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GUIDELINES FOR THE SAFE USE AND REUSE OF WATER IN FOOD PRODUCTION AND PROCESSING (CXG 100-2023): PROPOSED DRAFT ANNEX II ON FISH AND FISHERY PRODUCTS AND ANNEX IV ON WATER FIT-FOR-PURPOSE ASSESSMENT, SAFETY MANAGEMENT, AND TECHNOLOGIES FOR RECOVERY AND TREATMENT OF WATER FOR REUSE

(Prepared by the Electronic Working Group chaired by the EU, co-chaired by Honduras, India, Mauritania, Morocco, and the International Dairy Federation (IDF))

PROPOSED DRAFT ANNEX IV ON WATER FIT-FOR-PURPOSE ASSESSMENT, SAFETY MANAGEMENT, AND TECHNOLOGIES FOR RECOVERY AND TREATMENT OF WATER FOR REUSE

1. INTRODUCTION

1. The importance of a fit-for-purpose assessment on the use and reuse of water in view of appropriate water safety management has been illustrated in the General Section and the different sector specific annexes of these guidelines. This annex further provides recommendations for the fit-for-purpose assessment and water safety management that can be used across all sectors of food production and processing to ensure an efficient and microbiologically safe use and reuse of water.
2. The use of technologies for the treatment of water to make them fit for purpose and for the recovery of water for the purpose of reuse is becoming increasingly important along the food production and processing chain and, in case of reuse, to most effectively use often limited water resources.
3. The use of treated water and the reuse of reconditioned water should not jeopardize the safety of the food by direct or indirect contact.

2. PURPOSE AND SCOPE

4. This annex contains additional recommendations to the general section on:
 - the assessment that the water is microbiologically fit for purpose; and
 - the management of the water safety within a food hygiene system, based on fit-for-purpose assessment.
5. Also, this annex contains information or guidance on the technologies for the treatment of water as well as on the recovery and treatment of reuse water with recommendations for their safe application.
6. These recommendations apply across, all sectors of food production and processing, albeit variably and as appropriate for each sector. They are intended for food business operators (FBOs) and competent authorities, as appropriate, to provide practical and applicable use and reuse of water by applying the principle of fit-for-purpose using a risk-based approach.

3. USE

7. This annex should be used in conjunction with the General Section of these guidelines, its sector specific annexes when applicable, and the following Codex Alimentarius guidance:
 - *General Principles of Food Hygiene* (CXC 1-1969),
 - *Principles and Guidelines for the Conduct of Microbiological Risk Management (MRM)* (CXG 63- 2007),

- *Principles and Guidelines for the Conduct of Microbiological Risk Assessment* (CXG 30-1999),
- *Guidelines for the Validation of Food Safety Control Measures* (CXG 69 – 2008),
- *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997),
- *Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites* (CXG 88-2016), and
- *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG 79-2012).

4. DEFINITIONS

Cleaning-in-place (CIP) systems: water-based cleaning and disinfecting systems used to clean and disinfect product flow pipes and equipment without disassembly.

Cleaning-out-of-place (COP) systems: mechanical-based, recirculating cleaning and disinfection systems used for partially or fully disassembled equipment and utensils to minimize or eliminate manual hand cleaning.

Indicator microorganisms: microorganisms used as an indicator of quality, process efficacy, or the hygienic status of food, water, or the environment, commonly used to suggest the occurrence of conditions that potentially allow pathogen contamination or proliferation, a failure in process hygiene or in food processing. Examples of indicator microorganisms include mesophilic aerobic bacteria, coliforms, fecal coliforms, generic *E. coli* and Enterobacteriaceae.

Membrane bioreactor (MBR): A combination of a bioreactor and membrane filtration utilizing aerobic and anaerobic fermentation, ultra-filtration (UF) or micro-filtration (MF) delivering water (“permeate”) from a potential reuse water source.

Membrane filtration: The use of polymeric or ceramic materials for a filtering system to remove debris, non-dissolved solids and microorganisms from water. Examples include micro, ultra, nano and reverse osmosis (RO) filtration.

Reverse osmosis water (RO water): water, including reuse water, generated by membrane filtration with membranes of 0.001-0.0001 μm (1.0-0.1 nm) pore size using high pressure to overcome osmotic resistance, forcing water through a membrane retaining materials (retentate) and recovering the water (permeate), removing most dissolved solids.

Reverse osmosis polisher water (ROP water) RO water that is further polished/purified by an additional RO process, or by filtration using other technologies that give improved (chemical and) microbiological quality.

Water reuse scenario: the combination of reusable water source and reuse water application, including specifics such as recovery, reconditioning, storage and distribution (logistics and technologies).

5. WATER FIT-FOR-PURPOSE ASSESSMENT

8. See Section 7 of the General Section of these guidelines.

- A water fit-for purpose assessment should consist of the identification of known and/or potential microbiological hazards that have capacity to compromise water safety should be conducted identified at each step, particularly during water usage from external sources, and throughout the recovery, reconditioning and application of reuse reused water. The factors that should be considered when applicable are the microbiological hazards present in the water sources which are introduced into or recycled in the water system,
- hazards associated with other parts of the operation (e.g. factory environment, storage and distribution system) that could contaminate either the source or a reuse water supply;
- the nutrients that may be present in a reuse water supply after recovery and reconditioning, which may support the growth of biofilms, spoilage organisms (thereby limiting shelf-life) or pathogens;
- where the water is used, e.g. for food contact or non-food contact;
- the impact of physical and chemical substances on the effectiveness of controls (e.g. turbidity or concentration of organic or inorganic matter that may affect treatment efficiency);

- the history of the water source: whether reuse water that has been recycled or recirculated multiple times in a specific process operation could lead to biofilm formation or significant increase of spore levels;
- any particular measure for the prevention or control of microbiological growth during storage;
- the availability of a back-up fit-for-purpose water supply can be used in case the reuse water treatment system is not effective or not functioning properly;
- assessment of the current cleaning and disinfection procedure's impact in view of the recovery, reconditioning and application of the reused water.

9. In some cases, there may not be a need for a fit-for-purpose assessment if the source is confirmed to be safe for its intended purpose and periodically monitored, if needed, e.g., :

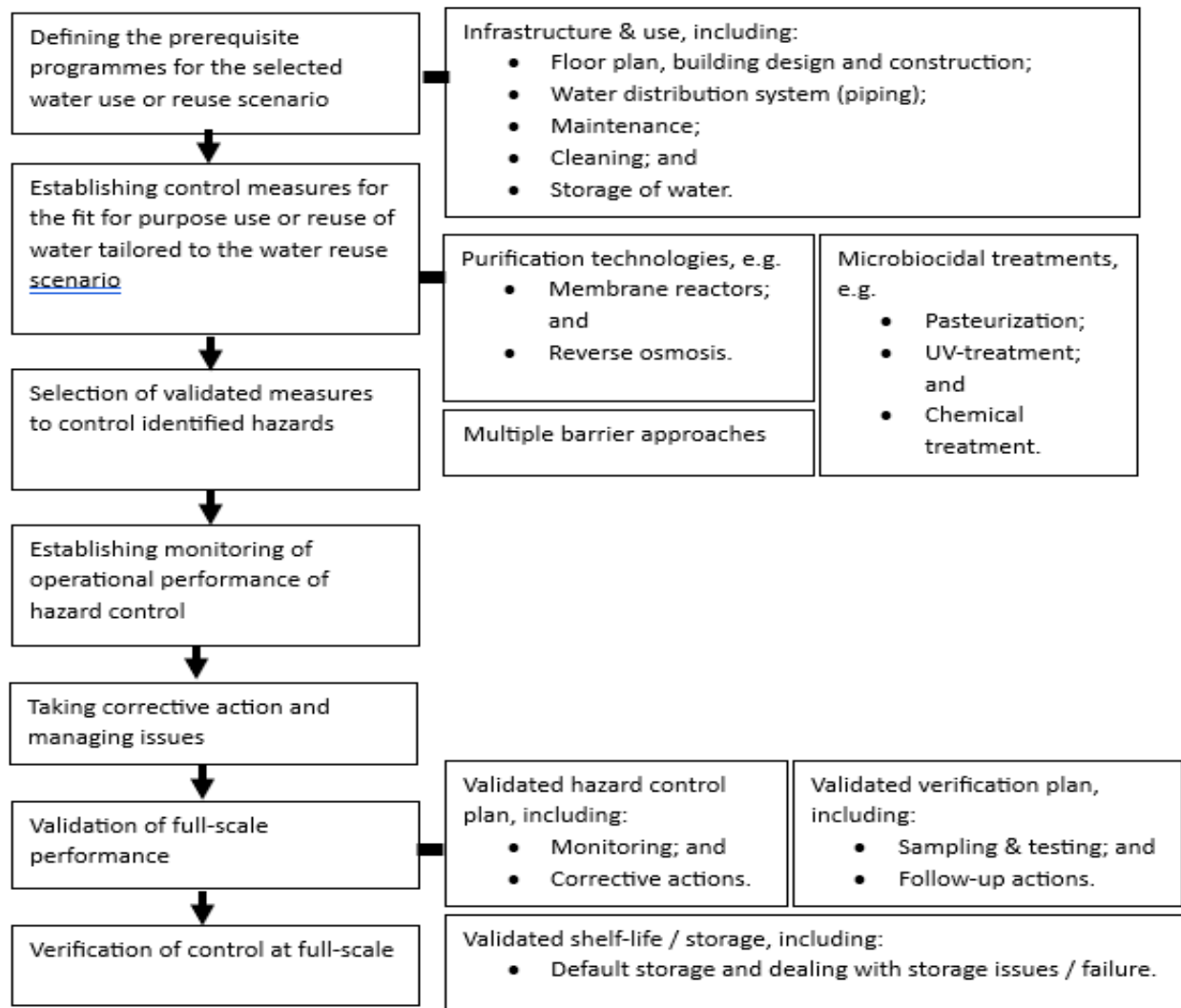
- potable water is used;
- water collected from deep wells, from bodies of surface water with a documented history of safety, or seawater known to be free of the risk of coastal contamination, is used;
- the reuse water will strictly be used for non-food-contact applications;
- the reuse water is free from microbiological hazards, for example, through the use of validated disinfection treatments before, during or after recovery and reconditioning, in so far as the effectiveness of such treatments is monitored, with a frequency appropriate to the use or treatment of the water;
- competent authorities have established criteria for the water to be reused to meet various fit-for-purpose requirements and the water meets these requirements.

6. WATER SAFETY MANAGEMENT

10. Based on the outcome of the fit-for-purpose assessment of the water and associated risks, the use and reuse of water should be managed by measures to be implemented within a food hygiene system and supplemented by monitoring, record keeping and verification activities to ensure that the system is operating as expected.

11. Figure 1 provides an example flowchart and an overview of the aspects that the FBO mainly in processing facilities should consider when establishing control measures for a safe water use and reuse in a scenario that is specific to its operation and is validated.

Figure 1: *Example of flowchart/steps for implementing measures in a water use and reuse scenario in a processing facility*



6.1 Prerequisite programmes (PRPs)

12. It is essential that proper PRPs are in place. All PRPs should be clearly written and implemented with procedures and specifications that will minimize hazard entry, spread and increase. PRPs should include in general:

- measures to exclude contamination with animal or human sewage;
- measures that ensure the maintenance of good hygienic conditions, such as the ability to conduct CIP, COP and/or manual cleaning to remove/reduce potential microbiological hazards;
- provisions to have a potable, clean water or other fit-for-purpose water supply available at the point(s) of water use to serve as back-up;
- measures to be taken when switching to the back-up system in the event of an issue with the primary system and prior to recommencing production (e.g. full washdown flush of the facility and water holding tanks to avoid contamination from residual water that is not fit for purpose);
- proper construction and maintenance to ensure the reliability of equipment in terms of operational performance and hazard control, e.g. specified requirements for RO processes, UV treatment systems and heat treatment/pasteurization processes, as well as calibration of monitoring equipment;
- measures to prevent/reduce the spread and/or increase of microbiological hazards, for instance, by

eliminating dead-ends (piping lengths of twice the diameter of the piping or greater from the fluid flow point to the end of the pipe or valve) or pockets in recovery collection system and the water distribution system; and, measures to reduce the likelihood of cross-contamination and inadvertent reuse of water for direct or indirect food-contact applications, which can introduce potential hazards, e.g. by using identifiable pipelines, regular maintenance and inspection of the entire water distribution to detect leaks, cross-connections, backflow, and other malfunctions; frequent monitoring of the collection, storage, treatment system (filtration, chemical and UV light) and end-use or application points.

13. Floor plan, design and construction of manufacturing plants:

- Systems for water distribution recovery and recirculation for both sourcing water as well as reused and recirculated water should be superimposed on the plant floor plan, drawn to scale with pipelines, valves, hoses, tanks and silo sizes. If possible, flow rates within the water system should be identified either on the plans or via a separate schedule.
- Facility design should ensure pipes, pipelines, tanks and taps used for food contact purpose cannot be interchanged with or contaminated by similar equipment used for non-food-contact water.
- Tanks, piping for the storage, treatments, and distribution system for water in the plants and facilities, should be designed for CIP, as appropriate, and should be able to withstand heat or cold exposure as well as wide range of corrosion and pH values outside expected values, or conditions, as needed.
- As needed and when not circulating or recirculating, the water system should self-drain.

14. Water distribution system (piping):

- All waterline discharge points and water taps should be secured against the backflow from potential contaminants caused by submerged inlets, for example, in case of loss of pressure.
- Where there are multiple water types, all water pipelines should be clearly marked with a word or code identifying the type of water (source, potable, clean, recycled, untreated reused, treated reused, etc.) as well as the direction of flow. Clear separation and identification between systems for the storage and distribution of water intended for-food-contact application and other water should be ensured. Different colours or marks should be used for water of different quality and intended use.
- Piping, buffer tanks and storage tanks should be installed such that no inadvertent mixing of water of lower quality can take place via backflows, improper valving and leaks in the pipes. If water of different qualities is mixed intentionally or unintentionally, the mixed water should always be categorized as that of the lower quality water used in the mixing.
- Pipes and tanks should be made from materials fit for food use and hygienically designed, manufactured and installed (i.e. smooth surface, proper welding, etc.).
- Tubes, pipes, tanks, etc., used for food products may also be used for handling reused water. If this multiple use of the same pipes and tanks is done, it is recommended they be clearly labelled to indicate this.
- Dead ends should be avoided to minimize piping locations where water may become stagnant (e.g. taps).
- All necessary measures should be taken to reduce or ideally eliminate condensation from forming on the outside of pipes and other equipment and to reduce fluctuations in the temperature of water inside the system. This may include taking measures like insulating pipes where temperatures inside the pipes or equipment vary from the temperatures on the outside of pipes or other equipment.
- Pipelines that are no longer used should be removed and sealed so as not to have dead ends.
- Operators should maintain documented oversight of the entire water pathway from source to point of use, including measures such as backflow prevention, color-coded distribution lines, and preventive maintenance controls.

15. Maintenance:

- FBOs should conduct regular inspection and maintenance of the entire water system and associated components to check for and repair any leaks or damages (e.g. leaky gaskets, valve seats, cross-connections, corrosion) that may lead to entry of microorganisms, formation of biofilms and contaminate

the water supply.

- Ensure the effectiveness of the membranes, if used, to avoid microbiological hazards bypassing the membranes. The performance of the membranes should be monitored and documented to identify when replacement should occur based on the recommendations by the manufacturer or the results of monitoring and verification if there is premature wear compared to the recommendations of the manufacturer, to ensure their effectiveness.
- Special attention should be made to check the integrity of gaskets and seals for pipelines and valves connected to piping.
- Maintenance incidents and problems related to the water system should trigger timely corrective actions.
- Implement a change control program to ensure like-for-like replacement of key water-system components and to enhance effective maintenance auditing during root cause analysis of system failures.
- A preventative maintenance schedule that includes all components of the water use and reuse system(s) should be developed and implemented, supported by a system of records (e.g. work orders).
- Records documenting the history of scheduled and unscheduled maintenance should be used to conduct trend analysis to identify and improve the preventative maintenance frequencies as well as identifying the need to replace equipment requiring increasing levels of maintenance.

16. Cleaning and sanitation:

- Facilities for the recovery, treatment, storage and distribution of water (including pipe ends where the water flow leads to the product) should be cleaned thoroughly with an appropriate biocide to remove/reduce possible microbiological hazards and done at a frequency that reduces the potential for the build-up of biofilm.
- All equipment making up the facility's water system should be emptied and cleaned regularly based on risk assessment that incorporates past history and the results of monitoring and verification programs. These, as well as specific knowledge about the potential problem areas and shortcomings of the facility's water system e.g. stagnant water in pipes/the distribution system, are important indicators in establishing the frequency of such emptying and cleaning.
- Equipment used for manufacturing foods and cleaned using CIP, COP or manual cleaning and sanitizing should conform to applicable standards and regulations, industry best practices and manufacturer's specifications. The specifics (e.g. time and temperature, pressure, flowrate and chemical concentrations) of a CIP, COP or manual cleaning and sanitizing regime should take into account the risk of contamination either upstream or downstream of the water treatment and meet fit-for-purpose requirements. These can include microbiological, chemical and physical characteristics, quality of reclaimed water, extent and type of fouling, and the characteristics of the surface(s) to be cleaned.
- If an automated CIP or COP system is out of operation for more than a prescribed period of time, the system should be evaluated and cleaned appropriately prior to use, as determined by risk assessment. If not assessed, a full and complete cleaning is recommended.
- All pipe and tank parts including the integrity of gaskets and seals should be able to withstand cleaning and disinfection procedures in place, such as temperatures and chemicals. The time and temperatures should be fit for purpose, based on manufacturer's recommendations.

17. Storage of water:

- Water intended for-food-contact application can normally be stored without temperature control for a limited period (e.g. up to two days at 15-20 °C in temperate and subtropical conditions). However, the temperature and time will depend on external climatic factors and the level of nutrients in the water that can support microbiological growth. If storing water without temperature control, physical and chemical parameters such as turbidity, total solids, suspended solids, chemical oxygen demand (COD), biological oxygen demand (BOD), total organic carbon (TOC) and pH should be measured and determined to be within specified limits depending on the situation.
- Storage time of water can be extended if it is refrigerated (e.g. < 7 °C, measured where the water is warmest) or hot (e.g. minimum 70 °C, measured where the water is coldest). Storage of water at other temperatures can be acceptable based on a risk assessment which may require an ongoing

microbiocidal treatment, e.g. by continuous recirculation through an UV treatment system, ozonation, chlorination or by a heat or chemical treatment with an established and monitored frequency.

- Stored water should be stirred to ensure the maintenance of consistent storage temperature, e.g. hot or cold, throughout the tank.
- The maximum storage time of any water should be established and validated based on monitoring and testing the water with regard to key criteria (such as total bacteria count, coliform, *Escherichia coli*, *Enterobacteriaceae* or *Pseudomonas* counts, turbidity, total solids, suspended solids, TOC, BOD, COD and pH, as well as organoleptic indicators (odour and appearance).
- Where appropriate, tanks used to store water should have a lid/be securely covered. Inlets, outlets and overflows should be screened or covered with suitable guards.

6.2 Development of a water safety management plan

18bis After consideration of the conditions and activities in the business, it may be determined that prerequisite programmes alone may be sufficient to manage the hazards. However, where significant hazards are identified that need to be controlled after the implementation of prerequisite programmes, it will be necessary to develop and implement a HACCP system. In this case, a water safety management plan should be developed.

18. A water safety management plan for the fit-for-purpose use or reuse of water should be developed based on a water fit-for-purpose assessment utilizing a hazard analysis to ensure the safe use and reuse of water within plants. The control measures in the water safety management plan should consider the equipment, source water characteristics, possible one-off events affecting the source of reuse water, intended use of the source water, collection and storage of the used water and the available treatment technologies and to develop an effective prerequisite program on water reuse.

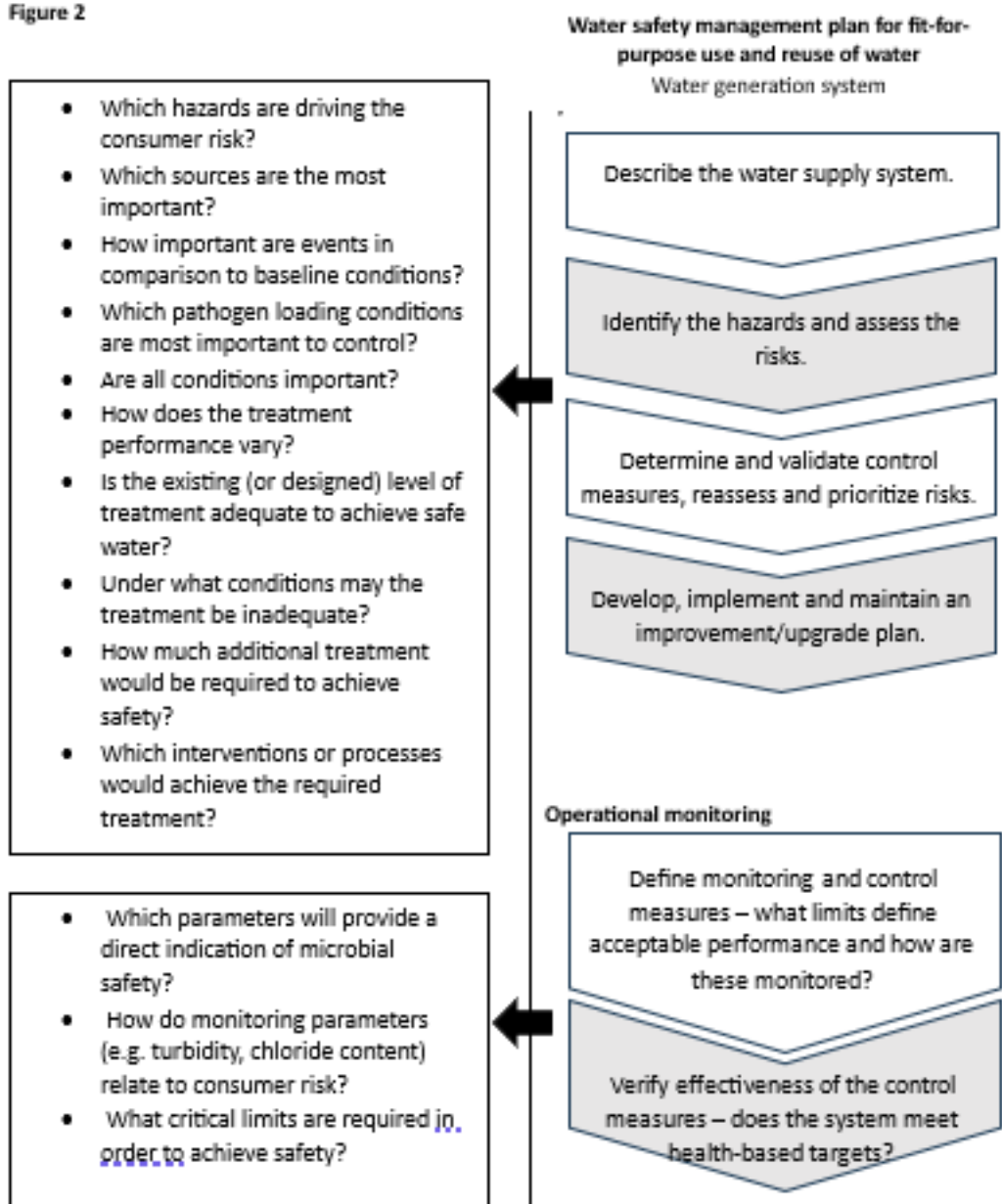
19. A flow diagram should specify the key process steps where water is introduced into the processing system, the food and steps where used water is removed from the food processing line, collected and stored as the basis for the hazard analysis.

20. All water uses should be included in the water safety management plan. If the water is intended for food contact (direct and indirect), the results of the hazard analysis of all reasonably foreseeable hazards should be included as input to the hazard analysis for the food products that will be impacted.

21. Figure 2 provides an example of input from an assessment to develop control measures for the fit-for-purpose use or reuse of water.

Figure 2: Examples of potential fit-for-purpose assessment questions that provide insights and inputs into the development of a water safety management plan for the safe use or reuse of water

Figure 2



22. The control measures described in the water safety management plan should be integrated into the food safety/Hazard Analysis and Critical Control Point (HACCP) plan.

23. Possible operational management approaches for a food operation should consider the use of water and plans to implement a water reuse system. A water safety management plan is typically managed through control measures identified through a risk-based hazard analysis. A food processing system is typically managed using control measures also established through a risk-based hazard analysis to ensure the food hygiene system (i.e. Good Agricultural Practices, Good Manufacturing Practices, Good Hygiene Practices (GHPs), HACCP) is adequate. Both follow essentially similar development and implementation steps.

24. When water is required only for non-food contact purposes, control measures can be used to manage the water system independently of the food hygiene system in place, provided cross-contamination of hazards in the water with food materials or food contact surfaces is not possible and they do not pose a food safety risk through the food processing equipment or food product to consumers.

25. When water is used as an ingredient or will be in direct contact with food processing equipment surfaces, management of the source water may best be integrated within the full risk-based food hygiene system. In this case, the food hygiene system needs to include hazard control throughout the water system and needs to include

procedures to monitor and verify the suitability of the water for its intended use (fit for purpose). This is applicable also to water not intended for food contact purposes when risk of its coming in contact with food through cross-contamination is identified.

26. A risk/hazard matrix such as Table 1 of Annex III of the General Principles of Food Hygiene (CXC 1-1969) or the Table 1 below can be used as the basis for the risk-based hazard analysis. The purpose of this is to identify the reasonably foreseeable hazards, their likelihood and potential severity (risk characteristics) for each processing steps, ingredients and intended water use., to better enable the identification of appropriate control measures (i.e. standard operational procedures, PRPs or critical control points (CCPs)). Specific examples can be found in the case studies in MRA40 (examples referred to below).

Table 1: Example of risk-based hazard analysis worksheet

Processing Step, Ingredient or Water Source & Intended Use	Hazard	Risk matrix			Justification for Risk Matrix decisions	Control Measures.
		Likelihood/frequency of hazard occurrence	Severity if hazard occurs	Significance based on Likelihood and Severity		
Reuse water use for CIP processing equipment	•Microbiological •Chemical¹ residue •Physical¹ (metal, glass, wood, debris, etc.)	• Seldom • Occasionally • Frequent • Almost certain/always	Death Severe illness Minor illness Product Recall	Extreme Major Moderate Minor		UV-treatment, filtration, chemical treatment, limitation of reuse cycles, etc.

6.3 Selection of measures to control identified hazards

27. . Based on the identification of the hazards to be controlled, appropriate control measures should be selected. The need for possible CCPs based on the HACCP principles should be considered for high-risk hazards, e.g. at the reconditioning of the water when the proper performance of the reconditioning control measure (such as temperature and time) is essential for acceptable hazard control.

28. When selecting appropriate control measures, the following factors, among others, should be taken into consideration:

- the quality and safety of the incoming source water;
- in-plant treatment of incoming source water and target safety and quality criteria;
- the “first” use of the incoming water;
- the age, characteristics and maintenance history of the facility’s fit-for-purpose and reuse water systems;
- the need for treatment and the quality of the fit-for-purpose water;
- the microbiological profile of the water, and that of disinfectant chemicals (e.g. chlorine) in the water;
- the risk and significance of the hazard such as:
 - changes in the risk levels of relevant hazards at each step in the water supply system;
 - the magnitude and frequency of such changes up to the application of the water;
- the impact of consumer exposure to the incoming or reused water;
- the effectiveness of individual or combined controls (in multi-barrier approaches) in reducing or eliminating the targeted microorganisms (could include spores, vegetative cells, and different pathogens) in the water to be used or reused.

¹ Out of the scope of this guidance but to be included in the hazard analysis.

29. Control measures are typically applied where the risk of a hazard can be eliminated or reduced and could include implemented and effective GHPs, PRPs and CCPs within a HACCP system. For example, purification or microbiocidal treatment at reconditioning might be appropriate control measures at CCP when essential for the control of hazards. When water is fit for purpose without reconditioning, it is likely that no CCPs are necessary to ensure the microbiological safety of the fit-for-purpose water. However, it may be necessary to assess and control hazards pertaining to storage (e.g. time and temperature factors during holding) when storage is required prior to use and there still may be a need to have controls in place to ensure that lower-risk hazards are controlled, minimized or eliminated.

30. To improve the microbiological quality of water, microbiocidal treatment such as heating, chlorination, ozonation, membrane filtration or UV treatment can be used.

6.4 Monitoring

31. The parameters of a water safety management plan that address the reconditioning processes such as TOC, COD, BOD, turbidity, pH or conductivity, based on the nature of the process should be monitored, with verification by microbiological or physicochemical testing at a determined frequency.

32. The frequency of monitoring should consider the water's fit for purpose use, required level of microbiological control for the water's intended use (e.g. is the reused water used for food-contact application or not), and the identified level of risk to the product and the consumer in case of a deviation.

33. Monitoring data across subsequent batches of source and reused water should be plotted for trending purposes to help benchmark information for building confidence in the water safety management plan and control measures used to ensure the safety of the incoming or reused water. When the water safety management plan is consistently performing well, this trending of monitoring data can provide signals when operation or control measures may be heading towards a compromise or complete loss of safety (failure), or when a loss-of-control situation may develop. Trend analysis is a powerful operational management tool advocated to improve the effectiveness of control measures.

6.5 Corrective actions

34. In the event of a loss of control (i.e. in case of failure of the overall manufacturing system or the control measures during water supply, recovery or use, resulting in a potentially unsafe water), several actions described below should be considered to ensure that the affected and future water supply do not impact the safety of food products:

- Immediately, and in parallel with the initiation of investigation into the water system failure and its effects, assess the risk of affected product that 'potentially unsafe' water came into contact with;
- gather as many observations, facts and findings as possible regarding the specific loss of control, e.g. who, what, when, where, how, how many, etc.;
- use the accumulated information to identify the problem in writing by conducting a root cause analysis to determine the fundamental cause(s) of the loss of control; identify changes that will restore control; establish corrective measures to prevent recurrence; and amend the control measures or other aspects of the water system or the food safety management system, as appropriate;
- isolate water that does not meet the required safety and quality performance criteria until root-cause has been identified and corrected. Consider reconditioning or discarding;
- re-evaluate the risk-based hazard analysis and make the necessary changes in the monitoring, verification, record-keeping and corrective actions, based on the outcome from the prior steps; invest in physical improvements to the water system (including treatment) to eliminate or reduce weak "links" where contamination has happened in the past or is suspected of happening in the future;
- if the loss of water safety controls is associated with the incoming water supply, stop using this supply until the root cause of the loss of control can be determined and addressed in a permanent manner;
- switch the use of water to a lower-level fit-for-use criteria, i.e. from for food-contact application to non-food-contact application as appropriate;
- consider an increase in monitoring frequency until confidence in the control measure has been regained with the understanding that monitoring frequency alone is not likely to be able to demonstrate with a high level of confidence that the water supply safety and quality are under control again.

6.6 Validation

35. Validation of control measures used in the water system should be carried out in accordance with the *Guidelines for the Validation of Food Safety Control Measures* (CXG 69-2008).

36. Specific validation strategies and documentation are highly dependent on the intended fit-for purpose use and plant-specific treatments and storage conditions. Consideration should be given to validating water storage time, i.e., how long the water may be stored prior to use or how many times can it be reused while still suitable for its fit-for-purpose application before a full sanitation of that operation is implemented. Validation will need to be re-done if any significant water conditions or treatments change.

6.7 Verification and testing

37. Verification of the water safety management plan should be carried out by:

- reviewing and evaluating monitoring data and corrective actions;
- conducting an internal audit on the water safety management system;
- conducting sampling and testing;
- calibrating monitoring instruments.

38. Routine testing of water for pathogens is not recommended, because the level of pathogens in water, if present, are likely to be low making detection by reasonable sampling plans improbable. It is more practical to test for suitable indicator microorganisms to verify that process controls are effective and to identify potential out-of-control situations. Suitable indicator microorganisms generally occur in water at levels that allow quantification. Notwithstanding, enhanced sampling and testing for pathogens may be warranted for validation of reconditioning processes or during an event where a loss of control may have resulted in water becoming contaminated with pathogens. Such water should be discarded and all equipment and utensils that were in contact with such water, re-cleaned and re-sanitized after the root cause of the pathogen presence has been identified and corrected.

39. Microbiological testing for indicator microorganisms such as total viable bacterial count, coliforms, Enterobacteriaceae and/or Pseudomonas counts in water, have proven to be useful and preventative in many circumstances. However, the microbiota relevant for verification of water often is plant or operation specific. It is, therefore, recommended to conduct an operation-specific study to determine which indicator organisms may be appropriate for use in evaluating water safety and quality.

40. The FBO should determine and document the acceptable microbiological limits in the water to be used as reference for verifying operational control. A maximum limit should be established for each relevant hazard or indicator organism applicable to the fit-for-purpose intent of water supply system for its intended purpose at each stage of the process.

41. Examples of microorganisms and their limits that can be considered for the monitoring of certain reuse water can be found in Section 6.3 of the FAO/WHO meeting report “Safety and quality of water use and reuse in the production and processing of dairy products” (MRA40)². These are examples only and other criteria could be applicable.

6.8 Example of fit-for-purpose considerations for reuse water

42. Table 2 provides an overview of fit-for-purpose considerations for different applications of reuse water and types of water available. For-food-contact applications, the reliable utilization of a reusable water supply, including recovery and any reconditioning, needs to be validated and verified within the overall food safety plan of the processing operation.

Table 2: Example of overview of fit-for-purpose considerations for different applications and types of reuse water

PURPOSES	RECIRCULATED WATER	RECLAIMED WATER	RECYCLED WATER
	e.g. Closed loop	e.g. Recovered from food (for example milk)	e.g. Recovered from a processing step

²<https://doi.org/10.4060/cc4081en>

Food ingredient	Not fit for purpose unless appropriate treatment is applied and the microbiological parameters of potable water are complied with	Fit for purpose if no significant microbiological hazards present, either as recovered or after reconditioning and the microbiological parameters of potable water are complied with
Direct food contact	Not fit for purpose unless appropriate treatment is applied	Fit for purpose if no significant microbiological hazards present, either as recovered, or after reconditioning
Indirect food contact	Fit for purpose as recovered if no significant hazards are present or food contact is avoided	
Non-food contact	Fit for purpose as sourced	

7. TECHNOLOGIES

43. Several technologies have been developed to treat water at source or at recovery from production or processing for reuse. Reconditioning may use treatments or a combination of treatments such as membrane filtration, UV-treatment, or other microbiocidal treatments (e.g. chlorination or ozonation). Technologies are constantly evolving and improving and therefore this annex is not exhaustive. Other technologies, such as ultrasonication³ or bactofugation⁴ may also be an option. Such reconditioning treatment should be validated considering the source of reuse water and the final intended use of the water, to ensure fitness for purpose. Key parameters of the treatments should be monitored and verified to ensure efficacy. Biocides used for reconditioning treatments may be subject to approval by the competent authority. Information provided in Sections 7.1 – 7.3 are primarily for reuse water.

44. When applying one or several (multiple barrier approach) of these technologies, the following should be documented:

- determination of microbiological⁵ characteristics of the water and possible microbiological hazards, taking into account, when applicable, pre- and post-treatment;
- sources of water intended for reuse;
- method of capture, storage and treatment of water intended for reuse;
- acceptable end-use applications (fit-for-purpose) and microbiological criteria of the water intended for reuse;
- validation, monitoring and verification of the water reuse systems; and
- procedures to be followed if the water reuse system fails.

7.1 Recovery by sedimentation, coagulation, filtration, flotation and/or centrifugation⁵

45. These technologies may be applied, alone or in combination, to effluents (e.g. of dairy manufacturing). Examples are sedimentation, coagulation-sedimentation, high-rate sand filtration, activated carbon filtration and

³ the application of intense ultrasound waves into liquids

⁴ process of removal of microorganisms from a liquid using centrifugal force

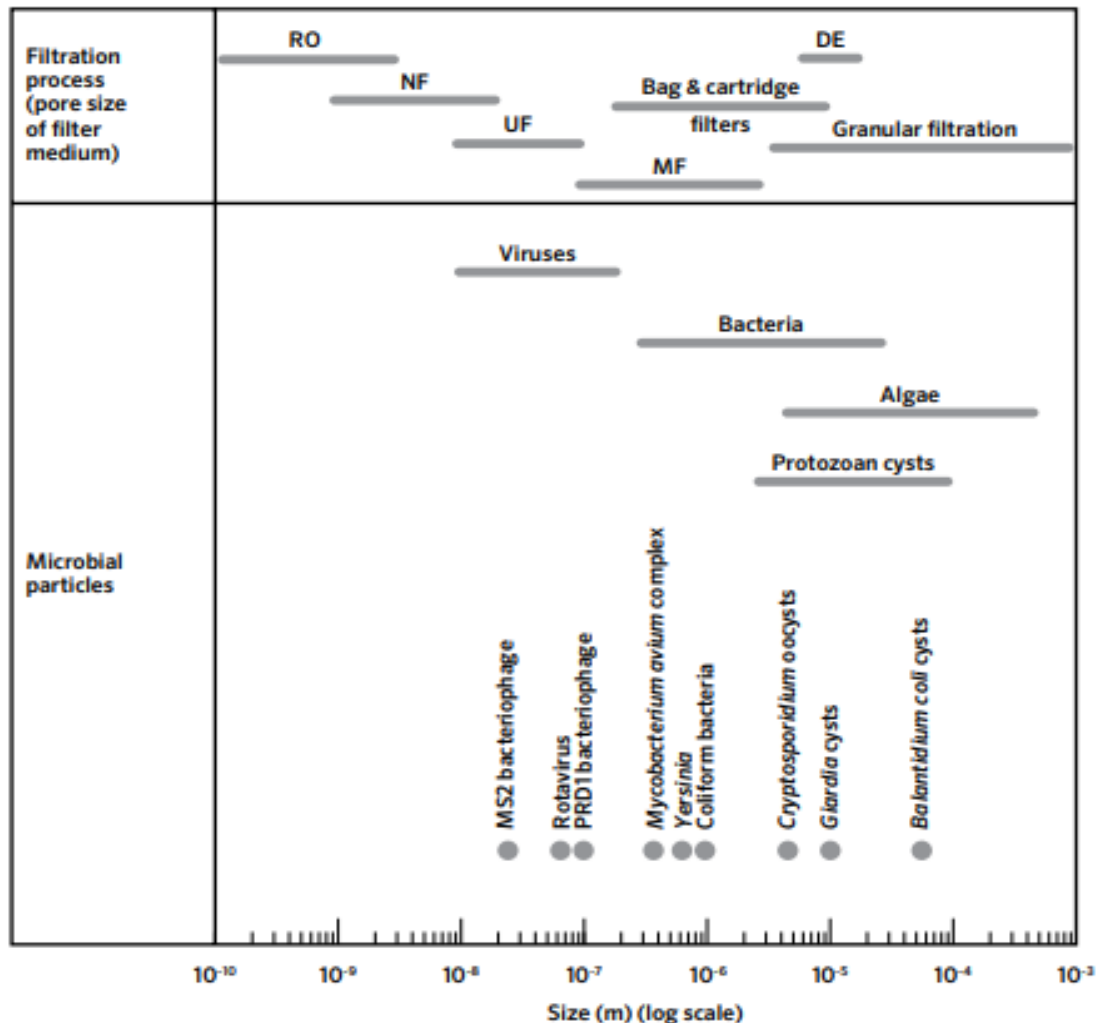
⁵ Chemical and physical characteristics and hazards are out of the scope of this guidance but relevant to be considered.

dissolved air flotation to remove organic matters. They should be considered as preliminary treatments since they will not remove all contaminants, including pathogens if present. These technologies should be followed by treatment procedures for recovered water from any source to reduce or eliminate the presence of pathogens to meet fit-for-purpose requirements.

7.2 Purification technologies

46. Several membrane purification methods can be applied to water used or reused in food manufacturing plants such as reverse osmosis (RO), nanofiltration (NF), ultrafiltration (UF) and microfiltration (MF) in addition to other types of filtration systems. Their differences in performance for water purification are illustrated in Figure 3.

Figure 3: Average pore size for different filtration systems: RO, NF, UF, MF, bag & cartridge filters, diatomaceous earth (DE), granular filtration and the size of different particles of microorganisms



47. RO is a membrane filtration technology, widely used in food manufacturing plants. The main purpose of RO is to remove dissolved and undissolved materials from water, but secondarily it also reduces levels of bacteria and viruses. The integrity of the membrane should be monitored at a regular frequency as small leaks or microscopic holes in the membrane may negate the antimicrobial barrier. Depending on the filtration system and pore size used, certain dissolved components may be removed.

48. RO can be supplemented with other approaches/barriers for further purification referred to as "ROP". This can consist of a secondary treatment, e.g. RO, deionization, use of activated carbon, etc. ROP water's shelf life can be extended with the use of microbiocidal treatments (such as UV) and/or using chilled or hot temperature storage, when validated and verified.

49. Other membrane filtration technologies (MF, UF and NF) are typically used before RO to reduce fouling of the RO membrane (build-up of organic matter and undissolved materials) and to enhance maintenance of constant flux/flow through the RO membrane. These filtration technologies by themselves may not remove all microorganisms (including pathogens) that may be present in the water and further treatment may be required for fit-for-purpose water applications.

50. Membrane bioreactor (MBR) (aerobic or anaerobic digestion) can be used for the pretreatment of wastewater. The water from the MBR may be further reconditioned by RO or other treatments to reduce minerals, organic material, and bacterial “load” to achieve acceptable fit-for purpose water safety and quality criteria. Many portable aerobic or anaerobic digester technologies are available for bulk reconditioning of wastewaters.

51. Membrane systems should be operated as per manufacturer’s specifications to optimize membrane efficiency, control microbiological growth and avoid damage. All membranes require periodic cleaning and backflushing, and may also require periodic replacement, to prevent fouling or various mineral (e.g. calcium) deposits (scaling). The frequency of backflushing is dependent on the material make-up and construction of the membrane, as well as the feed material and pressure differences. Some membrane systems/configurations do not allow backflushing.

7.3 Microbiocidal treatments

52. Chlorine, chlorine dioxide, ozone, hydrogen peroxide and peracetic acid are examples of chemical products used for the microbiocidal treatment of water in food manufacturing plants. They should be used in accordance with the label instructions and may be subject to competent authorities’ requirements. The following considerations should be made:

- Reuse water from food processing operations is known to contain microorganisms that can form biofilms on food contact surfaces which may or may not contain pathogenic bacteria, including pathogenic strains of *E. coli*. It is therefore important that reuse water has an appropriate disinfection treatment that meets the microbiological fit-for-purpose criteria at the point of use within the water distribution system that is furthest from the treatment.
- The choice of disinfection treatment should also consider whether a residual disinfectant will persist throughout the maximum storage time of the reuse water, and, if not, then an additional treatment may be needed.
- The optimal choice of disinfectant will vary based on the specifics of each food manufacturing facility, the food being processed, the intended fit-for-purpose use of the water, the method of recovering water for reuse, the characteristics of the source and reused water, such as the level of organic loading which can quickly deplete the efficacy of the disinfectant. Consideration should be given to evaluation on a trial basis in a laboratory or pilot setting, to determine organic loading and optimal concentrations of disinfectant(s). Resistance among microorganisms to disinfectants may develop but can be prevented by changing disinfectants periodically or combining with UV treatment.
- Chlorine disinfection is generally a reliable, inexpensive and effective approach against a wide spectrum of pathogenic microorganisms. However, if ammonia or organics remain in reuse water and these are exposed to chlorine, in any form, they may produce chloramines, chlorates, perchlorates and trihalomethanes, which may result in chemical risks. When water containing bromide ions and residual chlorine is irradiated with ultraviolet light, the formation of bromate may be promoted. If UV treatment facilities are installed after chlorine injection, it may be necessary to pay attention to bromide ions in the water to be treated. Chloramine, while significantly less effective at inactivating pathogens, especially viruses, reacts slower compared to free chlorine, and has the advantage of being effective for a longer period.
- The FBO should be aware of the suitability and the effectiveness of the disinfectants chosen, including the risk of residual disinfectants, potential by-products, and compatibility with equipment and other relevant surfaces (e.g. potential for corrosion, pitting etc.).
- The use of disinfectant chemicals should be well-controlled with records providing full documentation of use; for example, the level (e.g. chlorine) should be used at recommended concentrations as per label instructions for the applicable use; the level should be monitored at a frequency to ensure effectiveness against microbiological contamination.

53. Heat treatment, such as pasteurization, sterilization or boiling, can be used to render reuse water microbiologically fit for purpose. It can be used in a multibarrier approach e.g. after RO treatment to inactivate any remaining pathogens and microorganisms in order to render the water fit-for-purpose. Considerations to take into account are:

- treatment parameters should be validated to eliminate the risk of pathogens and spoilage organisms;
- the heat treatment temperature and flowrate or time spent at designated heating temperatures should be measured continuously and recorded automatically by a calibrated thermometer and timing device or similar automated and calibrated temperature recorders; proper holding time, being a critical component in a heat treatment process. This applies to both continuous-flow and batch-type pasteurizers.
- for continuous flow pasteurization or sterilization systems using a holding tube, the holding time is determined according to the length of the holding cell/tube and the flow rate (max L/s) of the pump, which should be set so that at least the minimum desired holding time is achieved at all times;
- a flow diversion valve should be in place so that, if the minimum required temperature is not achieved, it will redirect the reuse water flow for reconditioning back to the balance tank. The flow diversion valve should be tested at a frequency recommended by the manufacturer to ensure it is functioning properly;
- when using thin-walled plate heat exchangers for continuous pasteurization systems, continuous monitoring for under or over pressure on the heat-treated side is strongly recommended to ensure any potential leakage of water or other fluid moving from the unheated side to the heated side of the thin-walled plates via worn or misaligned gaskets or micro-fractures in the thin-walled plate(s). This is an important failsafe measure.

54. UV treatment of reuse water can be used to reduce some populations of bacteria, viruses, moulds, yeast and protozoa, if the effective UV wavelength and dose are applied. Continuous monitoring (including alerts), regular maintenance and cleaning and correct calibration of the treatment parameters are essential to maintain the microbiocidal effect. Further treatments may be required downstream. Critical factors to consider are:

- the optimum UV light wavelength for anti-microbial effect is 254 nanometers, recognizing the optimum wavelength for anti-microbial effect needs to be validated depending on the pathogen. The dose (mJ/cm²) is determined by required log reduction of a target organism. A dose of 40 mJ/cm² or equivalent is typical for control of most bacteria.
- transmission of UV light, i.e. the level of turbidity or color in the water; even if there is a slight turbidity/cloudiness or color in the water, the use of UV light may be ineffective as a microbiocidal treatment;
- preventative maintenance of the UV treatment system, such as measuring the existing UV wavelength and overall performance of the UV lamp, including its age, and wear of protective sleeves that may prevent light from reaching some pathogens;
- the fastest operational flow past the UV light source; the flow should be turbulent in most cases; note that flow that is too high or too low can cause uneven dose distribution of the UV light and leave some water without adequate disinfection;
- geometric configuration of the disinfection chamber; longer exposure time and reducing the distance between the UV light source and the point in the chamber farthest away from the UV light source provides more confidence in the effectiveness of the UV photon/microbe interaction and inactivation.

55. UV treatment systems must be set up to be adequately cleaned without significant infrastructure disassembly (i.e. cleaned, using a validated CIP approach), with cleaning and its frequency done in accordance with the manufacturer's recommendations, often enough to ensure that the system always delivers the specified UV dose. If CIP is used, it should have the capability of removing fat, protein and mineral coatings (e.g. calcium) from the UV light-emitting equipment.