribution of discharges from the waste water treatment plant;
- (3) soil structure and properties according to the pedological features of the area;
- (4) presence of permeable areas (including information on vegetation types, woods) and of impermeable surfaces (including parking lot or streets);
- (5) changes in typical weather conditions: temperatures, precipitation, humidity, wind.

^(*) Directive 2000/60/EC of the European Parliament and of the Council of 23 October 2000 establishing a framework for Community action in the field of water policy (OJ L 327, 22.12.2000, p. 1, ELI: <http://data.europa.eu/eli/dir/2000/60/oj>).

Assessment of risks to the environment and to human and animal health

The assessment of risks to the environment in accordance with point 5 of Annex II to Regulation (EU) 2020/741 shall include the following:

- (1) an analysis of the potential routes of exposure for the environmental compartments (identified in accordance with point 4 of Annex II to Regulation (EU) 2020/741) and of the corresponding (group of) hazards (identified in accordance with point 3 of Annex II to Regulation (EU) 2020/741);
- (2) a screening of hazards (pathogens, pollutants and other substances identified in the reclaimed water) against relevant environmental quality standards or any other limit set in EU, national or local legislation for pathogens, pollutants or other substances relevant to a given environmental compartment (including groundwater, surface water, soil, crops) considering site-specific conditions, and determining the allowable concentration of the hazard in the reclaimed water;
- (3) an assessment of the range of exposure on the basis of the concentration of each hazard identified in reclaimed water, the routes of exposure, and exposure levels, ranked according to their likelihood and severity, determined by taking into account the irrigation method and practices, as well as the volume, frequency, and duration of irrigation;
- (4) an assessment of the likelihood that a certain hazard will reach a water body, by using the method proposed by the ISO 16075-1:2020 standard, which assesses the vulnerability of groundwater and surface water to infiltration or run-off of reclaimed water, taking into account the hydrogeology of the site, or by applying the Commission guidelines to support the application of Regulation (EU) 2020/741 or any other equivalent method;
- (5) a characterisation of the environmental risks for each identified hazard or group of hazards and for each route of exposure and hazardous event;
- (6) an assessment of the likelihood of exposure and the severity of the consequences by using risk matrices that combine likelihood and severity, including those proposed in the ISO 20426: 2018 standard ⁽⁵⁾, or in the Sanitation Safety Planning Manual ⁽⁶⁾ of the World Health Organisation (WHO), or in the Commission guidelines to support the application of Regulation (EU) 2020/741 and in the technical guidance prepared by the Joint Research Centre (2022) ⁽⁷⁾;
- (7) an assessment of the risks to soil or crops based on existing reference values of parameters of agronomic concern depending on the local context (including soil type and soil acidity), including the ones set out in the ISO 16075-1:2020 standard or equivalent.

The assessment of risks to human and animal health in accordance with point 5 of Annex II to Regulation (EU) 2020/741 shall include the following:

- (1) an analysis of the potential routes of exposure for the populations (identified in accordance with point 4 of Annex II to Regulation (EU) 2020/741), and the corresponding (group of) hazards (identified in accordance with point 3 of Annex II to Regulation (EU) 2020/741);
- (2) where relevant, an evaluation of dose-response relationships to determine the response of a population being exposed to a certain concentration of a hazard and the probability of potential adverse health effects of a determined severity, by considering, as a minimum, the pathogens in reclaimed water that could cause health problems (i.e. adverse effect caused by a substance in a living organism) to exposed populations (including operators or farmers);
- (3) an assessment of potential ranges of dose or exposure relevant to human health and animal health on the basis of the pathogens, pollutants and other substances present in the reclaimed water and their concentrations, taking into account the types of crops (consumed raw crops or processed food crops) and the methods and practise for irrigation (including the frequency and duration of irrigation);

⁽⁵⁾ ISO 20426: 2018. Guidelines for health risk assessment and management for non-potable water reuse.

⁽⁶⁾ WHO, *Sanitation safety planning – step-by-step risk management for safely managed sanitation systems*, Geneva, 2022.

⁽⁷⁾ Maffettone, R. and Gawlik, B.M., *Technical guidance: water reuse risk management for agricultural irrigation schemes in Europe*, European Commission, Luxembourg, 2022, JRC 129596.

- (4) a characterisation of the health risks for each identified hazard or group of hazards and for each route of exposure and hazardous event;
- (5) an assessment of the likelihood of exposure and the severity of the consequences, by using the methods set out in the ISO 20426: 2018 standard or in the WHO Sanitation Safety Planning Manual or any other equivalent method.

Types of risk assessment

While qualitative methods may be used to assess risks and may follow published guidelines and standards ⁽⁸⁾ (including the 2016 WHO guidelines ⁽⁹⁾, the ISO 20426: 2018 standard and Food and Agriculture Organisation (FAO) and WHO 2019 guidelines ⁽¹⁰⁾), quantitative methods referred to in point 5 of Annex II to Regulation (EU) 2020/741 shall be used if sufficient data are available for the geographical area where the specific water reuse system is proposed, or if a project is likely to pose a high risk to the environment or public health.

Quantitative methods may also be used to assess only a specific hazard linked to an element of the water reuse project, in combination with a qualitative or semi-quantitative methodology for the rest of the project.

Quantitative risk assessments estimate risks numerically, usually on the basis of a dose-response model, based on a calculation of the predicted environmental concentration of a hazard and of the predicted no-effect concentration.

Assessments of the risks to the environment and to human and animal health may include an evaluation of the level of uncertainty or confidence attached to the assessment, based on a documented method or protocol.

Methodologies may be consulted in Annex 3 to the Commission guidelines to support the application of Regulation (EU) 2020/741.

Requirements and obligations to be taken into account in the risk assessment

The below specifications set out how the requirements and obligations deriving from the legislation and guidelines listed in point 5 of Annex II to Regulation (EU) 2020/741 are to be taken into account in the risk assessment:

- (1) the requirement to reduce and prevent water pollution from nitrates in accordance with Council Directive 91/676/EEC ⁽¹¹⁾: the risk assessment shall identify any potential impact, as a result of the use of reclaimed water for agricultural irrigation (including via run-off or infiltration) and resulting in possible excessive exposure to nitrates, on surface water or groundwaters, which have been identified by a Member State as possibly affected by (nitrates) pollution in accordance with that Directive;
- (2) the obligation for protected areas for water intended for human consumption to meet the requirements of Directive (EU) 2020/2184 of the European Parliament and of the Council ⁽¹²⁾: the risk assessment shall identify surface water or groundwater that is classified as a drinking water protected area and would potentially be affected by the use of reclaimed water for agricultural irrigation (including via run-off or infiltration);

⁽⁸⁾ Any reference to published guidelines and standards shall be construed as a reference to the latest updated version of such guidelines and standards.

⁽⁹⁾ WHO, *Quantitative Microbial Risk Assessment: Application for Water Safety Management*, Geneva, 2016.

⁽¹⁰⁾ FAO, WHO, 'Safety and Quality of Water Used in Food Production and Processing – Meeting report', *Microbiological Risk Assessment Series*, No 33, Rome, 2019.

⁽¹¹⁾ Council Directive 91/676/EEC of 12 December 1991 concerning the protection of waters against pollution caused by nitrates from agricultural sources (OJ L 375, 31.12.1991, p. 1, ELI: <http://data.europa.eu/eli/dir/1991/676/oj>).

⁽¹²⁾ Directive (EU) 2020/2184 of the European Parliament and of the Council of 16 December 2020 on the quality of water intended for human consumption (OJ L 435, 23.12.2020, p. 1, ELI: <http://data.europa.eu/eli/dir/2020/2184/oj>).

- (3) the requirement to meet the environmental objectives set out in Directive 2000/60/EC: the risk assessment shall identify potential risks of deterioration of the status of water bodies covered by that Directive due to the use of reclaimed water for agricultural irrigation (including via run-off or infiltration);
- (4) the requirement to prevent groundwater pollution in accordance with Directive 2006/118/EC of the European Parliament and of the Council ⁽¹³⁾: the risk assessment shall identify potential risks of deterioration of the chemical status of groundwater bodies due to the use of reclaimed water for agricultural irrigation;
- (5) the requirement to meet the environmental quality standards for priority substances and certain other pollutants laid down in Directive 2008/105/EC of the European Parliament and of the Council ⁽¹⁴⁾: the risk assessment shall identify potential risks of deterioration of the chemical status of surface water bodies due to the use of reclaimed water for agricultural irrigation;
- (6) the requirement to meet the environmental quality standards for pollutants of national concern, namely river basin specific pollutants, laid down in Directive 2000/60/EC: the risk assessment shall identify potential risks of deterioration of the ecological status or potential of surface water bodies as a result of the use of reclaimed water for agricultural irrigation;
- (7) the requirement to meet the bathing water quality standards laid down in Directive 2006/7/EC of the European Parliament and of the Council ⁽¹⁵⁾: the risk assessment shall identify water bodies used for bathing activities and that are potentially affected by the use of reclaimed water (including via run-off);
- (8) the requirements concerning the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture under Council Directive 86/278/EEC ⁽¹⁶⁾: the risk assessment shall identify if the use of sewage sludge in agricultural fields combined with irrigation with reclaimed water can pose cumulative risks;
- (9) the requirements regarding hygiene of foodstuffs as laid down in Regulation (EC) No 852/2004 of the European Parliament and of the Council ⁽¹⁷⁾ and the guidance provided in the Commission notice on guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene ⁽¹⁸⁾: the risk assessment shall identify if the use of reclaimed water may pose a risk of not meeting the requirements set for the production of fresh fruits and vegetables;
- (10) the requirements for feed hygiene laid down in Regulation (EC) No 183/2005 of the European Parliament and of the Council ⁽¹⁹⁾: the risk assessment shall identify if the use of reclaimed water may pose a risk of not meeting the requirements set for the production of feed (non-food crops including crops used to feed food-producing animals);

⁽¹³⁾ Directive 2006/118/EC of the European Parliament and of the Council of 12 December 2006 on the protection of groundwater against pollution and deterioration (OJ L 372, 27.12.2006, p. 19, ELI: <http://data.europa.eu/eli/dir/2006/118/oj>).

⁽¹⁴⁾ Directive 2008/105/EC of the European Parliament and of the Council of 16 December 2008 on environmental quality standards in the field of water policy, amending and subsequently repealing Council Directives 82/176/EEC, 83/513/EEC, 84/156/EEC, 84/491/EEC, 86/280/EEC and amending Directive 2000/60/EC of the European Parliament and of the Council (OJ L 348, 24.12.2008, p. 84, ELI: <http://data.europa.eu/eli/dir/2008/105/oj>).

⁽¹⁵⁾ Directive 2006/7/EC of the European Parliament and of the Council of 15 February 2006 concerning the management of bathing water quality and repealing Directive 76/160/EEC (OJ L 64, 4.3.2006, p. 37, ELI: <http://data.europa.eu/eli/dir/2006/7/oj>).

⁽¹⁶⁾ Council Directive 86/278/EEC of 12 June 1986 on the protection of the environment, and in particular of the soil, when sewage sludge is used in agriculture (OJ L 181, 4.7.1986, p. 6, ELI: <http://data.europa.eu/eli/dir/1986/278/oj>).

⁽¹⁷⁾ Regulation (EC) No 852/2004 of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, (OJ L 139, 30.4.2004, p. 1, ELI: <http://data.europa.eu/eli/reg/2004/852/oj>).

⁽¹⁸⁾ 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).

⁽¹⁹⁾ Regulation (EC) No 183/2005 of the European Parliament and of the Council of 12 January 2005 laying down requirements for feed hygiene (OJ L 35, 8.2.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/183/oj>).

- (11) the requirement to comply with the relevant microbiological criteria set out in Commission Regulation (EC) No 2073/2005 ⁽²⁰⁾; the risk assessment shall identify if use of reclaimed water may pose a risk of not meeting the requirements set for the production of food;
- (12) the requirements regarding maximum levels for certain contaminants in food set out in Commission Regulation (EU) 2023/915 ⁽²¹⁾; the risk assessment shall identify if the use of reclaimed water may pose a risk of not meeting the requirements set for the productions of food;
- (13) the requirements regarding maximum residue levels of pesticides in or on food and feed set out in Regulation (EC) No 396/2005 of the European Parliament and of the Council ⁽²²⁾; the risk assessment shall identify if the use of reclaimed water in agricultural fields used to produce foodstuff and feed stuff to which pesticides are applied, may pose cumulative risks (if the risk assessment has identified pesticides as potential hazards that could be present in the reclaimed water);
- (14) the requirements regarding animal health set out in Regulation (EC) No 1069/2009 of the European Parliament and of the Council ⁽²³⁾ and in Commission Regulation (EU) No 142/2011 ⁽²⁴⁾; the risk assessment shall identify if the use of reclaimed water to irrigate fodder crops or any other crops for animal feed may pose a risk of not meeting the requirements set for animal health (through feed ingestion or exposure in the field).

Additional or stricter requirements for water quality and monitoring

Where additional requirements are necessary to ensure adequate protection of the environment and of human and animal health (in accordance with point 6 of Annex II to Regulation (EU) 2020/741), additional or stricter parameters or indicators for reclaimed water quality shall be selected and their thresholds determined on the basis of the list of hazards (identified in accordance with point 3 of Annex II to Regulation (EU) 2020/741) and on the outcome of the health and environmental risk assessments (carried out in accordance with point 5 of Annex II to Regulation (EU) 2020/741), while taking into account the specific water reuse system and local conditions.

Additional or stricter parameters for monitoring (some of) the hazards identified in the reclaimed water or in the environment (including in water bodies or soil) shall also be determined on the basis of the outcome of the risk assessment. Monitoring requirements, including sampling points at critical points identified in the system, may be included in the protocol of management systems described in accordance with points 8 and 9 of Annex II to Regulation (EU) 2020/741.

Preventive measures and barriers

Preventive measures may be used to prevent or eliminate risks to health or the environment or to reduce them to an acceptable level and may be applied to different parts of the water reuse system, including:

- (1) the reclamation facility (or the urban waste water treatment plant, if different), including by evaluating and optimising the processes in place or by identifying additional advanced treatments;

⁽²⁰⁾ Commission Regulation (EC) No 2073/2005 of 15 November 2005 on microbiological criteria for foodstuffs (OJ L 338, 22.12.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/2073/oj>).

⁽²¹⁾ Commission Regulation (EU) 2023/915 of 25 April 2023 on maximum levels for certain contaminants in food and repealing Regulation (EC) No 1881/2006 (OJ L 119, 5.5.2023, p. 103, ELI: <http://data.europa.eu/eli/reg/2023/915/oj>).

⁽²²⁾ Regulation (EC) No 396/2005 of the European Parliament and of the Council of 23 February 2005 on maximum residue levels of pesticides in or on food and feed of plant and animal origin and amending Council Directive 91/414/EEC (OJ L 70, 16.3.2005, p. 1, ELI: <http://data.europa.eu/eli/reg/2005/396/oj>).

⁽²³⁾ Regulation (EC) No 1069/2009 of the European Parliament and of the Council of 21 October 2009 laying down health rules as regards animal by-products and derived products not intended for human consumption and repealing Regulation (EC) No 1774/2002 (OJ L 300, 14.11.2009, p. 1, ELI: <http://data.europa.eu/eli/reg/2009/1069/oj>).

⁽²⁴⁾ Commission Regulation (EU) No 142/2011 of 25 February 2011 implementing Regulation (EC) No 1069/2009 of the European Parliament and of the Council laying down health rules as regards animal by-products and derived products not intended for human consumption and implementing Council Directive 97/78/EC as regards certain samples and items exempt from veterinary checks at the border under that Directive (OJ L 54, 26.2.2011, p. 1, ELI: <http://data.europa.eu/eli/reg/2011/142/oj>).

- (2) systems for storage and distribution of reclaimed water, when applicable;
- (3) irrigated fields or the area around them, when applicable, including by considering alternative irrigation methods that minimise risks of exposure, by providing buffer zones, or similar methods, or by protecting workers and farmers (requiring the use of specific personal protection equipment or by adopting hygiene protocols, in addition to possible measures already taken to comply with rules on health and safety at work).

Where barriers are applied, they shall be set on the basis of an evaluation of existing irrigation methods, type of crops and class of water and taking into consideration the following elements:

- (1) the application of barriers shall lead to the fulfilment of the quality requirements for the reclaimed water quality classes set out in Table 2 of Annex I to Regulation (EU) 2020/741. The quality class may be determined by considering the accredited number of barriers and criteria reported in the Commission guidelines on the application of Regulation (EU) 2020/741;
- (2) barriers include treatment or non-treatment options and may be applied before or after the point of compliance;
- (3) multiple barriers may be used in combination (multi-barrier approach) to achieve different log reductions (in accordance with the ISO 16075-2:2020 standard⁽²⁵⁾ or other relevant guidelines) and to achieve the required overall log reduction necessary to minimise risks, on the basis of the selected reclaimed water quality class.

All preventive measures, including barriers, shall be periodically reviewed and updated in line with outputs and information collected during the operation of the water reuse system, including feedback on system performance, results from monitoring programmes, implementation of new control systems, occurrence of new hazards and hazardous events, and responses to incidents and emergency situations.

Quality control systems and procedures

In accordance with point 8 of Annex II to Regulation (EU) 2020/741, risk management shall include the setting up of quality control systems and procedures for the water reuse system, including its monitoring and maintenance, and provide for periodic review and update of those systems and procedures. The quality control systems and procedures may include:

- (1) standard operating procedures;
- (2) operation and maintenance schedule;
- (3) quality control measures;
- (4) a list of specific tasks and who is responsible for such tasks;
- (5) a list of the point of compliance and any other critical control points identified for the management of risks, including points where reclaimed water is delivered to the next party in the water reuse system; information on those points shall include the precise location (positioning on a GIS map or with geographical information, when possible) and method for sampling;
- (6) procedures for data acquisition through laboratory analysis or online systems;
- (7) procedures for sampling and analysis;
- (8) procedures or protocols for monitoring the reclaimed water for the relevant parameters;

⁽²⁵⁾ ISO 16075-2:2020 Guidelines for treated wastewater use for irrigation projects – Part 2: Development of the project.

- (9) maintenance programmes for the equipment (including probes for online detection);
- (10) maintenance programmes for preventive measures and barriers;
- (11) procedures for training for operators.

Environmental monitoring systems

Environmental monitoring systems are procedures to monitor parameters, identified through the environmental risk assessment, in the reclaimed water and in any environmental receptors, including surface water, groundwater, and soil.

The environmental monitoring system shall be set up in accordance with the following technical specifications:

- (1) shall be based on the results of the health and environmental risk assessment;
- (2) shall include procedures for fulfilling at least the minimum requirements on routine monitoring in accordance with Annex I to Regulation (EU) 2020/741, and for meeting any parameters and limits related to the reclaimed water that are identified as additional requirements based on the results of the health and environmental risk assessment;
- (3) shall include monitoring procedures for sampling and analysing reclaimed water (using laboratory analysis, real time sensors or analysers), with indication of location and frequency, and procedures to control the release of identified pollutants into the exposed environmental receptors (including surface water, groundwater and soil); the procedures shall include documented action to ensure ongoing health and environmental protection, including under extreme weather events;
- (4) shall include procedures that are in line with existing legislation, in particular water resources monitoring shall comply with Commission Directive 2009/90/EC ⁽²⁶⁾, ensuring that the results are comparable with those obtained through monitoring under Directive 2000/60/EC.
- (5) shall include monitoring of parameters in environmental compartments (including surface water, groundwater or soil), where relevant and according to the results of the risk assessment; if pathogens, pollutants and/or substances are identified in any of the monitored environmental compartments, it shall be evaluated whether their presence is due to the use of reclaimed water, or whether they originate from other sources.

Environmental monitoring systems may include documented procedures that are already in place, set up by authorities to monitor the environment. Where necessary, these systems and procedures shall be further developed or tailored, depending on the results of the risk assessment, to address site-specific issues.

The monitoring results shall be used to re-assess any risk and ensure that it remains low and acceptable during the project lifetime, and to evaluate whether the application of preventive measures (including barriers) or emergency measures indeed contributes to reducing and minimising risks.

Systems to manage incidents and emergencies

In accordance with point 10 of Annex II of Regulation (EU) 2020/741, protocols and procedures for managing incidents and emergencies, and ensuring prompt intervention in case any of the identified risks arise, shall be set up and periodically reviewed and updated.

These shall consist of protocols on how the information is to be communicated between actors, of formats and procedures for reporting accidents and emergencies, of notification procedures, sources of information and consultation processes.

The following emergency and incident management system shall be considered:

- (1) a list of corrective measures and the responsible persons for the identified hazardous events;

⁽²⁶⁾ Commission Directive 2009/90/EC of 31 July 2009 laying down, and pursuant to Directive 2000/60/EC of the European Parliament and of the Council, technical specifications for chemical analysis and monitoring of water status (OJ L 201, 1.8.2009, p. 36, ELI: <http://data.europa.eu/eli/dir/2009/90/oj>).

- (2) emergency procedures in case of failure of any treatments carried out at the urban waste water treatment plant or the reclamation facility that might result in the release of hazards into the reclaimed water;
- (3) emergency procedures in case of exceedance of the limit values, identified in accordance with the risk assessment, for hazards in the reclaimed water that might pose a risk;
- (4) emergency procedures linked to regular and exceptional maintenance events (including bypass or overflow);
- (5) procedures and flow charts on how emergencies are communicated between parties (including any emergency procedures to ensure that produce irrigated with potentially contaminated reclaimed water is not placed on the market);
- (6) online tools, sensors and controllers that will trigger real-time alarms based on the monitoring of specific parameters.

Coordination mechanisms

In accordance with point 11 of Annex II of Regulation (EU) 2020/741, mechanisms to ensure coordination and communication between the different actors involved in the water reuse system shall be set up, and periodically reviewed and updated, taking into account the outcome of incident and emergency responses and any changes of the responsible people and parties.

The following mechanisms shall be considered:

- (1) a list with relevant contact information of each party involved, identified only by their duty or position (manager of the reclamation facility, emergency operation centre manager), ensuring compliance with standards for data protection;
 - (2) procedures for reporting incidents or emergencies to the competent authorities and end-users;
 - (3) procedures for delivering warning notices; a list of information that need to be provided to the different actors in case of an emergency.
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