CODEX ALIMENTARIUS COMMISSION

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World Health Organization

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REPORT OF THE PHYSICAL WORKING GROUP ON THE DRAFT GUIDELINES FOR THE SAFE USE AND REUSE OF WATER IN FOOD PRODUCTION AND PROCESSING (CXG 100-2023):

Proposed draft Annex II: Fish and fishery products at Step 4, and Proposed draft Annex IV: Water fit-for-purpose assessment, safety management and technologies for recovery and treatment of water for reuse at Step 4

(Prepared by the Chair of the Physical Working Group, European Union, and the co-chairs, Honduras, Morocco, and the International Dairy Federation (IDF))

Background

1. A physical working group (PWG) was held on 14 December 2025 in Nashville, United States, immediately prior to CCFH55, chaired by the European Union and co-chaired by Honduras, Morocco, and the International Dairy Federation to discuss the proposed draft Guidelines for the safe use and reuse of water in food production: Annex II on Fish and fishery products and Annex IV related to water fit-for-purpose assessment, safety management, and technologies for recovery and treatment of water for reuse.

2. The Chair began the session by presenting a brief history of the work and the outcome of the electronic working group (EWG). He also presented some general questions posed in the report of the EWG as regards Annex II:

a. The EWG was consulted whether or not to keep paragraph 11 since it contained certain duplications with other parts of the text. The Chairs proposed to keep it based on comments received and to move it to the introduction (para 6). These proposals were supported by the PWG.

b. Most members also preferred option 1 as regards the subsections of Section 6 WATER USE. This was supported by the PWG.

c. Most members also preferred option 2 as regards Figure 4. Some Members still expressed support for option 1. The PWG concluded to forward option 2 for the plenary but keep the discussion open at the plenary.

3. The Chairs presented a revised version of the Annexes II and IV, which have been amended based on comments provided in CX/FH 25/55/5Add.1 and various CRDs. Changes that were not yet included in the revised draft distributed prior to the PWG were highlighted in different colours. The PWG focused initially on a few key points for discussion but finally managed to review both Annexes and its Figures/Tables. The following issues were discussed in detail.

Annex II: Fish and Fishery products

- At first the Chair introduced the concept on ‘in depth fit-for-water assessment” as a tool to differentiate what was expected to consider water fit for purpose in a risk-based approach e.g. pending on the category of water (e.g. potable, clean water, other fit for purpose water). The concept was described in paragraph 36 and should be referred to in several paragraphs as appropriate, including in Figure 5. This was well received by the PWG.

- Paragraph 6 and 16, having the purpose to illustrate the link between fit-for-purpose water, potable and clean water, were presented in detail. Only a reference to 'in-depth fit-for-purpose assessment' was added in both paragraphs.
- The changes proposed in Figure 2 were agreed on.
- Figure 3 was amended, going directly from question 2 to question 4 in case of closed systems since question 3 is not relevant in such a case.
- Figure 4: different views on the preferences were expressed. While proposing option 2, further discussion may be needed at plenary.
- Figure 5: in addition to referring to "in-depth fit-for-purpose assessment", the footnote was amended to avoid confusion on the possible use of coastal water.
- The Chair then presented the whole Annex II
    - In Section 3, the cross-reference to Annex IV was removed
    - "in personal use application" was removed at the end of paragraph 13 since it is not a good example
    - Paragraph 18 was amended as not needed to refer to each stage of processing as regards the source of water
    - In paragraph 34, the first two bullets were switched and the fourth bullet was removed since it did not fit in the context of general recommendation on the microbiological quality of water;
    - Paragraphs 51 and the second bullet of 56 were deleted as they are not related to the safe use of water, while paragraph 52 was removed because of duplication.
- Othe issues discussed
    - The Chairs, assisted by New Zealand will revise the use of the terms "coastal" and "offshore".

Annex IV: Water fit-for-purpose assessment, safety management and technologies for recovery and treatment of water for reuse at

The Chairs presented a revision of Figure 2, which was supported by the PWG, accepting one of the 2 proposals for amendment made.

- It was proposed to move Table 2 from Section 6 to Section 5 since it is more related to water-fit-for purpose assessment (becoming Table 1).
- In paragraph 8bis, the wording referring to external sources was removed.
- A proposal to amend Paragraph 9 was extensively discussed but not accepted by the PWG.
- A proposal to provide more flexibility in Paragraph 14 was accepted.
- The need to maintain a reference to the hazard analysis in 6.2 was questioned, however most interventions underlined the importance to maintain since water use is an essential part of the hazard analysis.

Recommendation

The PWG recommends CCFH55 consider the revised annexes included in this document as the basis for further discussion.

PROPOSED DRAFT ANNEX II ON FISH AND FISHERY PRODUCTS

1. INTRODUCTION

1. Fish and fishery products are generally regarded as safe, healthy, and nutritious foods. However, these products may be involved in infections and intoxications caused by viruses (e.g.~~,~~ norovirus and hepatitis A), bacteria (e.g.~~,~~ *Vibrio* spp. and *Salmonella* spp. and *Clostridium botulinum*), protozoans (e.g.~~,~~ *Giardia lamblia* and *Cryptosporidium parvum*), marine biotoxins (e.g.~~,~~ saxitoxin and ciguatoxin) and helminths (e.g.~~,~~ *Anisakis* spp.). The causes of such hazards are diverse, ranging from naturally occurring microorganisms and parasites to contamination of primary production environments and/or poor hygiene practices during processing, storage, distribution and handling prior to consumption. Depending on the pathogen, ~~they~~ it can remain infectious in water for a considerable period of time and affect the suitability of a site to produce or harvest fish and fishery products[1].

2. Water is a key element in the production and processing of fish and fishery products. Water of potable quality might be the safest option; however, many primary producers and food processors/handlers have challenges accessing potable water. The use of potable water is often not a feasible, practical or responsible solution, and other types of water could be also fit for some purposes, provided they do not compromise the safety of the final product for the consumer. The increasing frequency of extreme weather events (e.g.~~,~~ drought, flooding) have exerted greater pressure on the availability and quality of water resources.

3. Increasingly, minimizing water consumption and exploring alternative water sources (e.g.~~,~~ water recovered from food or a food operation that could be reused after making it fit for purpose by suitable treatments or reconditioning, if necessary) are being considered.

4. Water can contact food directly or indirectly and is used in the maintenance of hygiene and sanitation throughout the food chain.

5. An overall management strategy should be developed to prevent~~ that~~ the use of water that is, or could be, a source of microbiological contamination of fish and fishery products, taking into account risk factors and control measures applicable at each step. The strategy should be based on a water fit-for-purpose assessment, which encompasses the entire water supply from the catchment or source to its final use.

6. A more general use of 'water fit-for-purpose' is likely to be more feasible, effective and practicable, as proposed by FAO and WHO meeting report on Safety and Quality of Water Used in Food Production and Processing. Potable water is fit for purposes for use during all stages of processing of fishery products from a microbiological safety perspective without an in-depth water fit-for-purpose assessment~~except~~. Clean water is also defined according to the ~~codex~~ *Code of Practice for Fish and Fishery Products* (CXC 52-2003) as water from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish ~~-~~and their products intended for human consumption~~sea water or fresh water of a quality that does not contain microorganisms, harmful substances, or toxic plankton in quantities capable of directly or indirectly affecting the wholesomeness of fish, shellfish, and other aquatic organisms and their products intended for human consumption~~. ~~And C~~Consequently, clean water is~~tly~~, considered safe ~~within a specific context~~for processing fishery products (e.g., clean sea water, deep groundwater) and ~~is~~ can therefore be fit for purpose (FFP) for almost all uses of water without an in-depth water fit-for-purpose assessment~~except as an ingredient and for washing at the final stage of the preparation of filleted fishery products eaten raw~~. Water of other quality can become fit for purpose for specific usage following an in-depth water fit-for-purpose assessment~~.~~

2. PURPOSE AND SCOPE

7. The purpose and scope of this Annex is to provide recommendations for the microbiologically safe sourcing, use and reuse of water in production and processing of fish and fishery products for human consumption by introducing the principle of 'fit for purpose' and a risk-based approach. This Annex also provides examples of ~~Decision~~ decision t~~T~~rees for determining fit-for-purpose use and reuse of water for fish and fishery products focusing on fish or fishery products that could be eaten raw or undercooked.

3. USE

8. This Annex is complimentary to and should be used in conjunction with the General Section ~~and Annex IV~~ of these Guidelines and the following Codex Alimentarius guidance:

[1] FAO & WHO. 2023. Safety and quality of water used in the production and processing of fish and fishery products – Meeting report. Microbiological Risk Assessment Series, No. 41. Rome. https://doi.org/10.4060/cc4356en

- *Code of Practice for Fish and Fishery Products* (CXC 52-2003),
- *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),
- *Standard for Live and Raw Bivalve Molluscs* (CXS 292-2008)~~,~~ *and other relevant fish and fishery products standards.*
- *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

9. Refer to the General Section of these *Guidelines for the Safe Use and Reuse of Water in Food Production*.

10. Refer to the *Code of Practice for Fish and Fishery Products* (CXC 52-2003) for the definitions of aquaculture, conditioning, ~~fish,~~ depuration, extensive farming, fish, fish farming, glazing, growing areas, intensive farming and shellfish.~~, aquaculture, conditioning, extensive farming, intensive farming, fish farming, glazing and growing areas.~~

Brackish water: water occurring in a natural environment that has more salinity than freshwater but not as much as seawater. It may result from the dissolution of salt from mineral deposits, mixing of seawater with freshwater, as in estuaries, or artificial situations such as dikes or flooding of coastal marshland.

Closed aquaculture production system: any system of aquatic species production that creates a controlled interface between the farmed species and the natural environment. It includes rearing in raceways, tanks and ponds.

Open aquaculture production system: farming of any aquatic species in natural water such as oceans, bays, estuaries**,** coastal lagoons, lakes, or rivers.

Evisceration: The removal of viscera and other internal organs.

Fish and fishery products: Any species of fish, including crustaceans, molluscs (including bivalve molluscs, marine gastropods and cephalopods), echinoderms, tunicates, or part of them intended for human consumption.

Processing facilities: A facility (vessel or on land establishment) where harvested fish and fishery products ~~are~~ may be depurated, processed, graded, and packed for further transportation and consumption.

Refrigerated seawater: clean seawater cooled by a suitable refrigeration system~~ in fixed tanks chilled by mechanical refrigeration~~.

Reimmersion: Storing live bivalve molluscs in tanks, floats, or natural sites after harvesting from the original production area.

Undercooked fishery products: fishery products that are neither raw nor subjected to a cooking time and temperature sufficient to ensure the destruction of non-sporing pathogenic micro-organisms.

~~11. A more general use of 'water fit-for-purpose' is likely to be more feasible, effective and practicable, as proposed by FAO and WHO meeting report on Safety and Quality of Water Used in Food Production and Processing[2]. Potable water is fit for purposes for use during all stages of processing of fishery products. Clean water is defined according to the *Code of practice for fish and fishery products* (CXC 52-2003) as sea water or fresh water of a quality that does not contain microorganisms, harmful substances, or toxic plankton~~

~~[2] FAO & WHO. 2019. Safety and Quality of Water Used in Food Production and Processing – Meeting report. Microbiological Risk Assessment Series, No. 33. Rome. https://doi.org/10.4060/CA6062EN https://www.who.int/publications/i/item/9789241516402~~

~~in quantities capable of directly or indirectly affecting the wholesomeness of fish, shellfish, and other aquatic organisms and their products intended for human consumption. And consequently, considered safe within a specific context (e.g., clean sea water, groundwater) and is therefore fit for purpose (FFP) for almost all uses of water. Water of other quality can become fit for purpose for specific usage following a water fit-for-purpose assessment.]~~

5. WATER SOURCE

~~12.~~11. Water used in the production and processing of fish and fishery products can be obtained from many sources, such as:

- potable (drinking) water from a public/municipal water supply system;
- freshwater from surface sources
- freshwater from groundwater sources;
- collected rainwater;
- seawater and brackish water;
- desalinated water;
- reused water originating from agricultural activities (e.g.~~,~~ hydroponics);
- recycled/reused processing water within an establishment recovered from a processing step within the operation.

6. WATER USE

~~13.~~12. Water used in the production and processing of fish and fishery products should be subject to sanitary surveys/monitoring. It should also be subject to ~~and~~ a water fit-for-purpose assessment covering the whole water system from the source or catchment area, treatment and storage, distribution and up to the point of use (from “source to tap”). Water use should be part of an operation’s prerequisite hygiene programme and HACCP system, when applicable.

~~14.~~13. ~~Water that comes into direct contact with fish or fishery products or food contact surfaces should be fit for purpose.~~ Water used as an ingredient and at the final stage for the preparation of filleted fishery products eaten raw, should be of potable quality. There are many other non-food applications in vessels and processing facilities where there is no intended or expected contact of the water with food – e.g.~~,~~ ~~in personal use applications and~~ fire control systems.

~~15.~~14. Water use should be tailored to the particular conditions of the specific fish and fishery products processing operation to which it is applied. Consideration should be given to the potential reusable water sources of the operation, the different applications of the reused water, available recovery and treatment technologies, and the ~~capabilities~~ technical and operational capacity of the operator to monitor and maintain water quality.

~~16.~~15. ~~In processing facilities, some~~ Some common examples of where water is used in production or processing~~used~~ are:

- for washing whole fish and rinsing the fish cavity after beheading, evisceration, skinning, and trimming;
- for depuration or conditioning[3];
- for reimmersion in the case of live bivalve molluscs; ~~the reimmersion should not cause additional contamination in live bivalve molluscs;~~
- as an ingredient;
- to transport/convey fish and fishery products;
- to wash, help preserve (chill/freeze) ~~cool down~~ and cook fish and fishery products;
- to clean and sanitize facilities, utensils, containers, and/or equipment;

~~[3] Bivalve Molluscs Conditioning: Placing live bivalve molluscs in tanks, floats, or natural sites to remove sand, mud or slime and improve product acceptability.~~

- to make ice;
- for thawing of fish and fishery products;
- for other processing purposes such as brining, glazing of frozen fish and fishery products to maintain quality during frozen storage;
- for personal hygiene purposes; and
- for non-food contact purposes.

~~17.~~16. Considering the General Section and the *Code of practice for fish and fishery products* (CXC 52-2003), and recognizing the specificities of the fishery products sector, as well the diversity of water sources and uses across different countries, water can be differentiated into three categories based on the "fit for purpose" principle. ~~as follows~~The three categories can be used from a microbiological safety perspective as follows:~~:~~

a) Potable water

- Water fit~~-~~ for ~~-~~purpose for all uses~~.~~;
- Can be used as an ingredient in fish and fishery products and for washing at the final stage of the preparation of filleted ~~washing of~~ fishery products eaten raw (e.g. ceviche, sashimi);
- Standards of potability should align with the recommendations included in the latest edition of the Guidelines for drinking-water quality, issued by the World Health Organization~~Standards of potability should not be lower than those contained in the latest edition of the International Standards for Drinking-water issued by the World Health Organization.~~;
- Example: drinking water from a public/municipal water supply system~~, artificial seawater.~~ ; ~~When~~ when sourced from ~~a municipality or~~ a well, the potable quality of the water should be verified~~.~~; wastewater, can seep into drinking water sources e.g. after flooding and these sources should be monitored when there is any suspicion that this may have occurred;

b) Clean water:

- Water fit -for -purpose for all uses except as an ingredient and for washing at the final stage ~~for~~ of the preparation of filleted fishery products eaten raw~~.~~
- Should ~~at least comply with the microbiological safety of potable water e.g. water~~come from any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish and fishery products intended for human consumption.
- Example: includes offshore sea water, ~~or~~ deep groundwater ~~water~~ and artificial seawater[4]. The locations of the water sources should be ~~verified~~ assessed for appropriate proximity from higher risk factors (e.g.~~,~~ sea water is collected sufficiently offshore, wells that are sufficiently deep) and against any recent microbiological data relevant to the source.

c) Other ~~fit-for-purpose~~sources of water

- Can be used but only after an in-depth water fit-for-purpose assessment to specify what use is suitable for ~~or~~ and after implementing additional control measures to ensure food safety.~~.~~
- ~~The result of the risk assessment will specify what use it is suitable for.~~
- Example: surface groundwater, recycled/reused processing water within an establishment recovered from a processing step within the operation, or recirculated water, etc.

~~18.~~17. In any processing facility, contamination of the potable water system with non-potable water from other sources should be avoided. Non-potable water systems should be identified (for example, with labels or colour codes) and should not connect with or allow reflux into potable water systems. Contamination may occur for example, due to cross connections, dead legs, backflows or back siphonage in the water plumbing systems because of improper installations, or additions/modifications to the existing plumbing.

[4] a synthetic mixture of dissolved mineral salts that simulates natural seawater, primarily used in marine biology, aquaculture, and laboratory research.

~~19.~~18. Before ~~any~~ the use ~~at a processing stage~~ in ~~at~~ a processing facility, the source of the water coming into direct or indirect contact with material or product, should be identified and assessed~~,~~; where necessary, test~~ed and treated~~ing and treatment should be applied to ensure ~~so~~ that ~~it complies with appropriate standards and~~ the water is~~be~~ fit ~~-~~for ~~-~~purpose for the processing step in which it will be used.

~~20.~~19. Food Business Operators (FBOs) should consider the following in assessing and managing water:

- Sanitary surveys/monitoring and an in-depth water fit-for-purpose assessment may be important to determine if water is fit for purpose and the likelihood of contamination in the production and processing systems.
- Characterization of surface or groundwater safety in extraction points should be extended upstream, when possible, to include the whole water catchment area.
- A water fit-for-purpose assessment should consider the specific waterborne hazards (e.g.~~,~~ marine microbiological contaminants) that may impact the safety and quality of the fish and fishery product. Depending on the fishing ground of origin, seasonal and climatic factors affecting source water quality in the immediate area should be included.

6.1 Water use for aquaculture production

~~21.~~20. In primary production, any source of water can be used provided that~~-~~ its suitability for the intended use has been assessed~~the risks have been previously assessed~~, that the water complies with predefined microbiological criteria and that the water quality is regularly monitored. The type and source of water used in aquaculture systems varies by species, geographical location, and water availability.

~~22.~~21. Seawater is primarily used in marine aquaculture, while inland aquaculture systems primarily use water from surface and groundwater sources, although other water sources as per Section 5 can be used in both of these production systems.

6.2 Water use onboard vessels

~~23.~~22. Many different types and sizes of fishing vessels are used throughout the world for catching, harvesting, and/or processing fish and fishery products. Water may be used on onboard vessels for preservation, washing, holding of live seafood, and~~/or~~ further processing of fish and fishery products, as well as various non-food contact purposes.

~~24.~~23. Onboard preservation of fish and fishery products can involve chilling and/or freezing. Ice is most commonly used to chill fish and fishery products onboard vessels. Other means to chill fish and fishery products include chilled water, ice slurries and refrigerated seawater, including brine freezers. Ice may be brought on board from onshore sources and/or manufactured on board using brackish water or seawater.

~~25.~~24. Depending on a variety of factors (e.g.~~,~~ the geographical region, seasonality, proximity to marine dumping, proximity to congregation of marine life, industrial or sewage outflow (e.g.~~,~~ wastewater, storm water, sewer overflow), agricultural run-off and temperature), seawater can hold naturally occurring pathogenic microorganisms, such as *Vibrio* spp., that may require monitoring and control.

~~26.~~25. S~~If s~~eawater ~~is~~ used on fishing vessels, ~~it~~ should be taken from offshore areas that are sufficiently distant from known pollution sources (e.g.~~,~~ sewage outflow) to ensure that the water is of suitable quality. Cross-contamination should be avoided between the point at which seawater is taken on board, and wastewater streams, bilge water and engine coolant outlets or other potential contaminants from the fishing vessel when stationary or moving.

6.3 Water use at land-based processing facilities

26. Water is used for a variety of applications in land-based processing facilities for fish and fishery products. Recognizing the specificities of the fishery products sector, different ~~categories~~ sources of water may be used depending on the intended purpose as illustrated in Section 5~~. Thus, potable water is considered suitable for all intended uses, while clean water is suitable for all uses except for use as a food ingredient. These two categories of water are recognized as fit for purpose for their respective uses, and do not require prior risk assessment by food business operators.~~ Where seawater is extracted from coastal sources for land-based processing plants, it cannot be guaranteed to be free from pathogens from the marine microbiota or from faecal contamination. It cannot be classified as a fit-for-purpose source for processing without an in-depth water fit-for-purpose assessment, the appropriate monitoring and application of control measures where necessary.

~~27. In contrast, when other sources of water are to be used, a risk assessment must be conducted in advance. The result of this assessment will determine whether the water is fit for purpose or not.~~

~~28.~~27. In any processing facility, contamination of fit-for-purpose water by non-fit-for-purpose water should be avoided.

~~***[Option 2]***~~

~~**6.1 Seawater**~~

~~21. Many different types and sizes of fishing vessels are used throughout the world for catching, harvesting, and/or processing fish and fishery products. Water may be used on onboard vessels for preservation, washing, and/or further processing of fish and fishery products, as well as various non-food contact purposes.~~

~~22. Onboard preservation of fish and fishery products can involve chilling and/or freezing. Ice is most commonly used to chill fish and fishery products onboard vessels. Other means to chill fish and fishery products include chilled water, ice slurries and refrigerated seawater, including brine freezers. Ice may be brought onboard from onshore sources and/or manufactured onboard using brackish water or seawater.~~

~~23. Depending on a variety of factors (e.g., the geographical region, seasonality, proximity to marine dumping, industrial or sewage outflow (e.g., wastewater, storm water, sewer overflow), agricultural run-off and temperature), seawater can hold naturally occurring pathogenic microorganisms, such as *Vibrio* spp., that may require monitoring and control.~~

~~24. If seawater is used on fishing vessels, it should be taken from offshore areas that are sufficiently distant from known pollution sources (e.g., sewage outflow) to ensure that the water is of suitable quality. Cross-contamination should be avoided between the point at which seawater is taken onboard, and wastewater streams, bilge water and engine coolant outlets or other potential contaminants from the fishing vessel.~~

~~25. Where seawater is extracted from coastal sources for land-based processing plants and in case of coastal open aquaculture production systems, it cannot be guaranteed to be free from pathogens from the marine microbiota or from faecal contamination. It cannot be classified as a fit-for-purpose source for processing without an adequate water fit-for-purpose assessment, the appropriate monitoring and application of control measures where necessary.~~

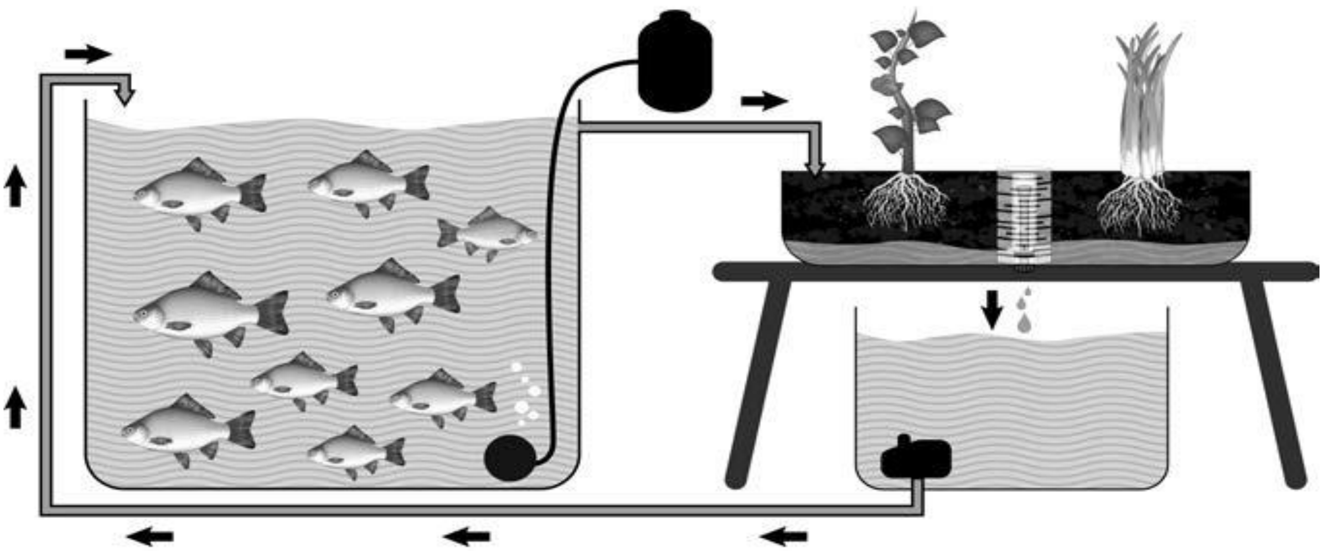
7. WATER INTENDED FOR REUSE

28. Water recovered from food, certain agricultural activities (e.g.~~,~~ hydroponics), processing activities (such as cooling) or treated wastewater, are good examples of water that can be reused as long as its microbiological quality is fit-for-purpose for its planned use. Its use could be ~~expended~~ expanded for additional applications after treatment. Any water treatment processes should be effectively monitored, controlled and recorded.

29. Examples of aquaculture systems where water can be reused include integrated multi-trophic aquaculture systems, where multiple aquatic species from different trophic levels are farmed in an integrated fashion (e.g.~~,~~ finfish and seaweed) and aquaponic systems[5], which integrates aquaculture and hydroponics into a single recirculating production system (see Figure 1). The reuse of water within these (or other) aquaculture systems should be subject to a water fit-for-purpose assessment and appropriate water safety management practices.

Figure 1. *Schematic of a simple aquaponic unit*[6]

[5] More information on Aquaponic System could be found in FAO & WHO. 2023. Safety and quality of water used in the production and processing of fish and fishery products – Meeting report. Microbiological Risk Assessment Series, No. 41. Rome.
https://doi.org/10.4060/cc4356en
[6] Source: FAO. 2014. Small-scale aquaponic food production. Integrated fish and plant farming. FAO Fisheries and Aquaculture Technical Paper No. 589. Rome, FAO. https://www.fao.org/3/i4021e/i4021e.pdf



30. All reuse of water in the production and processing of fish and fishery products should be part of the hygiene programme and HACCP ~~programmes~~system, when applicable.

8 WATER USE OR REUSE FIT-FOR-PURPOSE ASSESSMENT

31. Refer to section 7 of the general section and Annex IV [7] of these Guidelines in line with the recommendations in Annex IV.

32. It is important to note that the ~~dept~~ complexity of the water fit-for-purpose assessment required will depend on the situation and level of general understanding of the risk associated with a particular scenario e.g. ~~by~~ it might be sufficient to just ~~assessing~~ identify the source of water and the intended use (e.g.~~,~~ use of potable water, use of clean offshore water ~~from high seas~~ known to be free of risk of coastal or other contamination, use of deep groundwater), confirmed by relevant monitoring of the microbiological quality. For other water, the in-depth water fit-for-purpose assessment should include an evaluation of the specific operation, including the type and source of water used/reused to determine which indicator(s) are appropriate to be used to monitor the water source, including reconditioned water~~,~~.

33. In addition to the factors described in Annex IV of these Guidelines, fit-for-purpose assessments of water to be used/reused in the production or processing of fish and fishery products should consider process- or product-specific factors such as:

- whether the fish ~~or fishery products are~~is dead or alive;
- whether fish products are whole or processed; and
- whether the fish or fishery product is likely to be eaten raw or undercooked.

34. General recommendations on the minimum microbiological quality for water to be fit for certain purposes include:

- Water used in food contact applications for fish and fishery products that are potentially eaten raw or undercooked should be potable or clean water, or water demonstrated as fit for purpose through an in-depth risk assessment.
- Water used as an ingredient in a fish and fishery product and for washing at the final stage ~~for~~ of the preparation of filleted fishery products eaten raw, should be potable.

[7] Under development

- ~~Water used in food contact applications for fish and fishery products that are potentially eaten raw or undercooked should be potable or clean water~~, ~~or water demonstrated as fit for purpose through a risk assessmentand at least comply with the microbiological safety of potable water.~~

- Any water used in direct contact with fish and fishery products during preservation or processing activities (e.g.~~,~~ for chilling, washing whole fish, or rinsing the fish cavity after beheading, evisceration, skinning, and trimming) should not further contaminate the product.

- ~~Any water that can be used but afterfollowing the suitable outcome of a water fit-for-purpose assessment and implementation of additional control measures whenever necessary to ensure food safety. The result of the water fit-for-purpose assessment will specify what use it is fit for.~~

35. Evaluating risk of microbiological hazards in water in the fit-for-purpose assessment, should include information on local hazards of public health significance (e.g.~~,~~ epidemiological data). Waterborne microbiological ~~Bio~~hazards and their relative risk are listed in Table 1.

36. In an in-depth fit-for-purpose assessment, the first tasks in the decision processes are similar to the first steps and Principle 1 in the implementation of a HACCP system during food safety management. They include some or all of the following:

- description of the fish or fishery product;
- its intended use if known (e.g.~~,~~ eaten raw, cooked, …);
- understanding the product flow from production to consumption (e.g.~~,~~ harvesting, processing, transport, marketing, consumer handling);
- identifying water use (e.g.~~,~~ washing, processing, ice, ingredient) and inputs (e.g.~~,~~ water source types, storage and delivery);
- ~~source of water;~~
- identifying potential water-related hazards[8] at each stage; and
- analysing the microbiological hazards and considering any measures in the product flow stages that may prevent, eliminate or reduce the water-related ~~significant~~microbiological hazards introduced in the final product to acceptable levels.

37. When ~~characterizing~~ assessing the microbiological ~~quality~~ safety of surface or groundwater, it is important to extend the assessment upstream of extraction points, when possible. In addition, seasonal and climatic factors that may affect the microbiological quality of surface or groundwaters should also be considered.

8.1 Examples of Decision Trees

38. For practical guidance, a decision tree (DT) approach with underlying risk assessment (RA) is a useful decision support system (DSS) tool to identify whether the water is fit for purpose for use or reuse at a given step in the supply chain.

39. There is no single DT that applies/fits in all situations. The DTs below therefore should rather be considered as examples of an approach to evaluate a situation and draw attention to risk factors instead of as a tool fixed for all purposes. Competent authorities are encouraged to publish simplified national or regional decision trees to facilitate implementation by small-scale operators.

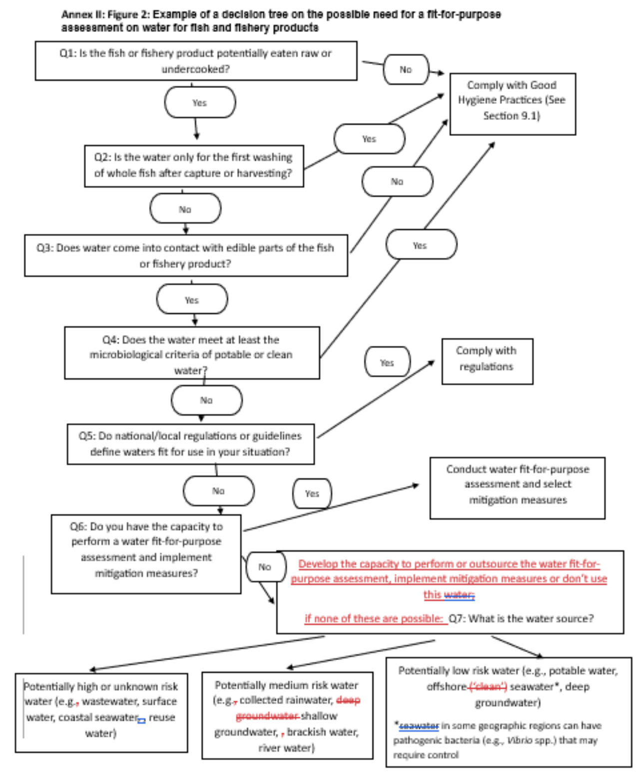
40. The DTs provide examples of how the quality of water used at each step in the process impacts final product safety, and hence whether the water available at that stage is fit-for-purpose or not.

41. Recommended good hygiene practices related to the appropriate use/reuse of water (see Section 9.1), historically identified using risk assessment principles, are considered sufficient to support decision making when fish and fishery products are intended to be cooked. In several cases, it will ~~not be~~is impossible to guarantee during the production and processing stage that fish or fishery products won't be eaten raw or undercooked~~exclude at the stage of production and processing that fish will not be consumed raw or undercooked~~. When not possible to guarantee that the fish will be cooked, the recommendations in these guidelines ~~i~~ on the use of water for the production and processing of raw or possibly undercooked fish, should be applied. Figure 2 provides an example

[8] Chemical and physical hazards are out of scope, but relevant to be considered.

of a DT ~~for determining when~~for examining the risk associated with the use of water, particularly when a fit-for-purpose assessment on water ~~may be necessary~~is warranted. It also outlines ~~and~~ potential risk characterizations for various water sources ~~when~~ in a situation where the capacity to perform a water fit-for-purpose assessment ~~and~~ or implement mitigation measures ~~does not exist~~is lacking. Water sources considered as a potentially medium, high or unknown risk should not be used unless monitoring demonstrates compliance with the microbiological criteria of potable water, after treatment if required. Alternatively, a water fit-for-purpose assessment should be outsourced or the internal capacity to conduct such assessments and implement mitigation measures should be developed.

Figure 2. *Example of a decision tree ~~on the possible~~to determine whether or not ~~need for~~ a fit-for-purpose assessment ~~on~~ of the water for fish and fishery products is warranted* and potential risk characterizations where the capacity to perform a water fit-for-purpose assessment or implement mitigation measures is lacking.



~~Water sources considered as a potentially medium, high or unknown risk should not be used unless monitoring demonstrates compliance with the microbiological criteria of potable water, after treatment if required. Alternatively, a water fit-for-purpose assessment should be outsourced or the capacity to perform grown.~~

42. Other DTs may assist in assessing if water is fit for purpose for fish and fishery products potentially eaten raw or undercooked. In such case, the water used should represent the lowest possible risk at each stage.

8.1.1 Example of DT to determine whether or not ~~fit-for-purpose~~the water ~~for use~~to be used in freshwater, marine or estuarine aquaculture production of fish and fishery products potentially to be eaten raw or undercooked, is fit for purpose.

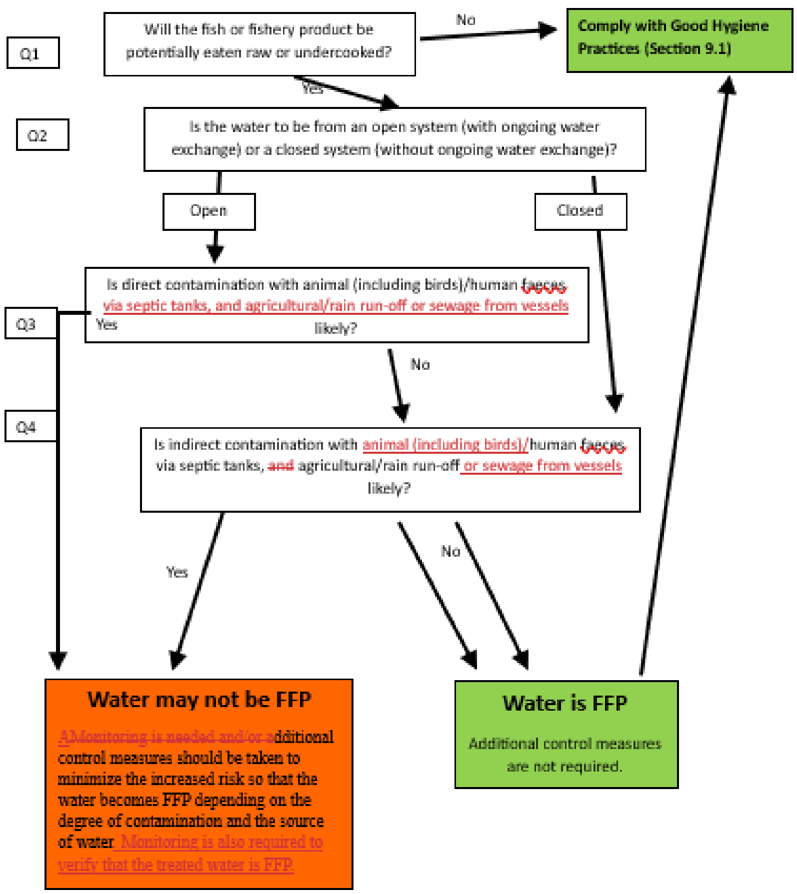
43. Figure 3 provides an example DT that can be useful in determining if water systems used for the aquaculture production of fish could have been subjected to conditions/events that increase the risk of microbiological hazards such that the application of control measures to the water are necessary. Since prevention of (faecal) contamination is a good hygiene practice for any fish production, this example DT could be applied both when the fish is to be consumed cooked or uncooked~~independently of the fish is consumed cooked or not~~.

44. When one or several possible sources of contamination (sewage nearby, faeces or surface run-off water entering the system) have been identified by the DT, the possible presence of pathogens should be considered a risk unless regular monitoring demonstrates that it is fit for purpose by an in-depth risk assessment or control measures have been put in place and validated (the control measures can be water treatment or processing measures subsequently applied to the fish and fishery products). Any water treatment processes should be

monitored, controlled and recorded. Detailed information on the possible control measures can be found in the FAO/WHO documents[9] ~~referred to by footnotes at different steps or~~ or in relevant national guides. For example, s~~Additional s~~pecific guidance to control contamination of *Vibrio* spp. in the Guidelines on the application of General Principles of Food Hygiene to the Control of *Vibrio* Species in Seafood (CXG 73-2010) should be taken into account.

45. The risk presented by water changes with the season.~~Seasonality may change or enhance the risk.~~ For example, in periods with high rain-fall in a short period, the risk of surface run-off water entering the growing waters or water supply may increase. Contamination by the faeces of mammals should be avoided (e.g. restricting access to growing waters or water supplies by fencing) while contamination by bird faeces should be minimize as much as possible (e.g. by removing perches as overhanging branches).~~in all cases while contamination by the avian faeces should be minimised as much as possible. For example, access to growing waters or water supplies can be restricted to mammals e.g. by fencing, and to birds, e.g. by removing perches such as overhanging branches.~~

***Figure 3**. Example of DT to determine ~~fit-for-purpose water~~whether or not the water used in freshwater, marine or estuarine aquaculture of fish and fishery products~~, potentially eaten raw or undercooked~~ is fit for purpose.*



8.1.2 Example of DT to determine fit-for-purpose water used for post-harvest handling or processing of fish and fishery products, potentially eaten raw or undercooked.

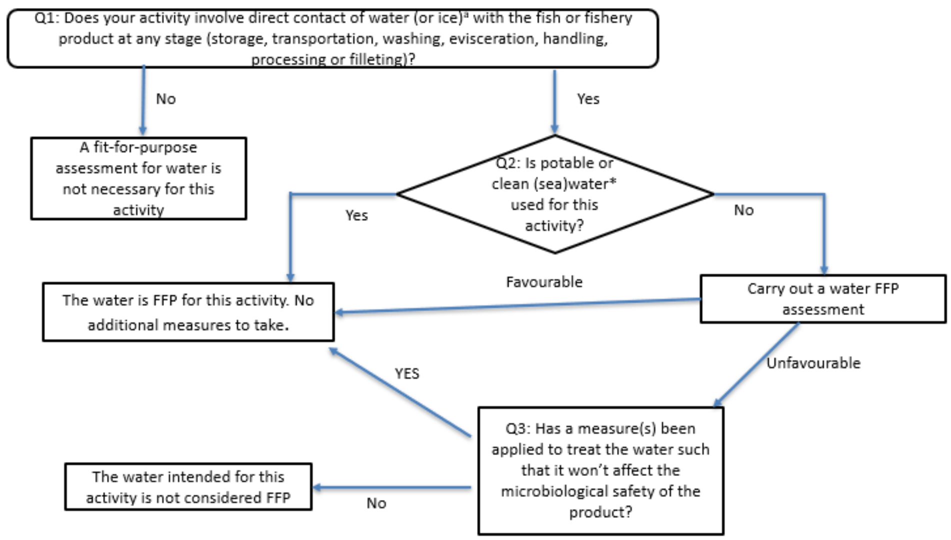
46. In case of post-harvest handling and processing of fish and fishery products, the DT in Figure 4 can be used to determine if the water is fit for purpose or will require prior treatment (e.g.~~,~~ because of unacceptable levels

[9] WHO Sanitation Safety Plan Manual- Second edition, https://www.who.int/publications/i/item/9789240062887, WHO Water Safety Plan. step-by-step risk management for drinking-water suppliers, second edition https://www.who.int/publications/i/item/9789240067691 , WHO Safe Use of Wastewater, Excreta and Grey Water. Vol 3. Aquaculture. https://www.who.int/publications/i/item/9241546840 .

of/ presence of pathogens) before use. ~~Use of other than~~Only potable or clean (sea)water would ~~not~~ be fit for purpose for descaling, eviscerating and washing the fish cavity or use during filleting. The use of other waters ~~without~~ would require an in-depth fit-for-purpose assessment and treatment of that water~~, for the~~ to minimize or eliminate ~~possible presence of~~ faecal pathogens. This also applies to water used on contact surfaces (knives, cutting boards). For the (first) washing or transport (ice) of whole (non-eviscerated) fish, water can still be fit-for-purpose if of lower quality.

47. Consideration should be given to prevent the presence of naturally occurring marine pathogens (e.g.~~,~~ *Vibrio* ~~*parahaemolyticus*~~spp.) where cross-contamination between fresh and seawater fish and fishery products may occur at this stage.

***Figure 4**. Example of DT to determine whether or not ~~fit-for-purpose~~ the water to be used for post-harvest handling and or processing of fish and fishery products, potentially eaten raw or undercooked, is fit for purpose*



*: ~~When seawater is used, the risk depends on the origin of seawater, e.g. the~~ Seawater from high seas has lower risk ~~compared to~~ while the possible use of seawater from near a coastline should be subject to an in-depth fit-for –purpose assessment.

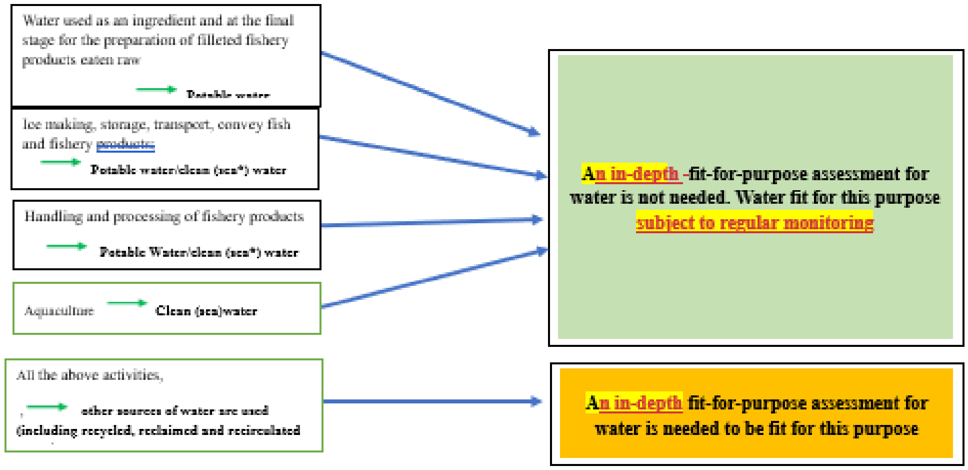
a: This also includes water used to clean all surfaces that come into direct contact with fish and fishery products.

8.1.3 Summary of examples of DTs

48. Figure 5 provides a summary of examples of water fit-for-purpose for use at certain steps with direct contact in fishery production and processing.

***Figure 5.** Summary of examples of water fit for purpose for use at certain steps with direct contact in fishery production and processing in case of fish and fishery products potentially eaten raw or undercooked*

Figure 5: Summary of water fit for purpose for use at certain steps with direct contact in fishery production and processing in case of fish and fishery products potentially eaten raw or undercooked.



* ~~When seawater is used, the risk depends on the origin of seawater, e.g. the s~~Seawater from high seas has a lower risk ~~compared to~~ while the possible use of seawater from near a coastline should be subject to an in-depth fit-for –purpose assessment.

9 WATER SAFETY MANAGEMENT

49. Refer to section 8 of the general section [and Annex IV~~(see footnote 5)~~] of this Guidelines.

9.1 Good hygiene practices

50. The good hygiene practices described in this Section should be applied as prerequisite programmes to ~~enhance~~ ensure the safety of any fish and fishery product by the use and reuse of water in direct and indirect contact with the product. Categorization of quality of water used at various processing steps varies and includes potable water, clean (sea)water, and other water fit for purpose for its intended use.

~~[Keeping the fish or fishery products at a low temperature (e.g., 4°C or less) is an effective measure to slow microbial growth after harvest.]~~

~~51. [Whenever possible, potable water (or other water supply of potable microbiological qualityfrom any source where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish and fishery products,) should be used for the final rinsing of fish and fishery products.]~~

~~52.~~51. When seawater is used on board fishing vessels, it is fit for purpose for any washing of whole fish, preservation and other processing activities when, for example ~~taken~~ the water is collected from offshore areas that are sufficiently distant from known pollution sources (e.g.~~,~~ sewage outflow, ship fleets and animal congregations). The point at which offshore seawater is taken on board should be located such that contamination from wastewater streams, bilge water and engine coolant outlets, or other objectionable substances from the fishing vessel is avoided.

~~53.~~52. Any water used in direct contact with fish and fishery products during preservation or processing activities (e.g.~~,~~ for chilling, washing whole fish, or rinsing the fish cavity after beheading, evisceration, skinning, and trimming) should not further contaminate the product. It is essential that water used on fish and fishery products that may be consumed raw or undercooked is free from microbiological hazards that could pose risks to human health.

~~54.~~53. Where an essential onboard treatment for ~~fish-contact~~ water used in direct contact with fish or fishery products has failed or malfunctioned, ~~it is essential that the~~ fish and fishery products should be ~~are~~ directed to further processing (e.g.~~,~~ cooking) to ensure food safety.

~~55.~~54. Storage and transportation of live fish:

- Water should not be contaminated with either human sewage or industrial pollution; holding tanks and transportation systems should be designed and operated in a hygienic way to prevent contamination of water and equipment.

  ~~[Water in holding and conditioning tanks should be well aerated before fish are transferred into it.]~~

- Where seawater is used in holding or conditioning tanks, for species prone to toxic algae contamination, the seawater shall not contain toxic algae or toxic phytoplankton in a quantity that could contaminate the contained fish and fishery products.

~~56.~~55. On fishing vessels, adequate facilities should be provided for the handling and washing of fish and fishery products and should have an adequate supply of cold potable water or clean (sea)water. ~~The~~ If not gutted, the catch should be immediately frozen or ~~can be~~ stored in tanks with refrigerated seawater~~ or~~, in clean seawater chilled with ice or in boxes containing ice. ~~If fish is not gutted, fish should be frozen or refrigerated immediately, and~~Refrigerated fish should be transported~~ should be~~ in ice water

~~57.~~56. Processing steps that use water can be the same on board or on land and for captured or cultured fish and fishery products and may include washing and evisceration, filleting, skinning, trimming and candling, glazing and mincing.

~~58.~~57. Processing of fresh, frozen and minced fish:

- Washing and evisceration: an adequate supply of clean (sea)water or potable water should be available for washing of:
  - whole fish, to remove foreign debris and reduce bacterial load prior to evisceration;
  - eviscerated fish, to remove blood and remaining viscera from the belly cavity;
  - surface of fish, to remove any loose scales;
  - evisceration equipment and utensils, to minimize build-up of slime, blood and offal.
- Filleting, skinning, trimming and candling: An adequate supply of clean (sea)water or potable water should be available for washing of:
  - fish prior to filleting or cutting, especially fish that have been scaled;
  - fillets after filleting, skinning or trimming to remove any signs of blood, scales or viscera;
  - filleting equipment and utensils to minimize build-up of slime and blood and offal.

~~59.~~58. Ice should be produced using potable water or clean water and it should be protected from contamination.

~~60.~~59. For operations that require steam, an adequate supply at sufficient pressure should be maintained. Steam used in direct contact with fish, fishery products or food contact surfaces should not constitute a threat to the safety or suitability of the food.

~~61.~~60. Washing live bivalve molluscs: Washing should be carried out using pressurized seawater fit for purpose or saltwater made from potable water. If saltwater other than seawater is used, it should be prepared from potable water and of ~~three~~ about 3 percent of food grade salt to minimize the uptake of moisture. The salinity of the saltwater should be monitored. Reimmersion should not cause additional contamination in live bivalve molluscs.

~~62.~~61. Washing shucked bivalve molluscs: Pre-chilling should include the immersion of the bivalve molluscs in clean refrigerated ~~fit-for-purpose~~ seawater ~~(clean seawater cooled by a suitable refrigeration system in fixed tanks chilled by mechanical refrigeration)~~ or ~~in~~ iced seawater.

~~63.~~62. Fresh, refrigerated and frozen products: Transportation of fish in an ice slurry, chilled seawater or refrigerated seawater (e.g.~~,~~ for pelagic fish) should be considered where appropriate. Chilled seawater or refrigerated seawater should be used under approved conditions.

~~64.~~63. Glazing: The application of a protective layer of ice formed at the surface of a frozen product by spraying it with, or dipping it into, clean (sea)water, potable water or potable water with approved additives, as appropriate.

~~65.~~64. Cleaning and disinfection of equipment and facilities: A good supply of clean (sea)water or potable water at adequate pressure should be available.

9.2 Implementation of a water safety management plan based on the fit-for-purpose assessment

~~66.~~65. Management procedures, such as a water safety plan, should be site specific. Their ~~elaborated~~ elaboration and ~~implement~~implementation should ~~ed~~ ~~that are site-specific and~~ consider particular characteristics of the site and the relevant hazards/hazardous events and the outcomes of the water fit-for-purpose assessment. The management procedures should include:

- all uses of water,
- measures to prevent contamination of water supplies,
- measures to prevent cross-connections between a supply of water determined to be microbiologically fit for its intended use(s) and other supplies of water with lesser microbiological quality or safety,
- any treatments, including the treatment parameters, necessary to control hazards such that the treated water is microbiologically fit for its intended use(s),
- validation of disinfection steps of water treatments,
- appropriate monitoring procedures and corrective actions.

~~67.~~66. A multi-barrier approach (e.g.~~,~~ protecting the water source from faecal contamination, treatment of water, and avoiding cross-contamination) is possible with regard to water safety management. The management procedures should include strict segregation measures for preventing cross-connections between supply waters of different qualities, and most importantly with wastewater systems.

~~68.~~67. When reusing water, the need for water treatments (e.g.~~,~~ biological, chemical, physical) should be considered to ensure that the water from the reuse system is fit ~~-~~for purpose, including conditions related to distribution, storage and intended use where relevant.

~~69.~~68. Revise and reinforce, as appropriate, operational monitoring, including periodic microbiological testing of water used in the production and processing of fish and fishery products to provide insight into the performance of the water safety management process. Such monitoring can enable identification of potential nonconformities and inform corrective actions, which may include additional microbiological testing of the process and/or the fish and fishery products.

9.3 Treatments for fit-for-purpose water

~~70.~~69. When the outcome of a water fit-for-purpose assessment or the risk characterization of a water source (see ~~Suggested~~ Figure ~~3~~2) indicates that control of microbiological hazards is necessary for water to be fit for its intended use, treatment options should be determined on a case-by-case basis considering the hazards that may occur through contamination (e.g.~~,~~ faecal pollution) as well as any naturally occurring microorganisms (e.g.~~,~~ pathogenic *Vibrio* spp. and *Clostridium botulinum*).

~~71.~~70. Treatment technologies that render water fit for purpose by eliminating or inactivating microorganisms or reducing them to acceptable levels for use/reuse water include, but are not limited to, heating (e.g.~~,~~ pasteurization or boiling); use of a chemical disinfectant such as chlorine, chlorine dioxide[10], ozone; and/or physical treatments such as membrane filtration and irradiation (e.g.~~,~~ UV light). Guidance on resistance to chlorination by different microbiological hazards ~~in~~ is provided in Table 1.

~~72.~~71. Appropriate treatment parameters should be monitored and recorded to ensure the effectiveness of any treatment technology used to control microbiological hazards in water to be used/reused in the production or processing of fish and fishery products. The efficacy of such treatments should be periodically verified through appropriate microbiological testing of the treated water.

~~73.~~72. For more information on water treatment technologies refer to Annex IV (see footnote 5) of this guidance.

~~74.~~73. If disinfection is part of the water processing facility treatment or other water treatment, the effectiveness should be validated. In this case, attention should also be paid to possible residues of disinfectants used.

9.4 Monitoring the microbiological quality of water

~~75.~~74. Monitoring of water is a core element of any food safety management system. It ~~and~~ is necessary for ensuring water ~~quality and~~ safety and it is important to ensure that various type of water use in the production and processing of fish remain fit for purpose ~~defining fit-for-purpose water in the production and processing of fish and~~

[10] Attention should be paid to the possible formation of toxic compounds when adding chemical disinfectants to seawater.

~~fishery products~~. The monitoring frequency must be risk-based and should be increased following unusual events (e.g. flooding, sewage incidents, harmful algal blooms) and tapered once trends stabilize and controls are verified.

~~76.~~75. The microbiological quality of any water used in the production and processing of fish and fishery products should be monitored at a frequency commensurate with the level of risk identified in the water fit-for-purpose assessment. Monitoring practices should cover the whole water system, from the source or catchment area, treatment and storage, distribution and up to the point of use (from "source to tap"). Historical data and information, including seasonal and climatic factors, should be considered when determining the frequency of monitoring. Additional monitoring should be carried out following weather events that may affect water being fit for purpose (e.g.~~,~~ flooding).

~~77.~~76. No single indicator microorganism (or group of microorganisms) is suitable for monitoring the ~~quality and~~ safety of water from all potential water sources and in all applications in the production and processing of fish and fishery products. The limitations of various indicator microorganisms to appropriately identify microbiological ~~quality and~~ safety of water in a specific application should be understood. There is rarely a direct correlation between indicator microorganisms (e.g. coliform bacteria), and enteric pathogens (e.g. protozoans or viruses) or naturally occurring pathogenic microorganisms (e.g. *Vibrio* spp.).~~-~~ In addition, pathogens may be present in the absence of indicator microorganisms. Notwithstanding these issues, testing for indicator microorganisms affords a better degree of health protection than testing for pathogens alone.

~~78.~~77. ~~Depending on the types and sources of water used/reused and the specific circumstances of an operation, testing for different indicator microorganisms for different waters and/or at different steps in the production and processing of fish and fishery products may be necessary. Given the lack of appropriate indicators for certain pathogens in some water use scenarios, direct monitoring for those pathogens at an appropriate frequency may also be considered. In some circumstances, monitoring certain physico-chemical parameters may be useful in assessing the microbiological quality and safety of water.~~If the water is not potable nor clean, the in-depth water fit-for-purpose assessment of the type and source of water to be used/reused/reconditioned should include an evaluation of processes and procedures specific to the operation to determine which indicator(s) are appropriate for monitoring the microbiological safety of the water. In some circumstances, monitoring certain physico-chemical parameters may be useful in assessing the microbiological safety of water. Direct monitoring for pathogens may still be required, at an appropriate frequency, where suitable indicators for particular pathogens are not available.

~~79.~~78. Geographical region and temperature of seawater should be considered as they may impact the level of ~~potentially~~ pathogenic bacteria, viruses, and parasites, and hence the utility of indicator organisms.

~~80.~~79. When monitoring water quality in a harvest region or area, contamination risks from surface or groundwater from the immediate area of the catchment, as well as further upstream in the catchment area should be assessed. In addition, seasonal and climatic factors across the whole water catchment area should be considered.

~~81.~~80. When establishing a new monitoring programme for the microbiological ~~quality and~~ safety of water, it may be appropriate to begin with frequent sampling ~~sample and~~ testing ~~water at a frequency~~ to rapidly establish a baseline profile of water ~~quality~~ safety. This baseline can then inform ~~and to consider~~ the design of subsequent monitoring, which may be ~~at a lesser frequency~~involve reduced sampling frequency, as appropriate. The selection of an analytical method for water testing should meet the information and management needs of the monitoring program as determined by the fit-for-purpose assessment of the water system and its historical data. The selection may also consider the laboratory and human resources available, the speed of analyses required, and validation of the method for the specific type of water being analysed, among other factors.

~~82.~~81. Monitoring procedures should include a description of corrective actions that will be taken when testing identifies a potential problem with the microbiological quality or safety of water used/reused in the production or processing of fish and fishery products. The corrective actions can include additional microbiological testing of water (collected from various processing steps from the water supply to point of use) and/or the fish and fishery products.

Table 1. *Risk Ranking on the most significant waterborne microbiological hazards of relevance to fish and fishery products and their resistance to disinfection by chlorine*[11]

Microbiological HAZARD	RISK RANKING	RESISTANCE TO CHLORINE
Bacteria		
Aeromonas hydrophila	++	Moderate
Bacillus cereus	++	High (spores)
Campylobacter jejuni/*C. coli*	+++	Low
Clostridium botulinum	+++	High (spores)
Escherichia coli, pathogenic	+++	Low
Listeria monocytogenes	+++	Moderate
Pseudomonas aeruginosa	+	Moderate
Non-tuberculosis mycobacteria	+	High
Salmonella enterica, all serovars	+++	Low
Salmonella, typhoid	+++	Low
Shigella spp.	+++	Low
Vibrio cholerae	+++	Low
Vibrio parahaemolyticus	+++	Low
Vibrio vulnificus	+++	Low
Vibrio, other species	+	Low
Yersinia enterocolitica	++	Low
Viruses		
Enteroviruses	+++	Moderate
Hepatitis A virus (HAV)	+++	Moderate
Hepatitis E virus (HEV)	+++	Moderate
Norovirus and ~~sapovirus~~Sapovirus	+++	Moderate
Rotavirus	+++	Moderate
Protozoans		
Acanthamoeba spp.	+	High
Cryptosporidium parvum	++	High
Cyclospora cayetanensis	++	High
Entamoeba histolytica	+++	High
Giardia lamblia	+++	High
Toxoplasma gondii	+++	High
Helminths		
Anisakis spp.	+++	N.R.
Dracunculus medinensis	+++	Moderate
Schistosoma spp.	+++	Moderate
Diphyllobothrium latum	++	N.R.

N.R. = Not relevant.

Note: The risk ranking in the table refers to the risk for consumers of fishery products and is based on the perceived frequency and consequence of disease: (+) low risk to consumers; (++) common cause of foodborne disease, but of variable importance for fishery products; and (+++) cause of disease by fishery products and of potentially high risk to consumers. The hazards listed are assumed to represent all regions globally and include those hazards relevant to all types of water, including fresh-, brackish- and seawater. The selection of hazards when evaluating risk should be based on local circumstances, particularly where the water is used.

[11] Adapted from FAO & WHO. 2023. Safety and quality of water used in the production and processing of fish and fishery products – Meeting report. Microbiological Risk Assessment Series, No. 41. Rome. https://doi.org/10.4060/cc4356en

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 ~~and for~~as well as on the recovery and treatment of reuse water with recommendations for their safe application.

6. These recommendations apply across, ~~and should be used as additional guidance for,~~ 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-i~~I~~n-p~~P~~lace (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 ~~would~~ potentially allow ~~the potential presence or proliferation of~~ pathogen~~s~~ contamination or proliferation, a failure in process hygiene or in food processing. Examples of indicator microorganisms include mesophilic aerobic bacteria, coliforms, faecal 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 ~~F~~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 o~~O~~smosis 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 ~~under high-water pressure~~high pressure to overcome osmotic resistance, forcing water through a membrane retaining materials (retentate) and recovering the water (permeate), removing most dissolved solids.

Reverse o~~O~~smosis p~~P~~olisher 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.

8bis 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 aret~~The identification of known and potential microbiological hazards that have capacity to cause damage to water safety should be conducted at each step, where appropriate, for water usage from externally sourcing, and for recovery, reconditioning and application of reuse 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 an in-depth fit-for-purpose assessment if the source is confirmed to be safe for its intended purpose and periodically monitored, if needed,~~or it may be very simple~~ e.g., ~~when~~:

- 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 ~~of~~ 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.

10 Table ~~2~~ 1 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 1~~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
Food ingredient	Not fit for purpose unless appropriate treatment is applied and the microbiological criteria of potable water are complied with	Not fit for purpose unless appropriate treatment is applied and the microbiological criteria of potable water are complied with	Not fit for purpose unless appropriate treatment is applied and the microbiological criteria 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	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		

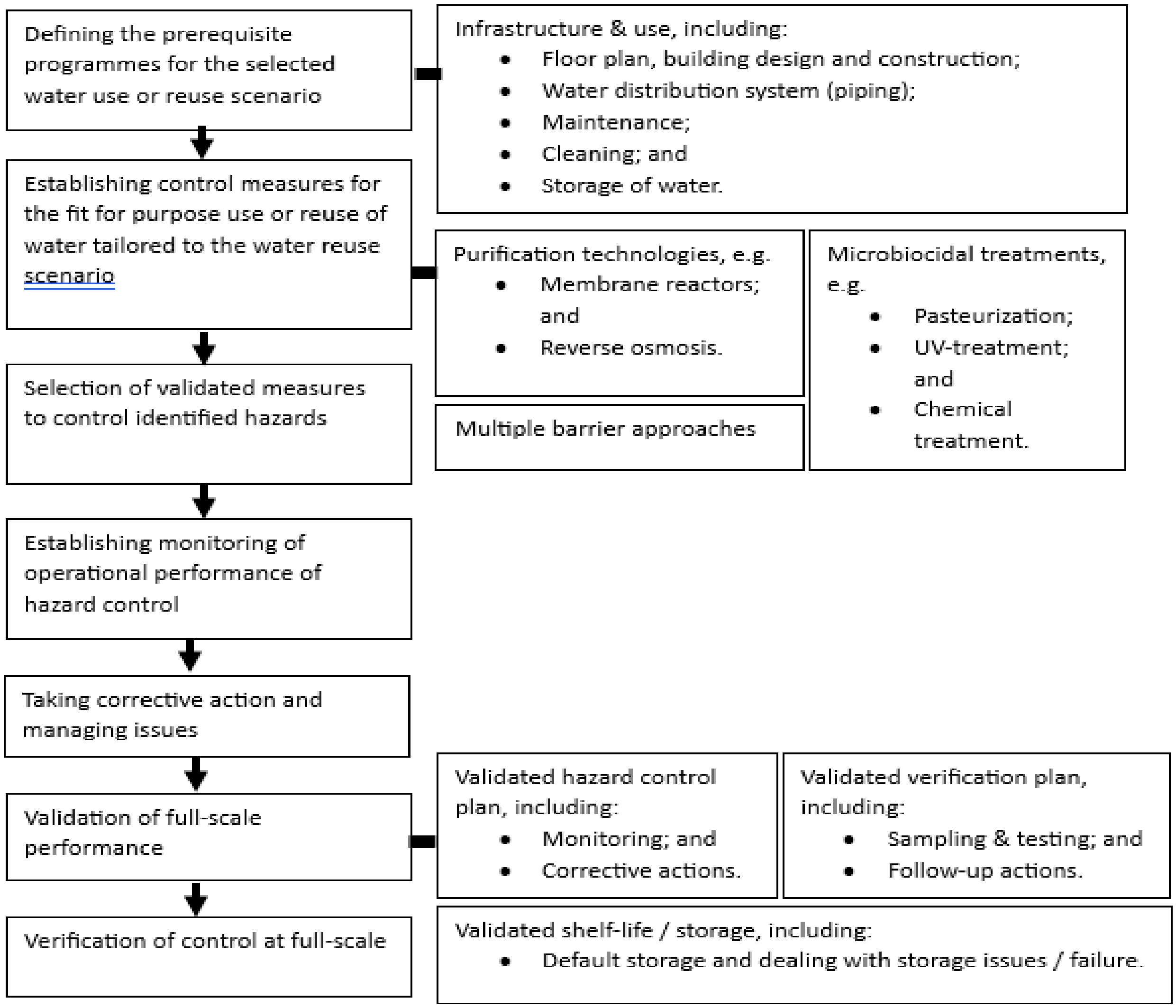
6. WATER SAFETY MANAGEMENT

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

12. 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.~~13. 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)

14. 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. ~~In the context of water reuse in a food manufacturing operation and for hazard control,~~ mainly for reuse scenarios in processing facilities, PRPs should, where applicable, 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.

15. 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 ~~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 as self-draining systems minimize biofilm formation and contamination risk during downtime.

16. 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 ~~things~~ 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.

17. 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 ~~be made~~given 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.

18. 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 ~~bactericidal agent~~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.

19. 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~~al~~ 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~~7~~) 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

"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. It may be determined that a pre-requisite program alone may be sufficient to manage the hazards, e.g. when only potable or clean water is used. For other situations, a hazard analysis to ensure the safe use and reuse of water within plants is required and control measures for the fit for purpose use or reuse of water identified. These 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 the available treatment technologies to develop an effective prerequisite program on water reuse."

20 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.

21. A water safety management plan for the ~~Control measures 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~~se~~ 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 ~~, use of the source water, collection and storage of the used water and the available treatment technologies~~ to develop an effective prerequisite program on water reuse.

22. 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.

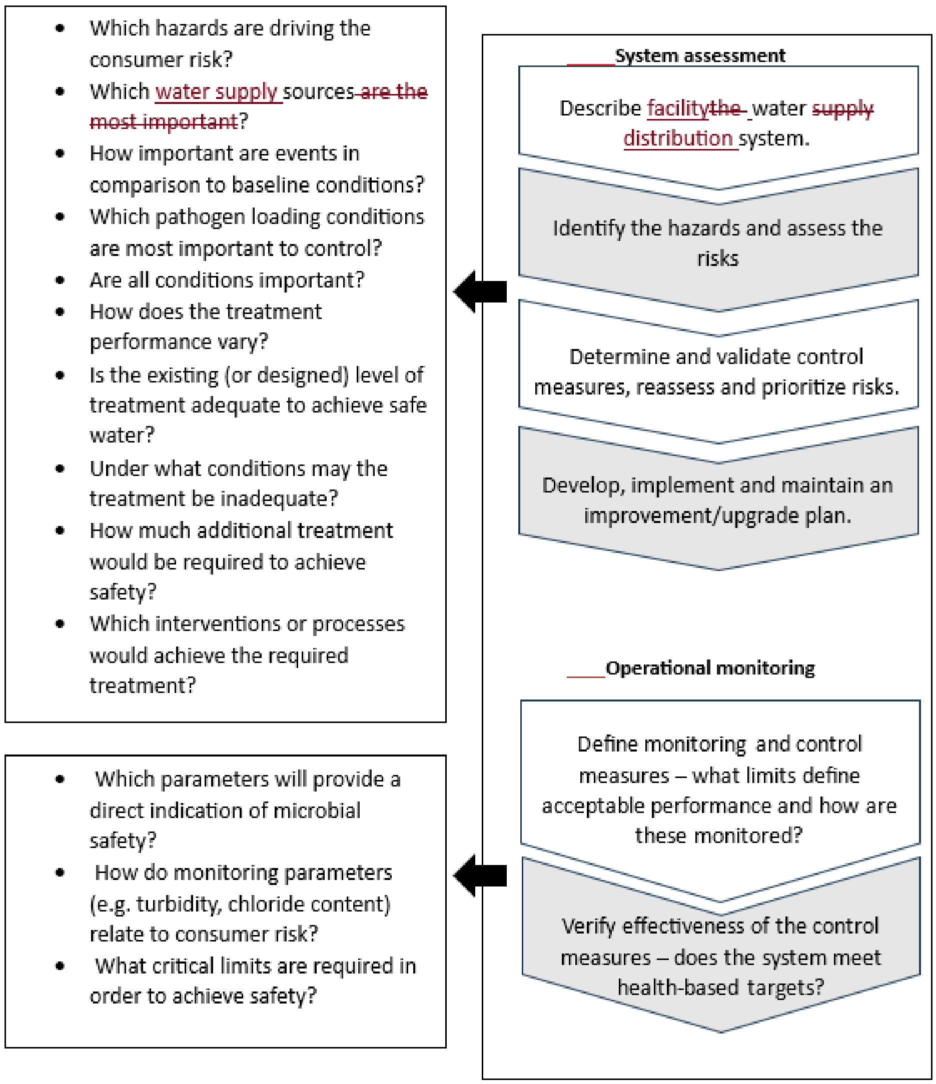
23. All water uses should be included in the water safety management plan. If the water is intended for food contact (direct and indirect), the results of the hazard analysis of all reasonably foreseeable hazards should be included as input to the hazard analysis for the food products that will be impacted.

24. 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 **Water safety management plan for fit-for-purpose use and reuse of water**

Water generation system



25. 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.

26. 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 Agricultur~~e~~al Practices, Good Manufacturing Practices, Good Hygiene Practices (GHPs), HACCP) is adequate. Both follow essentially similar development and implementation steps.

27. 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 ~~don't~~do not pose a food safety risk through the food processing equipment or food product to consumers.

28. 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.

29. 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~~ 2 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 2~~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 •Chemical[1] residue •Physical[1]~~1~~ (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.

~~6.2~~6.3 Selection of measures to control identified hazards

30. ~~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~~. 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.

31. 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 microbiological and chemical (for example chlorinated) profile of 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;

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

- 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.

32. 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 ~~control measures at~~ CCPs within a HACCP system. ~~Pe.g~~For example,~~.~~ purification or microbiocidal treatment at reconditioning might be ~~an~~ 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.

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

~~6.3~~6.4 Monitoring

34 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.

35. 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.

36. 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 ~~trending~~ 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.

~~6.4~~6.5 Corrective actions

37. 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;
- ~~i~~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~~isolate water that did not meet established safety and quality performance criteria and consider discarding, until root-cause has been identified and corrected, or consider reconditioning~~;
- 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;
- ~~separately assess risk of affected product that ‘potentially unsafe‘ water came into contact with;~~
- 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.~~;~~
- ~~identify any potentially impacted food products and take actions as appropriate.~~

~~6.5~~6.6 Validation

38. 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).

39. 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.

~~6.6~~6.7 Verification and testing

40. 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.

41. 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 control~~(~~s~~)~~ 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**.**

42. 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.

43. 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.

44. 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.

7. TECHNOLOGIES

45. Several technologies have been developed to treat water at sour~~c~~e or at recovery from production or processing for reuse. Reconditioning may use treatments or a combination of treatments such as membrane

[2] https://doi.org/10.4060/cc4081en
~~https://www.fao.org/3/cc4081en/cc4081en.pdf~~

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 ultrasonication[3] or bactofugation[4] 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.

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

- determination of microbiological[5] 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~~and/or centrifugation[5]

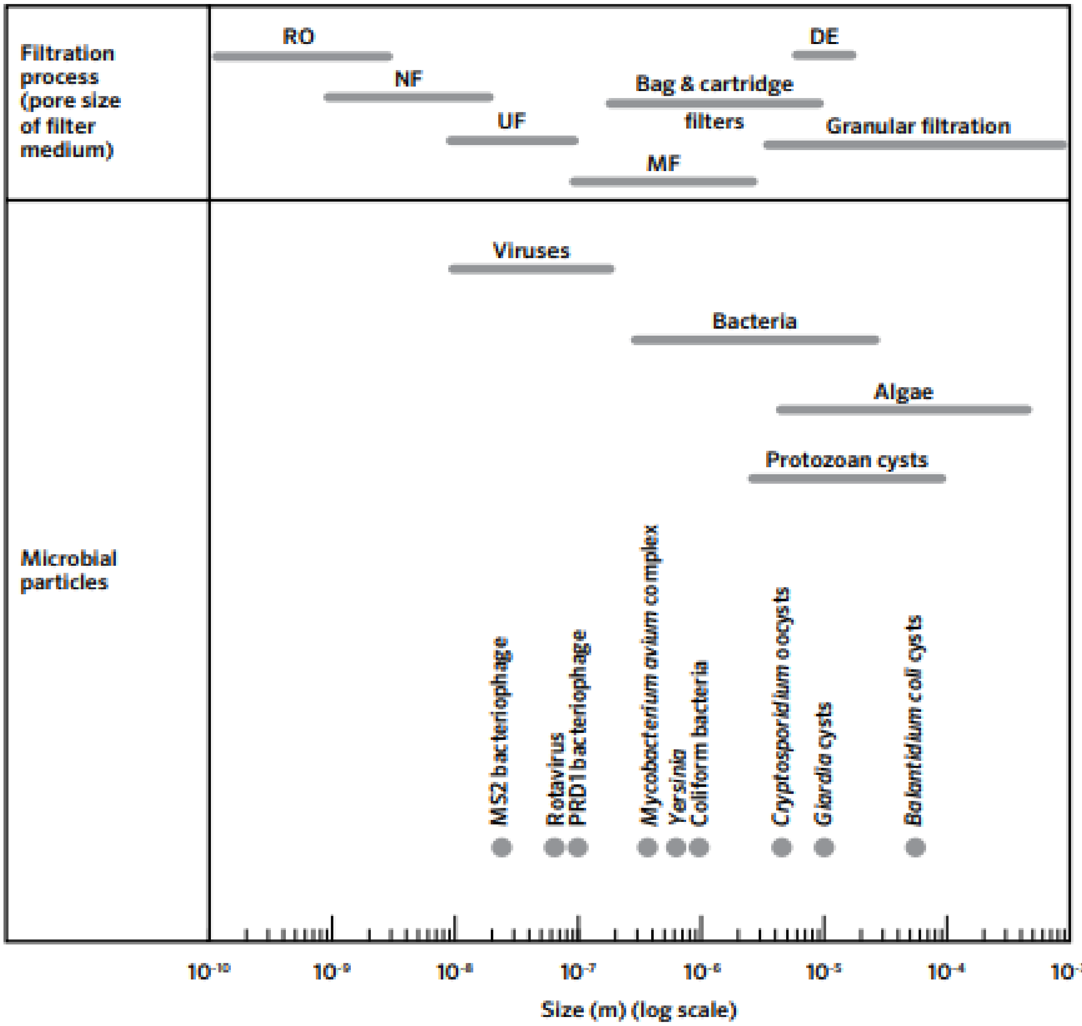
47. These technologies may be applied, alone or in combination, to effluents (e.g. of dairy manufacturing). Examples are ~~simple~~ sedimentation, coagulation-sedimentation, high-rate sand filtration, activated carbon filtration and dissolved air flo~~a~~tation to remove organic matters. They should be considered as preliminary treatments since they will not remove all contaminants, including pathogens ~~that might be~~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

48. 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*

[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 ~~hazards~~ characteristics and hazards are out of the scope of this guidance but relevant to be considered.



49. 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 ~~must~~ 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.

50. 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.

51. 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.

52. Membrane bioreactor (MBR) (aerobic or anaerobic digestion) can be used for the pretreatment ~~technology is a tool for the pre-treatment~~ 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.

53. 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

54. Chlorine, chlorine dioxide, ozone, hydrogen peroxide and peracetic acid are examples of chemical~~s~~ 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 ~~stainless steel~~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 microbiologic al 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, ~~this~~ which ~~might~~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, ~~and~~ reacts slower compared to free chlorine, ~~it~~ and has the advantage of being effective for a longer period.~~being more persistent.~~
- 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.

55. 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 ~~that~~ in order to~~would~~ render the water ~~not~~ 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.

56. UV treatment of reuse water can be used to reduce some populations of bacteria, viruses, moulds, yeast and protozoa, if the effective ~~correct~~ UV wavelength and dose are applied. Continuous monitoring (including alerts), regular maintenance, ~~e 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 ~~correct~~ optimum ~~range of~~ UV light wavelength for ~~effective~~ anti-microbial effect is 254 nanometers, recognizing the optimum wavelength for anti-microbial effect needs to be validated depending on the pathogen. T~~with t~~he 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.

57. 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.