CODEX ALIMENTARIUS COMMISSION

Food and Agriculture Organization of the United Nations

World Health Organization

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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

CODEX COMMITTEE ON FOOD HYGIENE

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Draft Guidelines for the Safe Use and Reuse of Water in Food Production and Processing (Annexes on water re-use in fish and fishery products (renamed from Fishery products) and on the production of milk and milk products (renamed from Dairy Products)

(Prepared by the electronic working group chaired by the European Union (EU) and co-chaired by Chile and the International Dairy Federation)

Codex Members and Observers wishing to submit comments on the discussion paper should do so as instructed in CL 2024/01/FH available on the Codex webpage/Circular Letters 2024: https://www.fao.org/fao-who-codexalimentarius/resources/circular-letters/en/

INTRODUCTION

1. At the 51st Session of the Codex Committee on Food Hygiene (CCFH51)[1] in November 2019, Honduras, Chile, Denmark, India, and the European Union introduced a discussion paper and project document on Guidelines for the safe use and reuse of water in food production. CCFH51 agreed to take on this new work and to structure the document to include overarching guidance followed by commodity-specific guidance. CCFH51 further agreed that the guidelines should be developed using a stepwise approach, with fresh produce and fishery products being priorities, followed by dairy products.

2. CCFH53[2] agreed to forward the proposed draft General Section of the Guidelines and its Annex I (Fresh produce) for adoption at Step 5/8 by CAC46 during its meeting from 27/11 till 2/12/2023. CAC46 adopted this text[3].

3. CCFH53 also agreed to establish an EWG, chaired by the EU and co-chaired by Chile and the International Dairy Federation (IDF) to:

a) further develop the Annex on fishery products (Annex II to the Guidelines) taking into consideration the written comments that were submitted through the OCS in response to CL 2022/49-FH, and CRDs submitted at CCFH53, as well as the general section of the guidance as agreed at CCFH53;

b) initiate the development of the Annex on dairy products (Annex III to the Guidelines), taking into consideration the general section of the guidance as agreed at CCFH53; and

c) prepare a report and revised text to be submitted to the Codex Secretarial three months before CCFH54 for circulation for comments at Step 3.

4. CCFH53 also agreed to establish a physical working group (PWG), chaired by the EU and co-chaired by Chile and IDF to be held in conjunction with CCFH54 to consider all comments received and to prepare a revised proposal for consideration by the plenary considering comments received at Step 3 and prepare recommendations for consideration by the plenary.

[1] REP20/FH para. 116
[2] REP23/FH para. 124
[3] REP23/CAC para. 31

PARTICIPATION AND METHODOLOGY

5. An invitation was sent to all Codex Members and Observers to participate in the EWG. Participants from 28 Members and 2 Observers were registered. The list of participants is attached as Appendix II. The EWG work was conducted using the Codex online platform.

6. Annex III on Milk and Milk Products (renamed from Dairy Products) went through two rounds of comments by EWG members and revisions by the co-chairs. An initial draft was posted on the Forum in March-April 2023 for the first round of consultation and a revised version was posted in the first half of July 2023 for the second round of comments by 15 September 2023. For the second round, comments were received from 15 Members and one Observer by 20 September 2023.

7. Annex II on Fishery Products went through one round of comments by EWG members and revision by the co-Chairs. The revised draft Annexes were posted on the Forum in the first half of July 2023 for comments by 15 September 2023. Comments were received from 17 Members by 20 September 2023.

8. Comments from the EWG have been addressed by the co-Chairs to the extent possible. Sometimes a compromise has been sought when comments were contradictory. A lot of comments were mainly editorial with the purpose of improving the draft.

9. The co-Chairs asked for input from the EWG on a number of issues in the documents circulated, including structure, definitions, inclusion of figures/decision trees and specific limits from JEMRA reports (relevant volumes from the Microbiological Risk Assessment (MRA) Series), consistency with terminology from the General Section or from the JEMRA reports and the inclusion of technologies for recovery, purification and treatment of water in Annex III on Milk and Milk Products.

SUMMARY OF DISCUSSION

10. On Annex II on Fishery Products, the main comments were related to the need for the alignment of the structures with Annexes I and III, which was taken into account. Comments were also received regarding the terminology used e.g. “fish and fishery products” was agreed as the title of the Annex and to be used throughout the whole document and “water safety plan” was changed into “water fit for purpose assessment” in line with the General Section. Finally, figures were redone based on the JEMRA reports for better understanding and usability.

11. On Annex III on Milk and Milk Products, members of the EWG overall expressed agreement with the proposed structure and definitions. The EWG agreed to the proposal of the co- Chairs to add “milk” in the title as the guidance includes primary production. It was also agreed by the EWG to replace “dairy products” with “milk products” for consistency with the wording of the Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004). As a result, the title was revised to refer to the production of milk and milk products.

12. Some members identified a certain repetition in Annex III with part of the General Section ("water fit for purpose assessment” and “water safety management”), but most found the more developed recommendations useful and preferred to maintain them. Some definitions were considered redundant and therefore deleted. There was general support to include specific limits proposed by JEMRA as examples in the draft Annex III. Positions were divided on referring to a “Water Safety Plan” (as in the JEMRA report MRA40) or rather align this terminology with the wording in the General Section. The co-Chairs decided to propose the second option.

13. The first drafts of Annex III contained an overview of technologies for the recovery and treatment of reuse water with recommendations for their safe application. These technologies are very much used in dairy production but are also relevant for the sectors covered in the other Annexes. The recommendations themselves were considered very useful by almost all members. The co-Chairs therefore propose to put them in a separate Annex IV containing an overview of technologies relevant for the different Annexes with recommendations for their safe application. Specific recommendations related to technologies for the production of milk and milk product were maintained in Annex III.

14. Based on the comments received, the co-Chairs have revised Annexes II, III and prepared a new Annex IV which are attached in Appendix I of this document.

15. The co-Chairs have included specific questions for Members when providing comments in response to the Circular Letter and by the Physical Working Group that will be convened at the margins of CCFH54.

CONCLUSIONS

16. The EWG completed the tasks assigned by CCFH53 and drafted a document composed of the Annexes on Fish and Fishery Products and on the Production of Milk and Milk Products, respectively. Since relevant for several Annexes, part of the original Annex on Production of Milk and Milk Products was separated out into a new Annex IV on technologies for recovery and treatment of water for reuse.

RECOMMENDATIONS

17. CCFH54 is invited to consider:

i. the proposed draft Guidelines as presented in Appendix I: Annexes II to IV, respectively on "Fish and Fishery Products", "Production of Milk and Milk Products" and "Technologies for recovery and treatment of water for reuse", and provide their inputs; and

ii. specifically provide input on the following:

a) whether you agree with the proposed new Annex IV and consider it appropriate to maintain it.

b) if the proposed Annex IV is maintained:

- whether you consider a restricted revision of the General Section appropriate with the purpose to introduce a cross-reference to this new Annex IV; and
- whether you consider a restricted revision of the Annex I on Fresh Produce appropriate with the purpose to introduce a cross-reference to this new Annex IV and indicate which technologies are most relevant for Annex I.

18. Following resolution of the above issues, it is recommended that CCFH54 consider advancement of these Annexes in the step process.

Appendix I

Annex II: Fish and Fishery Products

1. INTRODUCTION

1. The fisheries and aquaculture sector plays an important role in the economy of many countries and water is a key element in the production and processing of fish and fishery products.

2. Water used in the production and processing of fish and fishery products can be obtained from many sources, namely: potable water from a public or private water supply system, fresh surface water, groundwater sources, harvested rainwater, seawater and brackish water, desalinated water, recycled water from production or processing step within an establishment or reused water originating from agricultural activities (e.g. hydroponics), etc.

3. These waters can be subject to many detrimental effects from climate change, pollution associated with population growth and development, and higher demands for food production and other uses (JEMRA 2021).

4. Fish and fishery products are generally regarded as safe, healthy, and nutritious foods. However, these products have been associated with infections and intoxications mediated by viruses (principally norovirus and Hepatitis A), bacteria (principally *Vibrio* spp. and *Salmonella* spp.), protozoans (principally *Giardia lamblia*. And *Cryptosporidium parvum*), marine biotoxins and helminths (principally *Anisakis* spp.). The causes of such fishery products safety concerns are diverse, ranging from naturally – occurring microorganisms and parasites to contamination of primary production environments and/or poor hygiene practices during processing and consumption. Depending on the pathogen, they can remain infectious in sources of water for a considerable period of time and affect the suitability of a site to produce or harvest fish and fishery products[4].

5. Water has multiple applications in the fisheries and aquaculture sectors, and water quality could impact the safety of the final product. This annex provides guidance on ensuring quality of water used in aquaculture and in fish and fishery products processing at vessels and throughout processing facilities.

6. There are multiple opportunities for reusing water in these sectors, especially in processing activities. To avoid the use of excessive amounts of water in production and processing of fish and fishery products, there is also a need to implement more sustainable practices for the management and efficient use/reuse of water resources. The type of application for reused water will determine whether that water is fit-for-purpose and/or a specific treatment is required before it can be used. (JEMRA, 2021).

7. A Water fit for purpose assessment, which encompasses the use of a comprehensive risk assessment and further risk management approach to the entire water supply from the catchment or source to its final use, may be an effective means to ensure fit for purpose water.

2. PURPOSE AND SCOPE

8. 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 applying the principle of ‘fit for purpose’ and using a risk-based approach.

3. USE

9. This Annex is complimentary to and should be used in conjunction with the General section and the following Codex Alimentarius standards:

- *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),
- *Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods* (CXG 21-1997),

[4] 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

• *Guidelines on the Application of General Principles of Food Hygiene to the Control of Foodborne Parasites* (CXG88-2016)*, and*

• *Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food* (CXG79-2012)

4. DEFINITIONS

10. See the general part of these *Guidelines for the Safe Use and Reuse of Water in Food Production*.

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

Evisceration (gutting): The removal of gills, viscera, and other internal organs.

Fishery products: Any species of fish, including crustaceans, molluscs (including live bivalve molluscs), marine gastropods, echinoderm, tunicates, or part of them intended for human consumption.

Processing facilities: A facility where harvested fish and fishery products are processed, graded, and packed for further transportation and consumption.

5. AQUACULTURE PRODUCTION SITES (REARING), HARVESTING AND (ON-BOARD) PRESERVATION

12. In aquaculture systems, the source of water varies according to the species, geographical location, and water availability. Seawater is used in marine aquaculture while inland aquaculture uses mainly surface and groundwater sources. Depending on 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 indigenous potentially pathogenic bacteria, such as *Vibrio* spp., that may require monitoring and control.

13. Food Business Operator (FBO) should consider the following in assessing and managing water which is intended for use at rearing or harvesting:

- The use and reuse of water should be subject to a risk-based approach 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”). In this context, sanitary surveys/profiling and a 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 quality in abstraction points should be extended upstream, when possible, to include the whole water catchment area.

- Elaboration and implementation of fit-for-purpose assessment considering the specific waterborne hazards (e.g. marine microbiological contaminants) that may impact the safety and quality of the fishery product(s). In case of catchment of fish, seasonal and climatic factors affecting source water quality in the immediate area should be included.

14. Many different types and sizes of fishing vessels are used throughout the world for harvesting based on the environment and the types of fish and fishery products caught or harvested. Water use in the vessels may vary from onboard preservation purposes to evisceration and further processing of the fish and fishery products. Onboard preservation can be done by chilling or freezing the fish and fishery products. The most common means of chilling is using ice. Other means are chilled water, ice slurries (of both seawater and freshwater), and refrigerated seawater, including brine freezers. When considering sources of water, including for the manufacture of ice, chilling, or cleaning in onboard fishing vessels, brackish water or seawater will be the natural choice for the water source.

15. If seawater is used on fishing vessels, it must only be taken from offshore areas that are some distance away from pollution sources to ensure that the water is of suitable quality. There should be no cross-contamination between the point at which seawater is taken from offshore sources and wastewater streams and engine coolant outlets on a fishing vessel.

16. It is essential that the seawater used is free from microbiological hazards that could pose risks to human health and the following recommendations should be considered:

- When seawater or refrigerated seawater is used for on board product preservation, the potential hazards (e.g. faecal pollution or contamination with endogenous marine flora) conveyed via the water should be considered in the further processing steps.

- seawater known to have with high salinity and free from particulate material will increase seawater quality prior to treatment, since the level of presence of naturally occurring marine microorganism are associated with temperature and salinity as well as sediments.

- Water use in direct contact with fishery products during processing and preservation activities (such as washing whole fish and rinsing the fish cavity after beheading, evisceration, skinning, and trimming) should be fit for purpose and don´t add contamination to the fish or fishery product.

6. FISHERY PRODUCTS PROCESSING PLANT

17. Water is used in fishery products facilities for a variety of applications, including, washing fishery products, cleaning process areas, cooling, and other processing purposes such as brining, cooking and glazing. The characteristics of the process activity (e.g. direct contact with food) and the intended use of the fishery product (e.g. raw consumption or not) should be considered for the quality of water used. Water used as ingredient or water that comes into direct contact with fishery products or food contact surfaces should be of potable quality.

18. The use of non-potable water is allowed during handling and processing, as long as its use does not compromise the safety of the product(s) or further processing stages can eliminate the hazard posed by the non-potable water.

19. Water use and reuse should be tailored to the particular conditions of the specific fish processing operation it is applied to, considering the operation’s potential reusable water sources, the various applications of the reused water, available recovery and treatment technologies, and the capabilities of the operator.

20. In the fishery products production and processing industry, some common examples of where water is used are:

- for purification, depuration, conditioning[5] or reimmersion, in the case of live bivalve molluscs.
- as an ingredient,
- to transport/convey fishery products,
- to wash, cool down and cook fishery products,
- to clean and sanitize facilities, utensils, containers, and/or equipment,
- to make ice,
- other processing purposes such as brining fish, glazing of frozen fishery products to maintain quality during frozen storage,
- for personal hygiene purposes,
- for not food contact purposes.

21. If potable water is not available, or its use is not possible in the production and processing environment, a thorough identification of the risks linked to the water source is required and minimum quality requirements and criteria should be established based on risk-based approach.

22. In any production or processing facility, care must be taken to avoid contamination of the potable water system with non-potable water from other sources. 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 due to cross connections, backflows or back siphonage in the water plumbing systems and can result from improper installations, or additions/modifications to the existing plumbing. Before any processing or transformation stage at a fish and fishery products facility, water coming into direct or indirect contact with material or product must be sourced and, where necessary, tested and treated so that it complies with appropriate standards.

23. The decision on whether to use fresh or seawater in land-based processing plants, will depend on several factors, such as the type of water available, the availability of a regular water supply, the location of the ice plant, etc.

24. Coastal sources, used for abstraction of seawater in land-based processing plants, cannot be guaranteed to be free from pathogens from the marine biota or from faecal contamination, and cannot be classified as fit-for-purpose sources without the appropriate monitoring and control measures. Seawater from offshore sources (geographically away from inland or inland pollution) is generally considered safe. However,

[5] Bivalve Molluscs Conditioning: Placing live bivalve molluscs in tanks, floats, or natural sites to remove sand, mud or slime and improve product acceptability (CXC 52-2003).

depending on the geographical region and temperature, seawater can hold indigenous potentially pathogenic bacteria, such as *Vibrio* spp., that may require control.

7. GENERAL RECOMMENDATIONS

25. Where disinfection forms part of the water treatment or any other water treatment, the effectiveness should be validated.

8. WATER INTENDED FOR REUSE

26. Treated wastewater or water originating from agricultural activities (e.g. hydroponics) may be reused, as long as the microbiological quality of the wastewater is safe and thoroughly controlled.

27. Water reuse can be made more efficient by targeting the water quality requirements to specific processes. Matching water quality requirements with the type of water use requires an analysis of the critical control points (CCPs) and an evaluation of the potential for contamination of the food products. Reuse of water in the processing facility should be integrated into existing HACCP programs alongside the development of frameworks for water reuse in food/production and processing.

28. There are also multiple ways of reusing water in aquaculture, for example, integrated multi-trophic aquaculture systems, where multiple aquatic species from different trophic levels are farmed in an integrated fashion (e.g. finfish and seaweed) with benefits such as improved efficiency and reduced waste. Another example is the aquaponic system[6], which integrates recirculating aquaculture and hydroponics into a single production system as is shown in Figure 4.

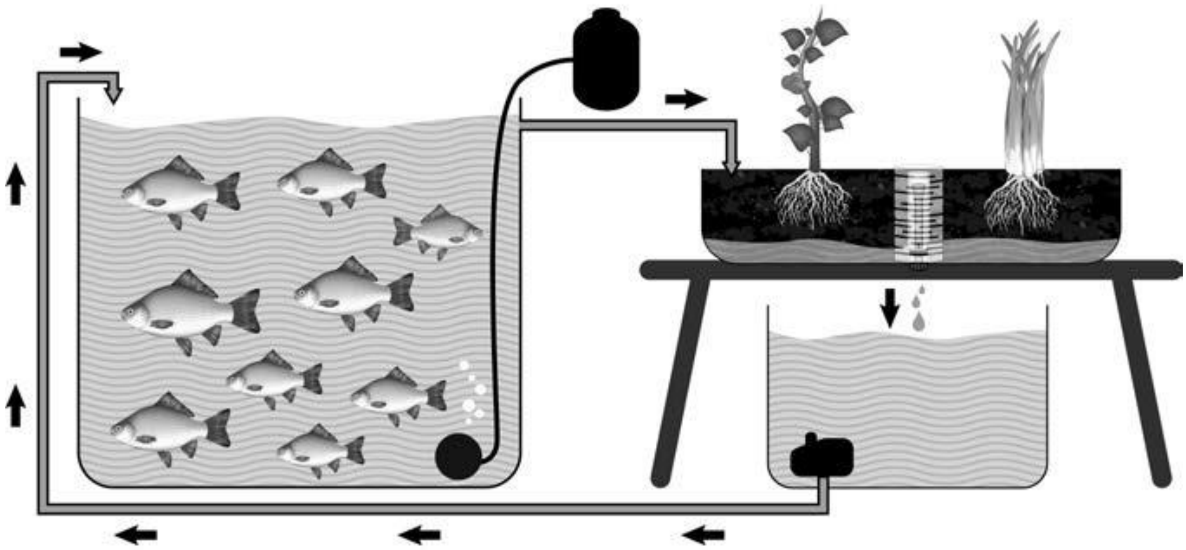


Figure 4: Schematic of a simple aquaponic unit[7]

9. WATER USE OR REUSE FIT FOR PURPOSE ASSESSMENT

29. Any water reuse scenario considered for implementation, should consider the following in assessing and managing microorganisms in water:

- ensuring the safety of water using a risk-based approach covering the whole water system from the source to the point of use;
- elaboration and implementation of fit for purpose assessment and management procedures and implement efficient monitoring plans; and
- ensuring fit for purpose assessment considers the specific waterborne hazards (e.g. marine microbial contaminants) that may impact the safety and quality of the fish and fishery product(s).

[6] 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

[7] 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. Some of the most relevant biohazards and their relative risk which may be considered under a water fit for purpose assessment are listed in Table 1.

9.1 Examples of Decision Trees (DTs) to identify possible critical control points (CCPs) with regards to water quality for fish and fishery products, potentially eaten raw or undercooked[8].

31. Recommendations on best hygiene practice related to the use and reuse of water in the Code of Practice for Fish and Fishery Products (CXC 52-2003) are considered sufficient to control the microbiological risk from such water in case fish is eaten cooked. DTs may help to estimate the need for the consideration of possible CCPs related to the use and reuse of water when the fish and fishery products are potentially eaten raw or undercooked.

32. The possible CCPs should aim at controlling (e.g. freezing as control measures for parasites) of the pathogens most significant for the fish production. These pathogens should be identified by a case-by-case assessment (e.g. based on epidemiological data). In case of marine or estuarine fish, *Vibrio parahaemolyticus* (Vp) is often of most concern but this highly depends on the origin/area where the seawater is collected. In case of freshwater aquaculture, faecal (enteric) pathogens mostly represent the primary public health risk[9].

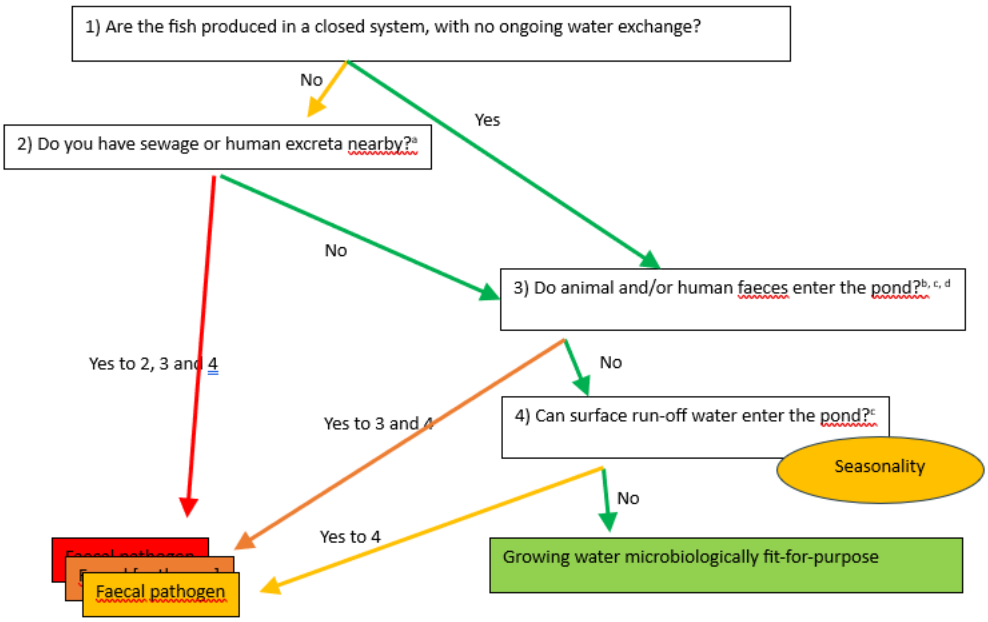
Example of DT to magnitude the risk of faecal pathogens in freshwater aquaculture (Adapted from Figure 4 of MRA33)

33. In case of production of fish in freshwater aquaculture, the DT in Figure 1 can be used to magnitude hazardous events (e.g. unacceptable presence of faecal pathogens) due to the use of water.

34. When one or several risk factors have been identified by the DT, the possible presence of faecal pathogens should be considered as a CCP until control measures have been introduced and validated. Detailed information on the possible control measures can be found in the FAO/WHO documents referred to by footnotes at different steps or in relevant national guides.

35. Seasonality refers to an enhanced risk in case of periods with higher temperatures or rain events increasing the risk of surface run-off water entering the pond.

Figure 1: Example of DT to magnitude the risk of faecal pathogens in freshwater aquaculture (*Adapted from Figure 4 of MRA33*)



a: WHO Sanitation Safety Plan Manual

b: Section 6 of the Codex Code of Practice for fish and Fishery products on aquaculture products

[8] Based on Microbiological Risk Assessment Series 33. Safety and Quality of Water Used in Food Production and Processing Meeting Report. https://www.fao.org/publications/card/en/c/CA6062EN/
[9] Table 2 of MRA33 provides a list of some fish associated pathogens. However, the list of enteric pathogens is long and may include others such as *Escherichia coli, Salmonella, Klebsiella, etc.* to be assessed on a case-by-case basis.

c: WHO Water Safety Plan. WHO/Europa 2014

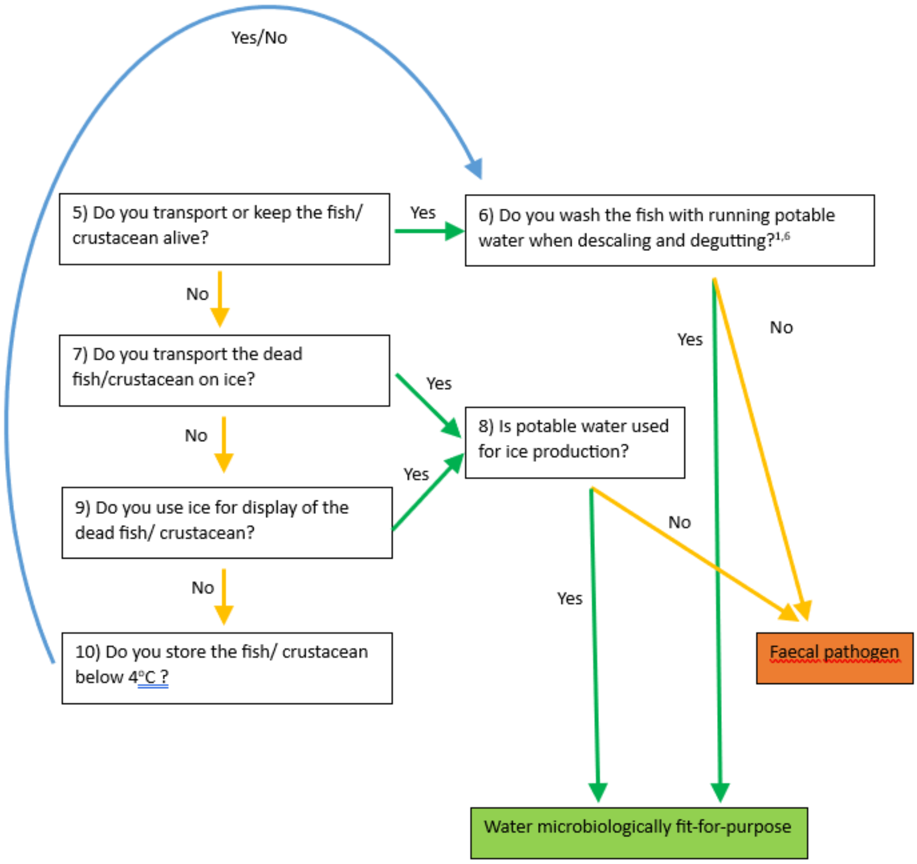
d: WHO Safe Use of Wastewater, Excreta and Grey Water. Vol 3. Aquaculture

Example of a DT for post-harvest handling and processing of freshwater fish which will potentially be eaten raw or undercooked (Adapted from Figure 5 of MRA33)

36. During post-harvest handling and processing of freshwater fish, the (continuing) DT in Figure 2 can be used to estimate the risk derived from the use of water.

37. Similar to freshwater aquaculture, when one or several risk factors have been identified by this DT, the possible presence of faecal pathogens should be considered as a CCP until control measures have been introduced and validated. Detailed information on the possible control measures at the descaling and degutting step can be found in Section 6 of the Codex Code of Practice for fish and fishery products or in national guides. The use of potable water at this step should also be applied for contact surfaces (knives, cutting boards). Keeping the fish at a low temperature (e.g. 4°C) is one of the most important measures related to fish preservation and microbial pathogen die-off after death. Seawater pathogens (e.g. Vp) may need to be considered when cross-contamination can occur at this stage between freshwater and seawater products.

Figure 2: Example of a DT for post-harvest handling and processing of freshwater fish which will potentially be eaten raw or undercooked *(Adapted from Figure 5 of MRA33)*



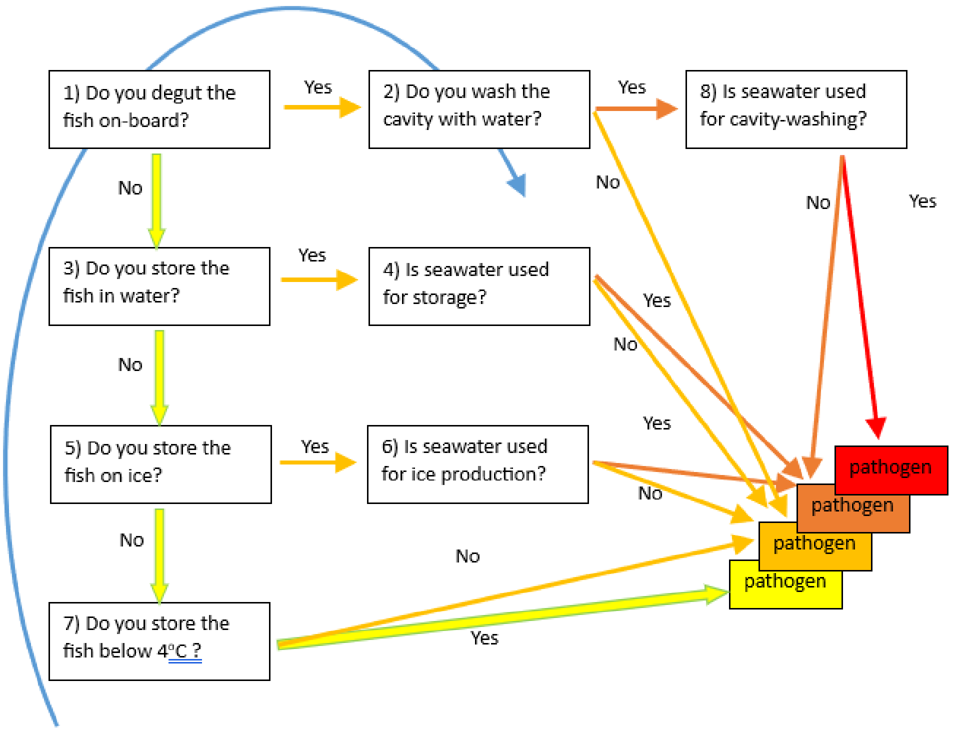
a: Section 6 of the Codex Code of Practice for fish and Fishery products on aquaculture products

Example of DTs in case of marine or estuarine fish, including crustacean, potentially eaten raw or undercooked.

38. In case of on-board handling and processing of marine or estuarine fish, the DT in Figure 3 can be used to magnitude hazardous events (e.g. unacceptable presence of Vp) due to the use of seawater.

39. The magnitude of hazardous event depends on the on-board activities such as degutting, cavity-washing and the storage conditions. Keeping the fish on-board at a low temperature (e.g. 4°C) is again one of the most important measures. When one or several risk factors have been identified by the DT, the possible presence of pathogens such as Vp should be considered as a CCP until the handling and processing have been reviewed to control the risk and this revision has been validated. The risk can be further reduced if seawater can be used from areas that are known to be less contaminated or when the possibility exists to use potable water on-board.

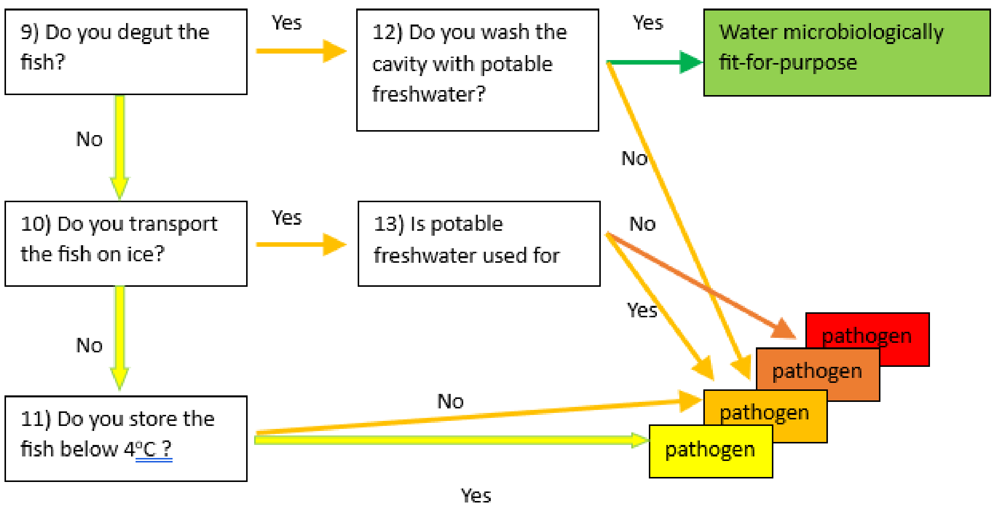
Figure 3: Example of DT to magnitude the risk of pathogens such as Vp, in on-board marine or estuarine handling and processing of fish (*Adapted from Figure 6 of MRA33*)



40. During onshore handling and processing of marine and estuarine fish, the (continuing) DT in Figure 4 can be used to estimate the risk from the use of water.

41. Similar to handling and processing of freshwater fish, when one or several risk factors have been identified by this DT, the possible presence of pathogens such as Vp should be considered as a CCP until control measures have been introduced and validated during on-shore handling and processing. Risk factors and control measures are similar as for post-harvest handling and processing of freshwater fish.

Figure 4: Example of DT to magnitude the risk of pathogens such as Vp, in onshore marine or estuarine handling and processing of fish (*Adapted from Figure 7 of MRA33*)



10. WATER SAFETY MANAGEMENT

42. Elaboration and implementation of management procedures, for instance the design of a management plan that should be site specific, consider relevant hazards and hazardous events and the outcomes of the fit-for-purpose assessment of the water system. Efficient and appropriate preventive measures should be

implemented, and possible corrective measures should be anticipated when required based on the outcome of the monitoring.

43. The management procedures should include measures for preventing cross-connections between the safe supply of water of potable quality and any unsafe or questionable supply of water of non-potable quality or sewer disposal system.

44. When reusing water, the need for water treatments (e.g. biological, chemical, physical, irradiation) should be considered to ensure that the water reuse system is safe, including conditions related to distribution, storage and use where relevant.

45. Implement plans with operational monitoring of the water used in the production and processing of fish and fishery products to provide insight into process performance and associated water safe and quality issues, enabling rapid remedial action in the event of nonconformity. Where appropriate, the plan should be supplemented with microbiological control of the finished fish and fishery products.

10.1 Treatments for fit for purpose water

46. Treatment options will have to be designed on a case-by-case basis and consider both the hazards from faecal pollution as well as those from the endogenous marine flora (e.g. pathogenic *Vibrio* spp. and *C. botulinum*).

47. There are several treatment technologies that can recover water of a quality that makes it fit-for-purpose or that can eliminate or inactivate microorganisms or reduce them to acceptable levels for use/reuse water. These treatment technologies including, but are not limited to, heating (e.g. pasteurization or boiling); use of a chemical disinfectant such as chlorine, chlorine dioxide, ozone; or physical treatments such as membrane filtration and irradiation (e.g. UV light). Guidance on resistance to chlorination by different microbiological hazards is provided in Table 1.

48. Appropriate parameters of treatments applied to reuse water intended to be used as a food ingredient or in a manner that will contact fish and fishery products should be monitored to ensure such water will be fit for purpose. The efficacy of such treatments should be periodically verified through appropriate microbiological testing of the treated water.

10.2 Water quality monitoring

49. Water monitoring is a core element of food safety management systems and is essential to ensure water quality and safety and to define fit-for-purpose water in the Fishery sector. Irrespective of the source, water used in the production and processing of fish and fishery products must be frequently monitored to ensure that it is safe.

50. Monitoring practices should be risk-based, covering the whole water system from the source to the point of use, including considering the historical data to determine the frequency of monitoring.

51. Fit for purpose assessment should include an operation-specific assessment to determine which indicator(s) (e.g. microbiological parameters) are appropriate to be used. Geographical region and temperature of seawater should be considered as they may impact the level of potentially pathogenic bacteria, viruses, and parasites.

52. No single microbiological indicator is suitable in all circumstances. Microbiological indicators have disadvantages that must be understood when using test results to assess the microbiological quality of water, when possible, testing for multiple groups of indicators should be more appropriate. Consideration should be given that on a sample-by-sample basis, there is rarely a direct correlation between indicator microorganisms such as coliform bacteria and indigenous marine pathogenic bacteria such as *Vibrio* spp. enteric protozoans, or viruses. The observed low correlations between microbiological indicators and pathogens, in different types of water used for food production and processing and the occasional failure of indicators to predict pathogen occurrence, should be given. However, testing for pathogens alone is also discouraged because this testing does not afford the degree of health protection given by testing for traditional non-pathogenic indicators.

53. An operation-specific assessment to determine which indicator(s) could be used to control the water source or the reconditioning treatment for water reuse should be more appropriate to conduct to control these hazards and reduce the risk of human exposure to pathogens.

54. When monitoring water quality in a harvest region or area, surface or groundwater quality should be characterized at abstraction points. In addition, upstream extension should also be considered, when possible, to include the whole water catchment area.

55. The selection of an analytical method for water testing should take into consideration the information and management needs of the monitoring program, the analytes and the laboratory and human resources

available, among others. The selection of parameters should be prioritized according to the outcomes of a fit for purpose assessment of the water system and its historical data.

Table 1. Risk Ranking on the most significant waterborne microbiological hazards of relevance to fish and fishery products[10].

Microbiological HAZARD	RESISTANCE TO CHLORINE	RISK RANKING
Aeromonas hydrophila	Moderate	++
Bacillus cereus	High	++
Campylobacter jejuni/*C. coli*	Low	+++
Clostridium botulinum	Low	+++
Escherichia coli, pathogenic	Low	+++
Listeria monocytogenes	Low	+++
Pseudomonas aeruginosa	Low	+
Nontuberculosis mycobacteria	Low	+
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	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.	+++
Dracunulus medinensis	Moderate	+++
Schistosoma spp.	Moderate	+++
Diphyllobothrium latum	N.R.	++

N.R. = Not relevant.

[10] 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

Notes: 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. 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.

Annex III: Production of Milk and Milk products

INTRODUCTION

1. Milk and milk products are an important and often essential source of food in many parts of the world and are a significantly traded food. Water is used for a wide range of activities in dairy operations, and the sector consumes a substantial volume of water for production processes, cleaning and disinfection. Other activities such as chilling and steam production may also have a high demand for water. At primary production, the availability of water fit-for-drinking for the animals may have a direct impact on animal health, as well as the amount, quality and safety of the milk being produced.

2. Milk naturally consists of 80 to 85% of water which may become available for use during certain processes (e.g. concentration and drying of milk products). Reuse of such water, being reclaimed water provides an additional source of water within dairy manufacturing plants. The reuse of reclaimed water from milk and other dairy products, and of recycled water in dairy manufacturing plants provides opportunities to significantly reduce the need for water from external sources. It can be an important tool for food business operators (FBOs) to address water scarcity and reduce the stress of water availability in certain parts of the world and/or under certain environmental circumstances.

3. If water used in the production of milk and milk products is not fit for its intended purpose, it may be a source of microbiological hazards such as *Listeria monocytogenes, Campylobacter* spp.*, Bacillus cereus, Staphylococcus aureus, Salmonella* spp. and Shiga-toxin producing *Escherichia coli*. The use of non-fit for purpose water in dairy operations may also contribute to the distribution and multiplication of such pathogens.

4. Guidelines on the fit-for-purpose use and reuse of water are essential to ensure the manufacturing of milk and milk products that are safe for consumption.

PURPOSE AND SCOPE

5. These guidelines provide recommendations for the microbiologically safe use and reuse of water from the dairy farm to the dairy manufacturing plant. These guidelines are intended for FBOs and competent authorities, as appropriate, to provide for practical and applicable reuse of water in the dairy sector. These guidelines also provide examples of fit-for-purpose use and reuse of water. The scope of these guidelines strongly focuses on the reuse of water since this provides a significant opportunity to limit the need for external water sources.

USE

6. These guidelines should be used in conjunction with the General Section of these guidelines and the following Codex Alimentarius guidance:

- Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004),
- 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 (CXG88-2016), and
- Guidelines on the Application of General Principles of Food Hygiene to the Control of Viruses in Food (CXG79-2012).

DEFINITIONS

Cleaning-In-Place (CIP) systems: water-based cleaning and disinfecting systems used to clean and disinfect product flow pipes and equipment without disassembly (*from MRA40*).

Dairy effluents: water from cleaning and disinfection, or other operations involving water, during the manufacture of milk products, including both for-food-contact applications and not-for-food-contact applications, and which contains identifiable substances. Dairy effluents do not include black[11] and grey[12] waters *(from MRA40).*

Indicator microorganisms[13]: microorganisms used as an indicator of quality, process efficacy, or the hygienic status of food, water, or the environment, commonly used to suggest conditions that would allow the potential presence or proliferation of pathogens. Examples of indicator microorganisms include mesophilic aerobic bacteria, coliforms or fecal coliforms, *E. coli* and Enterobacteriaceae (from the *Guidelines for the control of Shiga toxin-producing E. coli (STEC) in raw beef, fresh leafy vegetables, raw milk and raw milk cheeses, and sprouts*).

Permeate: the fluid derived from milk or other milk products obtained after removing milk constituents by membrane filtration (Ultra-filtration (UF), Micro-filtration (MF), Reverse Osmosis (RO), Reverse Osmosis & Polishing (ROP), Nano-Filtration (NF)) (*from MRA40*).

Stagnant Water: water that occurs as the result of setting, pooling or otherwise accumulating, allowing for the accumulation of organic matter and growth of unwanted microorganisms, yeast and mold. Usually found on floors and other areas that do not allow water to drain to floor drains.

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) *(from MRA40).*

PRIMARY PRODUCTION AND TRANSPORT FROM THE FARM

7. An adequate supply of water of a suitable quality (fit-for-purpose) should be available for use in the various operations, including further processing on dairy farms.

8. Water used as drinking water for animal should be fit for purpose and free from feed or faecal material to the extent of possible. Drinking troughs (or other vessels) should be regularly inspected and cleaned when dirty.

9. Fit-for-purpose water, preferably potable water, should be used when washing of the udder is recommended (e.g. when dirty), especially in the production of milk for raw milk products.

10. Water intended for drinking by animals should be analyzed periodically to determine microbiological quality (e.g. based on coliforms or aerobic total counts). The frequency of testing should depend on the risk associated with the water source and results from previous testing. The risk associated with the water source generally increases from municipality water, deep well water, hygienically collected rainwater, ground water to surface water.

11. Stagnant water in milking and storage facilities should be avoided.

12. Water fit for purpose should be available in areas designated for milking of dairy animals and milk storage, as well for use when rinsing, cleaning and disinfecting milking equipment, storage containers, vessels and tanks. It should be available at the dairy manufacturing plants, and elsewhere as required for the cleaning of transport facility equipment and tanks. Rinsing equipment, storage containers, vessels and tanks with water fit for purpose, should also be carried out after the use of biocides for disinfection, when necessary.

13. New water sources used for rinsing, cleaning and disinfecting the product contact surfaces of processing equipment, tanks, vessels and facilities for milk transport from dairy farms, should be tested for microbiological quality before first use, and then regularly thereafter in a similar way as in dairy manufacturing plants. Records of analyses should be kept and made available to competent authorities at their request.

14. When economically feasible at dairy farms or during transport, reusable water sourcing and reconditioning (as necessary) could add value for the milk production operations wishing to reduce overall consumption of externally sourced water, e.g. by collecting, recovering and reconditioning water used for rinsing and cleaning milking equipment and for cleaning on-farm milk storage containers, vessels and tanks. When reusing and reconditioning water, the guidance provided below for dairy manufacturing plants should be followed.

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[11] Source-separated wastewater from toilets, containing faeces, urine and flushing water (and eventually anal cleansing water in washing communities) (*definition from the "WHO guidelines for the safe use of wastewater, excreta and greywater"*)

[12] Water from the kitchen, bath and/or laundry, which generally does not contain significant concentrations of excreta (*definition from the "WHO guidelines for the safe use of wastewater, excreta and greywater")*

[13] Including utility microorganisms which are microorganisms occurring in food and food environments, originating from sources in which they are naturally present (e.g. water sources, raw materials or ingredients for foods) or from sources associated with food handling/processing (e.g. packaging material, the production environment, and utensils/utility equipment used in the operation) (from MRA40).

15. When raw milk is heat treated and concentrated using membrane filtration at the dairy farm, the water from the concentration process may be used for animals drinking, cleaning the milking and animal housing facility, as well as milking equipment, provided it is fit for purpose. Recycled sewage water or other water collected from the farm (e.g. from rinsing, cleaning and sanitizing, or from possible production of whey or wash of cheeses at the farm) can be used, for example, to irrigate grazing pastures or to clean non-food contact surfaces that cannot cause contamination.

DAIRY MANUFACTURING PLANT

16. Within a dairy manufacturing plant, water may be used as an ingredient, for cleaning and disinfecting production equipment, for heating and cooling of ingredients and finished milk products, as boiler feed water for the production of hot water and steam, and for facility (floors, walls, piping, etc.) cleaning, among other purposes. The availability and volume of water fit for purpose may be limited by geography, climate and competing demands. Also, the dairy industry is continuing to evolve, utilizing facilities with large processing capacities and subsequently, larger water requirements. This large, concentrated demand for water in a small geographic location can stress the availability of water for necessary purposes, such as drinking, irrigation, etc. Water reuse is an important strategy for reducing water consumption from external sources.

GENERAL RECOMMENDATIONS

17. Differentiation should be made between for-food-contact applications of water with direct or indirect contact with food materials (e.g. ingredient water, water used to wash, clean, or disinfect food contact surfaces) and non-food contact applications of water (e.g. technical steam, boiler feed, water needed to extinguish fires, or to wash vehicles (other than food and food ingredient transport vehicles), for cooling towers, to water lawns, to clean external surfaces or to flush toilets.

18. Measures should be taken to avoid or remove stagnant water, condensation or steam from dairy manufacturing plants by the design, operation and maintenance of the plant as quickly and frequently as possible. Ventilation should be adequate to reduce/eliminate steam and condensation accumulation.

19. Measures should be taken to capture in a sanitary manner, treat and reclaim water from various sources as quickly as possible after it first use or when it originates from milk, whey or other dairy products within a dairy manufacturing plant.

20. As a general recommendation, but subject to adaptation based on testing and evaluation, the following water could be considered as fit for purpose (See also Table 2):

- Potable water and reclaimed water from milk meeting potable water requirements can be used for any purpose in dairy manufacturing, including:
  - as a food ingredient;
  - for any direct or indirect contact with milk products, including for the cleaning, disinfection and final rinse of food-contact surfaces of processing equipment;
- Recycled water from the final rinsing of food-contact surfaces of processing equipment, tanks, vessels and utensils milking equipment, or from other sources subject to reconditioning, if necessary, can be used:
  - For the first or intermediate rinse during the cleaning and disinfecting of food-contact surfaces of processing equipment, tanks, vessels and utensils (with the possible addition of an acceptable level of biocides);
  - for cleaning non-food-contact surfaces (walls, floors);
  - For food-contact applications or for the final rinse, if the reuse water is subjected to a microbiocidal or other process, sufficient to reduce microbiological risk to an acceptable level (e.g. thermal, UV treatment, filtration, chlorination, ozonation).
- Other water may be used for boiler feed purposes, as cooling water/ice or for washing of other surfaces, if not in direct or indirect contact with food.

21. The dairy plant should have an external water supply providing enough water of potable water quality and the water handling systems within the plant should maintain water quality to the point of first use. It is the responsibility of the FBO to manage any microbiological contamination of the water supply on its premises. Sampling of water for microbiological testing is relevant upon any suspicion of contamination of the water on the premises.

22. Any external supply of other water to the dairy plant for the production of steam, firefighting and cooling is acceptable provided that the water handling system is dedicated for these purposes and is clearly marked.

23. If the FBO has identified contamination in the water supply, it should conduct an investigation and assess whether such contamination was a sporadic occurrence or represents a persistent problem that may require more extensive corrective actions. When a source of contamination is not evident, the FBO should contact relevant authorities, in most cases the municipality, to determine whether there is a general contamination of the water supply or whether the contamination originates at the plant and implement appropriate corrective actions to mitigate the cause of the contamination.

WATER INTENDED FOR REUSE

24. At dairy manufacturing plants, the technology to safely reuse water and dairy effluents to meet fit for purpose applications does exist, making this a viable option for dairy manufacturing plants to reduce their externally sourced water consumption. Attention must be given to address any health risks associated with using reuse water in food production.

25. The application for which water may be reused is dependent upon its source and how it is collected, stored and treated. Evaluating these elements will establish if the water is fit for the intended purpose. Water that potentially can be sourced for reuse include:

- water (reclaimed water) that originated from milk, dairy ingredients or was part of a milk product (e.g. in milk powder or cheese manufacturing), water that has come into a dairy operation in the form of potable water and is recirculated until it is no longer suitable as potable water,
- water that is being recirculated for heating or cooling purposes,
- water that has been used for cleaning processing equipment,
- water that has been used to clean facility floors, walls, ceilings, the outside of piping and processing equipment, etc., and
- water that is part of a dairy operation's effluent.

26. Based on the fit-for-purpose assessment such reuse water can be used for different purposes, subject to treatment when appropriate:

- as an ingredient;
- any direct or indirect contact with milk products and the product contact surfaces of dairy processing or milking equipment;
- the cleaning, disinfection and rinsing of product contact surfaces of processing equipment, tanks, vessels, pipelines, valves, utensils and equipment; water fit for purpose of rinsing before cleaning and disinfection (first rinsing) might not be fit for purpose of rinsing after cleaning and disinfection;
- cleaning non-product contact surfaces (walls, floors, etc.);
- boiler water feed; and
- heating or cooling of raw materials, ingredients and finished product.

Further, there might be laws and regulations addressing water reuse established by competent authorities that need to be followed.

27. Technical expertise, outside the dairy manufacturing plant, might be needed for the design of safe water reuse systems in dairy operations.

TECHNOLOGIES FOR RECOVERY AND TREATMENT OF WATER FOR REUSE

General recommendations

28. See Annex IV, including its definitions.

Specific recommendations for use of reverse osmosis in the reuse of water in dairy production

29. RO water recovered from permeates of for example whey or water mixtures resulting from equipment and pipeline flushes typically has very low microbial counts. When the performance efficiency of RO has been subjected to a hazard analysis and validated, and is verified to be consistent, RO water may be used for the following purposes within approximately 24 hours after generation without additional microbiocidal treatment[14] for example:

- ingredient in milk products, e.g. reconstitution of dry ingredients and dairy powders, scalding of cheese grains;

[14] Recommendation from MRA40.

- production of ice and steam, including steam for direct injection;
- washing of cheese curd to remove the casein/whey protein and to directly cool cheeses;
- cleaning, disinfection and rinsing in between cleaning steps;
- final cleaning, disinfection and rinsing of product contact surfaces for all processing lines used for heat-treated products;
- cleaning of membrane filtration systems or washing of boxes and product moulds;
- diafiltration, i.e. process applied in combination with another membrane filtration method, where water is added to the membrane filtration retentate to flush out constituents to reduce product viscosity and to make the purification of lactose and minerals more efficient;
- Preparation and dilution of brine used for brining cheese. The microbiological control of reuse water for diluting brine can be done as part of the normal verification process for the microbial quality of the brine.

30. In dairy production, RO water of which the microbiological quality is uncertain (e.g. no microbiological testing, indicating of poor quality or no validation of the testing) and that will not be used within approximately 24 hours, should be subjected to microbiocidal treatment.

Specific recommendations for the recovery of reclaimed water by condensation of vapours evaporated during concentration of milk and milk products

31. Condensate water is water recovered by condensing water vapor from the drying and evaporation processes used to remove water in the manufacturing of certain milk products, such as milk powders.

32. Due to the presence of organic material (different sources of milk products and technologies result in different qualities of organic material in this reclaimed water) which may support the growth of microorganisms, treatment of such condensate (e.g. by UV treatment, thermal treatment, microbiocidal treatment, biological filters, UF, MF, NF or RO filtration) may be required before this water is reused for some applications, such as a food ingredient or for food-contact application. Untreated condensate may be directly used for non-food-contact applications.

33. Reuse water from dairy processing operations is known to contain microorganisms that can form biofilms on stainless steel surfaces; as well as pathogenic bacteria, including pathogenic strains of *Escherichia coli*. It is therefore important that reuse water has an appropriate disinfection treatment that achieves the guideline values for the verification of microbial quality appropriate to the intended use. 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 preservative may be needed. Chemical disinfection of water will inevitably generate disinfection by-products whether it is externally sourced water or reuse water. The optimal choice of disinfectant will vary between different dairy manufacturing sites, depending upon their individual milk product range and method of recovering water for reuse, which will affect the organic loading. Unusual depletion of the disinfectant can arise from spikes in organic loading which need to be investigated rather than simply increasing the disinfectant dose. It is of paramount importance that effective disinfection against microbiological hazards must never be compromised in attempting to meet guidelines for disinfectant by-products.

WATER REUSE FIT-FOR-PURPOSE ASSESSMENT

34. See Section 1 of the General Section of these guidelines.

35. A thorough hazards analysis of water should be conducted for each step of water usage from externally sourcing of water, to recovery, reconditioning and application of reuse water, in order to identify the presence and levels of known and potential microbiological hazards. It is important to assess the types of hazards and levels at each step which may be present due to the technologies/methods applied from recovery to application. The factors that should be considered are:

- the microbiological hazards present in the original water sources from which the reuse water supplies originate (reusable water sources), and which are introduced into the water system, and 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 spoilage organisms (thereby limiting shelf-life) or pathogens;
- reuse water application;
- the impact of physical and chemical substances on the effectiveness of controls (e.g. turbidity or high loads of organic matters that may affect treatment efficiency);

- whether reuse water that has been recycled or recirculated multiple times in a specific process operation which could lead to biofilm formation or significant increase of spore levels;
- whether any particular measure for the preservation or control of microbiological growth is required over the established shelf-life of the reuse water supply;
- the availability of a back-up fit-for-purpose water supply, such as an external potable water source, that can be used in case the reuse water treatment system is not effective or not functioning properly;
- assessment of the current cleaning and disinfection regime put in place.

36. In some cases, there may not be a need for a fit-for-purpose assessment when reusing water e.g.:

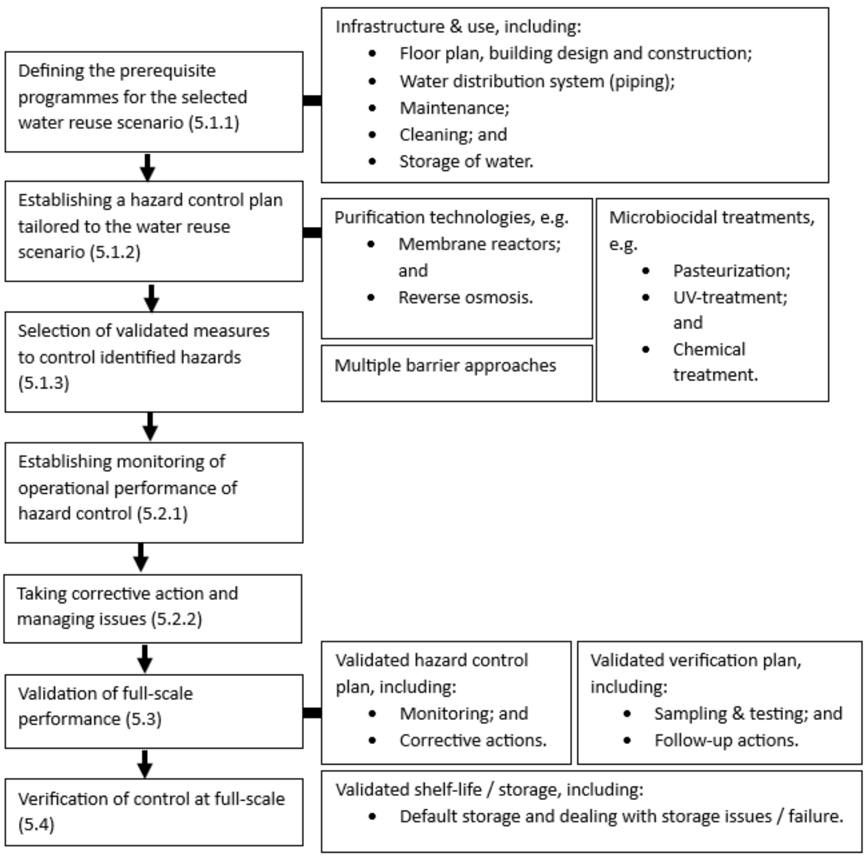
- the reuse water will strictly be used for non-food-contact applications;
- the reuse water is free of microbiological hazards, for example through the use of validated heat treatments before, during or after recovery and reconditioning;
- when competent authorities have established criteria for the water to be reused to meet various fit-for-purpose requirements and the water meets these requirements.

WATER SAFETY MANAGEMENT

37. Based on the outcome of the fit-for-purpose assessment of the water, risk associated with the 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.

38. Figure 1 provides an overview of the aspects that the FBO should consider when establishing measures for a water reuse scenario that is specific to its operation and is validated at full-scale.

Figure 1: Steps for implementing measures in a water reuse scenario into full scale operation (Source: adapted from *MRA40, Figure 4)*



Prerequisite programmes (PRPs) (*copied from MRA40, some adaptation of terminology to be consistent with the terminology in this guidance*)

39. It is essential that proper PRPs are in place. All PRPs should be supported by procedures and specifications that will minimize hazard entry, spread and increase. In the context of water reuse in a dairy manufacturing operation and for hazard control, PRPs should include in general:

- measures that ensure the maintenance of good hygienic conditions, such as the ability to conduct Cleaning-In-Place (CIP) and manual cleaning to remove/reduce potential hazards;
- provisions to have a potable water supply available at the point(s) of water use to serve as back-up;
- measures to be taken prior to switching to the back-up system in the event of an issue (e.g. full wash down flush of the facility and water holding tanks to avoid contamination from 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 hazards occurring and/or their levels, for instance, by eliminating dead-ends or pockets in the water distribution system;
- measures to reduce the likelihood of cross-contamination and inadvertent reuse of water for 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 and other malfunctions; frequent monitoring of the collection, storage, treatment system (filtration, chemical and UV light) and end-use or application points.

40. Floor plan, design and construction of dairy manufacturing plants:

- Systems for water distribution and recovery and recirculation for both sourcing water as well as reused and recirculation water should be superimposed on the dairy 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.
- All tanks, piping for the storage, treatments, and distribution system for (reuse) water in the plants and facilities, should be designed for CIP and be able to withstand heat or cold exposure as needed, as well as extreme pH values.
- As needed and when not circulating or recirculating, the water system should self-drain.

41. 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.
- All water pipelines should be clearly marked with a word or code identifying the type of water (source, potable, 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.
- Facility design should ensure pipes, pipelines, tanks and taps used for potable water cannot be interchanged with or contaminated by similar equipment used for water of other qualities.
- 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, 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 adequately manufactured (i.e. smooth surface, proper welding, etc.).
- Tubes, pipes, tanks, etc., used for milk and milk 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 (piping lengths of twice the diameter of the piping or greater from the fluid flow point to the end of the pipe or valve) 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 avoid fluctuations in the temperature of water inside the system. This may include things 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.

42. Maintenance:

- FBOs should conduct regular inspection and good maintenance of the entire water system and associated components to check for and repair any leaks or damages (e.g. leaky gaskets, cross-connections, corrosion) that may lead to entry of microorganisms and contaminate the water supply.
- Ensure the tightness of the RO membranes to avoid microbiological hazards bypassing the membranes. The “flux” and “life” of the membranes should be monitored and documented to identify when replacement should occur (based on the recommendations by the manufacturer) to ensure their effectiveness and proper performance.
- Special attention should be made to check the tightness of gaskets for pipelines and valves connected to piping.
- Maintenance incidents and problems related to the water system should trigger timely corrective action.

43. Cleaning:

- 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 to remove/reduce possible microbiological hazards and done at a frequency that prevents the build-up of biofilm.
- All equipment making up the facility’s water system should be emptied when not in use and cleaned regularly based on a hazards evaluation. Historical experience and specific knowledge about the potential problem areas and shortcomings of the facility’s water system e.g. stagnant water in pipes/the distribution system should be taken into account.
- CIP equipment used for dairy manufacturing plants should conform to applicable regulations, industry best practices, manufacturer’s specifications. The specifics (time and temperature) of a CIP regime should be fit for purpose and depends on different variables. These include microflora characteristics, quality of reclaimed water from milk, extent and type of fouling.
- If an automated CIP system is out of operation for more than a certain period of time (to be determined by hazard analysis), it should be evaluated prior to use. If not assessed, cleaning should be conducted prior to use if the CIP system has been out of operation for approximately 24 hours or longer.
- During cleaning, all pipe and tank parts should be able to withstand cleaning and disinfection procedures in place, such as temperatures and chemicals. It is recommended to heat pipe and tank parts to at least 60 °C for at least 30 minutes. If the equipment can withstand it, 80 °C for at least 10 minutes is preferred.

44. Storage of water:

- Potable water and reuse water intended for-food-contact application can normally be stored without temperature control (e.g. 15-20 °C in temperate and subtropical conditions) for a limited period (e.g. up to two days) if the nutrient levels that can support microbial growth is limited (can be approximated by measuring turbidity).
- Shelf-life can be extended if water is refrigerated (e.g. < 7 °C, measured at the top of the tank where the water is warmest) or hot (e.g. minimum 60 °C, measured at the bottom of the tank where the water is coldest). Storage of reuse water at other temperatures can be acceptable if combined with an ongoing microbiocidal treatment, e.g. by continuous recirculation through an UV treatment system, ozonation, chlorination or by a heat treatment.
- Water stored hot or cold should be thoroughly and frequently stirred to ensure the maintenance of proper storage temperature conditions throughout the tank.
- The maximum storage time of any water should be established and validated based on monitoring and testing the potable or reuse water with regard to key microorganisms (such as total bacteria count, coliform or Enterobacteriaceae counts, Pseudomonas counts), turbidity, pH, and titratable acidity, as well as organoleptic indicators (primarily smell and appearance).

Establishment of control measures

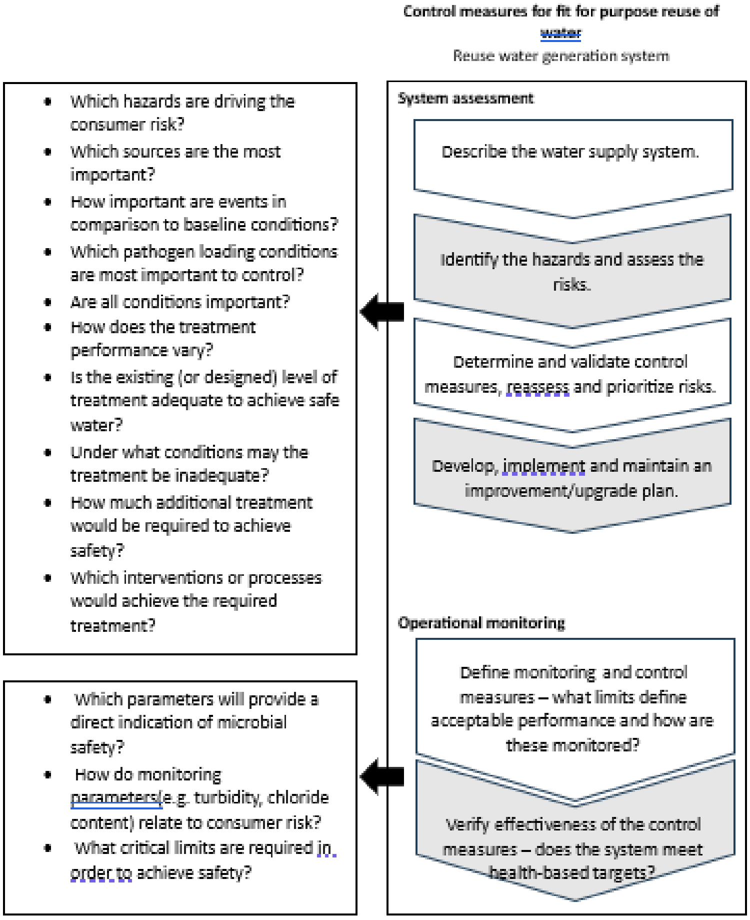
45. Control measures for the fit for purpose reuse of water should be developed based on a water reuse fit-for-purpose assessment utilizing a hazard analysis to ensure the safe use and reuse of water within dairy plants. The measures should include the consideration of the applied prerequisite programs and the available treatment technologies.

46. A flow diagram should specify the key process steps where reuse water is introduced to the food and steps where used reuse water is removed from the food processing line, as the basis for the hazard analysis.

47. All water uses should be included in the water safety management. If the reuse water is intended for food contact (direct and indirect), the results of the hazard analysis of the reuse water should be included as input to the hazard analysis for the milk products that will be impacted.

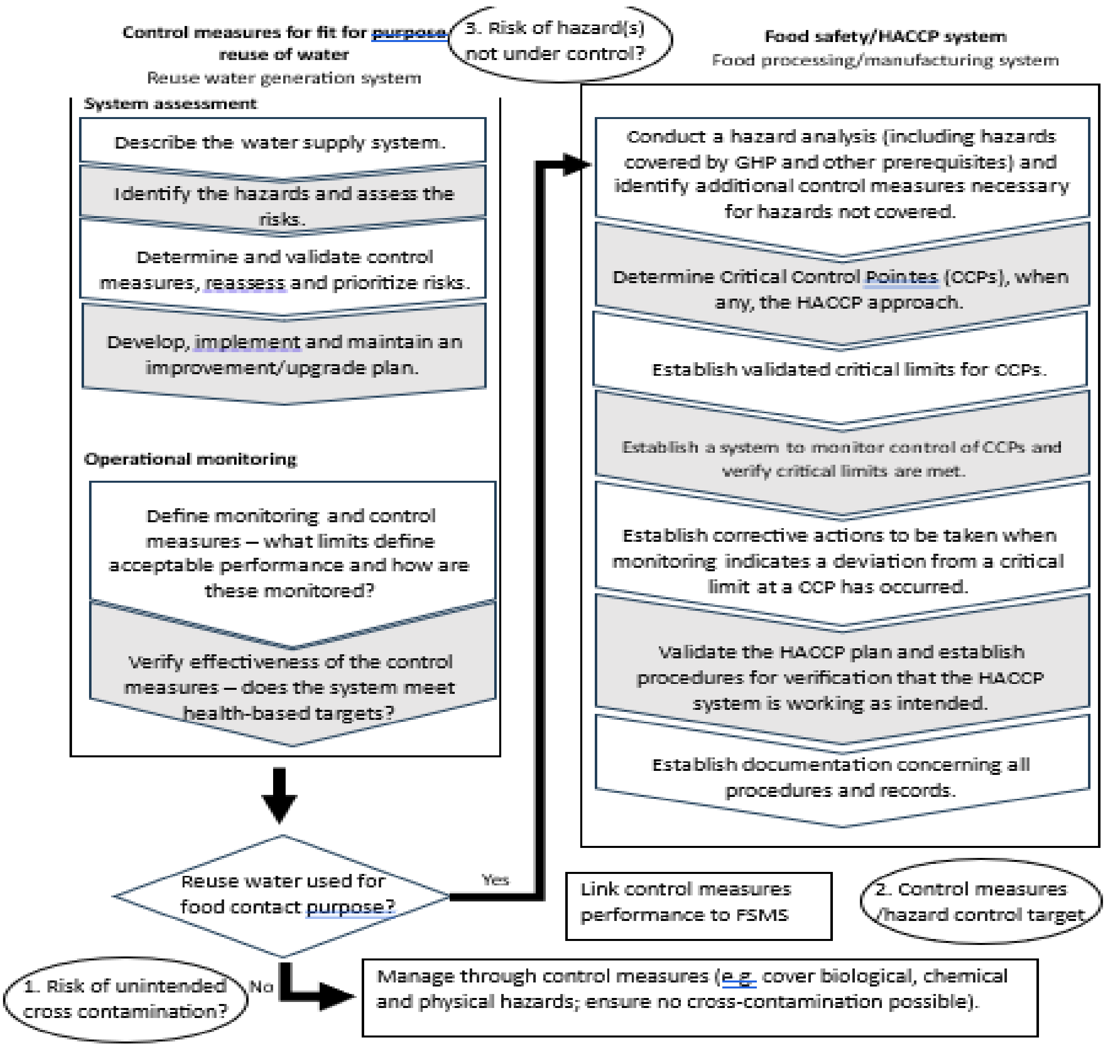
48. Figure 2 provides an overview of input from an assessment to develop control measures for the fit for purpose reuse of water.

Figure 2: Potential fit for purpose assessment questions that provide insights and inputs into the development of control measures for the safe reuse of water (*Source; adapted from MRA40, Figure 1)*



49. The control measures should be integrated into the food safety/ Hazard Analysis Critical Control Point (HACCP) plan as illustrated in Figure 3.

Figure 3: Integration of control measures for the fit for purpose reuse of water into the food safety/HACCP system (*Source: adapted from MRA40, Figure 2*).



50. A risk/hazard matrix such as in Diagram 2 of the General Principles of Food Hygiene (CXC 1-1969) or the Table 1 below can be used for the hazard analysis in order to link the hazardous event/step with the hazard and its risk characteristics, to better enable the selection of appropriate control measures. Specific examples can be found in the case studies in MRA40 (examples referred to below).

Table 1: Example of risk/hazard matrix with an indication of the likely associated level of risk and possible control options *(based on the risk matrixes provided in Annex 4 of MRA40).*

Event	Hazard	Risk/hazard matrix							Control options
E.g. cross-contamination, building of biofilm, carry-over from disinfection …	Patho-genic bacteria, chemical residue	Likelihood of hazard occurrence in the reuse water		Unlikely	Seldom	Sometimes	Frequent	Always	UV-treatment, limitation of recycling
		Risk to consumer in absence of control	Severe						
			Moderate						
			Minor						

Selection of measures to control identified hazards

51. Based on the identification of the hazards to be controlled, appropriate control measures should be selected. The need for possible critical control points (CCPs) within procedures based on the HACCP principles

should be considered, e.g. at the reconditioning of the reuse water when the proper performance of the reconditioning process (such as temperature and time) is essential for acceptable hazard control and no other controls are in place after the reconditioning step.

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

- the quality and safety of the original source water;
- in plant treatment of incoming source water;
- the age, characteristics and maintenance history of the facility’s potable and reuse water systems;
- the characteristics of the treated, reuse water matches the fit-for-purpose requirements including the needs for treatment and the quality of the fit-for-purpose water, such as whether the reuse water will be used for direct food-contact applications;
- the microbiological profile of the recovered or reuse water;
- the dynamics of the hazard such as:
  - changes in the 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 reuse water;
- the risk of possible consumer exposure;
- 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 reused.

53. Control measures are typically applied at CCPs within a HACCP system. When non-reconditioned water is fit for purpose, and when the food is subjected to microbiocidal treatments at a later step, there are no CCPs related to the verification of reconditioning performance. However, it may be necessary to assess and control hazards pertaining to storage (e.g. time and temperature factors during holding) when it is part of the water reuse scenario and there still may be a need to have controls in-place to ensure that lower-risk hazards are controlled, minimized or eliminated.

54. To improve the microbiological quality of water, heating, chlorination, ozonation or UV treatment can be used.

Monitoring

55. The parameters of validated water reconditioning processes (such as total organic compounds (TOC), chemical oxygen demand (COD), biological oxygen demand (BOD), turbidity, pH or conductivity, based on the nature of the process) should be monitored, with occasional verification by microbiological testing.

56. The frequency of monitoring should consider the level of control specified for the reuse water scenario, event or step (e.g. is the reused water used for-food-contact application or not), and the identified risk for the consumer in case of deviation.

57. Monitoring data across subsequent reuse water batches being generated should be plotted for trending purposes to help benchmark information to be used in building confidence over the systems of reuse water. When the water reuse systems are consistently performing well, signals can be early detected when the operation or control measures may be trending towards failure, or when an out-of-control situation may develop. Trend analysis is a powerful operational management tool advocated both for water safety plans and food safety plans.

Corrective actions

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

- identify the problem and analyze the root cause, correct the problem and establish corrective measures to prevent recurrence; amend the control measures, or other aspects of the reuse water generation system or the food safety management system, as appropriate;
- conducting a risk-based evaluation of the hazards and possibly new corrective action steps or procedures may reduce the frequency of these incidents or eliminate them;

- isolate reuse water that did not meet performance parameters and consider discarding or re-purposing it (i.e. to make a supply suitable for other fit-for-purpose applications);
- invest in physical improvements to the water system to eliminate or reduce weak "links" where contamination has happened in the past or is suspected of happening in the future.
- if the loss of water safety controls is associated with the reuse 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 reuse water to a lower level fit-for-use criteria, i.e. from for direct food-contact application to indirect food-contact application; consider an increase in monitoring frequency until confidence in the control 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 is under control again;
- Identify any potentially impacted food products and take action as appropriate.

Validation

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

60. Specific validation is highly dependent on the plant-specific treatments and storage conditions and should be carried out on the reuse water shelf-life, i.e., how long the water may be used/stored or how many times can it be recycled while still suitable for its fit-for-purpose application. Validation will need to be re-done if any conditions or treatments are changed.

Verification and testing

61. Verification of the water safety management system should be carried out by:

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

62. Routine testing of reuse water for pathogens is not recommended, because the level of pathogens in reuse water, if present, are likely to be present at very low populations making detection by reasonable sampling plans improbable. It is more practical to test for suitable indicator microorganisms to verify process control and to identify potential out-of-control situations. Suitable indicator microorganisms generally occur in reuse water at levels that allow quantification. However, enhanced sampling and testing for pathogens would be warranted during validation of reconditioning processes or during an event where a loss of control may have resulted in reuse water becoming contaminated with pathogens. Such water should often be discarded**.**

63. Microbiological testing and analysis of indicator microorganisms such as total viable count or coliforms in water, have proven to be useful in many circumstances. However, the microflora relevant for verification of reuse water often is plant or operation specific. It is, therefore, essential to conduct an operation-specific study to determine which microbiological parameters/indicator organisms may be appropriate for use in evaluating a particular water reuse scenario.

64. The FBO should determine and document the acceptable microbial limits to be used as reference for verifying operational control, by establishing a maximum limit for each relevant hazard or indicator organism that is tolerable in the water supply system being generated for for-food-contact and not-for-food-contact applications.

65. 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)[15]. These are examples only and other limits or criteria could be applicable.

EXAMPLES OF FIT-FOR-PURPOSE REUSE WATER APPLICATIONS[16]

Examples of water fit-for-purpose decision tools

66. Table 2 provides an overview of fit-for-purpose considerations for different applications of reuse water and types of reuse water available. All three reuse water types (recirculating, reclaimed from milk and recycled)

[15]https://www.fao.org/3/cc4081en/cc4081en.pdf
[16] Figures in this section were copied from MRA40.

can be used for direct food contact application, providing there are no significant hazards present or that their levels are reconditioned to acceptable levels, when necessary. All three reuse water types may be suitable as sourced for indirect food applications as long as food contact is effectively controlled and avoided. When such control to avoid food contact is not possible or variable, the application should be considered as potential direct food application, meaning that significant hazards need to be absent or be consistently controlled to be within acceptable levels. From a microbiological basis, the four water types in the Table 2 are fit for purpose, for not-for-food-contact applications. 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 processing operation.

Table 2: Overview of fit-for-purpose considerations for different applications and types of water reuse (*from Table 2 of MRA40. Terminology adapted to be consistent with the rest of the guidance*)

PURPOSES	EXTERNAL POTABLE WATER	RECIRCULATED WATER	RECLAIMED WATER	RECYCLED WATER
		Closed loop (CIP)	Recovered from milk	Recovered from a processing step
Food Ingredient	Fit for purpose as sourced	No likely application	Fit for purpose if no significant hazards present either as recovered, or after reconditioning	Fit for purpose if no significant hazards present either as recovered, or after reconditioning
Direct food contact	Fit for purpose as sourced	Fit for purpose until undue levels of significant hazards are found; needs reconditioning to reuse		
Unintended food contact	Fit for purpose as sourced	Fit-for-purpose as recovered if no significant hazards are present, or food contact is avoided		
Not for food contact	Fit for purpose as sourced			

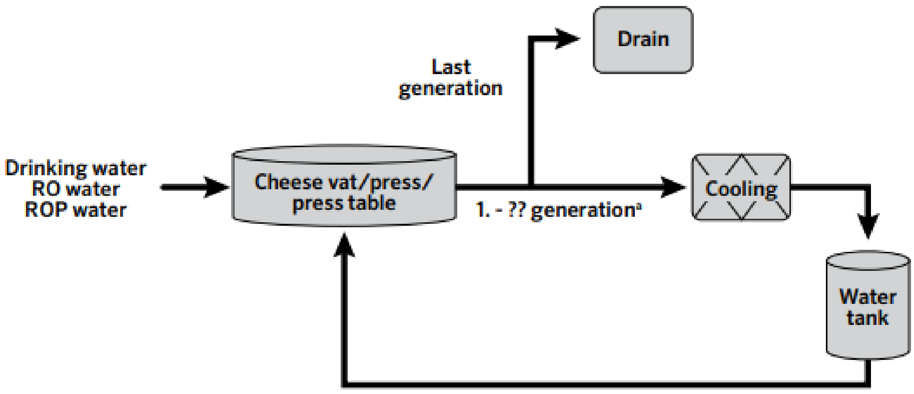
67. The examples below are for illustrative use. Any reuse scenario should be based on a proper hazard analysis before implementation.

Example of reuse of potable water by recirculation or recycling

68. After introducing potable water in a closed system, the water is recycled for a specific number of times. The number of acceptable cycles is based on the assessment of maximum levels of predefined parameters (e.g. microbiological criteria). The recycled water is then disposed of from the system, or is treated with a microbiocidal treatment (e.g. heat, UV or chemical disinfectants) when the number of acceptable cycles has been reached.

69. As an example, during cheese production, reclaimed water is used for the following cooling step and then recycled in a closed system as illustrated in Figure 4. It is derived from a detailed example that can be found in case study 2 of Annex 4 of MRA40.

Figure 4: Scheme shows the recirculation of water used for cooling cheeses.



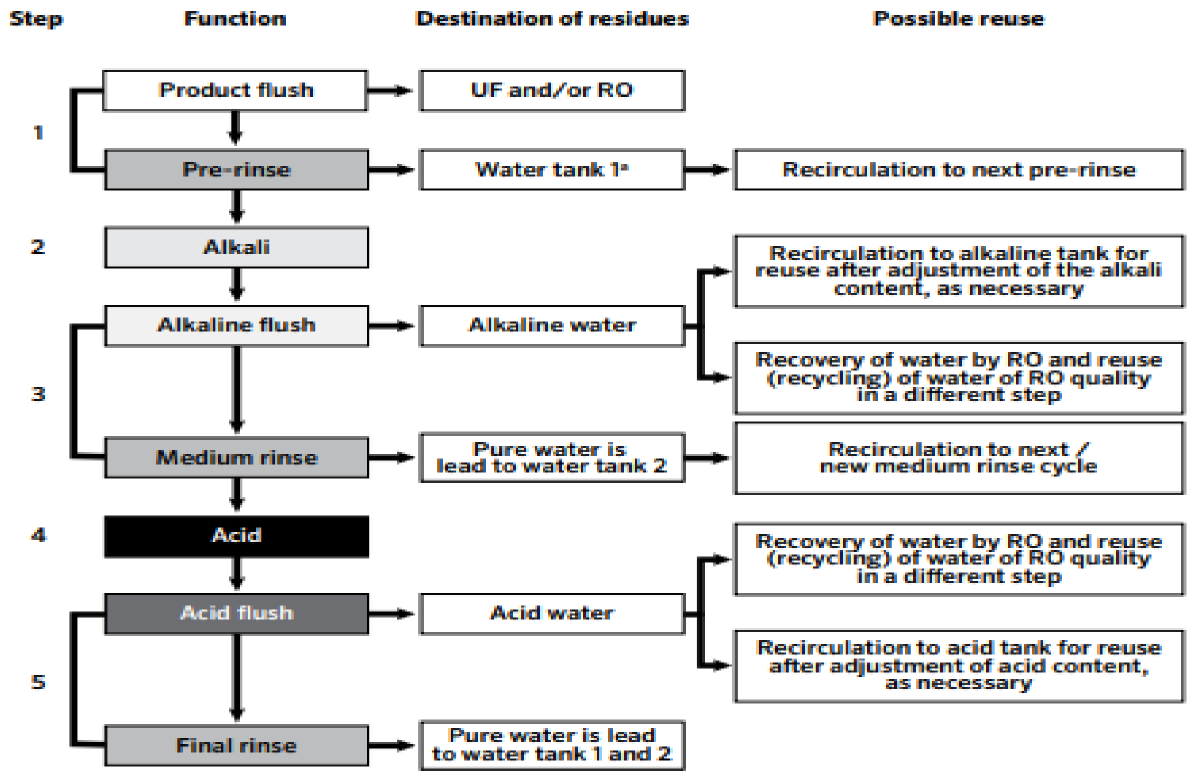
In this scenario, multiple runs of recirculation may apply. Recirculating externally sourced water for a new reuse, will produce a 2nd generation of water and recirculation of the 2nd generation would create the 3rd generation, etc. When the number of recirculations has reached its maximum (based on microbial testing) then the water is to be discarded as waste (last generation).

In case of recycling, the same principle should be applied, but before the water is being reused, a step of reconditioning/treatment should be applied as necessary.

Example of recovery and reuse of water from CIP systems

70. CIP systems are used in dairy manufacturing plants to remove product residues from food-contact surfaces and to remove or reduce biofilm formation. A CIP system consists of a number of consecutive rinsing and cleaning steps using fit-for-purpose water at minimum designated temperatures, flow rates, pressures and concentration of chemicals in which the fit-for-purpose water needs to comply with different microbiological, physical and/or chemical parameters. On certain occasions, water used within a step can be recycled for the same step or an earlier step, e.g. potable water needed for the final rinsing step can be recycled for earlier rinsing. This is illustrated in Figure 5, derived from a detailed example of the use of a CIP system that can be found in case study 3 of Annex 4 of MRA40.

Figure 5: Sketch for reuse of water streams in a 5-step CIP system, including recovery of RO water from CIP fluids. Illustrates the flow of water streams and the associated options for recirculation or recycling the water from CIP fluids at different steps using UF, RO, ROP.



ᵃ When flushing of non-pasteurized product, the water should be pasteurized before reuse. Alternatively, it is led to the drain.

Source: Adapted from **Heggum, C. 2020.** Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants.

Example of recovery and reuse of water from food production/processing (reclaimed water)

71. Water present in milk or milk products can be recovered during processing (reclaimed water) and reused. Reclaimed water can be obtained from different processes which will determine its microbiological safety and its need for reconditioning. Examples are condensate from evaporation processes, casein wash water, whey permeate, various permeates with additional treatments and milk product rinse water.

72. This condensate contains organic materials and chemical compounds such as milk solids and lactic acid, but it is generally very pure. Therefore, it can be used directly or be treated in a RO or ROP systems for reuse if it meets fit-for-purpose water criteria as a food ingredient or for cleaning and disinfection of food-contact material.

73. Casein wash water, and whey permeate lactose permeate and some other types of permeates are a good source of reuse water but may support microbiological growth due to the presence of small amounts of milk solids such as milk proteins or lactose. Reusing water conditions should therefore be carefully assessed, monitored and verified. Treatment/purification steps such as RO and UF should be considered.

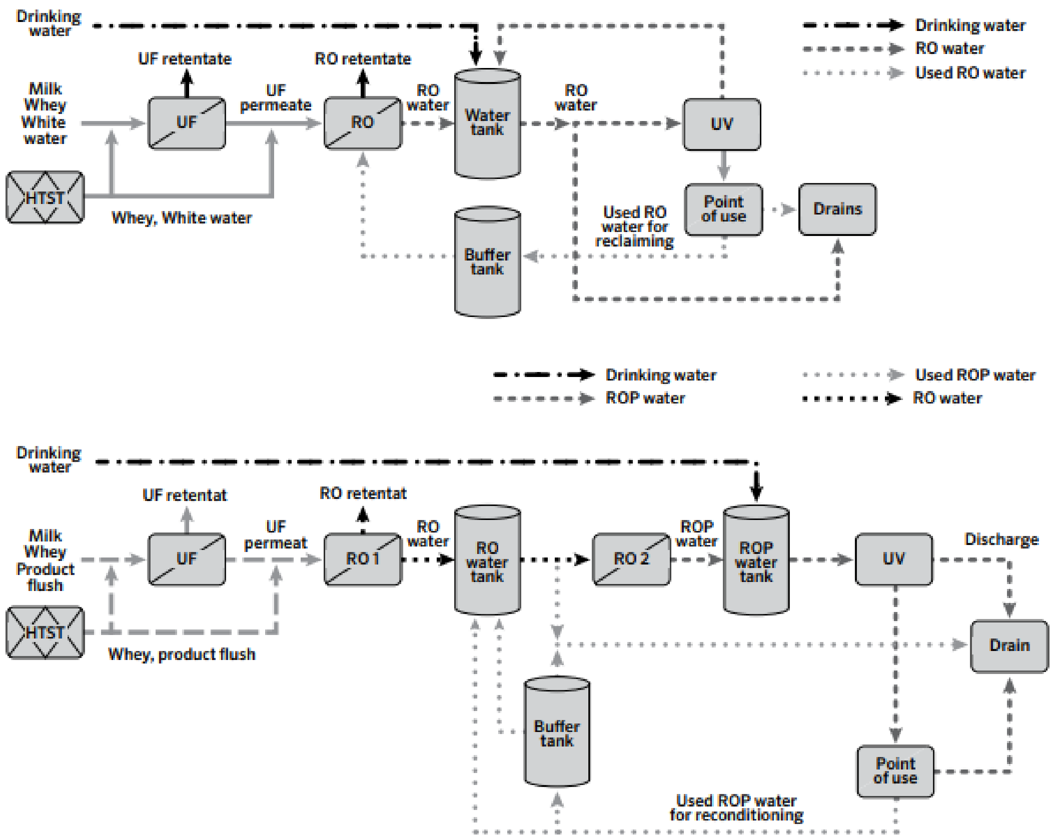
74. Product rinse water could be water recovered from the initial rinsing of pipes or tanks for milk and consists of a mixture of water and milk, milk-based food materials and deposits. Depending on the place of rinsing (e.g. equipment before or after pasteurization of the milk) and the presence/absence of biofilms, microbiological contamination might be different. Treatment of recovered and stored rinse water to inhibit microbiological growth may need to be considered.

75. There should be sufficient documentation to identify the source and treatment (if any) of the reuse water (initial lot production) and subsequent use (which subsequent lots were exposed to this reuse water) in case a food safety investigation is needed.

Figure 6 provides an example of the recycling of water from whey using RO or ROP. It was derived from a detailed example that can be found in case study 4 of Annex 4, of MRA40.

Figure 6

: Examples of two water reuse scenarios involving recycling of reusable water sources through RO/ROP and UV treatment(s). Top: describes the recovery of reclaimed water from milk, whey and product flushes using RO followed by UV treatment. Bottom: shows how the RO water is further purified by another RO process (a polisher), followed by UV treatment.



Source: Reproduced with permission from **Heggum, C.** 2020. Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants.

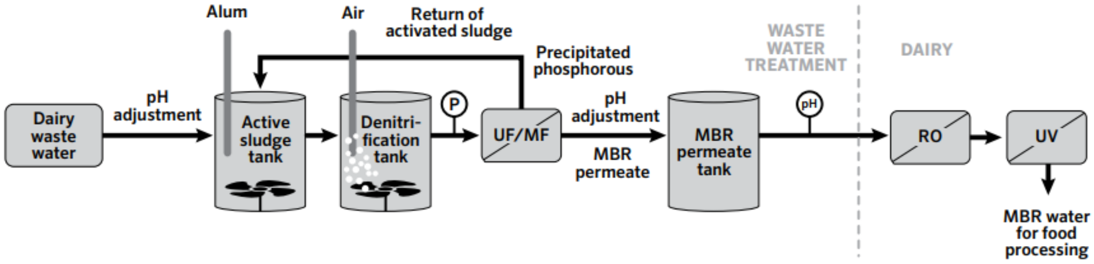
Example of recovery and reuse of dairy effluents

76. Effluents from dairy manufacturing plants such as dairy processing wastewater or sewage (wastewater from showers, bathrooms, toilets, wash stations etc.) that contain human pathogens, may be captured, treated and reused for certain applications when subjected to appropriate treatment and fit for purpose assessment and management measures. These effluents may not only contain milk constituents supporting microbiological growth, but other hazardous substances.

77. Such wastewater should be collected and handled in a manner that prevents cross-contamination of the reuse water, and meets local, regional or national government requirements. Figure 7 provides an example

of the recovery of water from dairy effluents using a Membrane Bioreactor and RO. It was derived from a detailed example that is provided in case study 5 of Annex 4 to MRA40.

Figure 7: Example of the recovery of water from dairy effluents using MBR and RO.



Source: Reproduced with permission from **Heggum, C.** 2020. Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants.

Example of water recovery and reuse from non-food manufacturing operations

78. Water originating from external sources such as private wells may vary in chemical, microbiological and physical content, and may contain unidentified components. If the manufacturing facility has its own wells, the water may or may not be potable. This will need to be determined through a collection of data that includes microbiological sampling and testing as well as organoleptic evaluation. Consideration should also be given to identifying the pH, turbidity, nitrate level and hardness of such water. This will need to be determined through an appropriate evaluation. If the well water has come in contact with surface water, it will most likely have microbial contamination but can still be used if properly treated or for any qualifying fit-for-purpose use. A fit-for-purpose assessment and management measures are needed to identify likely hazards and controls to minimize or eliminate them. Treatment of the water, if needed, should be captured in the HACCP plan.

79. Case study 1 in Annex 4 to MRA40 illustrates the use of water from local wells at or near the dairy manufacturing plant.

Annex IV: Technologies for recovery and treatment of water for reuse

DEFINITIONS

Membrane bioreactor (MBR): A combination of a bioreactor and membrane filtration deploying aerobic and anaerobic fermentation, ultra-filtration (UF) or micro-filtration (MF) delivering water (“permeate”) from a potential reuse water source (including dairy effluents, milk or milk processing steps, used potable water), purified in the bioreactor by anaerobic and/or aerobic fermentation *(adapted from MRA40 to provide a more correct description).*

Membrane Filtration: The use of fiber or ceramic materials for a filtering system to remove debris, non-dissolved solids and bacteria from milk, whey or other liquid dairy matrix. Examples include ultra, micro, nano and reverse osmosis (RO) filtration.

Retentate: the product obtained by concentrating milk constituents using membrane filtration (UF /MF/ RO / Reverse Osmosis and Polishing water (ROP)/ NF) technology for milk or milk products *(editorial from MRA40).*

Reverse Osmosis water (RO water): water, including reclaimed water, generated by membrane filtration with membranes of 0.001-0.0001 mm (1.0-0.1 nm) pore size and under high-water pressure which overcomes osmotic resistance, forcing water from the feed stock to the permeate side of the membrane resulting in a concentrated product (retentate) and recovering the water *(adapted from MRA40 since considering “feed side” more appropriate/clear than “retentate side” + 2 editorial improvements):*

Reverse Osmosis and Polishing water (ROP water): RO water that is further polished/purified, either by an additional RO process or by filtration with activated carbon or other technologies that give improved (chemical and) microbiological quality *(adapted from MRA40 “similar” is considered misleading and replaced by “improved”, “polished” added + editorial).*

TECHNOLOGIES

1. Several technologies have been developed to recover and/or treat water from dairy plants for reuse. Reconditioning may use treatments or a combination of treatments such as membrane filtration, UV-treatment, or microbiocidal treatments (e.g. chlorination or ozonation). 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. Certain parameters of the treatments should be monitored to ensure efficacy. Biocides used for reconditioning treatments may be subject to approval by the competent authority.

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

- determination of chemical, microbiological and physical characteristics of the water taking into account, when applicable, pre- and post-treatment;
- sources of water intended for reuse;
- capture, storage and treatment of water intended for reuse;
- acceptable end-use applications and 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.

3. Technologies are constantly evolving and improving and therefore this appendix is likely not to be fully up to date. Other technologies, such as ultrasonication or bactofugation can also be an option.

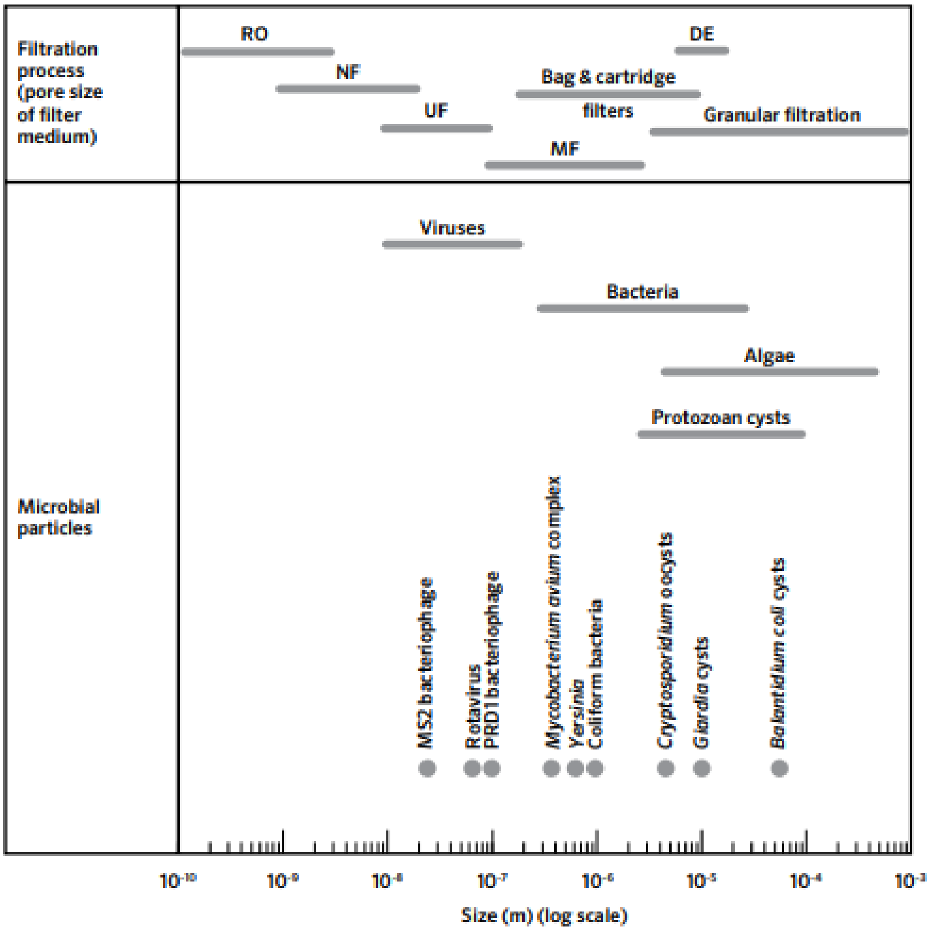
Recovery by sedimentation, coagulation and centrifugation

4. These technologies may be applied, alone or in combination, to effluents (e.g. of dairy manufacturing). They should be considered as preliminary treatments since they will not remove all contaminants, including pathogens that might be present. These technologies should be followed by treatment procedures for recovered water from effluents to reduce or eliminate the presence of pathogens to meet requirements for some types of fit-for-purpose reused water in direct or indirect food-contact applications.

Purification technologies

5. Several membrane purification methods can be applied in dairy manufacturing plants such as reverse osmosis (RO), nanofiltration (NF), ultrafiltration (UF) and microfiltration (MF). Their differences in performance for water purification are illustrated in Figure 1.

Figure 1: Average pore size for different membrane filtration systems: RO, NF, UF, MF, bag & cartridge filters, diatomaceous earth (DE), granular filtration and the size of different particles of microorganisms (Source: MRA40[17] Figure 1A).



6. RO is a membrane filtration technology, widely used in dairy manufacturing plants, in which water is forced under high pressure (e.g.31-60 bar) through a small (e.g. 1.0 to 0.1 nm) pore-size membrane from the retentate side to the permeate side. The main purpose of RO is to remove nutrients and chemicals from water, but secondarily it also reduces levels of bacteria and viruses.]

7. RO can be supplemented with other approaches/barriers for further purification referred to as “RO and Polishing” (ROP). This can consist of a second RO treatment or nanofiltration, deionization or treatment with activated carbon. It is estimated that ROP water has a short[18] default storage shelf life without temperature control (subject to hazards analysis and validation), but that shelf-life can be extended by microbiocidal treatments (such as UV) and/or using cold or hot temperature storage.

8. 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 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, such as disinfection and purification may be required for fit-for-purpose water applications.

9. Purification by membrane bioreactor (MBR) technology where wastewater is stored in tanks under aerobic or anaerobic conditions, is another pre-treatment tool. 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 water quality requirements. Many portable aerobic or anaerobic digester technologies are available for bulk reconditioning of wastewaters.

10. Fluids passing through membrane systems should be heated only to the temperatures as recommended by the manufacturer as higher heat can damage or destroy certain types of membranes.

[17] Microbiological Risk Assessment series 40. Safety and quality of water use and reuse in the production and processing of dairy products: meeting report. https://www.who.int/publications/i/item/9789240066588
[18] To ensure microbial counts remain low, the water should be used within approximately 48 hours after generation.

11. All membranes require periodic cleaning and backflushing, depending on the make-up of the membrane, the feed material and pressure differences to prevent fouling or various mineral (e.g. calcium) deposits (scaling).

Microbiocidal treatments

12. UV treatment of reuse water can be used to reduce some populations of bacteria, viruses, moulds, yeast and protozoa. Continuous monitoring, regular maintenance and cleaning, and correct calibration of the treatment parameters are essential to maintain the microbiocidal effect. Some further treatments may be required downstream. Critical factors to consider are:

- transmission of UV light, i.e. the level of turbidity in the water; if even slight turbidity/cloudiness 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.

13. UV treatment systems must be set up to be adequately cleaned without significant infrastructure disassembly (i.e. CIP-ed, 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 cleaning is used, it should have the capability of removing fat, protein and mineral coatings (e.g. calcium) from the UV equipment's quartz lenses.

14. Heat treatment, such as pasteurization 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 potentially remaining pathogens and microorganisms that could cause spoilage and limit the shelf-life of the water. Considerations to take into account are:

- treatment parameters (e.g. minimum temperature and holding time, those appropriate for pasteurization of milk are acceptable; alternative parameters should be validated to eliminate the risk of pathogens and spoilage organisms);
- the heat treatment temperature and flowrate or time spent in the holding tube 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 continuous treatment process, 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 the desired holding time is obtained;
- a flow diversion valve should be in place so that, if the pre-set temperature drops, it will redirect the reuse water flow for reconditioning back to the balance tank; the flow diversion valve should be checked daily to ensure it is functioning properly;
- continuous monitoring for overpressure on the heat-treated side by automatically recording the pressure as well as noting pressure differences between the water prior to heating and after heating is very important as a failsafe measure in case of equipment wear or malfunction.

15. Chlorine, chlorine dioxide, ozone and peracetic acid are the chemicals most commonly used for the microbiocidal treatment of water in dairy 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 dairy processing operations is known to contain microorganisms that can form biofilms on stainless steel surfaces as well as pathogenic bacteria, including pathogenic strains of Escherichia coli. It is therefore important that reuse water has an appropriate disinfection treatment that achieves the guideline values for the verification of microbial quality appropriate to the intended use;
- 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 preservative may be needed; the optimal choice of disinfectant will vary between different dairy manufacturing sites, depending upon their individual milk product range and method of recovering water for reuse, which will affect the organic

loading; unusual depletion of the disinfectant can arise from spikes in organic loading which need to be investigated rather than simply increasing the disinfectant dose.

- resistance among microorganisms to disinfectants may be build up; this can be counteracted by change of disinfectants after a certain period of use;

- generally, chlorine disinfection is a reliable and effective approach against a wide spectrum of pathogenic microorganisms; if ammonia or organics remain in the permeate and is exposed to chlorine, in any form, the result can be chloramines, perchlorates and trihalomethanes; these are significantly less effective at inactivating pathogens, especially viruses, and also react slower as compared to free chlorine; chloramines nevertheless, have the advantage of 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 chemicals should be well-controlled with full documentation; for example, the level (e.g. chlorine) should be used at proper concentrations as per label instructions for effective use; the level should be continuously monitored to ensure effectiveness against microbiological contamination;

Technologies specific for certain food

16. See food specific Annexes e.g. recovery of reclaimed water by condensation of vapours evaporated during concentration of milk and milk products.

Appendix II

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