



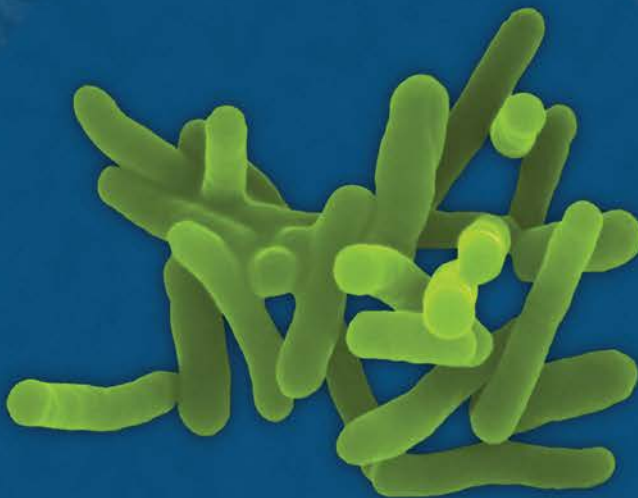
Food and Agriculture  
Organization of the  
United Nations



World Health  
Organization

# Safety and quality of water use and reuse in the production and processing of dairy products

Meeting report



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MICROBIOLOGICAL RISK  
ASSESSMENT SERIES



# Safety and quality of water use and reuse in the production and processing of dairy products

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Meeting report

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# Declaration of interests

All participants completed a Declaration of Interests form in advance of the meeting. The interests declared were not considered by FAO and WHO to present any conflict in light of the objectives of the meeting.

All the declarations, together with any updates, were made known and available to all the participants at the beginning of the meeting. All the experts participated in their individual capacities and not as representatives of their countries, governments or organizations.

# Abbreviations and acronyms

BOD	biological oxygen demand
CAC	Codex Alimentarius Commission
CIP	cleaning-in-place
CCFH	Codex Committee on Food Hygiene
CCPs	critical control points
COD	chemical oxygen demand
FAO	Food and Agriculture Organization of the United Nations
FBO	food business operator
FSMS	food safety management system
FTU	formazin turbidity unit
HACCP	hazard analysis and critical control points
JEMRA	Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment
MBR	membrane bioreactor
MF	microfiltration
NF	nanofiltration
mS	milli Siemens
(Q)MRA	(quantitative) microbiological risk assessments
RO/ROP	reverse osmosis/reverse osmosis and polishing
TOC	total organic compounds
TPC	total plate count
UF	ultrafiltration
WHO	World Health Organization
WOAH	World Organisation for Animal Health
WSP	water safety plan

# Terminology and descriptions

For the purpose of this report, the terms described below are used with the following understanding:

**Condensate:** Water recovered by condensing water vapor, for instance water vapor recovered from the drying of dairy raw materials/products.

**Dairy effluents:** Wastewater from cleaning and disinfection, or other operations involving water, during the manufacture of dairy products, including both food contact applications and non-food contact applications, and which contains identifiable substances. Dairy effluents do not include black and grey waters.

**Fit-for-purpose reuse:** An application for which the reuse of water meets the relevant microbiological parameters for food safety and stability of the specific application.

**Fit-for-purpose reuse water:** (a supply/volume of) Water for reuse that meets the relevant microbiological parameters concerning food safety and stability for a specific fit-for-purpose application (note: chemical and physical parameters will have to be dealt separately through risk assessment, risk management and the food safety management system of the food operation).

**Food business operator (FBO):** The person or entity responsible for a food operation/facility. In the context of this report, FBOs typically are dairy (processing) operations intending to reuse water.

**Food (production/processing) operation:** The facility ran by a food business operator, including factories, warehouses, offices and other buildings that are part of the facility.

**For-food-contact application:** The intentional application of water in a food operation such that the water becomes part of a food or comes into direct or indirect contact with food materials. Examples: ingredient water; water used to wash, clean, or disinfect food contact surfaces.

**Hazard control plan:** The hazard control plan is a documented report that include the following information for each control measure: a) food safety hazard(s) to be controlled; b) action criteria; c) monitoring procedure(s); d) corrective actions(s) to be made if action criteria are not met; e) responsibilities and authorities; and f) records of monitoring.

**Indicator microorganisms:** Contaminants that typically are not harmful but may indicate the effectiveness of processing/treatment steps, the hygienic state of an operation, the possible presence of pathogenic microorganisms or otherwise provide useful information for operational control.

**MBR (Membrane Bioreactor) permeate:** Membrane filtration deploying 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.

**MBR water:** Water recovered as MBR permeate and purified by RO filtration.

**Microbiological criterion (MC):** A MC is a risk management metric that indicates the acceptability of a food, or the performance of either a process or a food safety control system following the outcome of sampling and testing for microorganisms, their toxins/metabolites or markers associated with pathogenicity or other traits at a specified point of the food chain (e.g. the microbiological limit associated with a 2-class sampling plan) (FAO and WHO, 2013a).

**Microbiological limit:** A specification of a microbiological concentration (level) that, typically without a specified sampling plan or a defined method of detection, represents a tool for verifying whether a water supply or food material (i.e. a food component or final consumer product) meets the criteria established for (microbiological) safety of that water supply or food material in trade.

**Milk water:** Water recovered from whey or milk and, where necessary, reconditioned according to its intended use; other dairy products may also be used to recover reusable water from. Note that milk may be from cows, sheep, goats, buffaloes, camels, etc.

**Monitoring:** The activity of conducting a planned sequence of observations or measurements of control parameters to assess whether a control measure is under control. Such data records can be used as evidence in future verification (FAO and WHO, 2020a).

**Not-for-food contact application:** The intentional application of water in a food operation such that the water does not come in contact with food materials. Examples: technical steam, boiler feed, water needed to extinguish fires, or to wash vehicles (other than food and food ingredient transport vehicles), water lawns, clean external surfaces or flush toilets (FAO and WHO, 2019). In practice, sometimes referred to as technical water.

**Permeate:** The fluid derived from milk or other dairy products obtained after removing milk constituents by membrane filtration (UF /MF/ RO / ROP/ NF).



**Recirculation:** Use of the same water once or for several times in the same process (without reconditioning and replenishment), e.g. reuse of water for cooling.

**Reclaiming/recovering water:** Separation and collection of water from raw or pasteurized dairy materials, dairy products or dairy effluents through one or more process steps, as necessary, such as purification and/or reconditioning of the water sourced to achieve the required water quality.

**(Re)Conditioning:** The (re)treatment of water intended for reuse according to its intended purpose, and treated by means designed, to reduce or eliminate microbiological, chemical, and physical hazards.

**Recycling:** Use of water recovered from a process step and will be used in the same process step but with reconditioning and/or replenishment, as necessary.

**Retentate:** The product obtained by concentrating milk constituents by membrane filtration (UF /MF/ RO / ROP/ NF) of milk or dairy products.

**Reusable water source:** A supply/volume of used water that is or may be rendered suitable for fit-for-purpose reuse.

**Reuse:** Includes all reuses of water, including reclaiming, recirculation, and recycling of water from a food operation. Does not include first use of drinking water or potable water, nor the initial conditioning of raw water to produce drinking water/potable water.

**Reuse water:** A supply/volume of water that has been processed and is ready for application.

**Reuse water generation process/system:** The process/system that renders water from a reusable source ready for application, i.e. reuse.

**RO water:** RO (Reverse Osmosis) water, including milk water, is generated by membrane filtration with membranes of 0.001–0.0001 mm (1.0–0.1 nm) pore size and under high-water pressure (450–600 psi or 31–41 bar), which overcomes osmotic resistance, forcing water from the retentate to the permeate side of the membrane and thus, concentrating the product and recovering the water.

**ROP water:** RO (Reverse Osmosis & Polishing) water is RO water that is further purified, either by an additional RO process or by filtration with activated carbon or other technologies that give similar results.

**Safe and suitable water:** Water that does not adversely affect food safety and the suitability of food for human consumption when used as intended.

**Utility microorganisms:** 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). Such contaminants are typically not of food safety concern, but some types may reduce shelf-life or cause spoilage.

**Validation:** Obtaining evidence that a control measure or combination of control measures, if properly implemented, is capable of controlling the hazard to a specified level (FAO and WHO, 2020a).

**Verification:** The application of methods, procedures, tests, and other evaluations, in addition to monitoring, to determine whether a control measure is or has been operating as intended (FAO and WHO, 2020a).

**Water of drinking water quality:** Water that meets guideline target values for quality criteria that protect or improve drinking water quality and, therefore, human health (WHO, 2022).

**Water of potable quality:** Water that meets quality criteria of drinking water.

**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].

**Water safety plan (WSP):** A comprehensive risk assessment and risk management approach that encompasses all steps in water supply from catchment to consumer. It draws on many of the principles and concepts from other risk management approaches, in particular the multiple-barrier approach and a hazard analysis and critical control points (HACCP) (as used in the food industry) (WHO, 2009, 2016, 2022).

# Executive summary

In 2020, the 43rd session of Codex Alimentarius Commission approved the new work entitled “Development of Guidelines for the Safe Use and Reuse of Water in Food Production” proposed by the 51st session of Codex Committee on Food Hygiene (FAO and WHO, 2020b). To support this work, the Joint FAO/WHO Expert Meetings on Microbiological Risk Assessment (JEMRA) was asked to provide scientific advice regarding safe use and reuse of water in the dairy sector. JEMRA convened an online meeting from 14 June to 2 July 2021 to provide clear and practical guidance on risk-based approaches to assess and manage fit-for-purpose water sourcing, use and reuse in the dairy sector.

## **GENERAL VIEW ON WATER REUSE IN THE DAIRY SECTOR**

Water is used for a wide range of activities in the dairy sector, which consumes a substantial volume of first-use drinking water for production processes, cleaning and disinfection.

There is a great potential to exploit possible sources of reusable water in the dairy sector. In dairy processing facilities, for instance, water types that potentially can be sourced for reuse include water that:

- was part of a dairy product (e.g. in milk powder or cheese manufacturing);
- has come into a dairy operation in the form of drinking water and is recirculated until it is no longer suitable as drinking water;
- has been used for cleaning purposes in the food processing operation or other parts of a facility; and
- is part of a dairy operation’s effluent.

Applications of reuse water can broadly be categorized as not-for-food-contact or for-food-contact. The application for which a supply of water is intended to be reused, will determine whether that water is fit-for-purpose as recovered from a source within the dairy operation or whether a particular reconditioning process (e.g. purification, antimicrobial treatment) is required before it can be reused. Every water reuse scenario (i.e. the combination of reusable water source and reuse water application, including specifics such as recovery, reconditioning, storage and distribution) considered by a dairy operation needs to be thoroughly reviewed such that there is no undue consumer safety impact related to the food products it processes/manufactures.

Notably, when designing and operating a water reuse scenario, the prevailing regulatory requirements (e.g. laws, regulations, standards) and the advice of competent authorities will need to be carefully considered.

Implementing and continuous control of a reuse water scenario has to be within the operators' capabilities. The operator will need to prevent and/or control all potential hazards (including chemical, biological and physical) associated with the reusable water source and consider the intended application of the reuse water.

Importantly, the operational design and control of water reuse need to be tailored to the specific conditions of that particular dairy processing facility and be based on a good level of understanding and expertise concerning these following aspects:

- the microbiological status (e.g. presence and the level of hazards) of the reusable water source;
- the microbiological requirements associated with the reuse water application to ensure no undue impact on the safety of the food products made by food operation;
- the microbiological efficacy of the reuse water generation system, which is related to the combination of for instance the technologies, equipment and infrastructure deployed for water recovery, reconditioning, and storage;
- the need to consistently control the reuse water generation system as well as the application of the reuse water produced in the day-to-day operation; and
- the role of microbiological testing for validation and verification in designing and managing reuse water generation and use and the ability to apply appropriate testing approaches.

An assessment of potential microbiological hazards and a risk-based management approach used for achieving adequate control should support the design and implementation of water reuse scenario and, ultimately, its implementation at full scale.

When assessing potential microbiological hazards and establishing appropriate controls for reuse water generation and use, the following points are to be taken into account:

- the microbiological hazards present in the possible sources to generate reuse water supplies from (reusable water sources) as well as hazards associated with other parts of the operation (e.g. factory environment, storage and distribution system) that could contaminate a reuse water supply after it has been produced ;
- that nutrients may be present in a reuse water supply after recovery and reconditioning, which may foster the growth of spoilage organisms (thereby limiting shelf-life) or microbiological hazards (possibly increasing consumer risk, depending on the reuse water application);

- whether reuse water that has been recycled or recirculated multiple times in a specific process operation is leading to or has resulted in biofilm formation;
- whether any particular measure for the preservation or control of microbial growth is required over the set shelf-life of the reuse water supply; and
- the need to have available a back-up fit-for-purpose water supply, such as a drinking water source, that can be used in case the reuse water generation system is not under control or has failed.

There are clear similarities in how a food operation best controls food safety and how the generation of a water supply is best managed. In both cases, a risk- and evidence-based approach should be followed, from designing the overall reuse water scenario for an operation, to implementation and control at full scale. For the food operation, control measures will be necessary to ensure that any reuse water that comes in contact with food or food contact surfaces is fit-for-purpose. Such measures would include provisions to ensure that not fit-for-purpose water will not come in contact with food or food contact surfaces.

Operational control of the distribution and use of reuse water supplies should be managed through basic prerequisite programs (including a design and labelling of equipment and piping for water distribution that minimizes errors) and validated hazard control plans to control the reuse water generation and storage process, including monitoring and verification procedures to manage these aspects in day-to-day operation.

Hazard control plans for a reuse water generation process should be based on several steps derived from hazard analysis/risk assessment:

- identifying the known or potential hazards that a reusable water supply might have acquired through its earlier application;
- identifying hazards possibly contaminating the water in the course of reuse water generation, storage and use; and
- assessing the potential risk that any of the above identified hazards, based on the likelihood of their occurrence and concentration in the reuse water, may pose to consumer safety through the food being produced in the dairy operation. Hazard presence and levels may vary depending on the recovery or reconditioning process, storage conditions and the measures applied to reduce the hazards to acceptable levels.

Given that the microflora in water may differ in each situation, just like the specific recovery, purification or antimicrobial treatment conditions may vary between operations, it is recommended that the operator adequately validates each reuse water scenario, including key aspects such as the performance of the reuse water generation system so that it conforms with the required reuse water specifications

as well as the maximum shelf-life of the reuse water. Locally specific microbiological indicators of process or hygiene control may be of use for full scale operational validation and for verifying process control during routine operation.

For verification purposes, microbiological testing and analysis of, for instance, total viable counts or coliforms have proven to be useful. However, the microflora relevant for the reuse of water often is plant and operation specific. Hence it is generally not adequate to rely solely on testing for microbiological parameters such as the levels of coliforms that generally apply for (municipal) drinking water generation systems. For water reuse in the context of food operations such as in the dairy sector, coliforms may not be best suited but there may be other relevant microorganism(s) that may be better indicators of potential hazards, events or conditions (e.g. presence of nutrients) that may pose a risk. It is, therefore, essential to conduct an operation-specific study to determine which microbiological parameters/indicators maybe appropriate for use in controlling that particular water reuse scenario.

During operation, the reuse water generation process should be monitored daily, including timely verification of its microbiological status, in order to verify the effectiveness of the ongoing process control and thus, the suitability of the reuse water supply. Monitoring also enables taking timely actions should the process performance fail or found to be deficient.

For monitoring, microbiological verification may be too time-consuming compared to testing for physical or chemical parameters. The latter typically provides timelier results of ongoing process controls or for identifying situations trending towards out-of-control that microbiological tests, and thus may allow better for taking prompt action when needed.

For the safe reuse of water in dairy operations, technical expertise concerning the technologies underlying the recovery or reusable water and the reuse water generation system is essential. Equally crucial is the microbiological and risk-assessment knowledge/skills-base for determining fit-for-purpose reuse water scenarios. Third party suppliers and solution providers may assist the operations with such expertise and knowledge/skills. However, the ultimate responsibility rests with the management of the food business operation to ensure the safety and suitability of the food products being processed or manufactured.

This report focuses on the microorganisms that may pose health risks to consumers through food products when not adequately controlled at the point in the food supply chain where water is reused. Limited guidance is provided on pathogens of occupational health concern (e.g. *Legionella*), spoilage microorganisms that may alter food quality and stability, or pathogens involved in zoonotic diseases

(e.g. foot-and-mouth disease virus), nor is the control of potential chemical and physical hazards discussed in any detail. However, food business operators still need to establish effective operational control measures to prevent or control these hazards to ensure product safety, stability and quality as well as occupational safety of their workers.

## RECOMMENDATIONS

It is recommended that the food business operator (FBO) tailor each water reuse scenario to be implemented to the specific conditions of its particular food operation, taking into account: the purpose of water reuse, available sources of reusable water, the reuse water generation system and underlying processes, storage and shelf-life of reuse water supplies, the approach to managing reuse water generation and application, and the skills and expertise available to manage day-by-day the implemented water reuse scenario at the operational scale.

To discharge its responsibilities concerning the management of water reuse, it is recommended that the FBO ensures that the necessary resources required for water reuse are available from within its operation or from qualified external sources:

- Skills and expertise:
  - > to design and implement a fit-for-purpose water reuse scenario such that that all hazards (biological, chemical, physical) that may pose risks to consumer safety, occupational safety and animal diseases are controlled and any associated risks are managed down to acceptable levels and are in line with the intended purpose of water reuse; and
  - > to cover various technical, data and information, and managerial aspects for establishing a suitable water reuse scenario (including the generation, storage and application of reuse water supplies) and for managing it at full scale; these aspects include for instance, acquiring all necessary knowledge, data and evidence for the following:
    - hazard identification, hazard analysis, and (quantitative) risk assessment, including consideration of events or factors (e.g. nutrients in reuse water supplies; biofilms in water generation system and storage/distribution infrastructure) that may contribute to potential risks;
    - selecting adequate control measures and designing a robust hazard control plan;
    - the selection of suitable parameters (including acceptable limits/criteria) and data generation and analysis methods for validation of control measures, and/or for monitoring and verification of operational control; and

- > to take timely corrective action should the operation be trending towards out of control or should control be lost, including review and improvement of operational design and implementation.
- Equipment/infrastructure:
  - > to recover, recondition, store and distribute reuse water supplies, as necessary, ensuring that adequate logistics, zoning, labelling and other approaches control any unintended application of particular reuse water supplies; and
  - > to appropriately validate, monitor and verify the generation and application of reuse water supplies at full operational scale through the use of selected microbiological, chemical and physical parameters and methods.

Where an FBO resorts to using external resources, it is recommended that the specific water reuse scenario for a food operation is designed and implemented in close cooperation between the FBO and the external party, with the understanding that the final responsibility for the control of hazards and risks is with the FBO.

## KNOWLEDGE GAPS

While the interest in water reuse is increasing in dairy operations and other food sectors in several parts of the world, the practical deployment of water reuse scenarios in full scale operations is lagging behind. The awareness of stakeholders (i.e. from food industries and their service providers, government authorities, academia and consumers) on the urgency and benefits of increasing water reuse all along the food supply chain needs first to be raised.

There are notable gaps in the knowledge of food operators and other stakeholders concerning the development and operational management of water reuse, especially in settings that have limited technical and resource capacities.

In particular, the following gaps in knowledge and aspects of capacity/capability need to be considered when striving for further deployment of water reuse:

- the understanding of the types and levels of microbial hazards (as well as physical/chemical hazards) potentially present in reusable water sources within dairy operations as well as the ability to conduct appropriate risk assessment and hazard analysis for a particular water reuse scenario to evaluate consumer health risks (as well as worker or animal health risks);
- the ability to assess the effectiveness of individual or combined technologies for recovery and reconditioning of reusable water supplies and for mitigating relevant hazards to acceptable levels for the intended purposes, including



an appreciation of risk contributing factors such as biofilm formation and availability of nutrients;

- the validation of recovery, reconditioning, shelf-life/storage, and application technologies as well as the operational management during full scale operation, including how to monitor and verify key operational aspects to ensure overall control;
- the establishment and the use of microbiological parameters for verification of operational control and for validation and verification of water reuse operations. The parameters should be tailored to that particular dairy production and processing operation; and
- the deployment of suitable or alternative technologies for recovering and reconditioning water in dairy operations that have limited resources, capabilities, and technical infrastructure.

The gaps in knowledge and the needs to address capacities/capabilities, especially in low resource settings, may generally be alleviated by tailored international collaboration of various stakeholders and by sharing data, knowledge, evidence, expertise and other resources within and across various stakeholders. Especially relevant and urgent is the sharing of experiences and know how in setting up effective reuse water generation systems and fit-for-purpose applications of reuse water supplies in small to large dairy production and processing facilities, taking into consideration, the following areas of action:

- publicizing the hazards identified in reuse water scenarios as well as approaches to control and manage these used by industry and academia;
- mobilizing resources from the drinking water sector as they may provide useful insights into (reuse) water generation and operational control (including performance/effectiveness of technologies);
- sharing knowledge and evidence concerning the events and factors that may contribute to risk, such as carry-over nutrients/hazards into reuse water supplies, as well as options to avoid/control the associated risks;
- validation of technologies and control measures applied individually or in combination that can be studied in the laboratory, pilot or full scale by academia, industry, service providers, etc. Publishing these results may help to minimize efforts for individual operators, regulators and others from the need to conduct/require case-by-case validation of performance at all levels; and
- international collaboration across various stakeholders and the sharing of resources (including data, information, knowledge, expertise, etc.) may help those sectors and geographic locales where resources are limited to help develop tailored low-technology equipment and solutions that will enable them to embrace water reuse opportunities.

Sharing expertise and experience concerning monitoring and verification approaches, selection of microbiological parameters and best practices for batch-wise verification or trend analysis by industry as well as for competent authorities to develop suitable microbiological parameters for setting acceptable levels of microbiological hazards that are relevant to consumer health and is in line with policies on acceptable consumer risk.



# Introduction

## 1.1 BACKGROUND

At its 48th session of Codex Committee on Food Hygiene (CCFH), the Committee noted the importance of water quality and safety in food production and processing. CCFH requested the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to provide guidance for those scenarios where the use of “clean water” (i.e. water that does not compromise the safety of the food in the context of its use) was indicated in Codex texts and on where it is appropriate to use “clean water”. In particular, guidance was sought for the use of irrigation water and “clean” seawater and on the safe reuse of processing water.

To facilitate this work, FAO and WHO established a group of experts and convened two Expert Meetings (21–23 June 2017, Bilthoven, the Netherlands; 14–18 May 2018, Rome, Italy). The experts considered food safety aspects related to various types and purposes of water use and reuse for 1) fresh fruit and vegetables (FFV; pre- and post-harvest), 2) fishery products (FP; post-harvest) and 3) water reuse in establishments. They also considered risk management approaches to ensure the safety of water and food supplies (FAO and WHO, 2019). The experts developed risk-based fit-for-purpose approaches for water use and reuse in the FFV and FP sectors and for food processing operations. Where relevant, decision trees and/or decision support systems were developed.

As there were still crosscutting challenges in applying a risk-based approach (microbiological criteria, characteristics of microbiological hazards, data for risk assessments, etc.), a third expert meeting was convened (23–27 September 2019,

Geneva, Switzerland), which further explored the safety and quality of water used in the production of fresh fruits and vegetables (FAO and WHO, 2021a). The meeting discussed the feasibility and potential application of microbiological criteria for water to support decision-making when applying the concept of “fit-for-purpose” of water for use during pre- and post-harvest production of fresh produce. Practical interventions that could be applied pre- and post-harvest to mitigate microbiological food safety risks when water does not meet the requirement of fit-for-purpose were also considered.

In 2020, the 43rd session of Codex Alimentarius Commission (CAC) approved the new work entitled “Development of Guidelines for the Safe Use and Reuse of Water in Food Production” proposed by the 51st session of CCFH (FAO and WHO, 2020b). This work would elaborate guidelines for the safe sourcing, use and reuse of water in 1) fresh produce, 2) fish and fishery products from primary production to retail, and 3) in the dairy sector from milk harvest to manufacturing. The scope includes applications of water for direct and indirect product contact. Fit-for-purpose water sourcing, use and reuse would follow risk-based approaches and develop decision support tools, focusing on potential microbiological hazards (bacteria, viruses, parasites), and guidance concerning microbiological criteria as appropriate.

To support this work, the CCFH requested that JEMRA provide the scientific advice and case studies on sector-specific applications regarding fit-for-purpose water sourcing, use and reuse, focusing on potential microbiological hazards (bacteria, viruses, parasites), following risk-based approaches and, where appropriate, developing decision support tools and guidance concerning microbiological parameters such as microbiological thresholds (limits) or microbiological criteria.

As the third meeting already discussed and addressed the issue in fresh produce, this fourth meeting was convened as an online meeting from 14 June to 2 July 2021 considering the fish and dairy sectors. At this meeting, it was decided that the advice and guidance for these different sectors would best be captured in separate reports. This report concerns the fit-for-purpose water sourcing, use and reuse of water in the dairy sector, particularly in dairy processing operations.

## **1.2. SCOPE AND AIM OF THE MEETING**

The meeting was convened to develop clear and practical guidance on fit-for-purpose sourcing, use and reuse of water in the dairy sector, i.e. dairy production operations and dairy processing operations.

The main objective of the meeting was to provide practical advice and guidance on the generation of reuse water supplies from reusable water sources within dairy operations and their fit-for-purpose application in these dairy operations, which includes:

- to discuss the microbiological aspects of the water used in the dairy sector;
- to consider the potential reusable water sources that could typically be available for dairy operations and can be exploited to reduce the volume of first-use water, following a fit-for-purpose approach;
- to consider different microorganisms (utility organisms, indicator organisms, human pathogens), microbiological parameters (thresholds or criteria) and their levels that would be appropriate for assessing the fitness of a water supply for its intended purpose or for validation and verification of operational control over reuse water generation and use; and
- to illustrate water sourcing, use and reuse approaches in the dairy sector with examples of case studies.

### **1.3. STRUCTURE OF THE REPORT**

This report is compiled and structured to provide information relevant for the various steps to take in matching potential reusable water sources with fit-for-purpose applications in dairy operations:

- Determine available reusable water supply and the desired/prospective reuse water application.
- Identify microbiological requirements for safety and stability of the reuse water given the application foreseen.
- Establish whether the reusable water source meets such requirements as it is recovered, reclaimed or recirculated, considering any necessary transport/storage of the reuse water as well in the operation until the water is applied.
- When the water does meet requirements, no reconditioning/treatment may be required, and its application can be implemented in the dairy operation.
- When it does not meet requirements,
  - > identify the hazards and stability concerns associated with the reusable water supply and assess to what level they need to be reduced to meet the microbiological requirements for the application;
  - > design the reconditioning/treatment processes that bring the reusable water supply in line with the microbiological requirements and allow for the necessary transport/storage of the reuse water produced until its application (including back-up provisions, such as a first-use water source); and
  - > implement and operationalise reuse water generation, storage and application, including the necessary monitoring for control of the operations.

These steps provide a systematic approach to evaluate the utility of reusable water sources available to a specific dairy operation. For each source, the potential of water reuse needs to be assessed given the various food contact and not-for-food contact applications in a process and the means/capabilities of the operation to design and implement such suitable reuse water applications in a controlled manner.

Chapter 2 considers the range of uses of water in dairy operations. The water used in some of these may represent a source of water that can be reused, as illustrated in Chapter 3, by several water reuse scenarios. In Chapter 4, the microbiological characteristics of typical sources of reusable water are discussed. Chapter 5 elaborates on the design of tailored water reuse scenarios for specific dairy operations, considering the microbiology of several potential reusable water sources and using hazard analysis and risk assessment to establish key design aspects of operational control of a water reuse water scenario ensuring fit-for-purpose applications. The implemented and operationalized of such a design within the management systems of the operation is covered in Chapter 5 as well. Chapter 6 discusses the usefulness of microbiological testing for operational control of reuse water generation, storage and application, including for validation, verification and monitoring. Chapter 7 covers recommendations regarding water reuse in dairy operations and notes several knowledge gaps.

Three annexes (1–3) provide further technical details on water recovery, purification and antimicrobial treatment, whereas Annex 4 describes a number of case studies for different water reuse scenarios.



# 2

## Use and reuse of water in dairy operations

### 2.1 CODEX ALIMENTARIUS PROVISIONS CONCERNING WATER USE AND REUSE

The Codex Code of Hygienic Practice for Milk and Milk Products (FAO and WHO, 2009) states that water and other environmental factors should be managed in a way that minimizes the potential for the transmission, directly or indirectly, of hazards into the milk and that water used in primary production operations should be suitable for its intended purpose and should not contribute to the introduction of hazards into milk. **Table 1** lists the statement included in this code concerning the first-use and reuse of water in dairy operations.

These specific provisions for the dairy sector are complemented by general provisions on water use and reuse as stipulated in the General Principles of Food Hygiene CXC 1-1969 (FAO and WHO, 2020a):

- Water and ice should be stored and handled in a manner that does not result in their contamination.
- Water that is not fit for use in contact with food should have a separate system that does not connect with or allow reflux into the system for water that will contact food.
- Water recirculated for reuse and water recovered from evaporation and/or filtration, should be treated where necessary to ensure that it does not compromise the safety and suitability of food.

**TABLE 1** Codex Alimentarius provisions concerning the (re-)use of water in dairy operations

PROVISIONS	ADDITIONAL COMMENTS
Dairy processing establishments should have potable water available, which prior to its first use, should meet the criteria specified by the competent authorities having jurisdiction and should be regularly monitored.	
Appropriate safety and suitability criteria that meet the intended outcomes should be established for any water used in dairy processing.	These criteria depend upon the origin and the intended use of the water. For example, reuse water intended for incorporation into a food product should at least meet the microbiological specifications for potable water.
Water recirculated for reuse should be treated and maintained in such a condition that no risk to the safety and suitability of food results from its use	Proper maintenance of water conditioning systems is critical to avoid the systems becoming sources of contamination. For example, filter systems can become sources of bacteria and their metabolites if bacteria are allowed to grow on the organic materials that have accumulated on the filter.
Reconditioning of water for reuse and use of reclaimed, recirculated and recycled water should be managed in accordance with HACCP principles.	Any reuse of water should be subject to a hazard analysis including assessment of whether it is appropriate for reconditioning. Critical control point(s) should be identified, as appropriate, and critical limit(s) established and monitored to verify compliance.

Source: **FAO & WHO**. 2009. Codex Alimentarius. Code of Hygienic Practice for Milk and Milk Products (CXC 57-2004). Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/tr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B57-2004%252FCXC\\_057e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/tr/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B57-2004%252FCXC_057e.pdf)

## 2.2. WATER REUSE IN THE PRIMARY PRODUCTION PHASE

On dairy farms, options for water reuse are limited due to the infrastructure investment required for recovering and, where needed, reconditioning reused water. Some of the potential reusable water sources include:

- surplus drinking water, including municipal/urban treated water, potable water or water from suitable private wells;
- water from cleaning and disinfection activities, e.g. water used in the cleaning of trucks and storage tanks, or water used for cooling or transport; and
- wastewater/effluent from the production of whey, wash water (e.g. butter washing, casein wash), etc.

Rather than discarding or wasting water from such sources, it should be collected, recovered, reconditioned (e.g. purified and treated to reduce the microbial load), as appropriate, and used for many purposes in the dairy operation instead of first-use water.



Technologies and infrastructure typically available at primary production operations that could be used to exploit potentially reusable water sources are limited, and the same may be said about the capabilities (i.e. skills and expertise) of the operators at that stage. Still, reusable water sourcing and reconditioning (as necessary) could add value for the dairy production operations wishing to reduce overall consumption of first-use water, and any necessary capabilities may be accessible through third party experts.

Practical guidance on fit-for-purpose water reuse and on the operational control of the generation of reuse water supplies in dairy production operations would be the same as that for dairy processing operations. See guidance on the latter in the following chapters.

### 2.3. WATER REUSE IN THE PROCESSING PHASE

Dairy processing operations (Creameries) traditionally have a high consumption of first-use water that is potable and meets drinking water requirements (WHO, 2022). Most dairy processing plants consume from one to ten m<sup>3</sup> of first-use water per every m<sup>3</sup> of processed milk (Wojdalski *et al.*, 2013).

Some important reasons to conserve water and to reduce water wastes (EDA, 2018):

- Water and sewer charges will continue to increase.
- High water consumption is making availability critical in some cases.
- Future regulations may require water conservation and reductions in pollutant discharges

Additionally, responsible use of water underpins achieving UN Sustainable Development Goals, in particular Goal 6, Clean Water and Sanitation (UN, 2022).

Companies that adopt a systematic approach to water reduction can typically achieve a 20–50 percent decrease in the amount of first-use water consumed and the amount of effluent generated (Envirowise, 2007). In certain productions, the reduction rate can be even higher.

Water is used for a wide range of processes within a dairy processing plant. Cleaning of production equipment, cooling of products, boiler feed water for heat production, and purification of processing products all require water. The internal cleaning of production equipment is performed in a closed system without disassembly of pipes and with intact joints using the so-called cleaning-in-place system (CIP) to achieve the most sanitary result and avoid cross-contamination of dairy products.

Drinking water demands are expected to increase with the expanding human population. Drinking water resources are already under excessive demand in arid regions, with low rainfall, limited infrastructure and high population density. The mismatch between water availability and demand is likely to increase further in these areas, but also in temperate regions where intense agricultural, tourism and industrial activities result increasingly in frequent water shortages and/or expensive water supply solutions.

In this context, water reuse is considered an important additional approach to reduce first-use water consumption, for instance:

- Rather than discarding surplus drinking water (e.g. urban treated, potable water or water from suitable private wells), it can be recovered and recycled for a variety of purposes in the dairy operation.
- Rather than discarding water from cleaning and disinfection activities, that water could be collected, appropriately reconditioned, and reused in keeping with the technical capabilities and possible investments of the operator.

## **2.4. PRINCIPLES UNDERLYING FIT-FOR-PURPOSE WATER USE AND REUSE**

A key point of reference for the dairy operator on reuse water was the JEMRA work done earlier (FAO and WHO, 2019) on the principles underlying a fit-for-purpose approach to water use and reuse in food processing operations.

A fit-for-purpose approach recognizes that different types of potentially reusable water may be available in a food operation and could be suitable for particular applications as recovered, i.e. without further treatment. Where necessary, a reusable water supply needs to be treated to render it suitable by appropriate reconditioning in order to meet specific microbiological requirements associated with the intended use of the reuse water supply.

The fit-for-purpose approach advocated by FAO and WHO (2019) matches water use and reuse by following a risk-based approach in deciding whether the purpose of the reuse water application can meet the microbiological requirements for that application, such that the food being produced or processed in the food operation, does not pose an undue risk to the consumer. This approach can reduce the volume of first-use, potable water used in a food operation and in line with the provisions of Codex Alimentarius concerning water use and reuse in the dairy sector as well as in other sectors.

In food operations, there are basically two types of purposes of water application, with regards to the level of potential consumer risk posed by microbiological hazards in the context of water use and reuse:

- Water intended for food contact purposes: water that by design of the operation, will come in contact with food (directly or indirectly; intentionally or unintentionally). Examples are: water used as an ingredient in the food product processed or manufactured; water used for transport or transformation of raw materials; water used for washing/cleaning of raw materials or food contact surfaces and equipment. The level of consumer risk depends to a large part on the likelihood that water comes in contact with food and the likelihood that hazards are present in the reuse water supply. When using water as an ingredient, food contact is inevitable, but when using water for cleaning equipment, the likelihood of food contact may be relatively low. In all cases, microbiological requirements of the food need to be considered and actively managed to ensure consumer safety.
- Water intended for not-for-food-contact purposes: water that by design should not come in contact with food. For instance, water used for making technical steam or for firefighting; water used for heating/cooling offices or non-food related factory buildings; and water for personnel uses, such as hand washing, flushing toilets or for use in canteens. In most of these cases, where the likelihood of food contact is very low to non-existent, microbiological requirements for consumer safety are less important or irrelevant to consider.

In both cases, an operator must also consider factors other than microbiological risks, such as occupational safety, reuse water spoilage, and chemical or other hazards and risks.

If the microbiological quality of a reuse water as sourced or recovered is not suitable for food contact applications, that water can only be used for not-for-food purposes, unless it can be reconditioned, for instance by purification and or microbiocidal treatment, to meet the specific microbiological requirements for food contact application.

Water used for cleaning or other operations away from processing lines that, by design, are not intended to result in water contacting food, is sometimes referred to as water for “indirect” or “unintended” food contact applications. Examples include: cleaning and disinfection of equipment, floors, walls and heating and cooling steps during food processing. In these cases, cross-contamination of microbiological hazards in the reuse water supplies to foods or to food contact surfaces may occur. Hence, such contact or cross-contamination of hazards needs to be reliably evaluated and prevented or else actively controlled and monitored.

Overall, the fit-for-purpose approach should take into account three considerations:

- the microbiological quality of a reusable water source;
- the microbiological requirement for the water, given its purpose of application; and
- the ability of the food operation to design, implement and control the process to generate water from a reusable water source and to apply the reuse water supplies for the intended purpose, such that the operation does not compromise the safety of its dairy products.

**Table 2** provides a logistical overview that matches these three considerations to establish fit-for-purpose applications of reuse water.

Note that first-use water of potable quality is fit for any use purposes in a food operation, but that reuse water needs to be reconditioned or applied selectively. However, there is a good potential to use reuse water instead of first-use water, thereby, reducing first-use water consumption in the food operation.

All three reuse water types (recirculating, reclaimed and recycled) 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 the microbiological basis, all four water types are fit-for-purpose as sourced, for not-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.

Note that water reuse in food operations must comply with prevailing laws, and with regulations and standards for consumer safety and occupational safety, which may limit certain water reuse applications.

**TABLE 2** Overview of fit-for-purpose considerations for different water use purposes and types of water reuse

PURPOSES	FIRST-USE WATER	RECIRCULATED WATER	RECLAIMED WATER	RECYCLED WATER
e.g.	Potable source	Closed loop	Recovered from a food material	Recovered from a process step
<b>Food ingredient</b>	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
<b>Direct food contact</b>	Fit-for-purpose as sourced	Fit-for-purpose until undue level of significant hazards are found; needs reconditioning to reuse	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
<b>Unintended food contact</b>	Fit-for-purpose as sourced	Fit-for-purpose as recovered if no significant hazards are present, or food contact is avoided	Fit-for-purpose as recovered if no significant hazards are present, or food contact is avoided	Fit-for-purpose as recovered if no significant hazards are present, or food contact is avoided
<b>Not for food contact</b>	Fit-for-purpose as sourced	Fit-for-purpose as sourced	Fit-for-purpose as sourced	Fit-for-purpose as sourced

Source: Authors' own elaboration.





# Water reuse potential and typical water reuse scenarios in dairy processing operations

## **3.1. WATER REUSE POTENTIAL IN DAIRY PROCESSING OPERATIONS**

The quality of water that by design comes in direct contact with food during processing or that is used as a food ingredient, must be equivalent to drinking water microbiological quality standards, unless the food business operator can demonstrate (to the satisfaction of the relevant competent authority) that a supply of water used will not contaminate such food or that its use does not result in adverse health consequences for consumers.

This report distinguishes first-use water, which is water supplied to the dairy plant from external sources in the form of drinking water or other potable water sources, such as well water or waterworks water that are compliant with authoritative drinking water standard (e.g. WHO, 2022) and meets the necessary criteria for food use without any further conditioning (e.g. purification, microbiocidal treatment), from reusable water that may be available from various different sources within a dairy processing operation.

In principle, all water found within a dairy operation can be reused, but it depends on the water reuse scenario as to whether a reusable water supply is fit-for-purpose, or it needs to be conditioned prior to reuse. To ensure that water reuse does not lead to food contamination in the operation and possible consumer risks, a reusable

water supply should be analysed for hazards and assessed for possible consumer risks associated with its intended use in the dairy operation. When hazard analysis and risk assessment has identified particular hazards and risks, these will need to be controlled by an appropriately designed systems for reuse water generation and use.

There is a good potential for reusing water from many sources within the dairy operation. These potential sources include:

- drinking water or CIP liquids;
- water from milk or milk processing (e.g. milk powder, milk protein or cheese manufacturing);
- water from dairy effluents that, otherwise, would be discarded; and
- water from sources that are not related to food processing operations, such as rainwater, private well water on the premises, etc.

It is crucial to ensure that the sources of water for potential reuse are adequately treated to meet the fit-for-purpose specifications associated to that next use.

Typically, recovery and reconditioning of water for reuse are undertaken by the dairy operation, using a risk-based, fit-for-purpose approach to ensure that the water reuse scenario meets prevailing food safety and regulatory requirements. Licensed third party operators could provide supplies of fit-for-purpose water to a dairy operation by managing the recovery and/or reconditioning of reusable water sources from that dairy operation or from other operations (e.g. dairy, non-dairy, food or non-food operations).

In any case, it is crucial to ensure that the sources of water for potential reuse are adequately treated to meet the fit-for-purpose specifications for that particular next use. This responsibility lies with the dairy operator that is reusing the water in its operation, independent of whether reuse water generation is internally managed or through third parties.

Annex 1, 2 and 3 in this report provide information on the various technologies used in the recovery, separation, purification and microbiocidal treatment of reusable water supplies, for the purpose of reducing first-water use and increasing the reuse of suitable water sources internal or external from the dairy operations.

Typical water reuse applications in dairy operations are briefly illustrated below. The case studies included in Annex 4 provides detailed information on several fit-for-purpose reuse applications.



## **3.2. EXAMPLES OF WATER REUSE SCENARIOS**

### **3.2.1. Reuse of drinking water by recirculation or recycling**

Recirculation of drinking water in a closed system (i.e. without food contact and with no replenishment) is a type of reuse of water that should be acceptable as is, unless there is a chance of contamination over time and/or number of recirculations. In the latter case, there should be a defined end point for the number of times of recirculation, beyond which, the water can be recovered and recycled, but it may also need to be reconditioned depending on the intended purpose of reuse.

In Annex 4, Case studies 1 and 2 provide further details on the reuse of locally sourced drinking water as well as potable water that has been recirculated.

### **3.2.2. Recovery and reuse of water from cleaning-in-place (CIP) systems**

Large volumes of water in dairy processing operations are used in CIP systems. These are water-based cleaning and sanitizing systems used to clean and disinfect (sanitize) product flow pipes and equipment without disassembly.

The main objective of a CIP system is to clean and sanitise processing equipment and the surrounding environment to prevent the occurrence, spread and contamination of foreign materials and microbiological hazards. This is primarily achieved by removing dirt and food residues from food contact surfaces and to remove or reduce biofilm formation. Equipment that comes in direct contact with food or food packages must be sanitized after cleaning to prevent cross-contamination and to meet acceptable microbiological criteria.

The water used in the CIP system should be of a quality suitable for its intended use. If drinking water from municipal supplies is used, no microbiological criteria are required.

A typical CIP system consists of a five-step procedure:

- 1) Pre-rinsing/flushing
- 2) Alkali cleaning
- 3) Middle rinsing
- 4) Acid cleaning
- 5) Final rinsing

The CIP protocol should include a description of the water quality needed for rinsing in between chemical treatments and for the final rinse. It should also specify the frequency of emptying and cleaning the overall CIP systems.

For the recovery and reuse of CIP water, a dairy processing operator needs to determine the appropriate parameters for separating product rinsing/flushing water (steps 1, 3, 4 above), alkali water, and acid water, at what cut-off value to end their use, when to recover and reuse for what purpose.

For instance, the following examples of cut-off values as determined by automatic in-line measurements, may serve as a general guide for separation to be considered:

- Separate after product flushing, when chemical oxygen demand (COD) is  $\leq 100$  mg O<sub>2</sub>/L, turbidity is  $< 3$  formazin turbidity unit (FTU) and/or conductivity is  $\leq 300$  milli Siemens (mS)/cm.
- Separate after alkali rinse, when pH is  $< 8.0$  and conductivity is  $\leq 40$  mS/cm.
- Separate after acid rinse, when pH is  $> 6.0$  and conductivity is  $\leq 30$  mS/cm.

Some examples of how water recovered from CIP may be used (CSI, 2022):

- The caustic wash water can be returned to its tank and reused multiple times, which significantly reduces water, chemical and energy costs over a single tank system.
- The middle and final rinse water can be reused as a pre-rinse solution for the next cleaning (CIP) cycle or used to dislodge milk solids before first-use water is deployed.

If first-use/drinking water is used for CIP, the recovered water may be used as water of potable quality depending on the purpose of its use in the CIP system. For other reuse purposes, the recovered CIP water should be evaluated by a risk-based, fit-for-purpose approach, to assess the presence of possible hazards in the recovered water and to establish adequate controls throughout the recovery operation. Reconditioning the recovered CIP water may also be required depending on the purpose for reuse.

Case study 3 in Annex 4 provides further details on the reuse of CIP water.

### **3.2.3. Recovery and reuse of water from food production/processing**

Water presents in milk or milk products (referred to as “milk water”) can be recovered during the processing operation and reused within the operation to fit-the-purpose of the next application. Milk water may contain small amounts of milk components and, as such, does not meet the criteria established for drinking water.

There are many sources of milk water that may potentially be reused but these often differ in their microbiological quality. The following examples illustrate the range of reusable water sources, with some considerations regarding the microorganisms relevant for water reuse.

### Product flush/rinse

- Product flush/rinse water is used to "push" food materials out of processing pipes or deposits out of closed equipment prior to cleaning, so it is analogous to a pre-rinse.
- Product flush/rinse water consists of a mixture of water and milk, milk-based food materials and deposits. It may contain non-hazardous product residues and different microorganisms, depending on the initial microflora present in the water, milk or food materials or because microorganisms have been transferred from contact with pipes and other parts of the processing environment.
- Considerations concerning microorganisms/hazards:
  - > Product flush/rinse water collected from equipment used to process pasteurized products usually does not contain pathogens but may be subject to post-process contamination or contamination by bacteria detached from biofilms in the system. Such biofilms can be formed by bacteria (pathogens and non-pathogens) colonizing equipment surfaces, surfaces of milk transport pipes, milking containers, and accessories in the dairy industries, and impacts both safety and quality. Biofilms can be formed by viable cells or spores, but especially by thermoresistant *Streptococcus* (e.g. *S. thermophiles* and *S. macedonicus*) and thermophilic spore-forming bacilli (e.g. *Geobacillus*) which, when present, can survive pasteurization and contaminate the flush/rinse water supply.
  - > Product flush/rinse water purified via a membrane filtration process such as ultrafiltration (UF) may still contain pathogens. Even when low numbers of pathogens were present in the pasteurized milk, some may be retained on the retentate side of the membrane. For example, when the concentration of bacteria in the UF permeate has been reduced by 3 log cfu/g, that level of microorganisms will likely be retained in the UF retentate. Technology 4 in Annex 2 provides further details on the UF purification process.
  - > Biofilms can form in the membrane filtration processes and be flushed/rinsed out with the product. In such cases, the biofilm-forming organisms present in the product flush/rinse water are typically of the genus *Klebsiella*, *Bacillus* and *Pseudomonas*.
  - > Acidification of flush/rinse water inhibit microbial growth, but acid tolerant or resistant microorganisms need to be considered in hazard analysis/risk assessment.

### **Condensate**

- Condensate is milk water that has been obtained by full or partial evaporation of dairy products, including those by further drying of, for instance, milk, lactose, proteins or cheese to powder.
- Condensate typically contains some organic materials and is likely to support microbial growth.
- Lactic acid is the most commonly found chemical compound in milk condensate.
- Condensate from evaporators generally is very pure and almost free of chemicals, and as such, can be treated directly in a Reverse Osmosis Polisher (ROP) and achieve a COD of <10 mg O<sub>2</sub>/L.
- Technology 1 in Annex 1 provides further details on the recovery of condensate water.

### **Casein wash water**

- Casein production consumes large amounts of water to leach out milk constituents (e.g. lactose and minerals) from the casein curd.
- Casein wash likely supports microbial growth, since it contains whey proteins and water-soluble milk constituents (e.g. salts, amino acids, free fatty acids, lactose). Also, non-hazardous microorganisms, such as those from starter cultures, are probably present as well.
- Whey proteins can be separated from casein, wash water and the water recovered for reuse within the plant but may involve purification by Reverse Osmosis (RO). Carbon dioxide or hydrochloric acid may be used as a processing aid to neutralize casein water before RO treatment.

### **Whey and whey permeate**

- Whey is a by-product of syneresis during the production of cheese and casein/caseinate. It contains milk proteins (primarily whey proteins), lactose, milk salts, other water-soluble milk constituents (e.g. amino acids, free fatty acids), and possibly, residues of cheese milk additives (e.g. nitrate). Whey can also contain cheese residues, which typically are separated from the whey before it is further processed.
- Whey permeates results from the Ultrafiltration (UF) processing of whey for the purpose of recovering and purifying milk proteins. It contains lactose, milk salts, other water-soluble milk constituents (e.g. amino acids, free fatty acids), and possibly, residues of cheese additives (e.g. nitrate). Whey permeate is often treated by RO (also Technology 3, Annex 2).
- Whey permeate will support microbial growth unless it is adequately acidified.
- Case study 4 in Annex 4 provides further details on the recovery of water from whey and treatment involving RO.

### **3.2.4. Recovery and reuse of dairy effluents**

Dairy effluents generated in dairy processing operations can be recovered for reuse in fit-for-purpose applications. However, aside from containing milk constituents, these effluents can also contain identifiable components that require purpose-specific risk assessment and management prior to reuse. Examples of these components include detergents, residues of cleaning agents, used disinfectants, chemicals added for adjusting the pH (e.g. carbon dioxide or slaked lime) as well as agents added to the effluent at the treatment plant (e.g. aerobic or anaerobic microorganisms, polymers for sludge treatment in a digester, etc.).

Wastewater effluents such as blackwater (i.e. from toilets or urinals) or grey water (used for washing, laundry, baths or showers) are not fit for reuse. These may contain unidentified components and hazards that are difficult to risk assess and control in the operation. As a result, possible health or occupational safety concerns cannot be excluded.

Case study 5 provides further details on the recovery and applications of water from dairy effluents.

### **3.2.5. Water recovery and reuse from non-food manufacturing operations**

Water originating from external sources such as private wells may vary in chemical, microbiological and physical content, and may contain unidentified components. However, if risk assessment and management can demonstrate possible fit-for-purpose applications in the dairy processing operation without health and occupational safety concerns, these sources of water may be utilized as recovered/obtained provided that they meet the microbiological requirements of the intended purpose(s), e.g. for non-food contact purposes.

For food-contact purpose application, it is critical that the health impacts of risks of identified as well as unidentified components are carefully assessed and managed, and that the water are reconditioned as required to mitigate risks.

Case study 1 illustrates the use of water from local wells at or near the premise of the food business operators (FBO).





# 4

## Issues to consider in designing a water reuse scenario

A dairy operator must be able to demonstrate that a reuse water supply has been generated and is used under operational conditions that are well managed and meets relevant legislative requirements. This is best carried out through a systematic approach for designing and implementing the water reuse scenario that a dairy operation wishes to deploy, supported by proper documentation of underlying rationales and decision-making processes.

At the designing stage, a risk assessment should be done to systematically evaluate possible water reuse scenarios, determining the step(s) in the dairy operation where water reuse may be applied, assessing whether sources of reusable water are available, and selecting the necessary controls for potential hazards such as to minimize food safety risks. The operator is responsible for ensuring that these hazards, if any, are adequately controlled such that the food material/product does not pose undue consumer health risks.<sup>1</sup> A risk assessment, therefore, is a decision supporting tool that provides managers of dairy operations with an objective and rational picture of what is known (or assumed, based on expert judgement) about the likelihood of the risks associated with the reuse water scenario and the robustness of the full scale operation management.

The operational manager needs to know the microbiological characteristics of the raw materials used in making their dairy products and that of the operation environment, as the introduction of hazards into the operation and food processing

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<sup>1</sup> Next to possible consumer health risks, the operator has to account for occupational health risks.

steps will impact the microbiological quality of the reusable water sources and the generated water for reuse.<sup>2</sup>

Understanding the microbiological quality of a reusable water source is crucial for ensuring the safety of the food products being processed in the operation, for ensuring that regulatory standards are met, and for making decisions on the recovery and reconditioning technologies to be used, as well as whether in-house or third-party expertise is needed for managing the reuse water generation operation. Some general information on the microbiological characteristics of raw materials used in dairy products is provided below (section 4.1).

Once a water reuse scenario is implemented, the reuse water generation and the application will need to be controlled operationally, following practices such as good hygiene and a HACCP for managing the food safety aspects and/or Water Safety Plan for generating the reuse water. The operator has to control the process generating the reuse water as well as the supply of water to be reused in the food operation (including transport, delivery, storage). Based on the assessment of the microbiological hazards and possible associated consumer risks, reuse water generation and application at the full scale operation need to be managed to ensure water and food safety, taking into account other risks (e.g. occupational) or concerns (e.g. quality). The design of the full scale operation will have to consider the available infrastructure, technologies and technical capabilities available to the food business operator. Such capabilities relate to implementation and day-to-day control of the full scale operation, including validation, monitoring and verification of reuse water generation and application (Chapter 5). If the capabilities and resources of the operator are limited, use of external support will be essential.

## **4.1. MICROBIOLOGY OF RAW DAIRY MATERIALS AND PRODUCTS**

Although chemical and physical hazards are also important factors to consider when setting up a suitable reuse water generation system in a dairy processing operation, this report focuses mainly on understanding the microbiological quality of potentially reusable water sources. In particular, this concerns understanding the microbial pathogens and other microorganisms typically associated with raw, partly processed and final dairy materials and products from which water can be reclaimed or water and effluents from the processing operations from which water can be recovered for reuse.

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<sup>2</sup> Next to microbiological hazards, the operator has to account for potential chemical and physical hazards, as well as for shelf-life/quality issues of food products processed/manufactured, the totality of which is not covered in this report.



### 4.1.1. MICROBIOLOGY OF RAW MILK

Milk is generally regarded as sterile in the udders of healthy animals. However, once it is milked, it can become contaminated with microorganisms from the handling, equipment, environment and many other sources. As a result, the microflora of raw milk, regardless of the animal source, is very complex and comprises many different genera of Gram-negative and -positive bacteria. A comprehensive review of raw milk flora described studies that used both culture-based and gene sequencing methods found over 25 genera and 100 species of bacteria in raw milk sourced from cow, goats, sheep and buffalo (Quigley *et al.*, 2013). A variety of viruses have also been isolated from raw milk, especially milk from infected animals (Herlekar *et al.*, 2013; Wellenberg *et al.*, 2002). Surveys of raw milk obtained from various animal sources worldwide reported that the levels of indicator bacteria like coliforms and *Escherichia coli* in raw milk can range from <1 to 6 logs cfu/ml and 1 to 4 logs cfu/ml, respectively (Metz *et al.*, 2020). Different pathogenic bacteria that can cause severe human illnesses can also be present in raw milk. Microbiological analysis of bulk tank milk in the United States of America showed the presence of *Campylobacter* spp. ranged from 0.9 to 12.3 percent, Shiga toxin-producing *E. coli* (STEC) from 0.8 to 3.8 percent, *Listeria monocytogenes* from 1 to 12.6 percent and *Salmonella* spp. from 0.2 to 8.9 percent (Oliver *et al.*, 2005). Outbreaks caused by *Campylobacter* spp., *Salmonella* spp. and STEC have been associated with the consumption of raw milk (Mungai *et al.*, 2015).

### 4.1.2. Processing impact on microbiology of milk

An effective means of increasing the safety of milk is pasteurization, a process whereby liquids or foods are heated to kill disease-causing microorganisms, such as *Brucella*, *Campylobacter*, STEC O157:H7, *Listeria*, *Mycobacterium bovis*, *Salmonella*, and *Yersinia*, to name a few. Both FAO and WHO have defined pasteurization as “A microbiocidal heat treatment aimed at reducing the number of any pathogenic microorganisms in milk and liquid milk products, if present, to a level at which they do not constitute a significant health hazard. Pasteurization conditions are usually designed to effectively destroy the target organisms *Mycobacterium tuberculosis* and *Coxiella burnetii*” (FAO and WHO, 2009).

Different strategies and conditions have been used to pasteurize milk:

- High-temperature-short-time (HTST), milk is pasteurized at 71.7 °C for 15 seconds.
- Low-temperature-long-time (LTLT), milk is pasteurized at 62.8 °C for 30 minutes.

- Ultra-pasteurization, milk or cream is heated to 137.8 °C for 2 seconds (extends product shelf life from 60 to 90 days at refrigerated temperatures).
- Ultra-high temperature (UHT), heating milk to 137.8 °C to 150 °C for 1 or 2 seconds followed by airtight packaging (allows unrefrigerated storage of the product for up to 90 days.)

Bacterial pathogens vary in their tolerance to heat (Sarkar, 2015) but for the most part, pasteurization conditions are effective in reducing pathogen levels and thus, reducing health risk. The effectiveness of pasteurization and the microbiological quality of pasteurized milk is greatly affected by the quality of the raw milk (initial microflora and microbial), the pasteurization process parameters used and the safe handling and the hygienic conditions at the plant. It is important to use raw milk of good microbiological quality in dairy processing in order not to overwhelm the effectiveness of the pasteurization process, or else high levels of microorganisms in the pasteurized milk may possibly cause product spoilage, cross-contamination and biofilm formation.

Viruses are not very resistant to heat and pasteurization. Temperatures of 62.5 °C are usually enough to reduce the viral load by several logs or to below detectable limits (Pitino *et al.*, 2021). For the dairy industry, the small RNA virus that causes foot-and-mouth disease (FMD) is a major concern. Although it poses no health risk to humans, FMD virus (FMDV) is highly contagious to cattle and can be present in all tissues and fluids of infected dairy cows, including the milk (Tomasula *et al.*, 2007). Studies on the effects of pasteurization on FMDV showed that minimum pasteurization parameters may not be sufficient to eliminate FMDV in milk (Tomasula and Konstance, 2004). Similarly, HTST pasteurization did not completely inactivate viral infectivity in whole and 2 percent milk, possibly due to the protective effects of milk fat and the casein proteins, but it did greatly reduce the risk of viral transmission via milk (Tomasula *et al.*, 2007). WOAHA Terrestrial Animal Health Code (WOAHA, 2021) specifies the followings as procedures for the inactivation of FMDV in milk and cream for human consumption: 1) a process applying a minimum temperature of 132 °C for at least one second (ultra-high temperature [UHT]), or 2), a process applying a minimum temperature of 72 °C for at least 15 seconds (high temperature - short time pasteurisation [HTST]) combined with reducing the pH to less than 7.0, or, 3) if the milk has a pH of 7.0 or greater, the HTST process applied twice.

Pasteurization is not very effective against bacterial spores. Spore-forming bacteria, especially of *Bacillus* species, are common contaminants of raw milk. *Bacillus* spores are highly resistant to heat and able to survive heating for 40 minutes at 100 °C. A study by Lin *et al.* (1998) showed that *B. cereus* contaminant in raw milk was the major source of *B. cereus* spores detected in pasteurized milk and that bacterial spores will survive various pasteurization conditions, including UHT (Kmiha *et al.*, 2017).

Pasteurization is broadly used worldwide but unlike with the sterilization process, pasteurized milk is not free of microbes. Studies from many countries worldwide showed that pasteurized milk can contain various bacteria, including pathogens (Sarkar, 2015).

#### **4.1.3. Microbiology of milk products**

Aside from being processed into pasteurized milk, raw milk is also used in many countries worldwide to make a variety of raw dairy products, including raw milk cheeses, raw ice cream, and raw yogurts. If high numbers of bacteria and pathogens are present in the raw milk, they can survive processing, such as the cheese making process, and be present in the end products (Metz *et al.*, 2020). Different bacterial pathogens in raw milk cheeses have caused foodborne infections worldwide (Costanzo *et al.*, 2020; Currie *et al.*, 2018; EFSA, 2018).

Studies have shown that various bacteria that can be present in raw milk like *Pseudomonas*, *Aeromonas*, *Staphylococcus*, *Bacillus*, *Listeria*, lactic acid bacteria, and members of the family *Enterobacteriaceae*, which include *Salmonella* and STEC pathogens, can adhere and aggregate on stainless steel surfaces and form biofilms in milk storage tanks and in various parts of the processing line (Marchand *et al.*, 2012). Biofilms allow bacteria and pathogens to persist in the dairy processing plant and increase the risk of cross-contamination of the processed dairy products, by-products or pieces of equipment.

Presence of high levels of bacteria and pathogens in raw milk may also result in their presence in the whey or other liquid by-products extracted from dairy processing. Similarly, large volumes of water extracted from the production of powdered milk, yogurt, whey powder and other dairy products, as well as the water used in processing can contain bacteria and pathogens as a result of contact with contaminated raw materials, products or the environment. Hence, the microbiological quality of water or liquid that is extracted from products need to be well understood, which may require microbiological analysis. Such water or liquid may also require reconditioning to achieve a microbiological quality suitable for its intended reuse purposes.

#### **4.1.4. Foot-and-mouth disease virus (FMDV) concerns associated with dairy operations**

Foot-and-mouth disease (FMD) is a highly contagious disease that infects cattle, swine, sheep, goats, and other cloven-hoofed ruminants and remains to be one of the most widespread epizootic animal diseases worldwide.

FMDV transmission can occur both directly and indirectly via air, water, feed, litter, tools, transport vehicles, milking equipment, footwear, etc. In high relative humidity (>60%) and under certain wind and weather conditions, the virus can spread from farm to farm across long distances (250–300 km) and even across oceans. On humans, FMDV remain viable on the skin and mucosa for several days and so humans can be a vehicle for cross-contamination.

The infectious concentration of FMDV is expressed as TCID<sub>50</sub> (Tissue Culture Infective Dose), which stands for the dose required to infect 50 percent of the tissue culture cells. The highest level of FMDV detected in milk was  $4 \times 10^6$  ID<sub>50</sub>/ml (Donaldson, 1987). Because of the dilution factor, in farm bulk milk tanks, the maximum level of FMDV in milk collected from an FMDV infected herd has been estimated to be  $1.6 \times 10^2$  ID<sub>50</sub>/ml (Schijven *et al.*, 2005). For milk or milk by-products obtained from food processors and used for feeding cattle or pigs, a safe target for control of FMDV has been established as  $10^{1.3}$  ID<sub>50</sub>/ml, based on a safety factor of 100 and a serving size of 20 Liters of milk/milk product.

To prevent spreading of FMDV, milk products or products derived from milk (e.g. milk water) must be subjected to two heat treatment cycles (72 °C /15 sec.), a UHT treatment, or a heat treatment (72 °C /15 sec.) combined with a pH decrease in the product to <6.0 for at least one hour. FMDV is quickly inactivated by pH of <6.0 or >9.0.

#### **4.1.5. Testing for microorganisms in the potentially reusable water sources**

Microorganisms that can affect product safety or stability may be found in reusable water sources or in reuse water generated from these sources. Their presence can be determined by testing for the specific pathogens, viruses or for the microorganisms that can spoil or destabilize food products. Individual or groups of microorganisms that are present in the reusable water sources or in reuse water supplies may serve as indicators for monitoring and verifying operational control of the water generation process (ICMSF, 2011, 2018).

Many microbiological assays are available for sampling and testing of different water supplies to identify suitable reusable water sources, as well as for use in validation, verification, and monitoring of the reuse water generation process. Many of these microbiological assays are standard methods that are culture-based for identifying and enumerating viable organisms. However, advances in molecular biology have introduced technologies such as polymerase chain reaction (PCR), next generation sequencing (NGS), microarrays, biosensors, etc., that enable more sensitive and specific detection and characterization of microbial pathogens, viruses and other

microorganisms. These advanced assays, some of which have been validated, are well described in the FAO/WHO report on the Safety and Quality of Water Used with Fresh Fruits and Vegetables (FAO and WHO, 2021a).

Routine testing for pathogens in reuse water can be costly as multiple targets may need to be tested. It is also not practical since the presence and prevalence levels of pathogens in reuse water are likely to be very low. Similarly, it is impractical to test reuse waters for the low levels, if any, of bacterial spores that may be present. It is more practical to choose suitable environmental organisms or indicator organisms for routine testing to monitor process control and to signal potential out-of-control situations. However, testing for particular pathogens would be warranted in out-of-control operational situations where the reuse water may potentially have been contaminated with pathogens and will often be discarded. In line with this rationale, dairy processing operators most often test for bacterial indicators/environmental organisms to assess the safety and quality of reuse water.

Further details on the usefulness of testing for pathogens and other microorganisms, as well as examples of microbiological criteria are provided in Chapter 6.

## 4.2. RISK ASSESSMENT APPROACHES TO INFORM DECISION-MAKING ON WATER REUSE

### 4.2.1. Basic principles of risk assessment<sup>3</sup> for food safety and water safety

Food safety risk assessment is a scientifically based, systematic process consisting of four steps: hazard identification, hazard characterization, exposure assessment, and risk characterization (FAO and WHO, 2014). It provides risk managers in both public and private sectors with the information and evidence needed to support effective decision-making. A detailed guideline on Microbiological Risk Assessment (MRA) applied in the food area has been compiled by FAO and WHO (2021b), based in the principles for MRA compiled by the Codex Alimentarius (FAO and WHO, 2014)

In the context of a dairy processing operation:

- **Hazard identification (HI)** is a qualitative process intended to identify microbial hazards that are of potential concern to consumer safety and possibly associated with food products. Such hazards can potentially contaminate food

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<sup>3</sup> Although this report focuses on microbiological hazards relating to food safety, “Relevant hazards” should also include chemical and physical hazards, as well as microbiological hazards relevant to occupational safety or spread of zoonotic illnesses.

products via many different routes, such as being present in raw materials, ingredients or in partially processed materials or being introduced into an operation or transferred from the food operation environment, or due to poor practices or lack of personal hygiene of food handlers, etc.

The water used or reused can also be a transmission vehicle for hazards, possibly spreading them throughout the processing environment or causing cross-contamination of food materials. In the hazard identification step, the likely associations of such hazards with the operation and with the food material/product leaving the operation is identified. When hazards are found to be associated and is identified, the level of consumer health risk related to the level at which they are present needs to be determined through characterization of the hazard and exposure assessment, followed by the establishment of control measures required to adequately control the identified hazards.

- **Exposure assessment (EA)** is the (qualitative and/or quantitative) evaluation of consumer health risks resulting from the ingestion of hazards present in the food processor's materials or final food products. EA considers both the likelihood of occurrence and the level of each relevant hazard, taking into account the uncertainties in both aspects. Typically, EA considers how specific activities, processes and handling practices throughout the food processing operation may impact hazard occurrence and level.

These insights can then be used to determine whether and to what extent the consumers may be exposed to the hazard, taking into consideration the likely presence of the hazards in the food and the amount/frequency of food consumed. EA thus ultimately determines the dose of exposure to a consumer to the identified hazard at consumption and provides for a view of the hazard dynamics in the course of the value chain, including insights in variability and uncertainty.

- **Hazard characterization (HC)** is the (qualitative and/or quantitative) assessment that provides for an understanding of the likely impact to consumer health of the dose of a hazard that a consumer is exposed to at consumption. Ideally, there is a quantitative understanding of the relationship between the hazard exposure dose and the consumer health impact.

More often than not, quantitative insights from HC are incomplete (e.g. available data may not be representative or account only for part of an exposed consumer population), based on surrogate data (e.g. data obtained in animal or laboratory studies) or otherwise to an extent inadequate. This may result in significant uncertainty in the quantitative understanding of consumer impact,

which in itself may be rather variable. However, such understanding from quantitative HC or even from qualitative (or semi-quantitative) descriptions of hazard dose-consumer impact relationships may still be adequate for the characterization of the consumer risk in support of informed decision-making.

- **Risk characterization (RC)** integrates the three previous steps to derive a qualitative/quantitative assessment of likely consumer risk, i.e. the likelihood and severity of consumer health impacts that may be associated with the identified hazards of concern. Whether a detailed quantification of consumer risk is possible and can be expressed as a risk estimate, depends on whether EA and HC have provided sufficient quantitative insights. A detailed quantification may not be necessary when orders of magnitude of impact already form a solid enough basis for interpreting possible consumer risk levels.

Importantly, uncertainty in EA and HC insights is best expressed as uncertainty in the risk characterization outcome, e.g. in the risk estimate, as this is important information for risk management decision-making. Evidently, such decision-making should consider not only the risk characterization outcome, but also specific details brought together systematically in the risk assessment on the dynamics of the hazards of concern in the operation and the impact of pertinent activities (processes and/or handling) on the likelihood of occurrence and the levels that the identified hazards are present at. These details and the outcomes of risk characterization may provide risk managers with the best available science and evidence for controlling food safety risks.

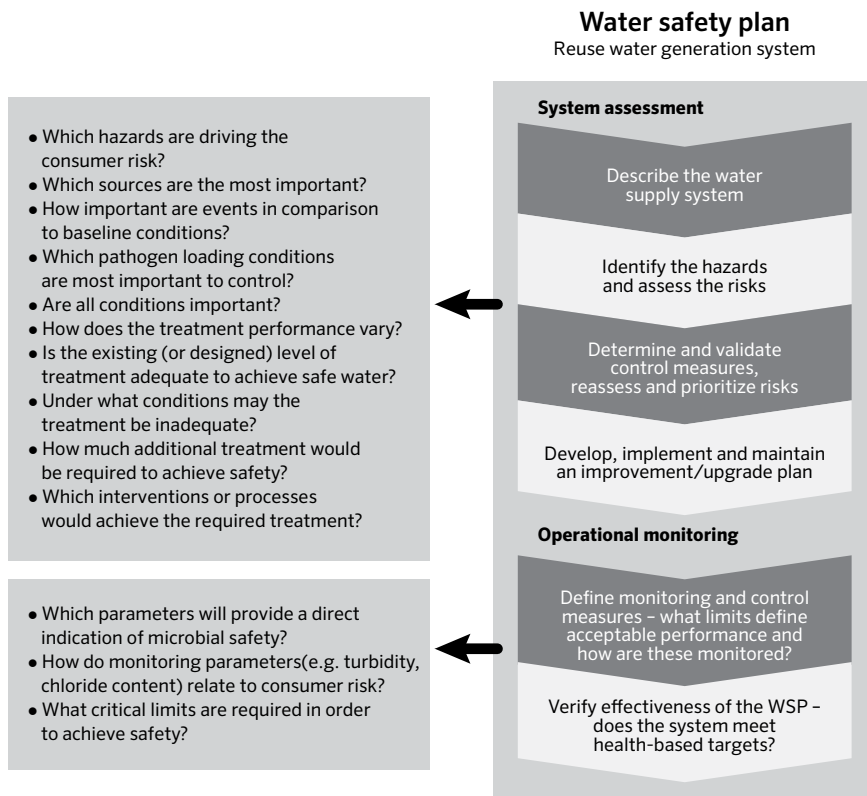
Prevailing food legislation and food safety standards are among the important benchmarks to inform risk managers about the acceptability of consumer's risk level. When projected levels are not acceptable, measures have to be taken to reduce hazard levels at consumption and/or to mitigate consumer exposure. This may involve implementing measures in the dairy processing operation to control hazards associated with reuse water generation and application. Duly considering the variabilities and uncertainties, the EA and HC steps can be used iteratively to evaluate what control measures and mitigation approaches would ensure food safety and prevent undue consumer risks.

In general, risk assessments should be as simple as possible, finding the right balance between seeking more details to add to the evidence base and the use of assumptions and expert judgement. The right balance is the one that is considered adequate to inform the responsible managers on the options for risk management. It should also be focused mainly on consumer health risks, while operational or business risks such as the quality/wholesomeness of food and reputational aspects are best managed by individual operators according to their specific circumstances.

Note that the WHO document “*Quantitative Microbial Risk Assessment: Application for Water Safety Management*” uses a slightly different risk-based framework to deal specifically with water-related hazards (WHO, 2016). It consists of problem formulation, exposure assessment, health effects assessment and risk characterization, which essentially mirrors the steps for food safety risk assessment detailed above. The water safety risk assessment process systematically evaluates:

- hazards, that may have an adverse impact on the people's health;
- hazardous events, i.e. events that may introduce hazards into a water supply or fails to remove them; and
- hazard controls, i.e. the adequacy of controls to prevent contamination, to remove hazards from a water supply system or to reduce hazards to acceptable levels.

**FIGURE 1** Potential risk assessment questions that provide insights and inputs into the development of a Water Safety Plan (WSP)



Source: Adapted from WHO. 2016. Quantitative microbial risk assessment. Application for water safety management. Updated November 2016. <https://www.who.int/publications/i/item/9789241565370>



The WHO water safety risk assessment document provides guidance in the context of the preventative, risk-based approach recommended in the WHO water quality guidelines (WHO, 2022). It illustrates how risk assessment may help to implement this approach through the development of, for instance, water safety plans (WSPs). Guidance is provided on several risk assessment approaches, e.g. risk scoring, risk matrices and quantitative microbial risk assessment (QMRA). While focus is on hazard analysis and risk assessment concerning drinking-water systems, the basic principles are also applicable to water reuse. WSPs are the recommended framework for managing risks associated with water reuse applications. **Figure 1** illustrates how risk assessment supports WSP development (WHO, 2016).

Conducting a risk assessment for both reuse water safety and food safety is crucial to establish a clear and science-based understanding of whether there are significant hazards in a reusable water source that potentially may be recovered and used to generate reuse water supplies for a particular purpose. Especially for scenarios where a reuse water supply is used for direct food contact purposes, or in situations where food contact cannot be excluded, a water safety risk assessment may provide the necessary identification of hazards of concern or hazardous events and the control measures needed to be in place so that food safety is ensured.

Prior to the operational implementation, a risk assessment may reveal that a water reuse scenario (which is the specific plan for the recovery of a reusable water source, generation of reuse water supplies and application of reuse water in the dairy operation) is principally in line with food safety and acceptable consumer risk benchmarks such as governmental standards/guidelines. It may also provide information for planning the full scale implementation of the reuse water generation and application systems/controls, including validation, monitoring and verification needs and possible methods/approaches to use. Moreover, the risk assessment may also highlight concerns or shortcomings in the design of these plans and thus, a need for redesign, which most likely will require risk management engagement and decision-making. Importantly, it can be used for setting operational targets and critical limits for water treatment in the management of the reuse water generation system.

By going systematically through the water reuse scenario and considering the entire dairy processing operation, including aspects of first water use, foreseen recovery and conditioning steps of the reusable water, and intended reuse water application, risk assessment can evaluate and determine important factors and events that may challenge the ability of the operator to adequately control the water reuse scenario. A few examples of such factors and events are listed in **Table 3**.

The variability of factors and events listed in **Table 3** are most often specific to the dairy operation. So are the sources of reusable water and the recovery and reconditioning technologies. It is therefore, very important that the risk assessment fully considers and duly documents the particular conditions and technical/infrastructural aspects of a dairy processing operation. In this way, the design of the WSP for the control of the reuse water generation system as well as the food safety management system are fully tailored to this operation.

For managing the operation and for regulatory compliance/due diligence (e.g. when a regulation or guideline has specified a log reduction of a hazard as a treatment target), it is necessary to design and monitor the proper functioning of the reuse water generation and application systems as well as of the various relevant control measures, so that the specified treatment target is reliably and consistently achieved. Monitoring control measures predominantly rely on suitable physico-chemical process indicators (e.g. residual chlorine in a disinfection treatment; turbidity in a UV treatment unit-operation) rather than on microbiological sampling and testing. More guidance on the operational control and development of a WSP for the reuse water generation system is discussed in Chapter 5.

Water reuse scenario and case studies and technologies involved in water reuse are presented in the Annexes. They illustrate the utility and effects of several treatment technologies and, where available, the typical reductions in levels of food safety hazards or of other microorganisms that may be achieved with purification and microbiocidal treatments. Note that some operators use multiple barrier approaches, deploying different treatments or processes (i.e. in sequence or in combination) to control the presence, viability or activity of microorganisms.

#### **4.2.2. Risk assessment for informed decisions on fit-for-purpose water reuse application**

A food processing operation may have one or more potential water reuse scenarios, including reusable water sources and reuse water applications, for which decisions are required, regardless of whether such a scenario is fit for purpose. These decisions are best informed by tailored risk assessments made for each relevant scenario.

Different risk assessment approaches can be applied to assess the risk(s) that microbiological hazards associated with reusable water sources may pose to the consumers. Thus, it is critical to determine what reconditioning or treatment of the reusable water is required to reduce the associated consumer health risks to acceptable levels.

**TABLE 3** Examples of factors and events that may challenge operators to adequately control a water reuse scenario, the impact of which can be explored using risk assessment

FACTOR OR EVENT	IMPACT OR RISK CONTRIBUTION
Variations in composition of a reusable water supply as recovered over time in the operation, e.g. variations in microorganisms, chemical and organic content in raw materials/effluents	May affect the efficacy of control measures and/or of the conditioning treatments, resulting in hazard occurrences at levels beyond what was considered in the design of the reuse water scenario, thus possibly representing higher than projected consumer risks
Post-recovery or post-conditioning, cross-contamination with hazards of concern from environmental/other sources in the operation	May increase hazard occurrences and levels beyond what was considered in the design of the reuse water generation and application scenario
Purification or microbiocidal treatments not delivering the expected target hazard reduction and/or targets dropping below critical limits, e.g. failing in filtration or disinfection systems or gradually losing capacity and impact	May result in insufficient log reductions of hazards of concern. Sub-lethal treatments may select for tolerant or resistant variants of vegetative microbes and for spore-forming hazards
Unaccounted presence of nutrients in reusable water sources and carry-over of nutrients into the reuse water supply generated	May support growth of surviving microorganisms, including hazards of concern, to beyond expected levels. Note: some bacteria like <i>Pseudomonas</i> spp. can proliferate with minimal nutrient, and may be a useful indicator in cases of nutrient carry-over
Time and temperature events that provide opportunity for microbial growth, such as prolonged interim storage during reduced reuse water demand or inadequate piping/distribution system that allow colonization of microorganisms	May support proliferation of surviving microorganisms, including hazards of concern, to levels posing risks beyond what was expected in the design of the system.
Differences in scales (pilot scale/full scale; full/reduced capacity), which depends on operation characteristics related to recovery and conditioning (e.g. geometry, loading rates, hydrodynamics)	May cause differences in microbiological occurrences and levels in the reusable water sources and the reuse water generated. Factor should be considered in the operational design, so as not to compromise operational control

Source: Authors' own elaboration.

The selected approach to risk assessment needs to address a number of critical questions, including:

- Are there any hazards in the reusable water source and the reuse water generated that pose a risk to the consumers and how likely are they to occur?
- What is the severity and likely level of risk posed by the hazards identified when they do occur?
- What level of risk reduction is required to mitigate consumer risks and what are feasible options to consider in a water reuse scenario for the operation at hand?

Given the specific water reuse scenario(s) considered within a dairy processing operation, the answer to these questions may be straightforward by conducting a basic, qualitative and/or quantitative risk assessment within the skillset of the food business operator, or perhaps may require a more elaborate risk assessment requiring third-party expertise.

Notably, the decision-support tree proposed by FAO and WHO (2019; Figure 8) for water reuse applications in processing operations provides for a practical way to combine the application purpose with the need and ability to control microbiological hazards and serves as a starting point for conducting a risk assessment that informs on potential consumer risks and important operational controls. Here are a few different scenarios which illustrates the need for considering different risk assessment approaches.

- In cases where a reusable water source will not be applied for a food contact purpose and its operation and application can be well controlled (i.e. unintentional food contact is well managed), there are most likely no consumer risks in this water reuse situation. Thus, a more detailed risk assessment may not be required, but operational control to ensure the absence of unintentional food contact (e.g. by physical separation through infrastructural measures) will be key in implementing this water reuse scenario.
- When a recovered reusable water source is free of microbiological hazards, it may be fit for food contact applications without posing consumer risks, provided that adequate verifications are in place to ensure that the reuse water generation process is operating as designed. Any potential contamination post recovery or bacterial growth during storage, will also need to be considered, but these can often be addressed by qualitative or semi-qualitative risk assessment approaches.
- In cases where a reusable water source has been reliably recovered and reconditioned (e.g. though validated heat treatments) and assured to be absent of microbiological hazards, the reuse water can be applied as a food contact water without undue consumer risk (at least from a microbiological safety perspective). Again, a more elaborate risk assessment may not be required for this scenario, provided that the steps of recovery, reconditioning and storage have been adequately verified to ensure proper control over the reuse water generation process.

Especially for food contact applications, reuse water generated from reusable water sources in which hazards have been found to be present, there will be a need for an adequate description to address this in the risk assessment.

This response, however, can still be at a rather qualitative level. For instance, based on existing knowledge of the operator (or of a third-party supplier) that the recovery/reconditioning process are within their skills and capabilities and that these will consistently control the potential hazards identified in the reusable water source, which does require that the level of hazard reduction by control measures is well understood and can be consistently achieved in the operation.

However, when such knowledge does not exist to the right level or when there is uncertainty concerning the hazards present in the reusable water source, severe consumer risks posed by the deployment of such reuse water supplies cannot be ruled out. In such instance, a more refined, targeted and ideally quantitative risk assessment approach will likely be required to adequately identify the relevant hazards, assess the impact of recovery, reconditioning and storage processes (as appropriate) on hazard occurrences and levels and, thus, on possible consumer risks, and to evaluate what measures are needed to adequately control the hazards to acceptable levels.

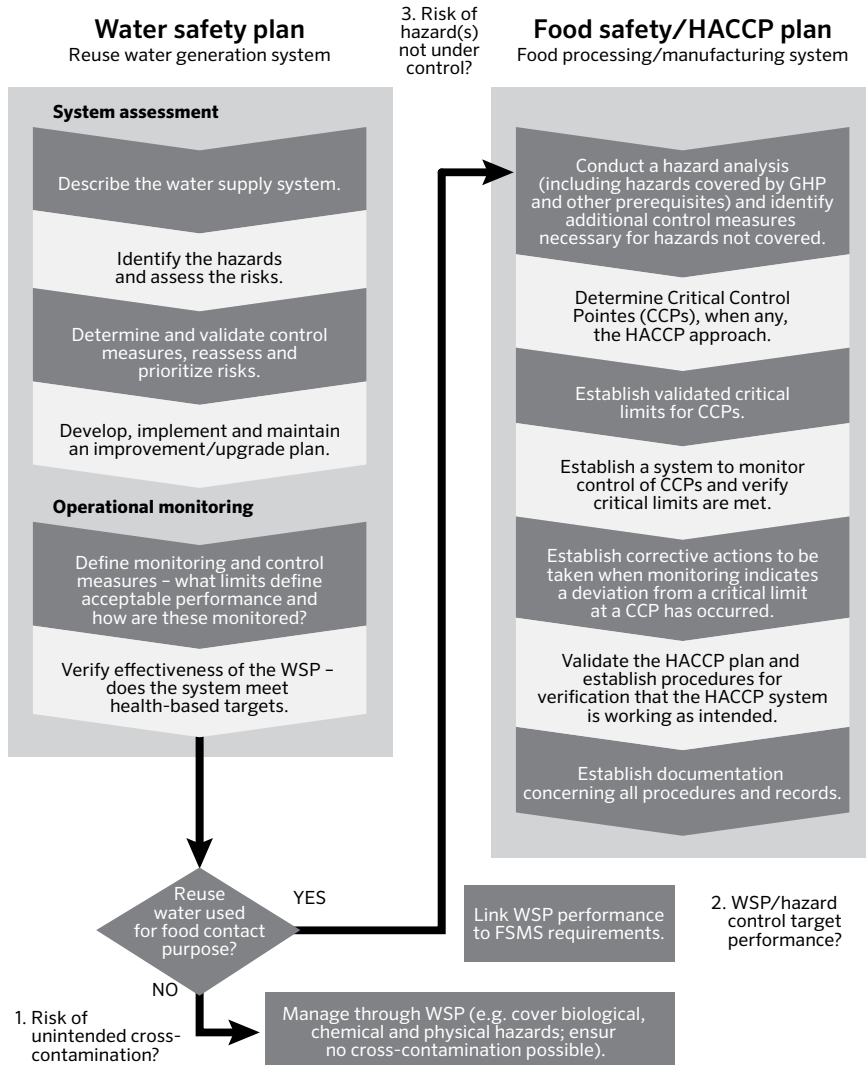
Microbiological risk assessment provides data and knowledge to the management of a dairy processing operation to be able to make key decisions when developing and having operational control in the generation and use of reuse water (Figure 2).

#### **4.2.3. Considerations on water scenario risk assessments involving third parties**

Reuse water supplies delivered by a third party, whether recovered from the specific dairy processing operation or from elsewhere, should be fit-for-purpose and meet the specific application as initially recovered or as reconditioned. The receiving dairy processing operator shall ensure that supplied water is reused for the intended purpose.

The management of the dairy operation has the ultimate responsibility for deploying safe water for reuse in a dairy processing operation. The management is responsible for designing an effective reuse water generation system and fit-for-purpose reuse water application, including monitoring the appropriate controls during daily operations, and keeping records of all measurements, e.g. results of monitoring and verification as well as corrective actions.

**FIGURE 2** Graphical representation how a Water Safety Plan (WSP) for managing the generation of reuse water supplies in an operation may be linked to the Food Safety Management System (FSMS) that manages the processing of food in that operation and illustrating by three examples how data for WPS and FSMS development can be derived from questions addressed by microbiological risk assessment or hazard analysis



Source: Authors' own elaboration, based on **FAO & WHO**. 2020a. Codex Alimentarius. General Principles of Food Hygiene. CXC 1-1969. Rome, FAO. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B1-1969%252FCXC\\_001e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXC%2B1-1969%252FCXC_001e.pdf); **WHO**. 2016. Quantitative microbial risk assessment. Application for water safety management. Updated November 2016. <https://www.who.int/publications/i/item/9789241565370>

To form an effective partnership, the dairy processing operator and the third-party experts need to work together to identify the microbiological hazards but should also consider other microorganisms of operational concern (e.g. those potentially causing spoilage of water supplies or food materials or those that pose occupational safety risks) associated with the water reuse scenario.

Based on mutually agreed approaches and requirements, the reuse water generation system to be used by the third-party reuse water supplier (including recovery and any reconditioning and storage) needs to meet fit-for-purpose food safety requirements of the dairy operation.

The dairy operator and the supplier should control and coordinate their respective operations via specific monitoring and verification procedures. The supplier has to ensure that the reuse water generation system is operating as intended and that the reused water delivered to the dairy operator consistently meets the fit-for-purpose application requirement.







# 5

## Implementation and operationalization of a water reuse scenario

To implement and put a water reuse scenario into a dairy operation, the operator has to establish and manage the reuse water generation system and the use of the reuse water supplies, in addition to the already existing system for managing the processing of food materials and products.

The operator can choose between three approaches to manage the generation and application of reuse water (**Figure 2**):

- To manage both reuse water generation and use by the water safety plan (WSP) approach.
- To manage both reuse water generation and use by the food safety management system (FSMS) approach.
- To manage reuse water generation by the WSP approach and use the FSMS approach for the application of the reuse water.

In **Figure 2**, the WSP and FSMS approach are set next to each other to show how they can be interlinked when a dairy sector food business operator (FBO) chooses to manage reuse water generation and food processing as two separate systems. The WSP and FSMS approaches essentially follow the same risk-based principles and logic, including conducting a hazard analysis, establishing control measures, monitoring effectiveness of the control and taking corrective action when required. Note the figure gives some examples of key questions concerning effective control of hazards in a reuse scenario for which the answers would come from risk assessment/hazard analyses.

The approach the operator chooses may depend on factors such as the particular fit-for-purpose water reuse applications to be implemented, the complexity of the water reuse generation systems to be used and/or the specifics of the food being processed or manufactured (e.g. intended consumer, ability to support hazard growth post manufacture, etc.). The infrastructure and technical capabilities of the operator may also play a role.

The WSP approach can be used to manage both reuse water generation as well as the actual deployment of reuse water in a not for food contact application. In this case, there is no direct link with the food safety and the quality aspects of the food products being processed/manufactured, but the operator has to control possible hazards in the recovered (and reconditioned) water supplies and be confident that no cross-contamination occurs from the reuse water supplies generated, stored and distributed with any food materials/products.

Managing integrally both reuse water generation and use in the FSMS would be most relevant when reuse water supplies are generated for food contact applications. This integral management ensures that the processes for reuse water generation are fully considered in the overall management of the operation, i.e. conform with general hygiene provisions and a HACCP plan(s). However, in case that the microbiological quality of a reuse water supply does not represent a critical point that needs to be controlled within the FSMS, this integrated management system may lead to some unnecessary complexity.

Using a WSP approach for reuse water generation and the FSMS for the reuse water deployment allows the operator to design and manage the reuse water generation system separately from FSMS. In case of not for food contact use, the FSMS does not need to be engaged if there is no risk of unintentional cross-contamination. When an operator chooses to manage reuse water generation using the WSP approach, the hazard control plan of the WSP needs to be adequately linked to the facilities' FSMS food safety management system when the reuse water is intended for food-contact applications or when (indirect) contact with food cannot be avoided for not-for-food application purposes of reuse water supplies. After all, the performance of the WSP (i.e. the quality of the reuse water being produced) needs to match the specific requirements established for the reuse water application, which has to be covered in the FSMS.

## 5.1. PLANNING IMPLEMENTATION OF A WATER REUSE SCENARIO

Reuse water supplies should be safe for their intended purpose and not contain chemical, physical and biological hazards at unacceptable levels. After being generated or during storage, such supplies should not be susceptible to cross-contamination or transmission of microbiological hazards that would compromise the safety of the final dairy products and pose risks to consumers' health.

To ensure food safety, the use of both first-use and reuse water in a dairy operation is managed within the FSMS, which is recommended to be based on the General Principles of Food Hygiene (GPFH) that includes basic hygiene practices and the HACCP approach for controlling hazards (FAO and WHO, 2020a). The dairy operator should also follow the code of hygienic practice for milk and milk products (FAO and WHO, 2009), as this helps to establish a tailored hazard control plan for dairy operations and provides basic guidance on implementing water reuse scenarios.

Hazard control plans such as ISO 22000:2018 (ISO, 2018) essentially follow the same principles, but use somewhat different terminologies, hazard categorizations, pre-requisite systems and for the establishment of operational or critical control points for system management.

Key elements that a robust WSP/FSMS should include are:

- Effective pre-requisite programmes/good hygienic practices of the dairy operation, and insight into the extent that these contribute to hazard control;
- Identification of possible hazards in the reusable water sources and an understanding of the food safety related microbiological specifications required for the food material or products of the dairy operation;
- Insight into the impact of water recovery and (where relevant) reconditioning processes (e.g. purification, antimicrobial treatment) on the occurrence and level of potential hazards and other microorganisms (e.g. those causing spoilage) in the reuse water supplies generated;
- Identification of relevant hazards in the reuse water supplies, especially when reuse water may come into contact with food, and tailor additional control measures to eliminate or reduce hazards to acceptable levels in the food materials/products of the dairy operation;
- A plan for the generation of meaningful monitoring data, including through microbiological sampling and testing, to evaluate the performance of water reuse generation and application in the operation; and
- How relevant monitoring data will be used for verification of operational control and initiation of appropriate action when necessary.

Disregarding management in through either a WSP or FSMS, or a combination of both, the hazard control plan should be specifically tailored to the conditions of the dairy operation and that any water reuse generation and application are managed and controlled such that the reuse water supplies generated are safe and suitable for their intended applications.

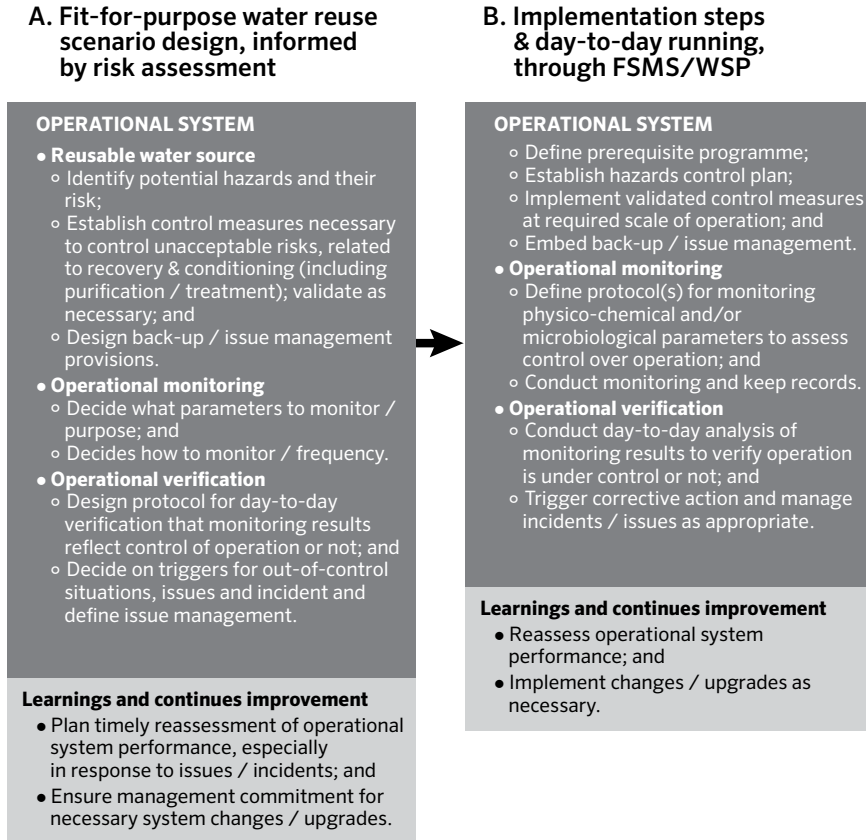
To support the establishment of a robust hazard control plan, a tailored risk assessment or a systematic hazard analysis will be needed for each water reuse scenario. This starts by identifying any food safety hazards (i.e. all the relevant biological, chemical, and physical hazards) potentially present in the reusable water sources and their levels. It should include an assessment of the required microbiological quality of the reuse supplies generated for an application and how this relates to the hazard dynamics during recovery, purification, treatment, storage, distribution and use steps foreseen. This will then determine whether additional control measures will need to be included in the FSMS. An analysis of hazards and controls should consider such factors such as variability and uncertainty in the data/knowledge available, operational variabilities, the scale of the operation, and the shelf-life of reuse water supplies, as well as include backup provisions in case of system failures and issues (**Figure 3A**).

When a risk analysis has provided sufficient evidence and insight into the design of a robust hazard control plan for a specific water reuse scenario, the process of implementing the hazard control plan at full scale in the operation may proceed in line with the operator's capabilities and confidence to run the operation (**Figure 3B**). Note that the hazard control plan of the FSMS should consider not only all hazards possibly associated with the reuse water supplies being used (in case food contact is foreseen or cannot be excluded), but should also control overall the hazards relevant to the food materials/products being processed (e.g. from raw materials, ingredients, other water sources and recirculation of water, operational environment, food handlers, etc).

Regardless of the operational management system of the reuse water, there are many aspects that the operator has to consider when developing a suitable hazard control plan for the full scale operation.

For instance, under every management system, the hazard control plan has to consider basic provisions regarding infrastructure, equipment, and programmes for managing hygiene in the operation, which may have an impact on hazard occurrence and levels. For each specific combination of reusable water source and the intended reuse application, any relevant hazards that may be present will need to be controlled by a single or combinations of control measures. These measures may include purifications and/or antimicrobial treatment or other control measures to condition the reusable water supply and should also consider the need for storage of the reuse water supply by default or in cases when issues arise.

**FIGURE 3** Using the evidence and decisions made at the design stage (A) to implement the operational hazard control system (through WSP/FSMS) at full scale (B)



Source: Author's own elaboration based on WHO. 2016. Quantitative microbial risk assessment. Application for water safety management. Updated November 2016. <https://www.who.int/publications/i/item/9789241565370>

Ultimately, the hazard control plan will need to be validated and at the full operational scale level, with all elements properly documented, including amongst others:

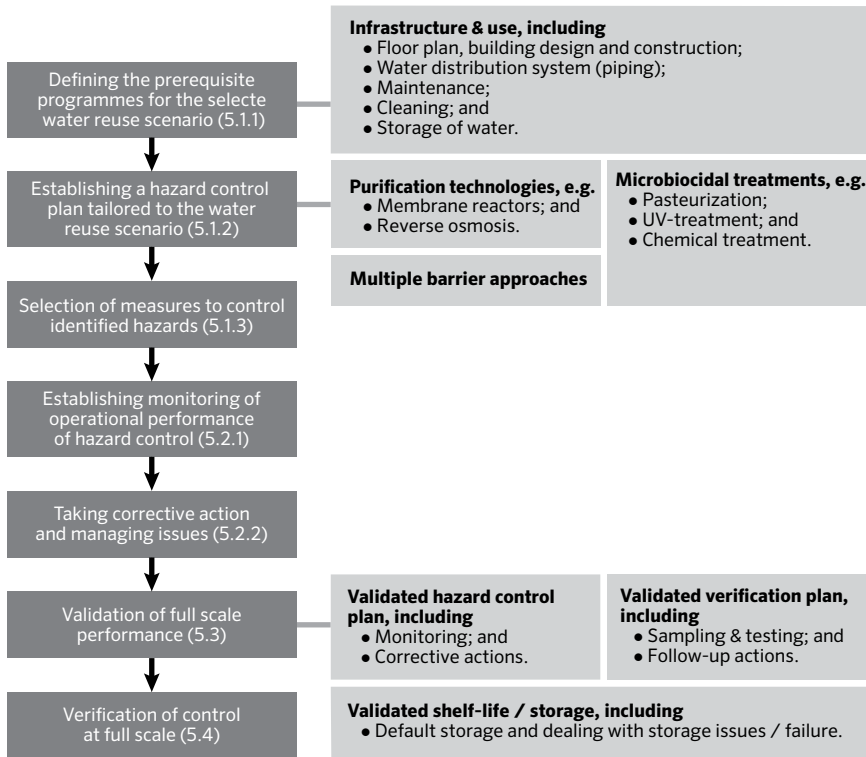
- Procedures for monitoring the performance of the full scale operation;
- A plan for timely verification of operational control, with methods and metrics documented and specified;
- Pre-specified corrective actions to take in case of out-of-control trends or situations, including when verification results signal ineffective hazard control;
- Procedures for taking corrective actions and follow-up review and improvement of the hazard control plan and other aspects of the management system.

Monitoring and verification functions provide and document data to track system performances and identify deviations or loss of control. In day-to-day operation, the monitoring and or verification data should be readily available to provide timely verification that the systems for reuse water generation and use are under operational control. When a potential control issue or an actual out-of-control situation arises, the necessary corrective action needs to be taken with urgency to restore various operational control such that the potentially affected reuse water supplies do not jeopardizes water safety and/or food safety. Out of control situations and corrective actions taken should be reviewed and, if needed, amendments should be made to the hazard control plan or other aspects of how the water reuse scenario is implemented or managed.

**Figure 4** provides an overview of the aspects that the FBO should consider when establishing a hazard control plan for a water reuse scenario that is specific to its operation and is validated at the full scale. The numbers depicted in the Figure corresponds to the sections and sub-sections shown in this Chapter. In each (sub)-section, some guidance is provided based on the flow of information, and the options and decisions relevant to the implementation and operation process. These decisions need to be based on a thorough risk analysis, the principles of which have been discussed in Chapter 4, section 2.

In cases where a third-party provides reuse water generated outside of the dairy operation, the FBO needs to ensure that the reuse water is fit for the intended use, that the supplier is in control of the water quality, and that the application of the reuse water is duly managed within the food safety management system of the dairy operation. Both the dairy operator and the reuse water supplier will have to coordinate to develop, implement and operationalize a dedicated hazards plan tailored to their respective operations and conforms to the intended water reuse scenario.

**FIGURE 4** Steps in implementing and putting a hazard control plan for a water reuse scenario into full scale operation



Source: Author's own elaboration.

### 5.1.1 Defining the prerequisite programmes for the selected water reuse scenario

Prerequisite programs (PRPs) for operational water reuse typically consist of activities, procedures and/or measures that are aimed to ensure the appropriate environmental and hygienic conditions for water reuse. They provide the basis for effective hazard control.

In the context of water reuse in a food operation and for hazard control, PRPs should include:

- measures that ensure the maintenance of good hygienic conditions, such as the ability to Clean-In-Place (CIP), and remove/reduce potential hazards;

- provisions to have a drinking water supply available at the point(s) of water use to serve as back-up;
- proper maintenance to ensure the reliability of equipment in terms of operational performance and hazard control, e.g. specified requirements for Reverse Osmosis (RO) plants, UV plants and pasteurization plants, as well as calibration of monitoring equipment;
- measures to prevent/reduce the spread and/or increases of hazards occurring and/or their levels, for instance, by eliminating dead-ends or -pockets in the water distribution system, which can harbour hazards and promote biofilm formation as well as by regular inspection of piping, membrane loops and valve controls, etc.; and
- reduce the likelihood of cross-contamination and inadvertent food contact application of reuse water, which can introduce potential hazards, e.g. by using identifiable pipelines, regular inspection of the tightness of gaskets and RO membranes.

The PRPs should be supported by procedures and specifications that will minimize hazard entry, spread and increases, at these following pertinent sites:

#### **Floor plan, design and construction of dairy buildings**

- Systems for water recovery and recirculation should be to scale and designed for having as large a flow and consumption as possible;
- All tanks, piping for the storage, treatments, and distribution system of (reuse) water in the plants and facilities, should be designed to be CIP and be able to withstand heat exposure at pH 1–13. Tanks and other equipment must be able to be completely drained; and
- All taps should be secured against the backflow of CIP liquids, product, water, etc.

#### **Water distribution system (piping)**

- All water pipelines must be clearly marked with a word or code identifying the water quality;
- Pipes, pipelines, tanks and taps used for drinking water should not be mixed up with 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 and leaks in the pipes. If water of different qualities is mixed intentionally, the mixed water will always be categorized as that of the lower quality water used in the mixing;
- Tubes, pipes, tanks, etc., used for milk and milk products can, without special labelling, also be used for handling milk water with/without added drinking water and water of potable quality;



- Dead ends in the piping should be avoided and the length of piping where water may occasionally become stagnant (e.g. taps) should be minimized;
- To avoid condensation on the outside of the pipes and to reduce the heating of water inside the pipes, it is recommended to use insulated pipes in “warm” rooms; and
- Pipelines that are no longer used should be removed.

### **Maintenance**

- Good maintenance and regular inspection of the system to check for any leaks or damages (e.g. leaky gaskets) that may lead to entry of microorganisms into the reuse water supply;
- Ensure the tightness of the RO membranes to avoid hazards bypassing the membranes, and the membranes should be replaced at regular intervals to ensure their performance;
- Special attention should be made to check the tightness of gaskets for valves that connect to drinking water pipes; and
- Maintenance results should trigger timely corrective action.

### **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 hazards and done with a frequency that prevents the build-up of biofilm;
- All facilities should be emptied when not used and CIP is done regularly in accordance with risk assessment insights concerning stagnant water in pipes/ the distribution system and be based on validation;
- CIP equipment used for dairy plants should follow prevailing regulations and supplier specifications; for instance, CIP systems have to be able to withstand exposure to high heat and extreme pH ranges (across pH 1 to 13);
- If the CIP system is out of operation for more than 24 hours, cleaning is recommended;
- During cleaning, all pipe and tank parts must be heated to at least 60 °C for at least 30 minutes, but if the equipment can withstand it, 80 °C for at least 10 minutes is preferred;
- Membrane systems are heated to a maximum of 50 °C or as recommended by the supplier;
- RO membranes require periodic cleaning, depending on the feed material, to prevent the build-up of organic matter (fouling) or calcium deposits (scaling); and
- UV treatment plants must be set up to be adequately cleaned without infrastructure disassembly (i.e. CIP-ed; using a validated cleaning in place approach). Cleaning is done in accordance with the manufacturer’s

recommendations and done often enough to ensure that the system always delivers the specified UV dose. The CIP program must be able to remove coatings (e.g. calcium) from the quartz lenses.

### **Storage of water**

- Potable water and reuse water intended for food contact application can normally be stored without temperature control (15–20 °C) for a limited period, provided that nutrient levels that can support microbial growth are minimal;
- Shelf life can be extended if water is stored cold (< 7 °C, measured at the top of the tank where the water is warmest) or hot (min. 60 °C, measured at the bottom of the tank where the water is coldest). Storage at other temperatures can be acceptable if combined with an ongoing microbiocidal treatment, e.g. by continuous recirculation through an UV plant or by a heat treatment before commissioning;
- Water stored hot or cold should be stirred frequently to ensure the maintenance of proper storage temperature conditions; and
- The maximum storage time of any water depends on its nutrient content. A validated default shelf-life could be set based on the worst-case scenario of nutrient content and the anticipated microbiological growth that may ensue, or the shelf-life could be adjusted upwards/downwards with varying nutrient levels depending on the verification results of microbiological analyses.

### **5.1.2. Establishing a hazard control plan tailored to the water reuse scenario**

Based on the basic provisions/PRPs, the hazard control plan should identify all relevant hazards and appropriate controls designed for that specific water reuse scenario, including the technologies/methods applied for recovery, conditioning, storage and distribution, to ensure that the quality of the reuse water generated and applied is fit-for-purpose.

A thorough risk analysis of water and food safety (Section 4.2) should be conducted for each step of water usage from first-use, to recovery, to conditioning and to application of reuse water, in order to identify the presence and the levels of known and potential microbiological hazards. Especially, the dynamics and differences in the hazard presence and level related to the selection of particular technologies/methodologies applied from recovery to distribution are important to assess. The factors that must be considered are: the impact of the PRPs/good hygiene programmes on the potential presence and levels of hazards, the presence of nutrients or chemicals in the reusable water recovered and conditioned,

and the impact of physical and chemical materials on the effectiveness of controls (e.g. turbidity or high loads of organic matters that may affect treatment efficiency).

For each step, any relevant chemical (disinfectants, cleaning or chemical by-products, processing aids, etc.), and physical hazards that may possibly be present in the water after the first use and/or multiple reuses should also be identified.

A risk/hazard matrix such as that suggested in Annex 4 could be used to link the hazardous event/step, with the hazard and its risk characteristics, to better enable the selection of adequate control measures.

The data gathered is used to select the appropriate measures and determine their required performance (stringency) to consistently control all relevant hazards identified.

### **5.1.3. Selection of measures to control identified hazards**

Based on the identification of potential hazards to be controlled and the stringency required, appropriate control measures are selected that can consistently mitigate these potential hazards to acceptable levels in compliance with existing regulations and standards/guidelines relevant for the FBO.

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

- The requirements for treatment and the quality of the fit-for-purpose water, such as whether the reuse water will be used for direct food contact purposes;
- The microbiological profile of the recovered, or reclaimed water identified in the hazards analysis step;
- The dynamics of the hazard such as: (i) changes in the levels of relevant hazards at each process step, (ii) the magnitude and frequency of such changes up to the application of the reuse water and (iii) ultimately, the consumer risk of possible exposure; and
- 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.

Control measures are typically applied at critical control points (CCPs) within a HACCP context as defined by Codex in the General Principles of Food Hygiene (FAO and WHO, 2020a). For instance, a CCP may be the reconditioning (e.g. purification or microbiocidal treatment) of water from a reusable source, when the proper performance of that conditioning process is essential for hazard control and no other adequate controls are in place after the reconditioning step. However,

when a non-reconditioned water is fit-for-purpose, there are no CCPs related to the verification of reconditioning performance, but it may be essential 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. Casani and Knöchel (2002) provide a decision-tree to support decisions on critical control for water reuse in the context of food production.

The individual or combined performance of selected control measures should be validated under conditions relevant for the specific water reuse scenario in the particular dairy operation. Validation entails the use of technical and scientific knowledge, information and evidence. Validation studies can be undertaken at relevant small scales, but ultimately are required at full operational scale.

## **5.2. PUTTING A FIT-FOR-PURPOSE REUSE WATER SCENARIO INTO OPERATION**

### **5.2.1. Establishing monitoring of operational performance of hazard control**

Monitoring is the continuous collection of information and data (via measurements or observations) during practical, day-to-day operation. This information is then used to determine whether the defined operational conditions (including criteria and/or critical limits for operational parameters) are being met continuously, which indicates that the operation's performance is correct (e.g. control measures effectively reduced hazards as intended). The latter activity is verification.

The measuring method and equipment should enable timely assessment on the correct functioning of the control measure and, where necessary, supplemented with instructions or procedures for recording the correct measurements.

The frequency of monitoring should be tailored to the stringency of the control specified for that reuse water scenario, event, or step. For instance, if the water is being reconditioned to a quality fit for application in direct contact with food or food contact surfaces, a higher monitoring frequency may be required to ensure water safety, as compared to water reused for non-food contact surface applications. Process monitoring is imperative for the FBO to assure proper operation control and alert losses of control that may pose undue risks. Key to monitoring is to define and document the operational monitoring procedures and retain records to enable process improvement, if needed.

Failure to meet control measures criteria should trigger adequate corrective actions. At the same time, the FBO should consider whether amendments are required to any part of the food safety plan, and/or whether the monitoring frequency or

method has to be increased or altered for the ongoing control plan. Microbiological methods, even some rapid tests, are typically time and labour intensive and more costly to use for monitoring. Generally, it is preferable to have a continuous and inline monitoring system for physico-chemical parameters, as these results are typically real-time and allows for timely corrective actions. Examples of these are turbidity monitoring, which can be used as an indirect measure of microbial contamination or assessing temperature and time during distribution and storage of the reconditioned water before reuse (Casani and Knöchel, 2002).

### **5.2.2. Taking corrective action and managing issues**

A corrective action is defined as any action taken to re-establish control when a deviation occurs and to segregate and determine the disposition of the affected product, if any, and to prevent or minimize reoccurrence of the deviation (FAO and WHO, 2020a).

Corrective action procedures should already be established in a hazard control plan and implemented by the hazard control team, with pre-defined microbiological parameters (e.g. limits, criteria or other metrics) that are used to reflect the level of operational control of the system as a whole or of the individual control measures

In the event of a failure or loss of control situation (i.e. in case the system overall or (a) control measure(s) at an event/step during reuse water generation or use fail/ are not under control), 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:

- Stop using the reuse water supply or supplies affected and, in case of an application with possible food contact, switch to using the backup (potable) water supply until the reuse water supply is again fit-for-purpose; consider an increase in monitoring frequency until confidence in the control has been regained. In case of a not-for-food-contact application, switch to an alternative fit-for-purpose water supply;
- Identify the problem and analyze the root cause. Correct the problem and establish corrective measures to prevent recurrence. Amend the hazard control plan, or other aspects of the reuse water generation system or the food safety management system, as appropriate; and
- Isolate the reuse water supply or supplies 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). Conducting a statistically sound investigation into the possibility of using affected water supplies may be an option in principle but requires a significant investment in resources.

Monitoring data across subsequent reuse water batches being generated may help in building confidence over the systems of reuse water generation and use. When these are consistently performing well, it can signal early on when the operation or control measures may be trending towards failure, or an out-of-control situation may arise. Trend analysis is a powerful operational management tool advocated both for water safety plans (WHO, 2009) and food safety plans/FSMS (ICMSE, 2011, 2018; FAO and WHO, 2020a).

### **5.3. VALIDATION OF FULL SCALE PERFORMANCE**

#### **5.3.1. Validation of control measures at different scales**

Validation of a water reuse scenario in terms of its underlying control measures should be carried out in accordance with CXG 69-2008 (FAO and WHO, 2013b) and in keeping with the water safety plan (WSP) and/or food safety management system (FSMS) implemented in a particular food operation. Validated control measures should prevent the occurrence of identified hazards or should reduce identified hazards to acceptable levels within the water safety plan/food safety management system operated by the FBO. Validation and associated data collection should take into account system variations (e.g. by considering worst-case scenarios).

Control measure validation may start by collecting experimental or (pilot plant type) operational data as well as by using data/insights from relevant scientific and technical studies, or other documentation, e.g. industry codes, load tests, and expert advice.

Validation at full scale is ultimately required to demonstrate that a food business is implementing an appropriate water reuse scenario because the underlying control measures are effective in full scale, routine operation.

For dairy FBOs that operate plants at different sites that wish to implement a particular water reuse scenario with a defined set of control measures, it may be possible to carry out the validation of the relevant control measures for only one site. Full scale validation should still be carried out for each individual site, as each site needs to demonstrate that the WSP/FSM and the control measures implemented to deliver a specific water reuse scenario at that specific plant work as intended.

## EXAMPLES

### **Validation of individual measures:**

Quantitative demonstration of a log reduction of a specified pathogen obtained by a specific treatment is an example of validation of the fulfilment of a performance criterion (e.g. minimum 5 log reduction of *Coxiella burnetii*, as specified for milk pasteurization).

### **Validation of combination of measures:**

Quantitative demonstration of whether a product meets a performance target (e.g. <1 cfu/g of *Staphylococcus aureus*). The validation includes all measures on the processing line that contribute to/or deliver control. Most often, such validation will take place collectively, for example based on challenge tests in pilot plants.

## **Scientific/technical documentation**

Documents that can be used include:

- Published process guidelines that showed to achieve a stated reduction of a pathogen;
- Industry codes that have been assessed by government agencies;<sup>4</sup>
- Peer-reviewed scientific articles or technical data or information describing a process;
- Guidelines and expert advice from competent authorities;
- Challenge tests designed to determine reduction, increase or stabilization of risk factors in a process or process sequence;
- Predictive microbiological modelling programs and databases; and
- Data collected from the specific dairy processing operation;

In all cases, the scientific or technical documentation must identify:

- The combination of product or process and hazard(s) being validated, including product composition and built-in factors (e.g. pH, residual nutrients, etc.);
- Expected extent of reduction and/or growth of hazards that must be achieved or can be tolerated;

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<sup>4</sup> Example of such a code: Heggum, C - Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants. Chapter 8: Reuse of water in dairy processing plants. Aarhus, Denmark 2020. The Danish Veterinary and Food Administration endorsement this Danish sector guide for hygienic reuse of water in the dairy sector as suitable for guidance of food companies.

- Process steps that contribute to the specified reduction or maximum growth and all significant operational parameters; and
- How these process steps can be monitored.

### **Validation of water shelf life**

There are many different technical solutions and types of equipment for water treatment and storage. Also, the microflora of water can differ from plant to plant. It is therefore recommended to validate the shelf life of the reuse water being generated and use a plant-specific hygiene indicator for the validation. The validation is to be performed during implementation of the hazard control plan to assist the operator in making the final determination of target specific parameters that are fit for each scenario and suitable to the local conditions.

### **5.3.2. Validation of control measures at full scale**

Validation of implementation includes collecting monitoring and verification data (observations, measurements, microbiological test results) from the operation for at least one process line per water reuse scenario that demonstrate that the selected control measures are implemented correctly, are functioning as expected and can be expected to achieve the intended objectives in routine operation.

The validation of implementation at operational scale basically includes:

- Implementing the validated operational parameters for control measures in the actual plant and food production process based on experimental and operational data or relevant data/insights of scientific studies and other documentation;
- Validating a water reuse scenario with associated specific control measures type generated from at least one representative processing line (see 5.3.1). Where there are several water qualities covered under the same hazard control plan, the product that is most susceptible (greatest potential for microbial growth) should be selected for validation of the full scale performance of a water reuse scenario;
- Collecting and processing data from the essential operating parameters (e.g. pressure, temperature) during the production of each reuse water type associated to a water reuse scenario. Data for PRPs used to support the decisions in the hazard analysis and verification results should also be collected. Data should be collected for a number of independent runs of a water reuse scenario, so that there is sufficient basis to assess the effect and variability therein; and
- Analysis of the collected data to determine whether the operational parameters have been implemented effectively and that the intended control over the identified hazards is achieved.



If a dairy processor selects operating parameters for a full scale operation that are different from those validated based on experimental and operational data at smaller scales or those based on relevant scientific studies or other documentation (e.g. used in the design validation), or in case no such smaller scale data have been collected or relevant scientific studies or other documentation do not contain relevant data concerning the microbiological hazards identified or relevant surrogates, the company should not start operating the water reuse scenario at full operational scale, but:

- Collect the necessary microbiological data that validate the effectiveness of the selected control measures under actual full scale operational conditions. This data collection should be done for a sufficient number of process runs such as to demonstrate the effect of the selected scenario/measures; or
- Provide necessary scientific study or other documentation with relevant microbiological data showing the effect of the operational parameters is able to control identified hazards at full scale.

It is essential that the dairy FBO analyses the data collected and assesses whether the measures are implemented effectively for each specific plant operated. This analysis should include a review of all records generated during the validation period and if necessary, processing the data statistically, to determine whether the validation data support the scientific documentation.

#### **5.4. VERIFICATION OF CONTROL AT FULL SCALE**

Verify that the water safety system is working as planned at full operational scale by:

- Reviewing and evaluating monitoring data, including that all planned measurements have been taken and recorded, and that all corrective actions have been completed;
- Conducting an internal audit at least once a year; and
- Conducting routine sampling analyses. Using chemical or microbiological analyses and rapid or reference methods is plant specific. Emphasis should be placed on using relatively simple measurements that are well-known and suitable for either inline measuring and/or processed in the laboratory. If unacceptable results are found, perform follow-up actions which may include implementing additional, temporary verification until the problem is resolved and more stringent verification of the affected finished goods.

The quality of the water that has been subjected to RO filtration can be verified by microbiological analysis for hygiene indicators. Since the microflora on the membranes can vary and may be unique from plant to plant (Danish Environmental Protection Agency, 2017), it is not adequate to rely solely on testing for the microbial criteria that applies to drinking water. Instead, during validation of the implementation (during start-up), it is recommended that a locale-specific study be conducted on the prevalence of coliforms and other plant-specific hygiene indicators. This study should be repeated annually in the event that the microflora has changed over time. During the validation, 3–4 hygiene indicators can be tested to identify the best indicator for that particular plant. The fastest growing of these indicators will also determine the shelf life of that water, which is considered to be determined by the indicator type for which the concentration exceeds the specified maximum level first. Indicator threshold limits can be specified without any associated sampling plans.

In addition, measurements of conductivity, total organic compounds (TOC) or turbidity, which are primarily used for monitoring RO filtration, can also be done as part of verification at later processing steps, such as after microbiocidal UV or heat treatments. In-line measurement of bacterial activity or sampling for microbiological analysis can be done to detect leaks, membrane wear and especially the occurrence of “dead pockets” that can contain stagnant water.

Microbiological analysis is used primarily for validation and verification of control measures and for documentation of the levels of microorganisms present over time (trend analysis). But since it does not provide real-time results, it is not very useful for monitoring food safety or quality directly.

If verification demonstrates that the microbiological safety or quality of the reuse water may have been compromised, the FBO should promptly take action, including those based on the considerations stated in paragraph 5.2.2 and 5.3.2.



# Useful testing related to water reuse in dairy operations

## 6.1. USEFUL TESTING PRINCIPLES

Testing for the presence and level of microorganisms, such as pathogens, is by itself insufficient to ensure the safety of food (FAO and WHO, 2013a), nor that of water. However, it can be very useful for validation of control measures at the designing stage of a water reuse scenario in a food operation from small to full scale, and for the day-to-day verification that the reuse water generation system and its application are under control. Moreover, testing can be very useful in unexpected situations, when a system deviation or loss of control have occurred. In these cases, investigative testing may help the operator in identifying the situation and mitigating the risks through process adjustment and immediate control measures.

Microbial pathogens typically occur at very low levels in water or food, making it difficult to quantify their levels by enumeration methods or even to detect them by presence-absence methods. Testing groups of microorganisms, such as utility organisms and indicator organisms (ICMSF, 2011, 2018), may be useful alternatives as these generally occur in food or water at levels that allow quantification, and when properly chosen for that particular water reuse scenario, can help to signal in-control and out-of-control situations.

Utility microorganisms relate to groups of microorganisms that have no impact on consumer health but are naturally occurring in a water source, raw materials for food, production environments, and utensils/utility equipment used in the operation, etc. Some of these may reduce shelf-life or cause spoilage of water or

food. Examples of utility organism testing include yeast and mould counts, aerobic plate counts/total counts as references to natural contaminants, lactobacilli in mayonnaise or thermophilic spore-formers in sugar for specific spoilage types. In the context of water reuse, where the presence of nutrients in reuse water may contribute to microbial growth, useful tools may include aerobic plate counts/total counts done as a general reference or *Pseudomonas* spp. count as a more specific reference for naturally occurring microorganisms.

Indicator microorganisms may be contaminants introduced at a step in the water generation and/or the food production process due to inadequate control. They are normally not harmful, but some may indirectly indicate the presence of pathogens or actually include pathogens, such as STEC being part of an *E. coli* count. Other examples of indicators include, for instance, presence of spore-forming bacteria may indicate under-processing in commercial sterilization, *Enterobacteriaceae* or *S. aureus* in pasteurized products may indicate postprocess contamination or cross-contamination as a result of mishandling and/or unhygienic practices. Both utility and indicator organisms may be useful to signal situations where the operation is not fully under control, including anomalies such as in raw materials or water sources, the recovery and or reconditioning (purification and/or treatment) applied, the storage conditions, and/or the deployment of the reuse water. Causal relationships or correlations between presence of pathogen and indicators are not universal and there is no strict separation between utility and indicator organisms. For instance, coliform counts have been widely used as universal indicators of hygiene, but high coliform counts may also relate to their natural presence in raw materials, water sources or the environment.

Still, for drinking water, coliform counts are widely accepted as a good indicator of water quality related to municipal drinking water or first-use water for primary production of agricultural products, given that one of the key concerns is the possible contamination with human or animal faecal materials in which coliforms are prevalent. Generic *E. coli* is regarded by some as an even better faecal indicator than coliforms (Doyle and Erickson, 2006) and, along with coliforms, may be used as hygienic indicators. Some different indicators and their benefits or limitations in various reuse water applications for fresh produce are described in the FAO/WHO Report on the Safety and Quality of Water Used with Fresh Fruits and Vegetables (FAO and WHO, 2021a).

However, in a dairy food operation, a prime concern may not necessarily be faecal contamination of the reused water, but rather the potential contamination of reuse water supplies by hazards that cause consumer health risks when not properly controlled. Such hazards can be present in the reusable water source or the food production environment when reconditioning treatments or cross-contamination

controls may have been inadequate or have failed. These hazards may be very specific to the various conditions of the dairy processing operation and the implemented water reuse scenario, therefore, the selection of the type of microorganism(s) to be monitored needs to be well tailored to each individual food operation.

Despite the fact that routine testing for a specific pathogen is not adequate to ensure food safety, pathogen testing may be useful for the verification of a WSP/FSMS and for investigational sampling.

The food operation may determine the acceptable microbial limits to be used as reference for evaluating operational control, by establishing a maximum limit for each relevant hazard that is tolerable in the reuse water supplies being generated, with the understanding how this relates to the microbiological quality and safety of the food being processed.

For certain purposes, such as verification of environmental conditions or contamination of processing equipment, maximum limits may be set for every individual sample tested and predefining the number of samples to take to assess compliance and predefining where to take (targeted) samples. Importantly, the usefulness of the maximum limits and the sampling protocol chosen should be validated and the interpretation of findings linked to the procedures for corrective action and documentation.

For batches of reuse water or food materials/products, statistical tests such as the microbiological criterion approach may provide useful information for their acceptability at both validation and verification stages. Codex (FAO and WHO, 2013a), FAO and WHO (2016) and organisations such as IDF (2019), ICMSF (2011, 2018) have provided detailed guidance on the development and utility of Microbiological Criteria for general purposes and in the context of water reuse (FAO and WHO, 2019).

The establishment of useful microbiological testing approaches (i.e. choice of monitoring target microorganisms and sampling and testing plans) has to consider the specifics of each individual dairy operation. Each facility represents a unique combination of a particular reusable water source, the method or technology of recovery, the required reuse water quality, the reconditioning applied, the storage regime considered, the microbiological diversity and ecology of the operational environment, and the microbiological specification of the food processed.

Such a facility specific study should be done once the operator has decided to operationalize a water reuse scenario. The selection of relevant indicator microorganisms or pathogens for validation and/or verification testing, including tolerable maximum limits and sampling and testing protocols, is best based on

information derived from systematic risk assessment/hazard analysis of the water reuse scenario.

Note that it may be prudent to evaluate the performance and utility of several (3 to 4) different types of microorganisms to determine the best suitable for monitoring overall operational control or for control over aspects such as hygiene, process efficiency or maximum shelf-life.

The best-performing microbiological test(s) could then be chosen for routine verification of operational control at the full scale. A rather frequent testing regime can be used at the start of the operation but can be gradually reduced once confidence has been gained that the selected indicator works well with the specific design of the reuse water generation system and the reuse water application purpose in the dairy processing operation. It is highly recommended that the operator documents the performance of the WSP/FSMS over time, e.g. per batch of food or reuse water produced, and performs a trend analysis of the system(s) performance or outcome so that changes and variations leading to loss of control can be identified and mitigated in a timely manner.

Importantly, an operator should realise that existing technological capabilities, sampling and testing for microorganisms, do not typically provide real-time results to evidence operational control. Therefore, physical and chemical means should be considered for more timely monitoring and gathering of data for verification.

## **6.2. USEFUL TESTING CONCERNING REUSE WATER MICROBIOLOGICAL SAFETY AND SPOILAGE**

In verifying the suitability of an operation's environment and/or the source/condition of a supply of reuse water, the focus of testing may be on utility microorganisms or indicator groups that signal adequate system performance or hygiene. Microbiological limits for drinking water quality may serve as a reference.

For instance, the indicators often used by the dairy industry to assess the quality of reused water are total coliforms but there are regional variations on the preferred indicators to use, depending on the microflora of the region, raw materials and the processing plant. Heterotrophic bacteria count (HPC), also known as Standard Plate count (SPC) or Total plate count (TPC) is also used in some countries to assess reused water in dairy processing plants. HPC, which is used to test the quality of drinking water (WHO, 2003), is a simple culture-based method, where aliquots of water are plated onto a suitable culture medium, incubated and the number of colonies are enumerated.

There are no uniform microbiological criteria for reused water, as different countries may use different indicators or may have set different limits. As an example, the U.S. FDA Grade A Pasteurized Milk Ordinance (US-FDA, 2019) uses coliforms and HPC to assess the microbiological quality of reused water in the dairy industry. The Ordinance categorized water reclaimed from milk and milk products and heat exchangers or compressors in milk plants into three groups and with these microbial specifications:

- Category I. Use for portable water purposes. The water is tested for the presence of total coliform and if positive, the same sample needs to be tested for *E. coli* to ensure the lack of faecal contamination. In addition, the sample cannot exceed a HPC level of 500/ml
- Category II. Use for limited purposes, such as production of culinary steam, pre-rinsing of the product surfaces where pre-rinses will not be used in milk or milk products, and for cleaning solution make-up water. Same microbiological specification as Category I
- Category III. Use of reclaimed water not meeting the requirements are used as feedwater for boilers but not used for generating culinary steam. No microbiological specifications.

Examples of indicators used by others for different types of treated water for reuse in dairy facilities are described in detail in Section 6.3, including information on suitable microbial limits as well as situations where the need to test for pathogens may be warranted.

### **6.3. EXAMPLES OF MICROBIOLOGICAL LIMITS/ CRITERIA**

A number of examples of microbiological limits (or criteria) are mentioned below. These are for water reuse scenarios that mainly involve purification and treatment of a reuse water source for-food-contact-purposes, so the reuse water quality should be suitable for human consumption, i.e. equal to the microbiological quality recommended for drinking water (WHO, 2022). Note that the limits shown in the examples need to be validated for the specific dairy operation that is considering implementing them for full scale validation and routine verification of in-control operation. See Annex 4 for case-studies providing more background to the operational control of water reuse scenarios, including use of tailored microbiological testing for validation and verification.

## Microbiological limits used for RO and ROP reuse water produced from whey permeate

The microbiological performance of RO and ROP plants determines their stability against microbial growth as they differ in residual milk nutrients. Due to the effect of milk pasteurization and membrane filtration, the likelihood of any surviving pathogenic microorganisms in RO and ROP water is unlikely. **Table 4** shows the differences in the reuse water characteristics between RO and ROP reuse water.

The water quality can be verified with hygiene indicators. As the microbiological flora in the membranes can vary and is unique from plant to plant, it is inadequate to rely solely on testing for microbiological criteria that are applied to drinking water. Instead, it is recommended to conduct a site-specific study on the growth dynamics of coliforms and plant-specific hygiene indicators during the validation of the implemented reuse water operation (during full scale start-up). For this validation, 3–4 hygiene indicators are tested to identify which is best suited as an indicator of hygiene in that particular plant. Using the fastest growing of these indicators will also help to determine the maximum shelf life of the reuse water, which is set at before the indicator concentration exceeds the specified maximum level.

**TABLE 4** Microbiological criteria/limits used for RO and ROP reuse water produced from whey permeate

FACTOR OR EVENT	RO REUSE WATER	ROP REUSE WATER
<b>Nutrients</b>	<ul style="list-style-type: none"> <li>• Conductivity: Mean value: 124 mS/cm, s = 98 mS/cm</li> <li>• COD: 94 mg O<sub>2</sub>/L; s =81 mg/L</li> <li>• Urea: Variation 70–93 mg/L</li> <li>• Phosphate: 0.37–1.11 mg/L</li> <li>• Nitrate: Variation 0,31–0.53 mg/L</li> <li>• Total N: 36–47 mg/L</li> <li>• Chloride: Variation 18–24 mg/L</li> <li>• Low molecular sugars</li> </ul>	<ul style="list-style-type: none"> <li>• Conductivity: Mean value: 29 mS/cm, s = 38 mS/cm</li> <li>• COD: &lt; 15 mg O<sub>2</sub>/L</li> <li>• Urea: Variation 67–72 mg/L</li> <li>• Phosphate: &lt; 0.05 mg/L</li> <li>• Nitrate: Variation &lt; 0.23–0.78 mg /L</li> <li>• Total N: Approx. 28 mg/L</li> <li>• Chloride: Variation 17–29 mg/L</li> </ul>
<b>GROWTH OF PATHOGENS</b>		
<i>Staphylococcus</i> spp.	(Not known)	No
<i>Salmonella</i> spp.	Yes, at 20 °C and 30 °C, but not at 16 °C	No
<i>Listeria monocytogenes</i>	Yes	No, a reduction when stored at 30 °C
<b>Levels of microorganisms</b>	< 1–100 cfu/g	<< limits set for drinking water

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.



## Microbiological criteria/limits used for RO reuse water produced from milk water and reused milk water

The testing strategy and limits shown in **Table 5** is for routine testing for coliforms, *B. cereus* and one of the four plant-specific hygiene indicators. In addition, *E. coli* is to be tested if coliforms are detected and testing for *Listeria monocytogenes* and *Salmonella* spp. is triggered when extreme levels of the hygiene indicators are detected.

**TABLE 5** Microbiological criteria/limits used for RO reuse water produced from milk water and reused milk water

GENERAL HYGIENE INDICATORS			
Water recovered by RO and stored before use:	Routine testing (e.g. one sample unit per week):	Coliforms	Absent in 100 ml
	Tested if coliforms are detected	<i>E. coli</i>	Absent in 100 ml
	Routine testing (e.g. monthly)	<i>B. cereus</i> (vegetative cells and spores)	< 1 cfu/ml
	PLANT SPECIFIC HYGIENE INDICATOR SELECTED BY VALIDATION		
	Routine testing (e.g. one sample unit per week, but can vary depending on need)	<i>Enterobacteriaceae</i>	$n = 5; c = 2; m = 10 \text{ cfu/ml}; M = 100 \text{ cfu/ml}^a$
		<i>Pseudomonas</i> spp.	$n = 5; c = 2; m = \text{absent in } 100 \text{ ml}; M = 100 \text{ cfu}/100 \text{ ml}^a$
		Psychotropic count	$n = 5; c = 2; m = 100 \text{ cfu/ml}; M = 1000 \text{ cfu/ml}^a$
		TPC 22 °C	$n = 5; c = 2; m = 20/\text{ml}; M = 200/\text{ml}^a$
	PATHOGENS		
	If the level of the selected hygiene indicator does not meet the microbiological criterion, the system is emptied and cleaned. Water from the batch that has been generated is tested for <i>Listeria monocytogenes</i> and <i>Salmonella</i> . If detected, the affected water is discarded.	<i>Listeria monocytogenes</i>	Absent in 25 ml
<i>Salmonella</i> spp.		Absent in 25 ml	

<sup>a</sup> For these three-class attributes sampling plans,  $n$  denotes the number of samples to be tested; the acceptance number  $c$  refers to the maximum allowable number of marginally acceptable analytical units; the microbiological limit  $m$  separates the number of conforming from marginally acceptable units, and a limit  $M$  defines the number of non-conforming analytical units (FAO & WHO. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG_021e.pdf))

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.

## Microbiological criteria/limits used for reuse water produced from milk water through ROP

The rationale for the strategy and limits shown in **Table 6** below is for routine testing for total bacterial plate count (TPC) 22 °C, coliforms, *B. cereus* and one of the four plant-specific hygiene indicators. *E. coli* is not likely to occur in ROP water. In addition, testing for *S. aureus* is triggered if extreme levels of the hygiene indicators are detected; *S. aureus* can grow in ROP water.

**TABLE 6** Microbiological criteria/limits used for reuse water produced from milk water through ROP

GENERAL HYGIENE INDICATORS				
Water recovered by ROP and stored before use:	Routine testing (e.g. one sample unit per week, may vary with need)	TPC 22 °C	$n = 5; c = 2; m = 10$ cfu/ml; $M = 200$ cfu/ml	
	Routine testing (e.g. one sample unit per week)	Coliforms	Absent in 100 ml	
	Routine testing (e.g. monthly)	<i>B. cereus</i> (vegetative cells & spores)	<1 cfu/ml	
	PLANT SPECIFIC HYGIENE INDICATOR SELECTED BY VALIDATION			
	Routine testing (e.g. one sample unit per week, moving window)	<i>Enterobacteriaceae</i>	$n = 5; c = 2; m = 1$ cfu/ml; $M = 10$ cfu/ml	
		<i>Pseudomonas</i> spp.	$n = 5; c = 2; m =$ absent in 100 ml; $M = 10$ cfu/100 ml	
		Psychotropic count	$n = 5; c = 2; m = 10$ cfu/ml; $M = 100$ cfu/ml	
		TPC 22 °C	$n = 5; c = 2; m = 20$ cfu/ml; $M = 200$ cfu/ml	
	PATHOGENS			
	If the level of the selected hygiene indicator does not meet the microbiological criterion, the system is emptied and cleaned. Water from the batch that has been generated is tested for <i>S. aureus</i> . If detected, the affected water is discarded	<i>S. aureus</i>	Absent in 10 ml	

<sup>a</sup> For these three-class attributes sampling plans,  $n$  denotes the number of samples to be tested; the acceptance number  $c$  refers to the maximum allowable number of marginally acceptable analytical units; the microbiological limit  $m$  separates the number of conforming from marginally acceptable units, and a limit  $M$  defines the number of non-conforming analytical units (FAO & WHO. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=I&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=I&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG_021e.pdf))

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.

## MC and microbial threshold values for water of potable quality, derived by reuse of drinking water, RO water, ROP water or from dairy effluents.

The rationale for the strategy and limits shown in **Table 7** is for routine testing for coliforms, *E. coli*, *B. cereus* and one of the four plant-specific hygiene indicators. The risk of pathogen presence in such water is insignificant.

**TABLE 7** MC and microbial threshold values for water of potable quality, derived by reuse of drinking water, RO water, ROP water or from dairy effluents

GENERAL HYGIENE INDICATORS			
Water of potable quality, derived by reuse of drinking water, RO water, ROP water or from dairy effluents and stored before use	Routine testing (e.g. one sample unit per 2 weeks)	Coliforms	Absent in 100 ml
	Test if coliforms are detected	<i>E. coli</i>	Absent in 100 ml
	Routine testing (e.g. monthly)	<i>B. cereus</i> (vegetative cells and spores)	< 1 cfu/ml
	PLANT SPECIFIC HYGIENE INDICATOR SELECTED BY VALIDATION		
	Routine testing (e.g. one sample unit per 2 weeks but may vary depending on need)	<i>Enterobacteriaceae</i>	$n = 5; c = 2; m = 10 \text{ cfu/ml}; M = 10 \text{ cfu/ml}$
		<i>Pseudomonas</i> spp.	$n = 5; c = 2; m = \text{absent in } 100 \text{ ml}; M = 100 \text{ cfu/100 ml}$
		Psychotropic count	$n = 5; c = 2; m = 100 \text{ cfu/ml}; M = 1000 \text{ cfu/ml}$
TPC 22 °C		$n = 5; c = 2; m = 20 \text{ cfu/ml}; M = 200 \text{ cfu/ml}$	

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.

## Microbial threshold values for water extracted from whey by RO.

The rationale, strategy and limits shown below (Table 8) is for potential risk from surface water in the primary water supply, wherefore, *C. perfringens* is tested. As the reused water may be stored hot, testing for *Legionella* is warranted

**TABLE 8** Microbial threshold values for water extracted from whey by RO

GENERAL HYGIENE INDICATORS	
TPC 22 °C	< 100 cfu/ml
Coliforms	Absent in 100 ml
(generic) <i>E. coli</i>	Absent in 100 ml
<i>Aeromonas</i> 30 °C	< 10 cfu/ml in 10 ml
GENERAL HYGIENE INDICATORS	
<i>Legionella</i>	< 100 cfu in 1000 ml
<i>C. perfringens</i>	Absent in 100 ml

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.

## Microbial threshold values for water derived from whey by ROP and for food contact use

The rationale for the strategy shown below (Table 9) is that pathogens occurrence is unlikely and so, testing for hygiene indicators will suffice.

**TABLE 9** Microbial threshold values for water derived from whey by ROP for food contact use

GENERAL HYGIENE INDICATORS	
TPC 22 °C	Max. 100 cfu/ml
Coliforms	Max 0.9 MPN/100 ml <sup>a</sup>

<sup>a</sup> Most Probable Number

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.



# Recommendations and knowledge gaps

## **7.1. RECOMMENDATIONS**

### **7.1.1. General recommendations concerning the implementation of water reuse in dairy operations**

It is recommended that each water reuse scenario considered by an operator be carefully tailored to the conditions of its particular food operation. The factors include: the available reusable water sources, the purpose of reuse water application, reuse water generation system and underlying processes, and storage and shelf-life of the reuse water supplies. Adequate validation of hazard control needs to be undertaken when implementing the scenario at the full scale of the operation. Importantly, the operator must have the skills and expertise available internally or externally to manage the water production and application systems, and the implemented water reuse scenario at full scale and on a day-to-day basis.

To assess the potential of a particular water reuse scenario and design control over relevant microbiological hazards, it is recommended that the food business operator (FBO) considers all events and factors that may contribute to such hazards becoming food safety risks (through the food produced and consume), affect the safety of workers (by exposing them to hazards during reuse water generation and application) or impact on the health of animals (through spread of a hazard into the operation's environment or into value chains):

- Assess the hazards and the potential risks associated with applying water from a specific reusable water source for a particular purpose. An adequate evaluation of hazards (through hazard analysis/risk assessment) associated with a water reuse scenario is best conducted at a design stage before considering implementation of a water reuse scenario. Different water reuse scenarios may be evaluated for robustness based on different designs, e.g. the combination of reuse water sources, recovery and/or conditioning technologies, as well as storage, distribution and application approaches.
- Select the most robust water reuse scenario given the design and control options available to the operator at the stage of implementation and operationalization of the water reuse scenario. The goal is that the generation, storage and distribution of reuse water together ensure the availability of supplies of reuse water that consistently meet the microbiological specifications required for the fit-for-purpose application. A robust scenario includes having suitable back-up water supplies available, if needed.
- Validate the reuse water generation system according to the intended application purposes. For a food-contact application, the reuse water needs to meet the microbiological specification for that particular food materials/water supplies and conforms to the legal requirements of that food operation or to the distribution/marketing of that food materials. Key to adequate validation is the selection of suitable criteria and methods for validating the control measures and to generate supporting data.
- Establish adequate monitoring parameters and verification procedures that provide the necessary data and evidence to assess the effectiveness (or loss) of the operational control of reuse water production and application and that allow for the operator to take timely action when necessary. This includes selection of suitable methods as well as limits/criteria for monitoring parameters.
- Consider the events or factors favoring growth and persistence of different microorganisms, especially hazards, such as nutrients present in batches of reuse water being generated, as these may support proliferation of hazardous microbes or lead to the formation of biofilms (e.g. after multiple uses in recirculation or recycling applications).
- Determine the need for additional measures to control shelf-life during the storage of reuse water supplies.

For each water reuse scenario in a particular dairy processing operation, it is recommended to adopt the following steps during implementation and operationalisation of a water reuse scenario:

- Full scale validation of reuse water generation and storage (as relevant), consistently delivering a supply of reuse water that is fit for the intended purpose.

- Establish the necessary monitoring procedures to enable ongoing control over the generation and storage of reuse water supplies, including those that trigger timely action when required.
- Establish timely verification of the physico-chemical and microbiological parameters selected to control reuse water generation and storage, ensuring that these parameters are specific to the water reuse scenario and to the dairy processing operation.
- Ensure that the logistics of distribution of different water types and qualities in the food operation is such that cross-contamination or erroneous use of reuse water supplies does not occur.
- Establish contingency plans and procedures to deploy suitable alternative water supplies (e.g. first-use drinking water) when needed.

Note that the design and implementation of each water reuse scenario should be comprehensive and cover all aspects including recovering, reconditioning, storing and distributing reuse water supplies, validation, monitoring and verification of the operation, and ensuring that adequate logistics, zoning, labelling and other approaches control any unintended application of particular reuse water supplies.

More efforts are also needed to enhance the sharing of data, knowledge, and expertise within and across various groups of stakeholders. Especially relevant and urgent is the sharing of experiences and know how concerning the effective reuse water generation systems and fit-for-purpose applications of reuse water supplies, at both small and large dairy production and processing facilities.

It is important to increase communication to raise awareness of various stakeholders (from the food industries at large, including service providers of water and food, to government authorities, academia and consumers) concerning the importance and urgency of increasing water reuse all along the food value chain.

### **7.1.2. Specific recommendations on testing and microbiological parameters concerning the implementation of water reuse in dairy operations**

Microbiological sampling and testing are appropriate for validating individual or combinations of control measures/steps such as reuse water generation, storage and application, but also for investigational purposes and analysis of trends at the level of operational control.

Where routine microbiological sampling and testing do not adequately provide real-time verification of operational control over reuse water generation and storage, testing for relevant physical and chemical parameters is a better alternative and is recommended.

Sampling for specific microbial hazards (i.e. human pathogens) in most instances is not practical for verification but does have particular value for validation and for investigational sampling. For verification and routine monitoring purposes, groups of microorganisms (e.g. utility organisms; indicator organisms) may be considered useful parameters that could provide information regarding the level of control of hygiene or processing/treatment steps. The appropriate microbiological limits/thresholds or microbiological criteria for the individual or groups of microorganisms selected for validation/verification should be established on a case-by-case basis and be specific to the particular water reuse scenario and the dairy processing operation.

Ensuring that microbiological parameters (i.e. utility organisms, indicator organisms, and pathogens as well as their reference levels) chosen for that particular water reuse scenario are relevant. This includes: the microbiological quality of reusable water sources, the impact of reconditioning on the microorganisms/nutrients in the reuse water supplies produced, and the dynamics of microorganisms being transferred to foods that is being processed, in the case of for-food-contact applications, all needs to be well understood.

Since the presence of pathogens in reuse water used for-food-contact purpose would pose health risks to consumers, it is essential to validate that such pathogens are not present in the reuse water produced or be present at levels causing unacceptable risks. Such validation may rely on existing knowledge/data, supplemented with some microbiological testing of the relevant pathogen. Additionally, microbiological testing is most relevant for validating the reuse water generation process and for establishing suitable (maximum) shelf-life for storage of the reuse water supplies.

Verification of control by routine testing for pathogens is not practical as the likelihood that such hazards is typically very low, thereby routine pathogen testing is not a useful practice. However, in cases when an operation fails or underperforms, pathogen testing may become more relevant to assess the out-of-control situation and to determine appropriate corrective measures to regain control. Examples of operational failure could include leakages of membranes in the purification systems, inadequate antimicrobial treatment, as well as post-process contamination of the reuse water. In these out-of-control situations, hazard analysis and risk assessment help evaluate possible food safety risks, and pathogen testing may be useful in the revalidation and reverification of the optimized operation.

For routine monitoring, particular groups of microorganisms (e.g. total bacterial counts, *Pseudomonas* spp. count), that are relevant for the water reuse scenario and are present at levels that can be quantified, may be more suitable as parameters



than pathogens, to assess whether operational control is adequate or trending toward inadequacy or failure. The operator should also consider whether chemical or physical parameters (e.g. total organic compounds (TOC), chemical oxygen demand (COD), turbidity or conductivity) may be better alternatives to monitor control or failure, as testing results for these parameters will be available quickly or even immediate in case of in-line testing and they are often less costly than microbiological testing.

It is recommended that the operator conduct a validation (ultimately during start-up) to identify the level of relevant microbiological indicators and to select one of them for routine verification purposes. It is advisable to include trend analysis of the verification data for each water reuse scenario.

Reuse water supplies can be considered as the end product of a reuse water generation system. Both the control over the microbiological quality of this end product and the production process should be designed and implemented according to the following types of water applications:

- Reuse water applications without direct contact with food or where indirect contact with food is unlikely (e.g. water for gardening; extinguishing fires; cleaning of non-food transport vehicles);
  - > Such applications do not need to include microbiological testing for food safety for operational control.
- Water reuse applications where water is not intended for food contact or food contact surfaces, but where unintentional, indirect contact with food can be actively managed (e.g. water used for rinsing/flushing and in clean-in-place (CIP) steps, excluding the final rinse; water used for non-food contact cooling and steam applications; water used for cleaning the exterior of processing equipment not in contact with food materials, etc.);
  - > If the operational design can reliably ensure that reuse waters do not come into contact with food, there is no need for microbiological testing to ensure food safety.
  - > If the operational design cannot exclude the possibility of food contact, microbiological testing during the validation of the design and the verification of the operational controls becomes relevant to ensure the safety of the food products being processed.
- Water reuse applications where reuse water is directly or indirectly intended to come in contact with food or food-contact surfaces (e.g. water used for CIP rinses, including the final rinse, water used for cleaning food processing and transport equipment, brine used for cheese making, water used for ice and steam that comes in contact with food materials, etc);

- > Microbiological testing is essential for validation and verification purposes for the control of both reuse water generation as well as for controlling food production. Managing both reuse water and food production may be done via one integrated food safety management system or managed as two separate systems, such as using the Water Safety Plan to manage only the generation of reuse water.
- Water reuse applications where the reuse water is used as food ingredient or an integral part of food manufacturing (e.g. water for ice cream, yoghurt, water for cooling of cheeses, diafiltration of milk products, etc.);
  - > Microbiological testing is essential for controlling reuse water generation and for food production. These two can be managed through the food safety management system of the dairy processing operation or as two separate systems. In some countries, there are regulatory restrictions to using reuse water as a food ingredient.

Note that in all applications described above, the reuse water generation, storage and use need to be assessed for the presence of microorganisms of concern (e.g. FMDV) that could spread in the operational environment. Also, when such water is used or held at temperatures between 25 °C and 55 °C and the personnel maybe exposed to aerosols, monitoring for microorganisms (e.g. *Legionella*) that pose occupational safety risks is also relevant.

## 7.2. KNOWLEDGE GAPS

The aspiration to deploy reuse water in dairy and in other food sectors is increasing in several parts of the world, and more scientific papers are being published on relevant topics such as hazard control/risk assessment, methods and technologies for reuse water generation and application as well as risk management. However, the implementation of reuse water scenarios at full scale is still very much under development mostly due to knowledge gaps on how best to develop and deploy water reuse scenarios, especially in environments with limited technical capabilities and capacities.

In particular, the following gaps in knowledge and related aspects of capacity and capability, need to be considered to drive the deployment of water reuse scenarios further (note that some suggestions on the possible way(s) to move forward are noted with each knowledge gap):

- The understanding of the microbial hazards (as well as the physical/chemical hazards) in terms of both types of hazards and levels, that are potentially present in reusable water sources in a dairy food production or processing environment.

- > Encourage publications and knowledge dissemination by the industry and academia concerning typical hazards found in water reuse, especially on hazards identified in particular water reuse scenarios and specific food sectors.
- Enhance the capability and capacity to conduct appropriate risk assessment and hazard analysis for a particular operational situation and water reuse scenario, and to use tools such as predictive microbiology to evaluate possible control measures and examine consumer health risks.
  - > Research by academia, industry and others could generate data and develop predictive growth models of relevant hazards, which could be used for risk assessment and validation, as well as for overall management of operational water reuse.
- How to assess the actual performances of individual and combined technologies on the recovery and reconditioning of reusable water supplies in dairy production, and to assess their effectiveness in mitigating microbiological hazards under large, pilot scale/full scale operation conditions.
  - > Resources, expertise and experiences from the drinking water sector may provide helpful insights for the dairy sector water reuse scenarios through their targeted studies and sharing of results and outcomes.
  - > In addition to the impacts of control measures on microbiological hazards that pose consumer risk, operators also need to understand the performances characteristics of these control measures on organisms that may spoil reuse water supplies or foods being processed, as well as those that pose challenges to occupational safety or cause animal diseases (e.g. *Legionella*, FMDV).
- The impact of various chemical/physical matrices on potentially reusable water sources and the potential impact of chemicals on the efficacy of technologies used for the recovery and reconditioning (e.g. filtration/purification, microbiocidal treatment) of such water supplies. In particular, understanding the potential contribution to risk of nutrients on the growth potential of microbiological hazards in the recovered or reconditioned water supplies.
  - > Basic research and academic studies, as well as sharing of insights throughout industrial organizations may help build capacities and promote collaboration among other potential industry users and stakeholders.
  - > In particular, the carry-over of nutrients from recovered water supplies to those that are reconditioned and intended for food-contact applications may be an overlooked aspect, which warrants further research by

academia and industry to raise their awareness and provide useful data and solutions.

- The validation of recovery/reconditioning approaches (i.e. validation of the individual or combined technologies and other control measures) for a specific water reuse scenarios, taking into account aspects such as hazard control, shelf-life/storage, and the microbiological quality of the reuse water that is being applied in routine operation.
  - > Validation of technologies and control measures applied individually or in combination can be studied in the laboratory, pilot scale or full scale by academia, industry, service providers, etc. Publishing these results may help individual operators, regulators and other stakeholders to avoid or minimise the need to conduct/require case-by-case validation of performance at all levels.
- The operational management during routine operation needs to monitor key operational aspects to verify that the operation of reuse water generation and use is under control.
  - > Various experts can review monitoring and verification approaches and develop/share best practice approaches for: batch-wise verification on the suitability of reuse water supply, trend analysis to build confidence in the operational control process, timely early warning of failure.
- The establishment and the use of microbiological parameters for verification of operational control (including, target microorganisms or groups, their relevant levels as well as suitable sampling plans or strategies) and for validation and verification of water reuse operations. The parameters must be tailored to dairy production facilities and processing operation and must be in line with relevant regulatory requirements.
  - > Experts from academia, sector organisations, service providers, scientific organisations, and competent authorities can investigate and advice on the suitability of microbiological parameters selected to monitor water reuse scenarios and for verification purposes, such that individual operators can implement these as appropriate.
  - > Competent authorities can use these microbiological parameters to set acceptable levels of microbiological hazards that are relevant to consumer health. Industry can use such parameters to determine the limits of microorganisms (those that can affect quality and spoilage) that might be acceptable operationally.

- The deployment of suitable or alternative technologies for recovering and reconditioning water in dairy operations that have limited resources, capabilities, and technical infrastructure.
  - > In many parts of the world and in several sectors, there are limited technical and resource capabilities for which tailored and low-technology equipment and solutions are needed to enable them to embrace water reuse opportunities. This may be supported by international collaboration and by the sharing resources, including data, information, knowledge, expertise, etc.

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# Annexes



## Water recovery technologies

### TECHNOLOGY 1. RECOVERY BY CONDENSATION

Condensate recovery systems are widely used in the dairy industry to remove water from a liquid product to obtain a more stable and reduced volume product, which often is subsequently dried to powder form. Basically, evaporators are used to concentrate heat-treated milk from approximately 10% to around 50% total solids (UNEP & Dairy Australia, 2004).

There are two common ways to generate condensate water:

- 1) Recovery from boiler and steam supply systems, which can substantially reduce the operating and energy costs, chemical use and the amount of water required by the boilers.
- 2) Recovery by drying and the evaporation processes used to concentrate milk products or to produce powders.

The water recovered from evaporators or boiler condensate (Vourch *et al.*, 2008) can be used for non-food contact applications in various manufacturing operations. These applications include, for instance, water for feeding boilers, for cooling towers, for CIP systems, for preparation of dilute alkaline or acid rinse solutions, for intermediate rinsing, and washing equipment, floors, tanks or trucks, dryer wet scrubbers, indirect heating (via heat exchanger) and pump seal water (Daufin *et al.*, 2001, UNEP & Dairy Australia, 2004).

Notably, during the evaporation process, tiny particles of organic materials from the liquid products may end up in the condensate water through splashes during boiling or evaporation. Hence, the condensate water may contain organic materials and if it is not properly cooled or is stored at inadequate temperatures, it may support growth of microorganisms present, (UNEP & Dairy Australia, 2004). Such conditions potentially render the condensate unfit for reuse for food contact purposes. For food contact use, it is necessary that the evaporator or boiler condensate is purified by passing it through membrane filtration technologies or other treatment methods that will reduce nutrient content, microbial contamination and other hazardous substances (See Annex 2).

Organic matter carry-over and several other factors that potentially affect the fit for purpose application of the condensate water are shown in **Table A1**.

**TABLE A1** Factors affecting the quality and the safety of recovered condensate water

<b>Product-related factors</b>	<ul style="list-style-type: none"> <li>• The type of product being evaporated; the microorganisms typically present may include hazards of concern to human health or those that affect the stability of reuse water supplies or that of the food products being processed.</li> </ul>
<b>Process-related factors</b>	<ul style="list-style-type: none"> <li>• The performance of recovery and/or reconditioning technology: performance should be validated under operational conditions and, where required, further effective treatment (e.g. addition of disinfectants, carbon filtration, ion exchange, reverse osmosis and biocides) maybe considered to consistently meet the required microbiological quality for the intended reuse purpose.</li> <li>• The stability of evaporator operation: instability may result in underperformance or down-times, which may cause contaminants from being inactivated or prevent cross-contamination from occurring.</li> <li>• The step/site of water extraction and reuse (e.g. condensate from earlier stages of an evaporator may be used as boiler feed water, but condensate from the later stages is usually suitable only for washing floors and plant exterior).</li> <li>• When reuse water generation, storage and distribution are not properly controlled, cross-contamination from the operation’s environment, equipment or other sources may render the microbiological quality of reuse water supplies inadequate.</li> <li>• Logistics of reuse water distribution; unintended use (erroneous use) of reuse water supplies or mixing of condensate with other supplies that containing compounds (nutrients) that can support microbial growth could result in the microbiological quality of the reuse water supply being unfit for the intended purpose.</li> </ul>
<b>Environment- and operation related factors</b>	<ul style="list-style-type: none"> <li>• (Continuous/timely) inspection and monitoring of the condensate quality (usually done by conductivity and/or turbidity tests) to provide data on the operational control status for verification purposes.</li> <li>• The ability to chemically clean all parts of the systems used to collect and convey the condensate.</li> <li>• Training of operating personnel.</li> </ul>

Source: Authors’ own elaboration based on **UNEP & Dairy Australia**. 2004. Eco-efficiency for the Dairy Processing Industry. Fact sheet 2: Water recycling and reuse. Accessed 24 July 2022. [https://www.ecoefficiencygroup.com.au/wp-content/uploads/2017/11/ecodairy\\_fs2.pdf](https://www.ecoefficiencygroup.com.au/wp-content/uploads/2017/11/ecodairy_fs2.pdf)



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## TECHNOLOGY 2. RECOVERY BY SEDIMENTATION, COAGULATION AND CENTRIFUGATION

Dairy effluents are known to contain excessive amounts of organic matters, as reflected by the high Biochemical Oxygen Demand (BOD) values, which can be 250 times greater than that of sewage. Typically, they also have high total soluble solids, turbidity, Fat, Oil and Grease and high Chemical Oxygen Demand (COD) values. Aside from nitrogen, phosphorus, and maybe emitting odours from the acidification process, such effluents may also contain germicides, detergents, and other types of chemicals (Yonar *et al.*, 2018; Nabbou *et al.*, 2020) as well as constitute a considerable source of pollution if released into the environment.

With increasing concerns for water pollution, effluent standards have become stricter in many countries. Coupled with the global scarcity of water, many countries are exploring more efficient ways of treating discharge effluents and better yet, means to treat and reuse the large volumes of water that are generated from dairy industries. These treatment technologies include simple sedimentation, coagulation-sedimentation, high-rate sand filtration, dissolved air floatation to remove organic matters and others. The characteristics of dairy wastewaters may vary from industry and/or country and, also depending on the socio-economic situations, processors may not be using the same methods for dairy wastewater treatment.

Generally, dairy effluents are subjected to preliminary treatment to remove coarse solids and other large materials that may damage to pumps and cause clogs downstream. Preliminary treatment is inefficient in microbial pathogen removal from the liquid waste-stream, and it is not intended for that purpose. Following preliminary treatment, water is subjected to primary treatment, like sedimentation (or primary clarification by physical settling or filtration) where large solids are removed. Sedimentation is a rudimentary technique that has been used for years to clean water by removing dirt and turbidity. Primary sedimentation is often set up as a centralized or semi-centralized system, where suspended particles and floating material and heavy solids (scum) from liquid waste are separated by gravitational settling. In wastewater treatment plants, scum is usually disposed separately or in combination with sludge/biosolids (Oakley, 2018). Few data exist on pathogen concentrations in the scum, but it is assumed to be high. Even though pathogen concentrations in dairy industry effluents might be lower, the effluents should still be handled with care (Metcalf and Eddy, 2014).

The primary sedimentation process is designed specifically for the removal of suspended solids. Any reduction of viral, bacterial, and protozoan particles by sedimentation may be incidental and can range from 0 to 1 log, and from

0 to <1 log for helminths (Sobsey and WHO, 2002). Although not very effective, sedimentation can occasionally remove some microbes depending on the sizes of the organism. Individual bacteria or viral particles are too small to settle by gravity alone however, if they are clumped or there are suspended solids in the water, microbe sedimentation rates can be increased. One study examined faecal coliform in estuary water and showed that their sedimentation rate increased in proportion with the concentration of suspended solids in the water (Milne *et al.*, 1986). Similarly, the sedimentation of *Cryptosporidium* oocysts and *Giardia* cysts were increased by solid particles in the effluent, as the cysts often attached to the solid suspensions (Medema *et al.*, 1998).

If the dispersed, suspended and colloidal particles that cause turbidity and water colour cannot be removed sufficiently by simple sedimentation, the efficiency of sedimentation can be increased by chemically enhanced primary treatment (CEPT) and/or advanced primary treatment (APT) (also called high-rate clarification) to enhance the removal of solids particles that could not be separated by simple physical gravitational processes. With CEPT and APT, coagulation or flocculation agents such as salts of iron or aluminium are added to make the suspended particles cluster together and separate more easily by gravity settling. Both processes may have high removal efficiencies (80–90 percent) for total suspended solids and are reported to remove 1–3 log of helminth eggs from untreated wastewater (Jimenez *et al.*, 2010), and 1–2 log of viruses, bacteria, and protozoa (Sobsey and WHO, 2002).

Alternative to chemicals, natural coagulants may also be used to improve the effectiveness of sedimentation. The seeds of *Moringa oleifera*, a fast-growing, drought-resistant tree cultivated in many tropical countries, have been studied for use as a natural, cost-effective means of water treatment in many countries, and found to reduce turbidity and is an efficient coagulant (Panterniani *et al.*, 2010; Narayasamy and Mohd Saud, 2014). Another natural flocculant and coagulant is diatomite, and it has been shown in one study to remove *Staphylococcus* spp. and *E. coli* but the levels of removal can vary significantly with pH (Sha'arani *et al.*, 2019).

Combinations of simple, cost-effective technologies have also been explored to produce water of potable quality. A study from Bangladesh used *Moringa* seed powder as a coagulant and scallop shell powder as a bactericidal agent to treat water. The resulting clear water was then passed through an eight-fold sari cloth and/or natural bio-sand filtration system (Zaman *et al.*, 2017).

Microbiological analysis for various indicator bacteria and pathogens, as well as physico-chemical analysis of the treated water showed no significant differences as

compared to the U.S. EPA drinking water quality parameters (Zaman *et al.*, 2017). Furthermore, the quality of water stored for six months at room temperature was found to be acceptable, suggesting that this was a viable, low cost means of producing drinking water. How the various treatment methods described above will work for treating dairy effluents is uncertain.

Instead of relying on gravity as in sedimentation, the solid particles in water can also be removed by centrifugation. Continuous decanter centrifuges have been shown to be very effective in separating whey proteins from whey (Haller and Kulozik, 2019). The effectiveness of centrifuges to remove indicator bacteria from water was examined using manure slurries from dairy cows (Liu *et al.*, 2017). The study showed that two log (99 percent) reduction was achieved for both total coliforms and *E. coli* when the slurry was centrifuged at  $10\,000 \times G$ . ( $G$  = relative centrifugal force)

It is important to point out that the technologies discussed in this section may be useful for preliminary treatment of dairy effluents but will not remove all the microbes or pathogens that may be present. As a result, further downstream treatment and purification procedures will be needed to meet any reuse water requirements or to make potable quality water.

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# Water purification technologies

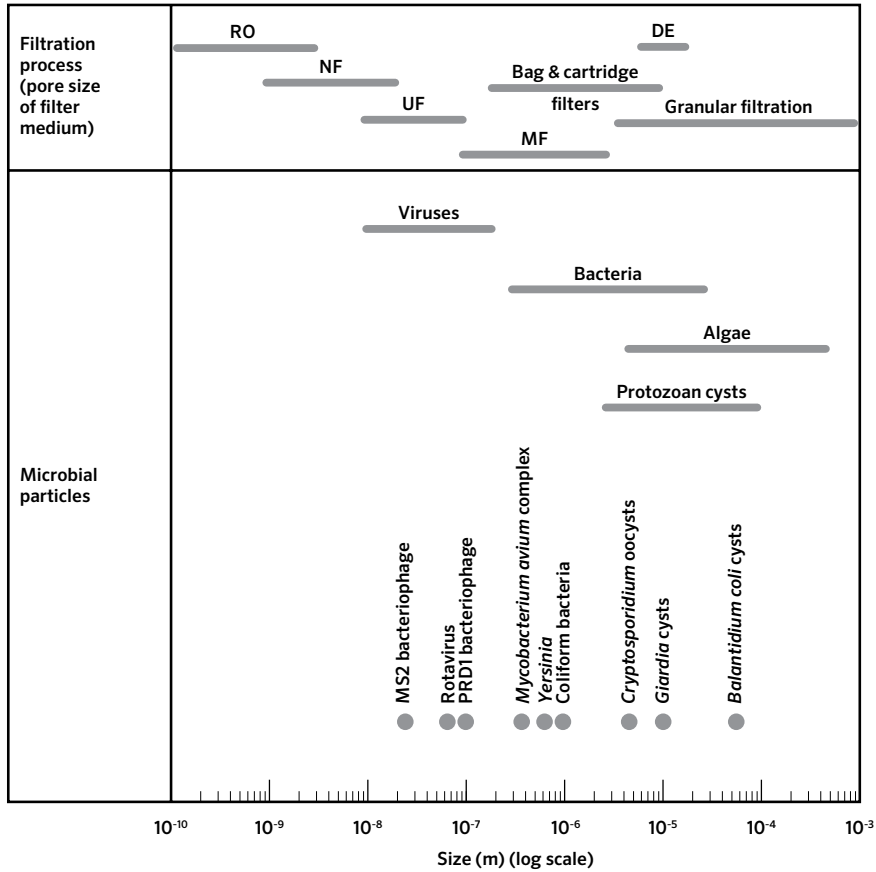
There are several types of technologies to filter and purify recovered water supplies, some of which support removal of microorganisms from water, e.g. membrane technologies, sand or carbon filter technologies, and sludge technologies. In the order that they are listed, the filtering effect is increasingly crude which, consequently, decreases the potential that microorganisms may be filtered out or otherwise removed.

The **Figure A1** below illustrates the approximate filtering performance of different technologies on a variety of microbial particles.

Membrane based systems have demonstrated good results concerning water reuse scenarios in the dairy sector (Fraga *et al.*, 2017; Vourch *et al.*, 2008) and demonstrated the value of single stage application via MF, UF, NF or RO, as well as two-stage operations such as NF + NF or RO + RO (Vourch *et al.*, 2008).

In this Annex, several aspects related to microbiological removal potential of these technologies and their utility in the generation of reuse water are discussed.

**FIGURE A1** The average pore size for different membrane filtration systems (RO: Reverse Osmosis; NF: Nano Filtration; UF: Ultra Filtration; MF: Micro Filtration; BF/CF: bag filters/cartridge filters; DE: diatomaceous earth; GF: sand filters) and the size of different particles of microorganisms



Source: Adapted from WHO. 2004. Water treatment and pathogen control: Process efficiency in achieving safe drinking-water. Chapter 2, removal processes. <https://www.who.int/publications/i/item/9241562552>



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### TECHNOLOGY 3. PURIFICATION BY REVERSE OSMOSIS (RO)

Reverse Osmosis (RO) is a well-known technology that has been at the forefront of water reclamation. It is known for its high efficiency in separating small particles, including bacteria and monovalent ions, such as sodium and chloride ions (Ezugbe and Rathilal, 2020). RO systems are already installed in most dairy processing plants and thus, staff and management are generally well-trained and can operate RO systems effectively.

RO is a membrane filtration technique that uses 1.0–0.1 nm pore-size membranes in combination with high water pressure (450–600 psi or 31–41 bar) to overcome osmotic resistance and forces water from the retentate to the permeate side of the membrane. This results in the separation of the concentrated organic material (the retentate) from the water (the permeate).

By using RO, valuable milk constituents, bacteria, viruses, salts and minerals are concentrated in the retentate. The RO permeate consists mainly of water, but it may contain traces of substances found in the retentate feed material, which could have passed through the membrane. Potentially, some microorganisms and growth supporting nutrients (e.g. urea) may be present in the permeate, which can cause growth of microorganisms downstream of the RO step and limit its intended use, especially for food-contact applications.

RO water recovered from permeates of whey, milk and product flushes typically has very low microbial counts. When the performance efficiency of RO has been validated and is found to be consistent (verified), RO water may be used for the following purposes within 24 hours after generation:

- Ingredient in dairy products, e.g. scalding of cheese grains.
- Production of ice and steam, including direct steam injection.
- Washing of casein/whey protein or direct cooling of cheeses.
- As rinse water in between cleaning steps, but not for final rinse of processing lines used for heat-treated products.
- Cleaning of membrane filtration systems or washing of boxes and product moulds.
- Diafiltration, i.e. process applied before another membrane filtration, 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.
- Dilution of brine used for brining yellow 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.

RO water that will not be used within 24 hours, should be subjected to microbiocidal treatments (see further details in Annex 3).

Depending on the requirements of the particular fit-for-purpose application of the reuse water, or considering the likely presence of hazardous microorganisms, RO can be supplemented with other approaches/barriers for further purification. Referred to as “RO and Polishing” (ROP), it can consist of a second RO treatment or nanofiltration, deionization, or treatment with activated carbon.

In RO and ROP water generated from milk water, urea constitutes the largest single component present, as urea is uncharged and cannot be effectively separated from the permeate by the membranes. Generally, other milk components are effectively filtered out.

It is estimated that ROP water has a default storage shelf life of approximately 2 days without temperature control, but that shelf life can be extended by microbiocidal treatments (such as UV) and/or using cold or hot temperature storage. Any storage scenarios are best validated specifically to conform to locally prevailing conditions.

Aspects of concern that can affect the performance efficiency of RO and ROP include:

- Membrane tightness can be compromised by fouling and damage (e.g. leaky gaskets).
- Membrane filtration efficiency is largely determined by the extent of fouling, where organic material (primarily proteins) can block the membrane pores. Extent of fouling is reflected by pressure differential across the membrane, which can also serve as an indicator of when to clean the membrane filtration plant.
- RO membranes can be difficult to clean, which can lead to the likelihood of fouling and building up of biofilms. Biofilm formation is most likely on the retentate side, but it can also develop on the permeate side and over time, biofilm can form on both the retentate and the permeate side of the membrane (Anand *et al.*, 2014).
- Due to the surface characteristic of roughness and the existence of microscopic holes that form negative pressure and can trap microbial cells, biofilms tend to form more easily on polyamide membranes than on membranes of other material (e.g. cellulose acetate) (SDT, 2015, page 142).
- Biofilm can act as reservoirs for different microflora, leading to persistent product contamination. Studies done on RO membranes used to filter whey showed that biofilms consisted of a mixed microflora of *Enterococcus*, *Staphylococcus*, *Micrococcus*, *Streptomyces*, *Corynebacterium*, *Bacillus*, *Klebsiella*, *Aeromonas*, *Pseudomonas*, *Streptococcus*, *Chryseobacterium* and *E. coli* (Anand *et al.*, 2014).

- With membranes pore sizes of  $< 0.2$   $\mu\text{m}$ , up to 1 percent of the bacteria in feed material can pass to the permeate side, but the bacterial cells did not appear to be viable and failed to grow on agar plates. Smaller microorganisms or membranes with larger pores, will presumably allow the passage of viable cells that can grow and proliferate (Goosen *et al.*, 2005).

Aspects of the characterization of surface fouling and biofilm formation related to water reuse scenarios in the dairy industry have been described (Stoica, 2018).

Annex 4 describes case studies involving RO and ROP, with details on operational process control, microbiological characterization of the potential reuse water source, validation and shelf-life assessment, as well as hazard control and verification plans.

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## TECHNOLOGY 4. PURIFICATION BY ULTRA FILTRATION

### Ultra Filtration (UF) and related filtration approaches

Filtration systems deploy a membrane as a barrier to separate two phases from each other by selectively restricting the movement (flux) of components across the membrane (Takht Ravanchi *et al.*, 2009). Membrane filtration is a pressure-driven process with the feed stream running parallel (cross flow) to the membrane surface and the permeate passing perpendicular of the flow direction. A review on ultrafiltration has been published by Ezugbe and Rathilal (2020).

The characteristics of the membranes can be classified as isotropic or anisotropic. Isotropic or symmetric membranes are uniform in composition and physical structure. They can be microporous, in which case their permeation fluxes are relatively high as compared to nonporous membranes that are dense, and their application is highly limited due to the low permeation fluxes. Isotropic microporous membranes are widely used as microfiltration membranes (Ezugbe and Rathilal, 2020).

Anisotropic or asymmetrical membranes used in pressure driven separation processes (MF, UF, NF and RO) are made from synthetic organic polymers, including polyethylene (PE), polypropylene, polytetrafluorethylene (PTFE), and cellulose acetate (Aliyu *et al.*, 2018; Tolkou *et al.*, 2021). Inorganic membranes are made from materials such as ceramics, metals, zeolites, or silica, are chemically and thermally stable, and used widely in industrial applications like hydrogen separation, UF and MF (Baker, 2012; Mallada and Menendez, 2008; Ezugbe and Rathilal, 2020).

A study of the potential water reuse through NF UHT flash cooler condensates from a dairy factory estimated that a NF plant able to treat 20 m<sup>3</sup>/h of condensates could achieve 87.5 percent water recovery (Riera *et al.*, 2016)

Typically, MF, UF, and NF are used as pre-treatment steps to RO to reduce fouling of the RO membrane and to enhance the maintenance of constant flux. Used jointly, these technologies serve as a multi-barrier treatment for removal of contaminants from wastewater (Bartels *et al.*, 2005; Ezugbe and Rathilal, 2020). However, UF or other filtration approaches by themselves, may not remove all microorganisms and pathogens that may be present in the water to be filtered. As a result, further treatment like disinfection and purification may be required depending on the reuse water applications.

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## **TECHNOLOGY 5. PURIFICATION BY ACTIVATED CARBON WATER FILTRATION (ACWF)**

Activated carbon is a natural product made of organic coal or coconut shells and is available as granules, pellets and powder. The binding capacity of activated carbon is extremely large because of the extensive surface area within the internal structure of the pores, which can grow into a size of 2000 square meters or more per gram of activated carbon. The choice of using activated carbon depends on the application and requirements within the industry (EuroWater, 2022).

ACWF uses an activated carbon media bed to remove chlorine, foul taste, odour and colour. ACWF systems can be used as a pre-treatment to RO systems, since RO membranes are vulnerable to the presence of chlorine in the feed water.

There are two common types of activated carbon, namely coal-based or coconut shell-based. The coal-based is best suited for treating surface water with high levels of TOC and for wastewater treatment. The coconut shell-based type is best suited for removal of trace-levels of organic substances.

ACWF may not remove all microorganisms/pathogens present in the water to be filtered. As a result, further treatment and purification may be needed depending on reuse water applications.

Some of the benefits of ACWF noted by Pacific Water Technology (2019) include rapid start-up and shut down as well as that systems can be designed to be portable and taken to the reusable water source.



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## TECHNOLOGY 6. PURIFICATION USING AEROBIC DIGESTER TECHNOLOGIES

Many aerobic or anaerobic digester technologies are available for bulk purification of waste waters, but with the understanding that the level of purification and removal of contaminants and microorganisms of concern is typically not very high. Also, few actual data exist on the impact of these technologies on the microorganisms that are relevant for water reuse in dairy operations.

Publications by Hansen and Cheong (2019) and Joshiba *et al.* (2019) provide a good overview of the key digester technologies and others and their advantages and disadvantages. Some technologies are discussed in more detail while for others, only sparse information, if any, are available concerning their impact on microorganisms.

### Anaerobic filter

Anaerobic filters are widely used in the treatment of biodegradable industrial wastewater. The following information has been summarized from Sustainable Sanitation and Water Management (2020):

- An anaerobic filter is a fixed-bed biological reactor with one filter chamber of multiple filtration chambers set up in series.
- Treatment is based on the combination of a physical (settling/sedimentation) and a biological treatment. The system is composed of several layers of submerged media, which provide surface area for settling the bacteria that contribute to waste degradation and biogas production.
- As wastewater flows through the filter, particles are trapped, and organic matter is degraded by the active biomass that is attached to the surface of the filter material.
- Some benefits of AF systems include:
  - > No electrical energy required for operation
  - > Low operating costs and long service life
  - > High reduction of BOD and solids
  - > Low sludge production
  - > Moderate space area requirement
  - > Biogas production
- Some drawbacks include:
  - > Low reduction of pathogens and nutrients
  - > Effluent and sludge generated require further treatment and/or appropriate discharge

- > Risk of clogging, depending on the types of pre- and primary treatment
- > Removing and cleaning the clogged filter media is cumbersome
- > Lengthy start-up time

Demirel *et al.* (2005) provides a review on the use of anaerobic filters in the treatment of dairy wastewaters and found that, generally, AF filter reactors were suitable for the treatment of dairy effluents that contained low concentrations of suspended solids.

Several low-cost technology solutions can be found in Tilley *et al.*, 2014.

### **Upflow Anaerobic Sludge Blanket (UASB) reactors**

Upflow anaerobic sludge blanket (UASB) is a form of anaerobic, methane-producing, digester often used in the treatment of carbohydrate rich wastewater. The UASB reactor technology which allows for compact, cheaper designs, uses a three phase (Gas-Liquid-Solid or GLS) separator located above the sludge blanket to separate solids from the mixture allowing liquid and gas to be released from the UASB reactor (IWA Publishing, 2022).

In the UASB treatment process, the influent (wastewater) is pumped into the reactor from the bottom, where it first passes through an expanded sludge bed that contains a high concentration of biomass. The remaining portions then passes through a less dense biomass, named the sludge blanket and continues to move upwards until the effluent leaves the reactor (IWA Publishing, 2022).

UASB reactors have been successfully deployed for full scale treatment of dairy wastewater for almost two decades (Anonymous, 1992). However, their use was mainly for CO reduction and revalorisation of waste, rather than for water reuse and for reduction of microorganisms in the effluent. Similarly, other types of anaerobic digesters, such as anaerobic rotating biological contact reactor (Patel and Madamwar, 1997) and up-flow packed-bed reactors (Zeeman *et al.*, 1997) have been used for (pre-) treatment and purification of dairy waste waters, but not for generating reuse waters.

The impact on microbial ecology by four different pilot scale digesters (anaerobic contact, anaerobic filter, anaerobic expanded/fluidized bed reactor and UASB reactor) used to treat ice-cream wastewater, was comprehensively examined during start-up by Morgan *et al.*, 1992.

While UASB reactors take a long lead time to start up and require a suitable ambient temperature range to drive the anaerobic process (15 °C to 35 °C), some of the following advantages of UASB reactors have been noted (IWA Publishing, 2022): the energy requirement for the treatment process is low, less biosolids are generated compared to aerobic systems, and biogas production adds value as an energy source

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## TECHNOLOGY 7. PURIFICATION BY MEMBRANE BIOREACTOR (MBR) TECHNOLOGY

Membrane bioreactor (MBR) technology is an activated sludge treatment system, but the treated wastewater is separated from the activated sludge by membrane filtration instead of by sedimentation as done in a conventional activated sludge plant.

The biological processes use microorganisms suspended in the water phase and follows the same activated sludge principle used in a conventional treatment plant. Separation of dissolved from suspended components is done via membrane filtration and ceramic membranes are typically used. In this process, the wastewater is pumped through a mechanical sieve (filter), which serves as pre-treatment, to remove larger particles (> 1.0–1.5 mm) prior to biological treatment. The waste liquid is then pumped to a biological fermentation tank where it is mixed with an aqueous slurry of bacteria, similar to those used in ordinary biological treatment plants and contains among others, ammonium-reducing bacteria.

Alum (aluminium sulphate) or aluminium chloride may be added to chemically precipitate phosphorus. A pre-denitrification process takes place in the anaerobic step followed by aerobic nitrification, where biological nitrogen is completely removed. The supernatant from the activated sludge tank is further fermented under aerobic conditions and free nitrogen, N<sub>2</sub>O (nitrous oxide) and CH<sub>4</sub> (methane) are discharged.

Excess sludge, including precipitated phosphorus (retentate from the membrane filtration) is returned to the active sludge tank or disposed of for biogas production.

The MBR permeate may be further purified by RO filtration to remove dissolved salts, so that high quality MBR treated water is obtained. Approximately 75 percent of the MBR permeate that are further filtered by RO yields water of drinking water quality (Jørgensen *et al.*, 2010).

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## Microbiocidal treatments

### TECHNOLOGY 8. UV TREATMENT

The use of UV treatment is relatively new to the dairy industry (Koca *et al.*, 2018) other than for treating fresh water. UV lamps are either monochromatic (single wavelength – usually 254 nm) or polychromatic (multiple wavelengths) but UV systems can be equipped with various UV lamps that cover a wider range. Shortwave UV-C has the best germicidal effect against bacteria, moulds, yeasts, and protozoa. With the popularity of low-pressure mercury lamps, 254 nm has been considered to be the ideal wavelength, although the maximum bactericidal effect is between 260 and 270 nm depending on the pathogen.

Inactivation of cells occurs through several mechanisms, including the formation of binary bonds in DNA that inhibit further DNA replication. Microorganisms respond differently to specific UV wavelengths, and some can repair UV damaged DNA.

Inactivation follows a log-linear relationship, of which the slope is specific to the microbial species. Due to clumping or to cells being protected by organic material, the inactivation curve may show a shoulder and a tail (Quintero-Ramos *et al.*, 2004), but it typically is linear at medium doses (Koutchma, 2009)

As a result of exposure to UV radiation from sunlight, many organisms have developed mechanisms to overcome the harmful effects of UV radiation. These organisms may repair UV-induced DNA damage, such as by photo-reactivation where the enzyme photolyase can reverse UV-induced DNA damage. While high levels of photo-reactivation are observed with low-pressure irradiation, medium-pressure irradiation at the same dosage has limited or no photo-reactivation (Zimmer and Slawson, 2002). UV dosages above 40 mJ/cm<sup>2</sup> are assumed to be high enough to virtually prevent reactivation (McElmurry and Khalaf, 2016). WHO recommends a minimum dosage of 40 mWs/cm<sup>2</sup> (see footnote)<sup>5</sup> (WHO, 2004)

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<sup>5</sup> 40 mWs/cm<sup>2</sup> equals 40 mJ/cm<sup>2</sup> or 400 W/m<sup>2</sup>.

and a minimum removal efficiency for viruses, bacteria and protozoa of 4 log (WHO, 2022). The FDA's Pasteurized Milk Ordinance (US-FDA, 2019) specifies that pasteurization-equivalent UV treatment must be able to reduce adenovirus by 4 log.

**Table A2** shows relationships between minimum UV dose and inactivation effect. For a range of microorganisms, the values in the table indicate the UV dosage (mJ/cm<sup>2</sup>) required to achieve a specified log reduction (between 1 and 6 log cfu/g). The green boxes show the dosage (mJ/cm<sup>2</sup>) required to achieve at least a 4 log cfu/g inactivation for specific microorganisms. Notably, UV dosages of 78–81 mJ/cm<sup>2</sup> were unable to reduce *B. subtilis* spore levels by 4 logs.

### Process control of UV plants

The UV treatment must be able to deliver the specified design UV dose, which is to be set considering variations and the likelihood of malfunctions.

The ability to continuously monitor operating parameters is important in the operation of a UV plant to ensure that disinfection is adequate. The continuous monitoring of process parameters and correct calibration of in-line monitoring equipment is essential to maintain the effect of the treatment.

Critical factors that can affect the ability of a UV system to reliably deliver the required dose at any given time are:

- Water permeability to UV light, i.e. the level of turbidity
- Performance of the UV lamp, including its age, and wear of protective sleeves that may prevent light from reaching some pathogens
- The flow and flow rate in the disinfection chamber. The flow should be turbulent. Flow that is too high or too low can cause uneven dose distribution and leave some areas without adequate disinfection (US-FDA, 2019)
- Geometric configuration of the disinfection chamber. Longer exposure time provides more options for UV photon/microbe interaction and inactivation.



**TABLE A2** Summary of studies reporting minimum UV dose (mJ/cm<sup>2</sup>) required to achieve certain log reductions in the level of different microorganisms

MICROORGANISM	UV DOSE (mJ/cm <sup>2</sup> ) REQUIRED FOR A PARTICULAR LOG REDUCTION (cfu/g)						REFERENCE
	1	2	3	4	5	6	
<i>Aeromonas hydrophila</i>	1.1 <sup>a</sup>	2.6	3.9	5	6.7		Chevrefils & Caron,1999
<i>Bacillus cereus</i> (vegetative)	6	7	9	12			Malayeri <i>et al.</i> , 2019
<i>Bacillus subtilis</i> (spores)	36	48.6	61	78			Chang <i>et al.</i> ,1985
	20	39	60	81			Sommer <i>et al.</i> , 1999
	24	35	47	79			
<i>Campylobacter jejuni</i>	1.6	3.4	4	4.6	5.9		Chevrefils & Caron,1999
	1.0	2.1	3.4	4.6	5.8		Malayeri <i>et al.</i> , 2019
<i>Escherichia coli</i>	3	4.8	6.7	8.4	10.5		Chang <i>et al.</i> ,1985
	3.5-7	4.7-6.5	5.5-9	7.7-11	7.7-12	9.6-15	Chevrefils & Caron, 1999
	1.5	2.8	4.1	5.6			IDF, 2005
STEC O157:H7	0.4-2.5	0.7-4.7	1-5.5	1.1-7	1.3-6		Chevrefils & Caron,1999
<i>Enterococcus faecalis</i>	0.9-7.1	1.6-10	2.4-17	3-13	3.4-13	6-15	Malayeri <i>et al.</i> , 2019
<i>Legionella</i> spp.	1.6-3.1	3.2-5	4.8-6.9	6.4-9.4			Chevrefils & Caron, 1999
				12.4	16.8	40	McKinney <i>et al.</i> , 2009
	2.2	3.0	3.2	4.1	4.6		Malayeri <i>et al.</i> , 2019
<i>Salmonella</i> spp.	<2	2	3.5	7	14	29	Chevrefils & Caron, 1999
<i>Penicillium expansum</i>	11	38	49	65			Malayeri <i>et al.</i> , 2019
Hepatitis virus	4.1-5.5	8.2-13.7	12.3-22	16.4-29			IDF, 2005
Rotavirus	7.1-9.1	14.8-19	23-25	36			IDF, 2005
	8-20	15-80	27-140	36-200			Chevrefils & Caron, 1999

<sup>a</sup> minimum UV dose (mJ/cm<sup>2</sup>) required for the particular log-reduction of that bacteria

Source: Adapted with permission from Malayeri, A.H., Mohseni, M., Cairns, B. & Bolton, J.R. 2019. Fluence (UV dose) required to achieve incremental log inactivation of bacteria, protozoa, viruses and algae.

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## TECHNOLOGY 9. HEAT TREATMENT

Heat sterilization can potentially eliminate all microbiological hazards, including heat tolerant and heat-resistant forms (e.g. spores). In the context of water reuse, pasteurization may be a sufficient solution to achieve the microbiological quality of reuse water supplies that is fit for purpose.

During pasteurization, water is heated to a specified temperature and held for a suitable time to inactivate microorganisms present. The effectiveness of the heat treatment process is controlled by the holding time and the temperature. Different bacteria can show variations in heat resistance, which also depends on the medium that was used in the many heating studies that are available in the literature (e.g. Spinks *et al.*, 2006; Firstenberg-Eden *et al.*, 1977; Pearce *et al.*, 2012; and Bozkurt *et al.*, 2014)

The following are among the critical focus points for controlling the heat treatment process:

- The heat treatment temperature should be measured continuously in the holding tube and recorded automatically by a calibrated thermometer or similar automated temperature recorders.
- 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. The flow diversion valve should be checked daily to ensure it is functioning properly.
- Proper holding time is a critical component in a continuous treatment process. Holding time is determined according to the length of the holding cell/tube and the maximum or pre-set flow rate (max L/s) of the booster pump, which should be set so that the desired holding time is obtained.
- Continuous monitoring for overpressure on the heat-treated side by automatically recording the pressure and note for pressure differences or by frequent reading and recording of the pressure differences.

Pasteurization may be used as part of a multibarrier approach to inactivate any microbial hazards and microorganisms that cause spoilage and limit shelf-life. These organisms may have passed through the RO membrane or have cross-contaminated the water from another source after the RO step or during storage.

Validation under operational conditions should ensure that the relevant microbiological hazards identified in the water reuse scenario are effectively eliminated or reduced to the specified levels by the heat treatment alone or when combined with other treatments.

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## TECHNOLOGY 10. CHEMICAL TREATMENT

The three chemicals most commonly used for microbiocidal treatment of water sources are chlorine, chlorine dioxide and ozone.

### Chlorine

Chlorine is the most widely used primary disinfectant in the production of drinking water and could be used for microbiocidal treatment of reuse water as well. Chlorine is a generic term for the active chemical hypochlorous acid (HClO), which acts as a disinfectant (IR-EPA, 2011). Note that when chlorine gas and hypochlorite salts are added to water, HClO and hypochlorite ions ( $\text{ClO}^-$ ) are formed that are accounted for in the term “free available chlorin”.

The three most common chlorine-containing substances used in water treatment are chlorine gas, sodium hypochlorite, and calcium hypochlorite. The choice of the chlorine type to be used often depends on cost, available storage options and on the pH conditions required (Pure Water Annie, 2013).

Generally, chlorine disinfection is a reliable and effective approach against a wide spectrum of pathogenic microorganisms, but possible chemical risks associated with chlorine disinfection need to be properly weighed when designing treatment.

If ammonia remains in the permeate and is exposed to chlorine, in any form, they can react to form chloramines. Although depending on the chlorine to nitrogen ratio and the operating parameters such as pH, temperature, and contact time, the dominant forms of chloramines resulting are monochloramine and dichloramine, with trichloramine being the less common form. These are significantly less effective at inactivating pathogens, especially viruses, and also react slower as compared to free chlorine (EPA, 2017)

The effectiveness of chlorination as a disinfectant depends on the pH and the consequent dominance of HClO formation over  $\text{ClO}^-$ , following the addition of sodium hypochlorite to water. As this HClO dominance decreases rapidly between pH 7 and 8, so does its effectiveness (IR-EPA, 2011).

Practical examples of chlorine dosages used in dairy processing plants are:

- Total chlorine: 0.4 – 2.0 ppm.
- Active chlorine: 0.1 – 1.0 ppm.
- Sodium hypochlorite (NaOCl): 2 ppm.
- Free residual chlorine = 0.2 – 0.4 ppm; < 1.0 mg/kg.
- Residual chlorine concentration of 0.4 ppm.

Chlorine is reduced by UV exposure and even though the extent of chlorine reduction is small (e.g. 0.1 to 0.2 mg/l at an UV dose of 40 mJ/cm<sup>2</sup>) as determined in bench-scale testing (IR-EPA, 2011), it is best to use a chlorine exposure/treatment after UV treatment, so that chlorination is unlikely to interact significantly with other treatment processes. Notably, chlorine also reacts with chlorine dioxide to produce chlorate, but it is unlikely that these oxidants would be used in such a way at a dairy processing plant for this interaction to occur (IR-EPA, 2011).

### Other disinfectants

- **Chlorine dioxide (ClO<sub>2</sub>).** Has a high oxidation potential and therefore is an excellent germicide. It is similarly effective as combined chlorine at inactivating bacteria, and as effective as free chlorine at inactivating viruses. Chlorine dioxide is inherently unstable and readily decomposes so it is typically generated onsite. Chlorine dioxide breaks down to form toxic disinfection by-products such as chlorite (ClO<sub>2</sub><sup>-</sup>) and chlorate (ClO<sub>3</sub><sup>-</sup>). The required dose for disinfection varies depending on the pH and the target microorganisms and are best managed by controlling the dose of chlorine dioxide applied to the water. Chlorine dioxide is generated on demand, usually by the reaction between sodium chlorite and hydrochloric acid (EPA, 2017; IR-EPA, 2011).
- **Ozone.** Ozone is a powerful oxidant, capable of breaking down organic compounds including taste and odour compounds and trace chemical constituents. Ozone is a potent chemical disinfectant with a redox potential of 2.08 V at 25 °C and is very effective at pathogen inactivation and even stronger than both chlorine (0.8 to 1.5 V) and monochloramine (0.7 to 0.8 V) at 25 °C (EPA, 2017). Used as a primary disinfectant, ozone levels cannot be monitored in drinking-water because it leaves no residues. Instead, the operator should control the conditions of ozonation. Ozone is a very powerful disinfectant compared to either chlorine or chlorine dioxide (IR-EPA, 2011), although it is relatively expensive to use.
- **Monochloramine.** The disinfection capability of monochloramine is poor compared to chlorine, so it is generally used to provide a disinfectant residue or preservative, during distribution, rather than being used for primary disinfection. The key advantages of monochloramine is that it does not form trihalomethanes (THMs), or other chlorination by-products when used in the presence of organic matter. Also, the sensory tolerance threshold is typically much greater than for chlorine alone (IR-EPA, 2011).
- **Hydrogen peroxide (H<sub>2</sub>O<sub>2</sub>).** The use of hydrogen peroxide in the treatment of potable water has been very limited. This is in part due to its instability in storage and the difficulty in preparing concentrated solutions. It is a strong oxidizing agent but a poor disinfectant that achieves little or questionable inactivation of bacteria and viruses (IR-EPA, 2011).

- **Peracetic acid (PAA).** The disinfection efficacy of PAA increases at pH values <7. PAA requires very low doses and short contact times to inactivate bacteria. Additionally, there is a significant body of information to suggest that PAA is effective against viruses and protozoa. PAA disinfection is not known to form harmful by-products (EPA, 2017).



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# Case studies on reusable water sources

In this chapter, several case studies are presented to illustrate fit-for-purpose applications of reuse water and the different technologies, often used in a multi-barrier approach, for the recovery, purification and (microbiocidal) treatment of reuse water.

As part of a designing and implementing robust management of an operational water reuse scenario (Chapters 4 and 5) it is recommended to do a microbiological risk assessment to identify and analyse the potential hazards in order to develop a hazard control plan and for selecting the stringency of control needed for a particular reuse water generation system (including performance efficiencies of purification, and treatment technologies to remove/reduce microbiological hazards). The decision on control stringency must consider the magnitude of health impact (acute consequences and chronic sequelae) that a hazard presents in the reusable water source may cause at the point of exposure/consumption. The magnitude of health impact (i.e. the consumer risk) considers the severity of the hazard and the likely level that it is present at the point of consumer exposure.

Given the risk level of a hazard when not controlled, the likelihood of its occurrence and its level in the reusable water source determine the controls needed for the reuse water generation system such that the hazard no longer pose an unacceptable risk. To achieve this, recovery, purification and/or treatment measures selected and implemented have to adequately control the hazard in the fit-for-purpose water reuse scenario considered.

The hazard analysis/risk assessment performed in assessing water reuse scenarios should provide the necessary insight into the occurrence/level of hazards and the required controls for the reuse water generation system to consistently produce fit-for-purpose reuse water. This insight includes the likely origin of the hazards, impacts of various technologies on the hazards, changes in hazard levels once the reuse water has been applied, and variability and uncertainty in all these aspects.

A risk/hazard matrix can be used to illustrate some of the aspects identified through a hazard analysis/microbiological risk assessment in **Table A3**:

**TABLE A3** Risk/hazard matrix for a microbiological hazard identified in the reusable water source

LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always
RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe		○			
	Moderate					
	Minor			✘		

Source: Authors' own elaboration.

Note that the categories chosen to reflect consumer risk (severe, moderate, minor) and the likelihood of occurrence (from unlikely to always present) are those used in the case studies described below, but other factors may also be considered.

Using symbols, key hazard analysis outcomes such as the potential consumer risk posed by a hazard (or group of microorganisms) identified in the reusable water source, its origin may be summarized:

○ = transfer of the hazard from previous steps

✘ = the hazard originates in this step

In the case study discussed in this chapter, every risk/hazard matrix is integrated into a larger matrix in order to put it into context with the risk of a hazard, its relevance in the water reuse scenario, and the stringency of control measures. The matrices used in the case studies described below show the hazardous event/step considered, the particular hazards (or group of microorganisms) of concern, and the control or countermeasures required, and all these will need to be built into the WSP or FSMS used to manage the reuse water generation system.

## CASE STUDY 1: USE OF CONTAMINATED WATER FROM FBO'S OWN WELLS

If the FBO has their own wells, the water may or may not be potable. This will need to be determined through a risk assessment. If the well water has come in contact with surface water, it will most likely have microbial contamination but can still be used as technical water for any purposes where food contact (including accidental contact) is unlikely to occur. Examples include use of water for fire control, boiler feed, water for central heating, for the production of steam that will not directly

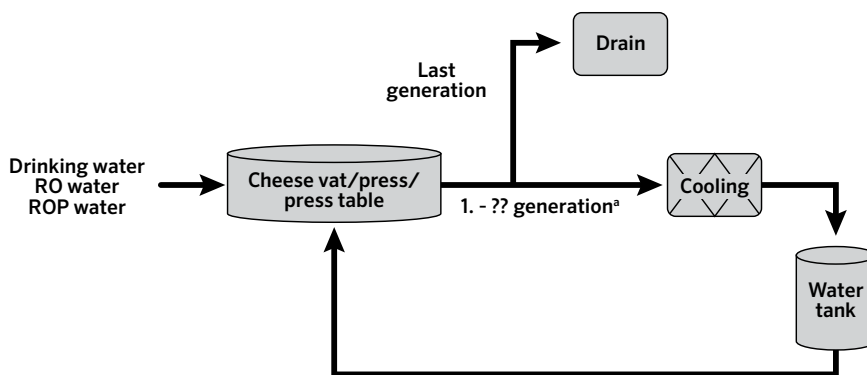
come in contact with food, or water for misting exhaust air from spray towers to reduce particle emission. Water for such technical water purposes should have a separate distributions and storage system, with closed pipes and tank equipment that does not connect with or allow reflux into water supplies intended for food contact applications.

Well water can be used for indirect cooling of products, e.g. in heat exchangers, cooling towers, condensers, evaporators, drying towers, etc. and for other applications provided that these do not pose consumer risks via contact with food/food surfaces. Contaminated well water impacts consumer health and may cause cross-contamination. Water from wells, therefore, should be mitigated by appropriate purification and reconditioning before use.

Potential hygiene indicators for contaminated well water are generic *E. coli* or coliforms, which may signal potential faecal contamination. *C. perfringens* is often used for monitoring microbial removal in wastewater treatments and can be used as an indicator for signalling sewage contamination.

## CASE STUDY 2: RECIRCULATION OF WATER USED FOR COOLING OF CHEESE

**FIGURE A2** Scheme that shows the recirculation of water used for cooling cheeses



<sup>a</sup> In this scenario, multiple recirculations/recycles may apply. So, if recirculate the first-use water for a new reuse, it will be the 2nd, generation, 3rd generation, etc., and when the number of recirculations has reached its maximum (based on microbial testing) then the water is to be discarded as waste (last generation).

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.

This case study describes the recirculation of water used for the cooling of cheeses (see **Figure A2**). Sources of first-use and reusable water used for cooling cheese include:

- Drinking water.
- Water of RO or ROP quality, derived from milk water.
- Recirculated and/or recycled potable water used for the same purpose.

### **Assessment of hazards, risks and control options**

The occurrence of microbiological hazards and other microorganisms of concern associated with the recirculation of cooling water during cheese-making is typically due to the carry-over of undesired microorganisms from previous cheese vats and from the build-up of biofilms in the water systems. Cross-contamination from the environment or other sources during the cheese cooling step is unlikely as the water used for cooling cheese is recirculated in a closed system. Material transferred via cooling water to new cheeses consists exclusively of cheese materials, which contain the same microbiological and chemical components as the cheese. Pathogenic bacteria or other microbiological hazards do not usually pose problems given their very low numbers, if present at all.

The microflora in the recirculated cheese cooling water is dominated by starter cultures used to make the cheese. However, microbial hazards and microorganisms of concern can eventually establish, specifically via formed biofilms, if the water has been recirculated too many times without microbiocidal heat treatment and/or the recirculated water was stored too warm in between recirculation times (generations). To avoid or at least minimize microorganisms from establishing themselves, water intended for recirculation should be kept refrigerated at the specified temperature necessary to cool the cheeses and after use, the water should be re-cooled before the subsequent use. Pasteurization/UV treatment could be other options for microbial control (recycled water).

The integrity of the recirculated or recycled water can be controlled by the number of generations and the storage temperature and monitored by sensory assessment of the surfaces of the cooled cheeses. For instance, practical evidence may be the presence of slime formed on the cheese surfaces by mucus forming bacteria.

Verification steps can consist of microbiological tests and sensory assessments of the surfaces of the cheeses being cooled. For example, the greasiness of cheese surfaces may be affected by the extent of transfer of cheese materials, starter cultures and other microorganisms that may have contaminated cheeses, pipes and tanks. Alternatively, the cooling water can be sanitized by microbiocidal heat treatment in between each use. **Table A4** summarizes the possible types of hazards and organisms of concern, with an indication of the levels of risk potentially associated with the hazards and the possible control options.

Testing for hygiene indicators can be used as verification of hygienic conditions or processing effectiveness. The indicator(s) selected should be specific to that

water reuse scenario, bearing in mind the possibility of testing interferences by flora, such as starter-cultures. Coliforms are best used in every case as an indicator for the presence of “foreign” bacteria (e.g. those cross-contaminating from faecal material) that may have intruded into the system.

**TABLE A4** The possible types of hazards and organisms of concern, with an indication of the likely associated levels of risk and possible control options

EVENT	HAZARD	RISK/HAZARD MATRIX						CONTROL OPTIONS	
Carry-over (cross-contamination) of undesired microorganisms from previous cheese vats	Pathogenic bacteria	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	Limit the number of times (generations) that water can be recycled
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
			Minor			×			
Cross-contamination from cheese material to water and spread of hazard	<i>L. monocytogenes</i>	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	Pasteurization or UV treatment before reuse
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe		×				
			Moderate						
			Minor						
Build up of biofilms in the water systems (e.g. equipment, pipes, storage tanks)	Pathogenic bacteria	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	Apply time-restricted storage and/or use cooling
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate		×				
			Minor						

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.

## Hazard control plan

A hazard control plan couples the hazards and their respective control measures in the water reuse scenario as a whole or is tailored to a specific processing step. The table below provides an overview of the hazard control plan for using

recirculated water for cooling of cheeses. Values shown in the hazard control plan and the verification plan (marked by # symbol) refers to the numbers of microorganisms (e.g. indicator organism for hygiene or process control) pre-determined in the validation process (Table A5).

**TABLE A5** Specific details of a hazard control plan for using recirculated water to cool cheeses

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE			
			Parameter	Recommended frequency	Recommended limit for taking corrective action	Corrective action(s) & type of correction
Water tank	Microbial growth	Cold storage	Temperature	On-going	Temp. > 7 °C	Adjust temperature to cool water
	Contamination from biofilms	Operational time between cleaning events	Number of recirculation cycles	On-going	Specified max level (e.g. × cfu/ Y ml) <sup>#</sup>	Empty and rinse the water tank and pipes before cleaning.

<sup>#</sup> the level of microorganisms pre-defined by validation. It can be a maximum value for one of more specified volumes of water tested or it can be a three-class sampling plan with the statistical parameters *n*, *c*, *m* and *M* pre-defined (ICMSF. 2018. Microorganisms in Foods 7. Microbiological Testing in Food Safety Management. Second Edition. Springer, Cham, Switzerland. FAO & WHO. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG_021e.pdf)). The values for the level and parameters must be specified in the plan that has been operationalized.

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.

## Validation<sup>6</sup>

The recirculation system should be validated during full scale start-up to demonstrate that the setup will provide the intended water quality. Validation will also help determine the required cleaning frequency and the verification parameters. The following validation procedure is recommended, but alternatives that can achieve the same goals can also be used:

- Test run 1. After each recirculation cycle, samples are taken from the site of use for analysis for the following indicator groups/types: coliforms, *Enterobacteriaceae*, psychotropic count, *Pseudomonas* and any plant-specific hygiene indicator(s) identified for that water reuse scenario. The water from each recirculation (generation) should comply with the microbiological limits pre-defined for the various indicator organisms. When the test result for any indicator exceeds the limit, the recirculation cycle before the non-compliant cycle is to be provisionally considered as the last and thus, is set as the basis for cleaning frequency.

<sup>6</sup> Some elements of “Validation” may be done at laboratory or pilot plant scale, but operational validation ultimately has to be performed at full scale.

- Test run 2. The testing described in run 1 is repeated. If this second set of tests results is the same or if more cycles have elapsed before the limits have been exceeded, that particular cycle number of test run 1 can be set as the last, before emptying and cleaning the system. If in run 2, fewer recirculation cycles resulted in the limits being exceeded as compared to run 1, then the last compliant cycle from run 2 is selected as the last cycle before cleaning should be done.
- The indicator organisms in run 1/run 2 that determined the cleaning frequency are selected as parameters for verification during operation. The pre-defined limits used for validation may also be used for monitoring, unless there is a need/reason to select a more stringent limit for verification (also see Verification plan).
- In validation, five samples of 25 ml each are taken for microbiological analysis for the presence of *L. monocytogenes*, which is the most likely pathogen of concern for dairy operations. If the pathogen is detected, the affected water is disposed of, the relevant process control parameters are adjusted, and Steps 1 and 2 repeated. If *L. monocytogenes* is not detected and other relevant pathogens are under control, proceed to step 4.
- The validation of the full scale starting operation can be concluded. However, if specific microbiological hazards or other microorganisms of concern have been identified through hazard analysis/risk assessment of the water reuse scenario, the operational control will need to be validated at full scale before the validation can be concluded.

The system should be re-validated when significant changes have been introduced (e.g. changes in the hazard controls, replacement of drinking water with RO water or ROP water, significant changes in cheese-making technology, etc.). Otherwise, re-validate at least once a year.

## Verification plan

A verification plan provides an overview of microbiological parameters that are being monitored during operation for the purpose of confirming that the process is under control, and also for triggering corrective action should the controls fail, and the microbiological quality of the reuse water has been compromised.

The Verification plan in **Table A6** describes taking samples from storage tanks, but sampling from other points after use, before reuse or at a different place of use can be chosen as well.

The values in the table (marked by # symbol) under “typically acceptable results” need to be selected, confirmed and validated under the relevant operational conditions of the specific water reuse scenario being put into operation.



**TABLE A6** Specific details of a verification plan for using recirculated water to cool cheeses

PARAMETER	RATIONALE/ PURPOSE	METHOD	RECOMMENDED FREQUENCY	TYPICALLY ACCEPTABLE RESULT <sup>#</sup>	FOLLOW-UP
<b>Coliforms</b>	Biofilm	Presence/ absence test (ISO 9308-1:2000); sample taken from the place of use	Most recent 3 cycles before expected cleaning	e.g. Not detected in 100 ml, $n=1^{\#}$	If coliforms detected, test for <i>E. coli</i> . In case of regular detections, consideration should be given to dropping the last recirculation cycle or reduce the generation number otherwise as appropriate.
<b><i>E. coli</i></b>	Possibly pathogenic	Presence/ absence test (ISO 9308-1:2000); place of use sampled	upon detection of coliforms	e.g. Not detected in 100 ml, $n=1^{\#}$	If detected, the pipes and tank are emptied and cleaned.
<b>Use the operation- specific hygiene indicator chosen at validation as the parameter to verify cleaning frequency (e.g. <i>Enterobacteriaceae</i>, <i>Pseudomonas</i> spp., other type/ group of organisms potentially signalling control over hygiene, processing, etc)</b>	Verification of operational control of hygiene/ processing based on recirculation cycles	Enumeration, split sampling <sup>a</sup> Sample taken from the place of use	Weekly	Result meets specified values for $m$ or $M$ (cfu/100 ml for each of 5 samples <sup>#</sup> )	In the event of repeated violations, pipes and tanks are emptied and cleaned. In case of regular violations, consideration should be given to dropping the last recirculation cycle.
	Build up confidence in operational control	“Moving window” <sup>ab</sup> on weekly results	The recent 5 analysis results are compiled continuously	e.g. out of 5 (= $n$ ) consecutive results, a maximum of 2 (= $c$ ) may be between $m$ and $M^{\#}$	If the “ $c$ ” is exceeded (over the last 5 samples by more than 2 were over $m$ ), consideration should be given to investigating root-cause and increasing the frequency of emptying and cleaning.
	Build up confidence in operational control and timely warning of potential loss of control	Trend analysis	Frequency should be in line with the number and volume of batches of reuse water supply being generated with the aim to obtain a timely signal of control or potential loss of control	No patterns of high numbers close to maximum acceptable levels. No increase in frequency of batches failing the pre-defined verification criteria	Patterns (e.g. upward trending numbers; large variations in numbers; large upsurges in numbers) can give clue as to the level of control over the operation to advert targeted corrective action. When corrective action (e.g. emptying the system and thorough cleaning) is taken, verification is best intensified temporarily by increasing sampling frequency (e.g. sampling the first and the last batch in the process).

**TABLE A6** Specific details of a verification plan for using recirculated water to cool cheeses (cont.)

PARAMETER	RATIONALE/ PURPOSE	METHOD	RECOMMENDED FREQUENCY	TYPICALLY ACCEPTABLE RESULT <sup>a</sup>	FOLLOW-UP
<i>Listeria</i> spp.	Cross-contamination	Presence/absence test; Sample taken from the place of use	Frequency should be in line with the number and volume of batches of reuse water supply being generated with the aim to obtain a timely signal of control or potential loss of control	e.g. Not detected in 25 ml, $n=1^a$	If detected, serotype the isolate and if identified as <i>L. monocytogenes</i> , pipes and tanks are emptied and cleaned. If the water has been in contact with food products, test affected batches of products for <i>L. monocytogenes</i> . If detected, designate and handle the food product as potentially unsafe In case of regular findings, reduce the number of generation cycles and investigate root-cause of the contamination to resolve the issue.

<sup>a</sup> level of microorganisms pre-defined by appropriate validation under operational conditions for the specific water reuse scenario. It can be a maximum value for one of more specified volumes of water tested or it can be a sampling plan with the statistical parameters  $n$ ,  $c$ ,  $m$  and  $M$  pre-defined (ICMSF, 2018. Microorganisms in Foods 7. Microbiological Testing in Food Safety Management. Second Edition. Springer, Cham, Switzerland. FAO&WHO, 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?Ink=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252Fstandards%252FCXG%2B21-1997%252FCXG_021e.pdf)). The values for the levels and parameters must be specified in the plan that is being operationalized.

<sup>a</sup> Split sampling refers to taking the required number of samples ( $n$ ) over a certain period of time.

<sup>b</sup> The use of moving windows to verify compliance with microbiological criteria is described in the Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (FAO and WHO, 2013a). It appears from this that moving windows are used for continuous verification of the entire system and not for the approval of specific lots. The follow-up of results included in moving windows is thus targeted at the system and not the specific batches from which the sample was taken. If there is a need to assess a specific batch, sampling is performed without the sample split.

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.

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- Heggum, C.** 2020. *Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants*. Available upon request from CHG@lf.dk.

## CASE STUDY 3: REUSE OF WATER FROM CIP SYSTEMS

### Sources of first-use and reuse of water

This case study describes the reuse water scenario depicted in **Figure A3**, which illustrates the reuse of CIP water that has been used in the five-step cleaning process. The various sources of water used in the preparation of CIP fluids are (first-use) drinking water or one of the following reusable water sources, provided they meet the necessary microbiological quality requirements for a for-food-contact-purpose:

- First-use drinking water used for the same purpose.
- Water of potable quality, recovered as such or generated through appropriate reconditioning.
- Water of RO or ROP quality.
- Used CIP liquids that can be recycled/reused.

### Purification of CIP liquids to obtain water of RO quality

Adequate RO purification is monitored by pH and verified by analytical content of relevant salts. The RO filtration must be able to remove sodium hydroxide from lye, and salts from used acids (e.g.  $\text{NO}_3^-$  from nitric acid,  $\text{PO}_4^{3-}$ ,  $\text{HPO}_4^{2-}$ ,  $\text{H}_2\text{PO}_4^-$  from phosphoric acid,  $\text{Cl}^-$  from hydrochloric acid,  $\text{SO}_4^{2-}$  from sulfuric acid,  $\text{CO}_3^{2-}$  from carbon dioxide, and  $\text{COOH}^{3-}$  from peracetic acid) including possible carriers mixed in with these chemicals.

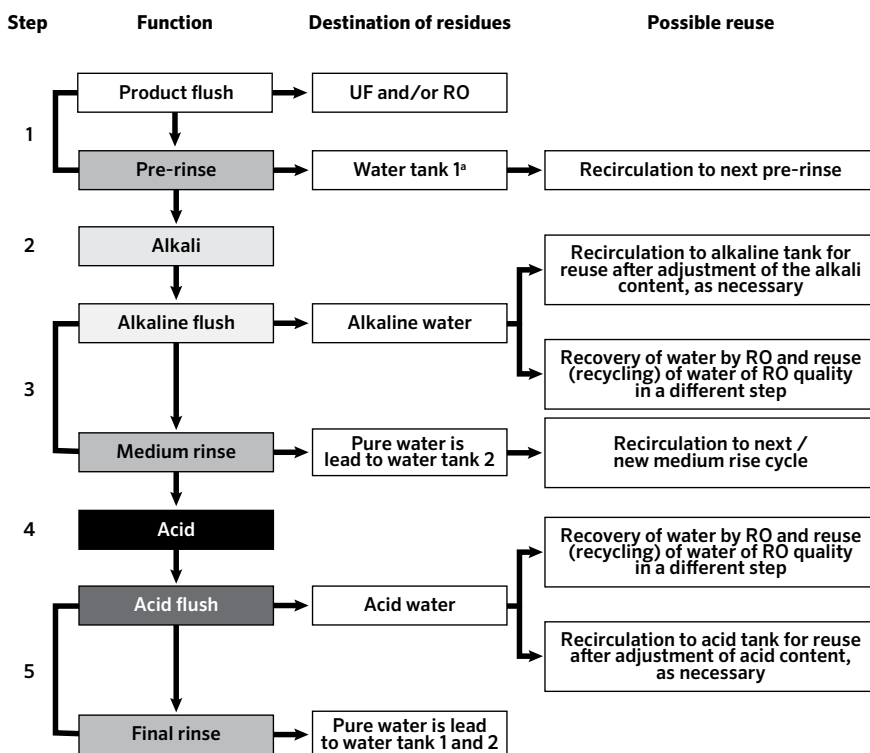
Since RO membranes can be damaged by free chlorines, the latter can be removed using activated carbon. Water softener can be added to remove calcium and magnesium before the water is fed to the RO system, so that membrane scaling (clogging of the membrane pores) is minimized. A minority of cellulose acetate membranes are sensitive to hydrolytic activity in feed water with pH >6 and so, may require pH adjustment. The addition of anti-scaling agents may also be necessary to prevent calcium carbonate scaling. Both antifouling and anti-scaling compounds are often added to feed water to prevent decreases in RO performance e (Pérez-González *et al.*, 2012).

### Assessment of hazards, risks and control options

Supplies of RO water recovered from CIP liquids do not usually contain micro-organisms at significant levels, but if they are stored, biofilm formation and accumulation in the equipment may occur and consequently, control measures will be required.

The occurrence of microbiological hazards in the reusable water sources discussed in the current water reuse scenario, which involves recirculated and recycling of water supplies, are typically due to the events noted in **Table A7** and relate to hazards that will need require operational control.

**FIGURE A3** Sketch for reuse of water streams in a five-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



<sup>a</sup> 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.

**TABLE A7** Possible hazards of concern, likely associated risks and possible control options for reuse of supplies of RO water recovered from CIP liquids that are recirculated or recycled

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	
Carry-over via product residues from step 1 into CIP liquid	Pathogenic bacteria	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					Monitor pH or conductivity to signal when increase fluid consumption is needed to maintain a fixed CIP fluid concentration. This also indicates that product residues may have accumulated and thus, increased the chance of hazards carry-over. Treat the liquid when necessary or discard.
			Moderate		○			
			Minor					
Carry-over via product residues from step 1	Foot-and-mouth disease virus	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					Heat-treat both the rinse water used to push product residues through the pasteurizer (product flush water) and water destined for the pre-rinse of water tank to prevent the spread of FMDV.
			Moderate					
			Minor	○ <sup>b</sup>				
Carry-over at step 1 via biofilm from processing equipment into CIP liquid	Pathogenic bacteria	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					Bacteria may come into the CIP liquids with the products being flushed but are eliminated by the high or low pH rinses. Treat the liquid when necessary or discard
			Moderate					
			Minor			○		
Building of biofilms in water systems (i.e. acid flush, alkali flush)	Pathogenic bacteria	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					Limit storage time via increasing frequency for emptying and cleaning.
			Moderate					
			Minor		×			

**TABLE A7** Possible hazards of concern, likely associated risks and possible control options for reuse of supplies of RO water recovered from CIP liquids that are recirculated or recycled (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS	
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always		
Carry-over of alkali from step 2	Alkali residues							The separation can be monitored by conductivity (e.g. meter) supplemented by test for neutrality (e.g. pH strips). Treat the liquid or discard when residues accumulate and thus, increased chance of hazards carry-over.	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
Moderate									
Minor						○			
Carry-over of acid from step 4	Acid residues								
Carry-over of disinfectants used (between steps 4 & 5)	Residues of disinfectants	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	Used disinfectant should not be reused but be discarded. When using chlorine-based disinfectants, rinse subsequently with potable water.	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						○ <sup>d</sup>
			Minor	○ <sup>c</sup>					
Recovery of water from CIP (steps 3 and 5)	Residues of product, alkali, or acid in RO water	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	The recovered water should be subjected to membrane filtration sufficient to remove product residues, sodium and salts, as appropriate	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
			Minor				○		
Microbial growth in RO water	Undesired micro-organisms	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	Control the storage shelf-life and/or temperature (e.g. apply refrigeration) of RO water supplies.	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate			✗			
			Minor						

<sup>a</sup> The above is illustrated using the following symbols:

○ = transfer of the hazard from previous steps.

✗ = the hazard originates in this step.

<sup>b</sup> In the event of an actual outbreak in animals, FMDV can cause major level of animal illness with serious economic consequences.

<sup>c</sup> Hydrogen peroxide and peracetic acid.

<sup>d</sup> Chlorine-based disinfectants.

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.

## Hazard Control Plan

Based on the hazard analysis, risk assessment, a plan for control of relevant hazards can be established, such as the one shown in **Table A8**.

**TABLE A8** Details of a hazard control plan for reuse of RO water recovered from CIP liquids that have been recirculated or recycled

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s) & correction
Outlet Steps 1 and 2	Product residues in alkaline CIP liquid	Liquid consumption for dilution of alkali	Liters of dilution water/day	Daily	To be determined locally for each plant	Adjustment of valve control for separation of product flush and water.
	Product residues in water (outlet)	Automatic valve control for separation of product flush and water	Conductivity, COD or turbidity	Ongoing	To be determined by the establishment.	Adjustment of valve control for separation of product flush and water.
Outlet Steps 3, 4 and 5	Acid residues in water (outlet)	Automatic valve control for separation of acid flush and water/ RO water	Conductivity or pH	Ongoing	To be determined by the establishment	Adjustment of valve control for separation of acid flush and water.
In case of disinfection: Outlet of final rinse	Disinfection residues in water outlets	Automatic valve control for separation of disinfection flush and water/RO water.	Conductivity	Ongoing	Present	Adjustment of valve control for separation of disinfection flush and water.
Water tanks for storing warm or cold water for final rinsing	Microbial growth	Cold or warm storage	Temperature	Ongoing	Cold: < 7 °C Warm: >60 °C	Emptying and rinsing the water tank before restarting.

<sup>a</sup> When reference is made to monitoring limits or frequencies being “determined locally” or “determined by the dairy establishment”, the selected values must appear in the Hazard Control Plan.

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.



## Validation<sup>7</sup>

### Recirculation within CIP

When reusable water is recovered from a step in the CIP process and recirculated for use in the same (or another) step within the CIP process, that water will not come into contact with food being processed at the dairy operation. Thus, there is no need to validate the water reuse at full scale as there are no food safety concerns. However, the efficacy of the individual CIP steps in being able to adequately clean the equipment may need to be validated.

### Recycling and reuse for other purposes

In the current case study (Figure A3) alkali and acid water could both be recovered and purified by RO for use in a different step other than CIP. The RO system should be validated during start-up to demonstrate that the system will provide water of the intended microbiological quality. Validation will also help to determine the required cleaning frequency and the best verification parameters.

The following validation procedure is recommended, but alternatives that can achieve the same goal can also be used:

- 1) During start-up and during the first 3 weeks of operation, observe the monitoring results for the control measures stated in the hazard control plan. If the monitoring data shows stability, proceed to Step 2.
- 2) Samples are taken to analyse the levels of the different salts that may be present in the RO feed water. If the limits detected exceed those applicable to drinking water, it will need to be assessed as to whether this constitutes a problem regarding the intended use of the water. If so, the water is drained and discarded, or it is reworked via the acid and/or alkali tanks. Otherwise, proceed to step 3.
- 3) Sampling is performed daily from the storage or use site for analysis for coliforms, the plant-specific hygiene indicators identified in the hazard analysis/risk assessment for that water reuse scenario, TPC at 22 °C, *Enterobacteriaceae*, psychotropic count and *Pseudomonas* spp. count. The indicator that first exceeds the pre-defined limit is selected as the verification parameter – see Verification Plan. If no limits are exceeded at the end of the 3<sup>rd</sup> week, the indicator that came closest to the limit is selected as the verification parameter. Proceed to Step 4.

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<sup>7</sup> Some elements of “Validation” may be done at laboratory or pilot plant scale, but operational validation ultimately has to be performed at full scale

- 4) The system is stopped and allowed to stand for 24 hours, then 5 samples are taken for microbiological analysis for *B. cereus*, given that its spores may survive pasteurization of milk, may pass through the RO filters and may establish biofilms, albeit rarely. If the results exceeded the specified limit, the relevant process control parameters are adjusted, and Steps 1–3 are repeated. If not, proceed to Step 5.
- 5) The validation of the start-up operation can be concluded, and routine operation can be started, provided that the results of the analyses in Step 3 showed that the quality requirements are being met.

The system should be re-validated no later than once a year or sooner when significant changes are introduced (e.g. changes in the plan for risk factor management, changes of feed material to the RO system, major maintenance, etc.).

## Verification Plan

**TABLE A9** Details of a verification plan for reuse of RO water supplies recovered from CIP liquids that have been recirculated or recycled

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Records of monitoring</b>	Check that data was recorded for the control measures.	Control of documen-tation	Determined by the dairy establish-ment.	Data was recorded	Inspect the measuring and recording equipment and ensure continuous operation. Defects are repaired; relevant parts replaced.
<b>Water quality – Physical/chemical parameters</b>					
<b>Turbidity</b> (where turbidity is not used as a control option in the hazard control plan)	Control build-up of product residues	Samples from water tanks intended for pre-flush; measure with turbidity meter.	Monthly	$\leq 3$ FTU <sup>a</sup>	If exceeded, the system is emptied and cleaned. Valve controls are checked and adjusted/replaced as needed.
<b>COD in RO water outlet</b> (Can be replaced by measuring conductivity, if that was not used as a control option in the hazard control plan)	Control membrane tightness and to signal leaks.	ISO15705	Monthly	<100 mg O <sub>2</sub> /L <sup>a</sup>	If exceeded, 3 samples are taken to confirm the result. If confirmed, a cause analysis is done, which includes inspecting membranes and gaskets for leaks, replacement of leaky parts and cleaning the systems. The effectiveness of the above steps is confirmed and documented by testing 3 new samples.

**TABLE A9** Details of a verification plan for reuse of RO water supplies recovered from CIP liquids that have been recirculated or recycled (cont.)

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Water quality – Microbiological parameters</b>					
<b>Total Plate Count (TPC) at 22 °C</b> in water used for final rinse	Control Biofilm formation	Removed from final flush to water tank 1. ISO6222	Monthly	<200 cfu/ml <sup>a</sup>	If exceeded, 3 samples are taken to confirm the result. If confirmed, the CIP program is re-evaluated to determine whether the system should be emptied and cleaned. The effectiveness of the above steps is confirmed and documented by testing 3 new samples.
<b>Coliforms</b> in RO water	Identify microbiological contamination	Presence/absence test ISO9308-1 or ISO2255	Once per week	Not detected in 100 ml, n=1#	Upon detection, a sample is taken from the same batch for <i>E. coli</i> analysis.
<b><i>E. coli</i></b>	Possibly pathogenic	Presence/absence test (ISO 9308-1); sample at site of use	Upon detection of coliforms	Not detected in 100 ml, n=1#	If detected, the pipes and tank are emptied and cleaned.
<b>Use the plant-specific hygiene indicator selected for validation as the parameter to verify cleaning frequency (e.g. <i>Enterobacteriaceae</i>, <i>Pseudomonas</i> spp., other type/group of organisms, to signal control over hygiene, processing, etc)</b>	Verification of operational control of hygiene/processing based on recirculation cycles	Enumeration; split sampling <sup>b</sup>	Once per week	Test result meets specified values for <i>m</i> or <i>M</i> (cfu/100 ml; n=1) <sup>a</sup>	If the preselected value for <i>M</i> is exceeded, 3 samples are taken to confirm the result. If confirmed, a cause analysis is done, and the effect of the RO system (e.g. increased flux) is reassessed. The effectiveness of the above steps is confirmed and documented by testing 3 new samples. In cases of repeated exceedances of <i>M</i> (over the last 5 tests), consider reducing the shelf life.
	Build confidence in the operational control	“Moving window” <sup>c</sup> on weekly results	The most recent 5 analysis results are compiled continuously	E.g. out of 5 (= <i>n</i> ) consecutive results, a maximum of 2 (= <i>c</i> ) may be between <i>m</i> and <i>M</i> <sup>a</sup>	If the “ <i>c</i> ” is exceeded (i.e. when over the last 5 samples more than 2 were over <i>m</i> ), consider investigating the root-cause and increasing the frequency of emptying and cleaning.
	Build confidence in the operational control and timely warning of potential loss of control	Trend analysis	Frequency should be in line with the number and volume of batches of reuse water supply being generated, with the aim for a timely signal of control or potential loss of control	No patterns of high numbers close to the maximum acceptable levels. No increases in frequency of batches failing the pre-defined verification criteria	Patterns (e.g. upward trending numbers; large variations in numbers; large upsurges in numbers) can be indicative as to the level of control over the operation to advert to targeted corrective action. When corrective action (e.g. emptying the system and thorough cleaning) is taken, verification is best intensified temporarily by increasing the sampling frequency (e.g. sampling the first and the last batch in the process).

**TABLE A9** Details of a verification plan for reuse of RO water supplies recovered from CIP liquids that have been recirculated or recycled (cont.)

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<i>B. cereus</i> (vegetative cells and spores) in RO water	Biofilm indicator	Presence/absence test ISO7932 or ISO 21871	Monthly	< 1 cfu/ml <sup>a</sup>	If <i>B. cereus</i> is detected (generally not detectable unless accumulated in biofilm), test 3 new samples and if results are confirmed, determine the root-cause, including an assessment of the need to: <ul style="list-style-type: none"> <li>• Change separation values in conductivity-controlled valves, and</li> <li>• The effect of the RO plant.</li> </ul> The effectiveness of the above steps is then confirmed and documented by testing 3 new samples

<sup>a</sup> Level of microorganisms or chemicals pre-defined by appropriate validation under operational conditions for that specific water reuse scenario. The microbiological level can be a maximum value for one of more specified volumes of water tested or it can be a three-class sampling plan with statistical parameters *n*, *c*, *m* and *M* pre-defined (ICMSF. 2018. Microorganisms in Foods 7. Microbiological Testing in Food Safety Management. Second Edition. Springer, Cham, Switzerland. **FAO & WHO**. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B21-1997%252FCXG_021e.pdf)). The values for the level and parameters must be specified in the plan that is being operationalized

<sup>b</sup> Split sampling refers to taking the required number of samples (*n*) over a certain period of time

<sup>c</sup> The use of moving windows to verify compliance with microbiological criteria has been described (ICMSF. 2018. Microorganisms in Foods 7. Microbiological Testing in Food Safety Management. Second Edition. Springer, Cham, Switzerland. **FAO & WHO**. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXG%2B21-1997%252FCXG_021e.pdf)). It appears from this that moving windows are used for continuous verification of the entire system and not for the approval of specific lots. The follow-up of results included in moving windows is thus targeted at the system and not at the specific batches from which the sample was taken. If there is a need to assess a specific batch, sampling is performed without the sample being split.

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.

## References

- ICMSE.** 2018. *Microorganisms in Foods 7. Microbiological Testing in Food Safety Management*. Second Edition. Springer, Cham, Switzerland.
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- Heggum, C.** 2020. *Dairy Sector Guide - Recommendations of the Danish Agriculture & Food Council on implementation of food safety management systems in Danish dairy plants*. Available upon request from CHG@lf.dk.
- Pérez-González, A., Urtiaga, A. M., Ibáñez, R. & Ortiz, I.** 2012. State of the art and review on the treatment technologies of water reverse osmosis concentrates. *Water research*, 46(2): 267–283. DOI: 10.1016/j.watres.2011.10.046

## CASE STUDY 4: RECOVERY OF WATER FROM WHEY USING RO OR ROP

This case study describes the recovery of milk water from milk, whey and product flushes using RO and UV treatments. Recovery of milk water takes place as a side-stream during concentration of milk constituents (retentate) and is done either at the establishment of origin before transport of the retentate, or at the recipient establishment.

RO, ROP and UV treatment can take place in one or a combination of the following ways (see **Figure A4**), with the system ultimately being emptied and cleaned as needed:

- The RO/ROP water is stored in a water tank where the content circulates over a UV system.
- The RO/ROP water is UV-treated at the inlet to the water tank and at the outlet (before use).
- RO/ROP water is UV-treated directly after RO and immediately before use (without storage).

### Sources of first-use and reuse of water

- Whey
- Permeate (from milk, whey, product flush, etc.)
- Condensate from evaporation of milk and milk products
- Casein wash water
- Drinking water
- Recirculated RO or ROP water

The UV-treated RO water that has been used for purposes that do not result in the accumulation of inorganic or organic material can be returned directly to the water tank. RO and ROP water that may have accumulated such materials can be RO- or ROP-filtered again before being returned to the relevant water tank for storage.

Studying the feasibility for reuse of cheese whey as water in CIP process operations, using combined UF and RO, Meneses and Flores (2018) found that a water recovery of 47 percent could be achieved through RO filtration.

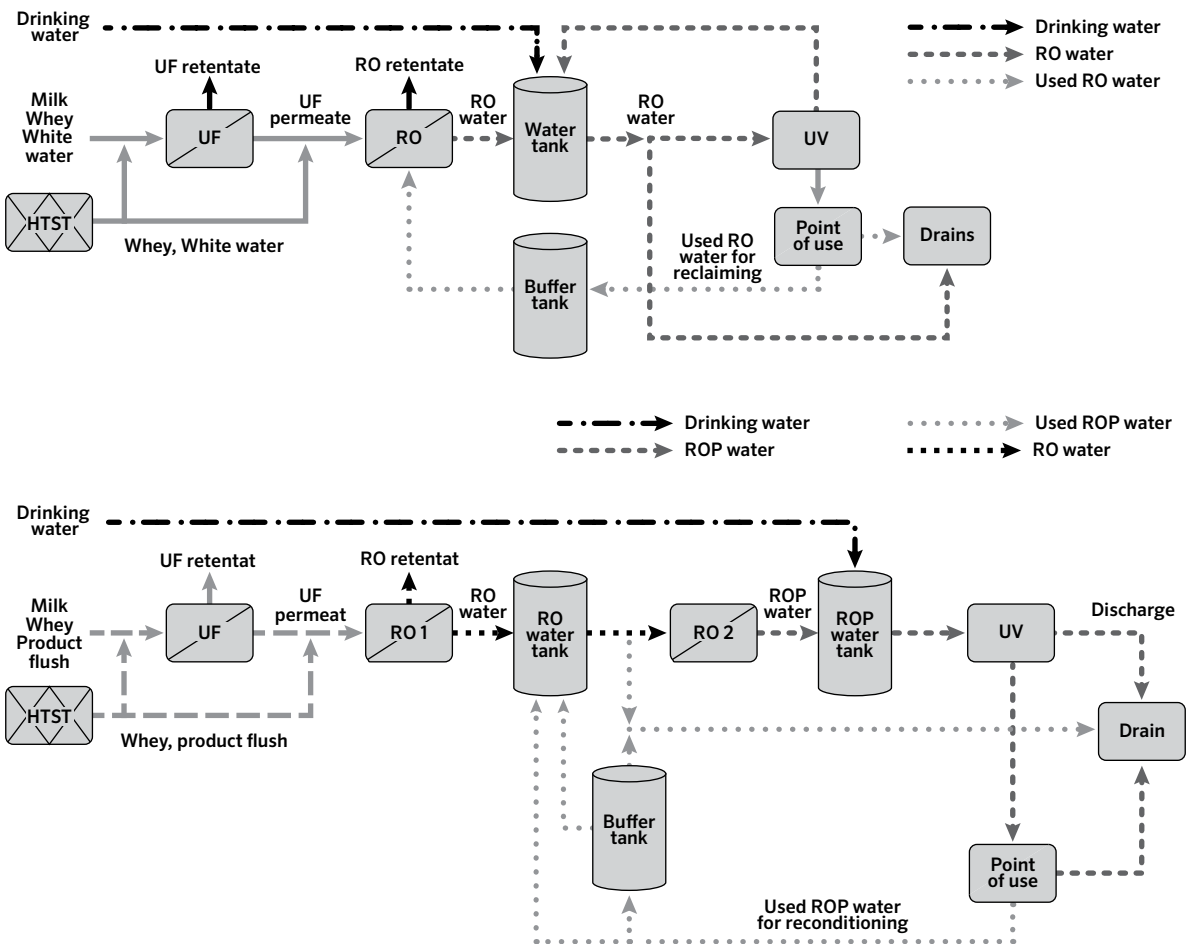
### Process control of RO/ROP plants

The purpose of the process control of RO and ROP filtration is to ensure efficient filtration during generation of water. This is accomplished by:

- Monitoring the degree of fouling on the retentate side, which may clog the membrane pores, and thus the need for cleaning.
- Monitoring that no leaks occurred in membranes, gaskets, etc.

The dairy company must determine the combination of monitoring parameters that best suits the specific RO plant and set action limits to ensure effective filtration. The correct determination of membrane specifications (material, type, membrane area, membrane thickness, pore size, etc.) should be common for all plants.

**FIGURE A4** Illustration of two water reuse scenarios involving recycling of reusable water sources through RO/ROP and UV treatment(s). Top: describes the recovery of milk 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.

During RO operation, monitoring the pressure, flow and temperature is crucial for ensuring optimum permeate flux (the rate, expressed as L/m<sup>2</sup>/hour, at which permeate is extracted). If permeate flux decreases during operation, it can be compensated by increasing feed pressure or flow to keep the flux stable. Parameters measured on the retentate side can also be used to control the process (e.g. degree of concentration). It is difficult to establish universal guidelines for process control for RO plants, as there are variations in RO plants and so process controls must be determined based on experience with the filtration plant used, and most often, with input from the RO/ROP materials/equipment supplier.

### **Microbiological characterization of RO/ROP water recovered from milk products**

For RO water, there is a special concern for the possible presence of pathogenic bacteria that have been identified as being significant hazards in the manufacture of dairy products. Among the typical pathogens of concern are non-typhoid *Salmonella*, *L. monocytogenes*, *S. aureus*, *E. coli* (including STEC), as well as certain spore formers, especially *C. perfringens* and *B. cereus*. These pathogens can be found sporadically in milk and/or the processing environment and can be transmitted to whey, permeate and product flush/rinse when control measures and other hygiene barriers fails during processing. Environmental bacteria that may also be found include *Enterobacter*, enterococci, *Klebsiella*, lactococci, lactobacilli, *Pseudomonas* spp., and streptococci.

The microorganisms that can be found in the dairy processing environment can be divided into transient microorganisms (including hazards that are introduced via raw materials and ingredients and thus, are spread to the manufacturing environment) and resident microorganisms (including those that colonize and persist in certain locations in the processing environment).

While the composition of the microflora can vary between dairy plants and some bacteria are specific to a particular plant (specific house flora), the occurrence of *Enterobacteriaceae* seems to be generic to all plants.

In RO plants used to purify drinking water, *Pseudomonas* spp. appears to be the fastest biofilm former among the drinking water flora (Flemming and Schaule, 1988).

ROP water typically contains a low number of mainly gram-negative microorganisms and the presence of pathogens in ROP water is unlikely (Balling Engelsen, 2021). Via REWARD website ([www.models.life.ku.dk/reward](http://www.models.life.ku.dk/reward)) and [CHG@lf.dk](mailto:CHG@lf.dk), further details can be requested.



### Availability of nutrients in RO and ROP water recovered from whey

Urea is uncharged and cannot be effectively filtered out by the membranes, so it is the single largest component in RO water generated from milk water. Urea in RO and ROP water can serve as a nutrient for urease-positive bacteria, such as *Klebsiella* spp., *Enterobacter* spp., staphylococci and *Proteus* spp., but *Listeria* and *Salmonella* generally do not grow in ROP water as they cannot utilize urea (see **Table A10**). However, RO water may contain other available carbon sources, as studies have shown that both *Listeria* and *Salmonella* can grow in RO water, even though they cannot utilize urea (Danish Environmental Protection Agency, 2017).

**TABLE A10** Ability of relevant bacterial groups to grow on urea

MICROORGANISM	UREASE FERMENTATION	
	Positive	Negative
<i>Salmonella</i> spp.		✓
<i>L. monocytogenes</i>		✓
<i>Acinetobacter</i> spp.		✓
<i>Bacillus</i> spp.		✓
<i>E. coli</i>		✓
<i>Lactococcus</i> spp.		✓
<i>Klebsiella</i> spp.	✓	
<i>Enterobacter</i> spp.	✓	
Staphylococci	✓	
<i>Proteus</i> spp.	✓	
<i>Pseudomonas</i> spp.	Some are positive	

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.

Due to the low retention of small, uncharged organic molecules by the RO membranes, ROP water can also contain a significant amount of urea (>50 mg/L). However, other substances like low molecular weight sugars are removed.

The presence and growth potential of microorganisms in RO/ROP water may limit the shelf life of reuse water supplies generated, but these could be treated or refrigerated to extend shelf-life.

## UV treatment

The UV treatment of RO/ROP water can be done immediately before use, at the point of use, or continuously as the RO/ROP water circulates over a UV system during storage.

UV treatment of RO/ROP water is to inactivate any pathogenic and/or non-pathogenic microorganisms that may be present in the water. Treatment also reduces bacteria that may have been released from biofilms or contaminants from the manufacturing environment and to decrease any bacterial levels due to growth.

The content of dissolved material (COD, turbidity) in fresh RO water is very low and bacteria would not be expected to be in large clumps (which needs to be validated per case). So, it is assumed that there is a linear relationship between the UV log reduction and the UV dose (mJ/cm<sup>2</sup>). However, bacterial growth during storage may result in significant clumping and therefore, treatments after prolonged storage of water may limit the effectiveness of UV.

As the potential content of microorganisms in RO water is expected to be very low, treatment with a UV dose that gives at least a 4 log reduction of the relevant microorganisms should suffice. Typically, doses above 40 mJ/cm<sup>2</sup> result in  $\geq 4$  log reduction for a range of bacteria, and even achieve  $>5$  log reduction for several significant pathogens (see Annex 3). WHO (2004, 2022) refer to a minimum removal of 4 log and a minimal UV dosage of 40 mWs/cm<sup>2</sup> (= 40 mJ/cm<sup>2</sup>) to protect against growth of bacteria. Those bacteria relevant for the water streams in dairy plants would include *Aeromonas hydrophila*, *Campylobacter* spp., *E. coli*, *Klebsiella*, *Listeria monocytogenes*, *Pseudomonas* spp., *Salmonella* spp., *Staphylococcus aureus*, *Yersinia* spp., yeasts and viruses.

Use of higher UV doses may be appropriate where the water has been stored for long periods or has not been circulated over a UV system. Vegetative cells of pathogens and of other microorganisms have been found to be variable in their tolerance or sensitivity to UV radiation. Mould and bacterial spores are much more resistant/tolerable than vegetative forms.

The effectiveness of UV treatments on target microorganisms should be validated.

As the effect of UV on *B. cereus* spores is not nearly as high as that for spores of other microorganisms (Malayeri *et al.*, 2006), it is recommended that UV-treated water be tested for *B. cereus* at regular intervals.

## **Shelf-life assessment of RO and ROP water**

Note: In this context, the shelf life is understood to be the period that has elapsed between each emptying and cleaning of the system.

The shelf life of RO and ROP waters is affected by the storage temperature and the availability of nutrients, which impact both the microbial growth potential and their survival in RO/ROP water.

It is estimated that RO/ROP water that has been either UV-treated before use or before storage can be stored without temperature control for up to 4 days and still regarded to be safe, on the assumption that the UV treatment has effectively eliminated the chance of any microorganisms emerging during storage (should be validated for specific local conditions). Refrigerated storage can extend the shelf-life of reuse water supplies.

Given that RO/ROP water is stored and distributed in essentially closed systems, it is assumed that there are no risks of contamination from the production environment, unless at the point of outlet of the RO treated water into other systems.

If the feed water into the RO/ROP plants has been pasteurized, it is assumed to be free of zoonotic, non-spore forming pathogens and FMDV. However, many countries require a double pasteurization or a pasteurization in combination with a pH reduction to <6.0 for one hour to ensure the elimination of the FMDV in the event that the water will be later incorporated into the feed of hoofed, domestic animals.

## **Assessment of hazards, risks and control options**

The occurrence of hazards in the recovery and reuse of ROP water is typically due to the factors such as those described in **Table A11**.

**TABLE A11** Possible hazards of concern, the likely associated risks and possible control options for recovery of whey water and reuse treatment using RO or ROP

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS	
RO system	Fouling and building up of biofilm on membranes	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Control of fouling on the retentate side of membrane.</li> <li>Monitor for leaks.</li> <li>Visual inspection of water permeability.</li> </ul>	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
	Minor				✘				
	Carry-over of product residues through leaks in RO membranes; consequential carry-over of undesired organisms)	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always		
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
Moderate									
Minor				○					
Microbial growth in ROP water	Pathogens (including <i>L. monocytogenes</i> )	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Storage with circulation over UV systems and/or storage with UV treatment before use.</li> <li>Control of the shelf-life of ROP water.</li> </ul>	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate		✘				
	Minor								
	Undesired micro-organisms	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always		
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
Moderate									
Minor				✘					

**TABLE A11** Possible hazards of concern, the likely associated risks and possible control options for recovery of whey water and reuse treatment using RO or ROP (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS	
Low liquid level in the UV reactor	Reduced UV effect and overheating of lamps	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Alarms to signal low liquid levels in the UV reactor.</li> </ul>
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
			Minor			○			
Insufficient UV exposure	Survival of micro-organisms	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Flow control.</li> <li>Control the age of the lamps.</li> <li>Monitor irradiance and conductivity or UVT.</li> <li>Alarms and automatic flow diversion valve for bypass or in case of lock-down.</li> </ul>
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate					○	
			Minor						
Broken equipment in UV systems	Glass splinters	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Alarms and automatic flow diversion valve for bypass or in case of lock-down.</li> <li>Disposal of affected water.</li> </ul>
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe		✘				
			Moderate						
			Minor						
	Mercury	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe		✘				
			Moderate						
			Minor						

**TABLE A11** Possible hazards of concern, the likely associated risks and possible control options for recovery of whey water and reuse treatment using RO or ROP (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>					CONTROL OPTIONS	
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent		Always
Microbial growth in RO water	Undesirable micro-organisms	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					• Control the storage shelf-life and/or temperature (e.g. refrigeration) of RO water supplies.
			Moderate			✘		
			Minor					

<sup>a</sup> The above is illustrated using the following symbols:

○ = transfer of the hazard from previous steps.

✘ = the hazard originates in this step.

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.

## Hazard Control Plan

Based on the hazard analysis and risk assessment, a hazard control plan can be established, such as those shown in **Table A12**.

**TABLE A12** Details of a hazard control plan for the recovery of whey water and reuse treatment using RO or ROP

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
RO plant	Foot-and-mouth disease virus	pH adjustment with acid	Addition of acid	Ongoing dosage	pH < 6.0	Dosage of acid is increased.
	Fouling and building up of biofilm on membranes	Control of fouling on the retentate side and scaling in membranes	Specific to the dairy plant as part of management strategy e.g. • Pressure control (Feed pressure till normal flux). • Permeate flux. • Degree of concentration, e.g. Brix.	Specific to the operation as part of hazard control and control verification plans	Specific to the operation as part of hazard control and control verification plans	Cleaning of the RO system once operating time limit has been reached.
			Operating time before cleaning, based on validation	Specific to the operation as part of hazard control and control verification plans	Specific to the operation as part of hazard control and control verification plans	Reduce operating time when verification fails.

**TABLE A12** Details of a hazard control plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
RO plant	Leakage in the plant (organic materials and microorganisms)	Measurement of permeate	Monitor that no leaks occurred, e.g. <ul style="list-style-type: none"> <li>• Conductivity.</li> <li>• Turbidity.</li> <li>• TOC.</li> </ul>	Ongoing	Specific to the operation as part of hazard control and control verification plans	<ul style="list-style-type: none"> <li>• Causal analysis: <ul style="list-style-type: none"> <li>◦ Inspect the membranes and gaskets for leaks.</li> <li>◦ Replace defective parts.</li> </ul> </li> <li>• Clean the systems.</li> <li>• Affected RO water is not used but can be reworked.</li> <li>• Verify that corrective action worked.</li> </ul>
		Light transmittance through the permeate	Visual check (use transparent pipes in the system)	Specific to the operation as part of hazard control and control verification plans	Specific to the operation as part of hazard control and control verification plans	
UV plant	<i>L. monocytogenes</i> , STEC, <i>S. aureus</i> , <i>B. cereus</i> , <i>Salmonella</i> spp.	UV dose	Irradiance, pre-set maximum flow rates and UVT to ensure an operational minimum dose of 40 mJ/cm <sup>2</sup> – if necessary, use higher dose.	Ongoing (sensor in plant)	Determined by site, depending on lamp type	<ul style="list-style-type: none"> <li>• Alarm and automatic activation of flow diversion valve if dosage is too low.</li> <li>• Rework.</li> </ul>
			Flow rate (if not pre-set to maximum).	On going	> Maximum flow rate determined and set by the dairy plant with input from the equipment supplier	<ul style="list-style-type: none"> <li>• Alarm and automatic activation of flow diversion valve if flow rate is too high.</li> <li>• Rework.</li> </ul>
			Flow diversion valve.	Before start-up	Defective	<ul style="list-style-type: none"> <li>• Alarm.</li> <li>• No start-up.</li> <li>• Service on valve and/or sensor.</li> </ul>

**TABLE A12** Details of a hazard control plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
UV plant	Low liquid level in UV reactor	Extent of filling	Automatic recording	On going	Determined by the dairy plant with input from the equipment supplier	<ul style="list-style-type: none"> <li>Alarm in case of low liquid level.</li> <li>Refill.</li> <li>If damaged, replace the lamp.</li> </ul>
	Decrease in UV effect	Off measurement will activate flow diversion	Abnormal Conductivity or UVT. Activate flow diversion in case of cloudy water.	On going	<b>Conductivity:</b> > 200 mS/cm For cleaning: > 100 mS/cm <b>UVT:</b> ≤ 95%	<ul style="list-style-type: none"> <li>Alarm and automatic activation of flow diversion valve if conductivity is too high or UCT is too low.</li> <li>Rework.</li> </ul>
	Glass splinters	Protect against contamination of the water	Intact glass tubes	On going	Damaged glass, presence of mercury	Alarm and automatic activation of flow diversion valve.
	Mercury					If the product is contaminated with glass or mercury, dispose the affected water supply.
<b>System (piping, UV system and tanks)</b>						
Storage without temperature control	Contamination from biofilm (e.g. <i>B. cereus</i> )	<ul style="list-style-type: none"> <li>Cleaning</li> <li>Water replacement</li> </ul>	Operating time (shelf life)	Determined by plant/operator based on validation	<b>UV treatment before use:</b> Default limit: <sup>b</sup> 4 days <b>Circulated over an UV plant:</b> Default limit: 6 days	Empty and CIP before restart.
Refrigerated storage	Contamination from biofilm (e.g. <i>B. cereus</i> )	<ul style="list-style-type: none"> <li>Cleaning</li> <li>Water replacement</li> </ul>	Operating time (shelf life)	Determined by plant, per validation	<b>UV treatment before use:</b> Default limit: 6 days <b>Circulated over an UV plant:</b> Default limit: 10 days	Empty and CIP before restart.
	Growth of microorganisms	Chilled storage	Storage temperature	Daily	≤ 7 °C <sup>c</sup>	



**TABLE A12** Details of a hazard control plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
System (tanks and pipes)	Contamination from biofilm (e.g. <i>B. cereus</i> )	Cleaning	Operating time (shelf life)	After use, clean at least once a day	None	None

<sup>a</sup> When reference is made to monitoring limits or frequencies being “determined locally” or “determined by the dairy establishment”, the selected values must appear in the Own-Control Plan.

<sup>b</sup> Note that default limit values are related to validation of shelf-life and are used for defining the length of the validation study (for instance 3 times the default period). Default implementation without validation is not recommended.

<sup>c</sup> suggested as it is the minimum temperature supporting growth of many microorganisms, but other temperatures could be used based on the insights of the operator concerning the relevant hazards.

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.

## Validation<sup>8</sup>

The RO/ROP-UV system should be validated during start-up to demonstrate that the setup will produce the intended water quality and to help determine the required cleaning frequency and verification parameters. The following validation procedure is recommended, but alternatives that can achieve the same goal can also be used:

- 1) During a test period of up to 3 times the pre-determined default shelf life,<sup>9</sup> analyse the monitoring results recorded in the hazard control plan. If the monitoring data demonstrate stability, proceed to Step 2.
- 2) Sample the storage tank or the use site daily<sup>10</sup> and test for coliforms, the plant-specific hygiene indicators, TPC 22 °C, *Enterobacteriaceae*, psychotropic counts and *Pseudomonas*. The first indicator that exceeds its specified limit is selected as the verification parameter – see Verification plan. If no indicator has exceeded its limit at the end of the test period, the indicator which came closest to the specified limit is selected as the verification parameter.

<sup>8</sup> Some elements of “Validation” may be done at laboratory or pilot plant scale, but operational validation ultimately has to be performed at full scale

<sup>9</sup> For UV treatment before use, storage without temperature control, the default shelf life is 4 days (i.e. test period 12 days); For UV treatment before use, storage refrigerated, the default shelf life is 5 days (i.e. test period 15 days); When circulating over UV systems, storage without temperature controls the default shelf life 6 days (i.e. test period 18 days); When circulating over UV systems, storage refrigerated, the default shelf life is 10 days (i.e. test period 30 days).

<sup>10</sup> Every 2 days for a test period of more than 10 days.

Proceed to Step 3. During the run-up period, testing for *Salmonella* spp. can also be considered, especially in dry manufacturing environments which can harbour *Salmonella*.

- 3) The treatment plant is stopped and allowed to stand for 24 hours, after which, 5 samples are taken for microbiological analysis for *Salmonella*, *B. cereus* and *L. monocytogenes*. If any of these bacteria is detected in one or more samples, the pertinent process control parameters are adjusted, and Steps 1–3 are repeated. Otherwise, proceed to Step 4.
- 4) The shelf-life of the water is established as the period from which testing was started to the day when the coliform count or the level of the specific hygiene indicator chosen has exceeded the specified limit. If none of the indicators has exceeded their limit, the pre-determined shelf-life can be used.
- 5) Normal operation can be restarted if the results of the analyses in Step 3 shows that the quality requirements have been met. Re-initiate the hazard control plan and the verification plan.

The system should be re-validated in a timely way considering specific operational conditions (e.g. frequency and volume of reuse water supplies being generated and risks related to hazards not being controlled) but no later than once a year or when significant changes are introduced (e.g. changes in hazard control, in feed material to the RO system, major maintenance, etc.).

## Verification Plan

**TABLE A13** Details of a verification plan for the recovery of whey water and reuse treatment using RO or ROP

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Records of monitoring of measures</b>	Check that the data is recorded	Control of documentation	Determined by the dairy establishment	Data is being Recorded	Inspect the measuring and recording equipment. Repair or replace defective parts.
<b>Equipment</b>					
<b>Flow diversion valve for the UV system</b>	Contaminated water	Per supplier instructions	Determined by the dairy establishment	Functional Flow diversion	The sensor is replaced or repaired. The UV system is emptied and cleaned before restart. Affected water supply is disposed of.
<b>Calibration</b>	Ensure accurate measurements of temperature, pH, pressure, conductivity, Brix etc.	According to local procedure as determined by the dairy establishment.			If readings are off, the equipment is adjusted, repaired or replaced.

**TABLE A13** Details of a verification plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Water quality – Chemical analyses</b>					
<b>COD in RO water outlet (before or after UV treatment or chlorination)</b> (Can be replaced by measuring for conductivity if it is not included in the hazard control plan)	Membrane tightness (leaks)	ISO 15705	Monthly	≤100 mg O <sub>2</sub> /L or ≤12 mg O <sub>2</sub> /L if use may result in the formation of chlorine compounds or corrosion.	If levels are exceeded, 3 more samples are taken and if results are confirmed, do a causal analysis, which includes inspecting the membranes and gaskets for leaks, replace the defective parts and clean the systems. Verify the corrective measure by testing 3 new samples.
<b>Chloride (water tank)</b>	Corrosion of stainless steel	DS 249	Determined by the dairy establishment	≤ 150 mg/L	The RO system is adjusted.
<b>Water quality – Microbiological analyses (water tank or site of use)</b>					
<b>Coliforms in UV treated RO/ROP water</b>	Indicator of microbiological contamination	Detection (n=1) ISO 9308-1 or ISO 2255	Once per week	Not detected in 100 ml	If detected, a sample is taken from the same batch for <i>E. coli</i> analysis.
<b><i>E. coli</i> in UV treated RO/ROP water</b>	Indirect indicator of pathogens	Detection (n=1) ISO 9308-1 or ISO 2255	When testing for coliforms	Not detected in 100 ml	If detected, take 3 new samples and if results are confirmed: <ul style="list-style-type: none"> <li>• Investigate the cause,</li> <li>• The cleaning procedure is reviewed,</li> <li>• The system is emptied and cleaned, and</li> <li>• Temporarily intensify monitoring for verification by increasing the sampling frequency for coliforms (e.g. sample the first and the last batch in the process). If testing is negative, no further action is taken. The effectiveness of the above corrective measures is documented by testing 3 new samples.</li> </ul>

**TABLE A13** Details of a verification plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Hygiene indicator selected by validation</b> (The indicator used to determine the cleaning frequency during the validation is selected as the verification parameter)	Accumulation of microorganisms	Enumeration (split sampling) ( $n=1$ )	Once every two weeks	$<M$	<ul style="list-style-type: none"> <li>If <math>M</math> is exceeded, test 3 more samples and if results are confirmed, do a causal analysis and the effect of the RO system (e.g. greater flux) is reassessed.</li> <li>If the exceeded level is very large (e.g. <math>5 \times M</math>), the system is emptied and cleaned.</li> <li>The effectiveness of the above corrective measure is documented by testing 3 new samples.</li> <li>If <math>M</math> is exceeded repeatedly over the last 5 tests, consider reducing the shelf-life</li> </ul>
		“Moving window” <sup>a</sup> on weekly results	The 5 most recent analysis results are compiled continuously.	Out of 5 ( $= n$ ) consecutive results, a maximum of 2 ( $= c$ ) may be between $m$ and $M$ .	<ul style="list-style-type: none"> <li>If “<math>c</math>” is exceeded (over the last 5 tests), search for the cause, and take appropriate corrective actions (e.g. extra cleaning). In <math>c</math> is exceeded repeatedly, consider reducing the shelf-life.</li> </ul>
		Trend analysis	Quarterly review of the recent year’s results	No observations of high counts or changes in the frequency of violations.	<ul style="list-style-type: none"> <li>Patterns can provide a clue as to the cause so that targeted corrective action can be taken.</li> <li>In the event of negative trend, corrective actions may include thorough cleaning and temporary intensify verification by increasing sampling frequency (e.g. sampling the first and the last batch in the process).</li> </ul>
<b><i>B. cereus</i></b> (vegetative cells and spores) in RO water	Biofilm indicator	Detection ( $n=1$ ) ISO 7932 or ISO 21871	Monthly	$< 1$ cfu/ml	If detected, test 3 new samples and if results are confirmed, search for the cause and also assess: <ul style="list-style-type: none"> <li>Changing separation values in conductivity-controlled valves,</li> <li>The effect of the RO plant, and</li> <li>The effect of the UV plant.</li> </ul> The effectiveness of the above corrective action is documented by testing 3 new samples. In case of repeated detections, consider reducing the shelf-life.

**TABLE A13** Details of a verification plan for the recovery of whey water and reuse treatment using RO or ROP (cont.)

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b><i>L. monocytogenes</i> in UV treated RO water</b>	Human pathogen	Detection (n=1) ISO 11290-1	Monthly. Can be removed from the sampling program if not detected for 12 months.	Absent in 25 ml	If detected, search for the cause, including: <ul style="list-style-type: none"> <li>• Changing separation values in, conductivity-controlled valves,</li> <li>• The effect of the RO system, and</li> <li>• The effect of the UV system.</li> </ul>
<b><i>Salmonella</i> spp. in UV treated RO water</b>	Human pathogen	Detection (n=1) ISO 19250	Monthly. Can be removed from the sampling program if not detected for 12 months or can be included in the validation	Absent in 25 ml	The effectiveness of the above corrective action is documented by testing 3 new samples. Affected RO water is not used but can be reworked. Batches of food products that may have been contaminated by the RO water in question are retained and tested for <i>L. monocytogenes</i> and <i>Salmonella</i> (n = 5). The end product can be released if all tests are negative. In the case of repeated detections, the shelf life should be reduced.

<sup>a</sup> The use of moving windows to verify compliance with microbiological criteria is described in Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (FAO and WHO, 2013a). It appears from this that moving windows are used for continuous verification of the entire system and not for the approval of specific lots. The follow-up of results included in moving windows is thus targeted at the system and not the specific batches from which the sample was taken. If there is a need to assess a specific batch, sampling is performed without the sample being split.

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.

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## CASE STUDY 5: RECOVERY OF WATER FROM DAIRY EFFLUENTS USING MBR AND RO

This case study describes the recovery of water from dairy effluents using MBR technology and RO and the water is for reuse in food production (see **Figure A5**).

Dairy effluent is wastewater derived from the manufacture of dairy products and includes floor drains from production areas but does not include black and grey wastewater.

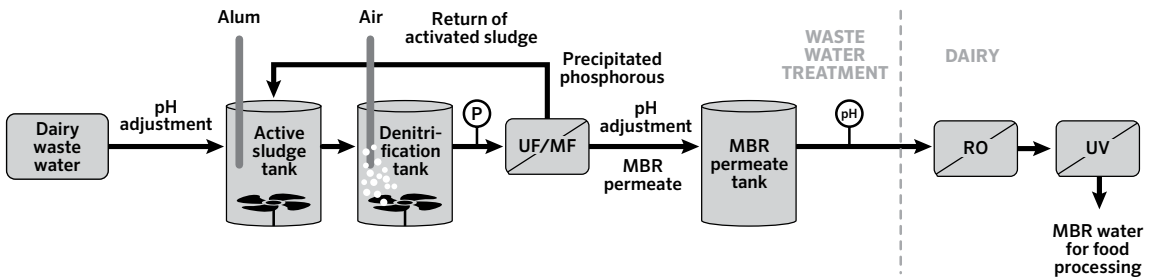
The dairy effluents are pumped into a fermentation tank, where they are mixed with an aqueous slurry of bacteria from ordinary biological treatment plants containing among others, ammonium-reducing bacteria.

Alum (aluminium sulphate) or aluminium chloride is added to precipitate residual phosphorus. The dosage of alum is controlled by means of sensors (in-line phosphorus measurement) or by taking laboratory samples for phosphorus analysis. A pre-denitrification process takes place in the anaerobic step followed by aerobic nitrification whereby biological nitrogen is completely removed. The supernatant from the activated sludge tank is further fermented under aerobic conditions (oxygen is added) and free nitrogen, N<sub>2</sub>O (nitrous oxide) and CH<sub>4</sub> (methane) are discharged. The optimum denitrification process is at pH 6.7–7.0 (> 6.5), so a pH adjustment is necessary.

The precipitated phosphorus is separated together with other materials from the water in an UF or MF plant. Excess sludge, including precipitated phosphorus (retentate from UF/MF) is returned to the active sludge tank or run off to biogas.

To ensure the shelf life and to counteract any contamination from piping between MBR plants and the dairy plant, bactericidal treatment is needed, e.g. UV treatment.

**FIGURE A5** Illustration 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.

## Effect of MBR

MBR treated water is almost completely free of particles and bacteria. The effective removal of suspended matter by MBR plants means that the purified MBR permeate is readily suitable for further treatment e.g. RO and/or UV treatment, to produce water of extremely high quality (Jørgensen *et al.*, 2010).

Particles of less than 1 mm are effectively retained by the RO membrane, so that RO-filtered MBR permeate (= MBR water) has a very low content of suspended solids (typically <1 mg/L).

MBR permeate is somewhat corrosive (pH 4–6) with low alkalinity (corresponding to 0 mg/L), which necessitates pH adjustment (e.g. with lye) to obtain a neutral pH and an alkalinity that corresponds to that of drinking water.

Based on the above descriptions of purification achievable with MBR technology, water generated from milk products using MBR (UF) and RO should, in principle, be suitable for use for all purposes in dairy production, while MBR (UF) permeate should only be used for purposes where the water will not come in direct contact with the finished product, such as technical water and water used for CIP cleaning (Jørgensen *et al.*, 2010).

## Hazard analysis

### Identification of hazards

If water obtained from dairy effluents is intended to be used for food contact, all chemical substances that may be found in the dairy effluents must be identified. In addition, all activities leading to the drainage of dairy effluents must be reviewed and any possible substances present must be identified.



Relevant chemical substances that should be assessed include:

- Residues of cleaning agents, including:
  - > Traditional CIP chemicals (nitric acid, sodium hydroxide, peracetic acid).
  - > Special cleaning agents (e.g. for membranes): enzymes, surfactants, EDTA (Ethylene Diamine Tetra Acetate).
  - > Any surfactants used to remove biofilms (provides uniform wetting of surfaces, to reduce surface tension of water by adsorption and contributes to the dissolution of bacteria from the surface).
  - > Detergents in water for clean-out-place (COP) uses, e.g. exterior parts of equipment, floors, etc.
  - > Polymers used in waste-water treatment plants.
  - > Hand soaps.
- Processing aids and food additives used, including those used in ingredients.
- Residues of lubricants used.
- Carriers and other materials that may be included in the above chemicals.

The user must consider whether each of the identified substances can be expected to decompose in the bioreactor or whether they will be retained by the membrane filtration. If this assessment is not possible, the purified MBR water should not be used for direct or indirect contact with food. Assessment of any degradation by-products during bio-fermentation must also be determined.

### **The bioreactor**

The biological treatment ensures the removal of organic materials (COD) to levels below  $\pm 30$  mg O<sub>2</sub>/l.

Depending on the data on nitrogen compounds in the MBR permeate, it can be assumed that the aerobic biological purification will ensure the removal of total-N to <5–6 mg/L (of which nitrate 2.2–2.37 mg/L corresponding to nitrate-N <0.5 mg/L and ammonium 1.5–2.72 mg/L corresponding to ammonium-N to <2.1 mg/L).

Failure of denitrification in the MBR plant will result in too high ammonium content in the MBR permeate, which can be an indicator of a stressed bio culture in the bioreactor and can lead to precipitation on the membrane.

### **The microfiltration/ultrafiltration**

Microfiltration or ultrafiltration can be used to separate the activated sludge from water, but fouling occurs relatively quickly, thus requiring flux monitoring to determine when flushing (e.g. back flashing) and/or cleaning is needed.

## Purification of MBR permeate

There are several options for further purifying the MBR permeate into e.g. MBR water:

- **Activated carbon filters.** To remove chlorine and chloramine by adsorption and may also remove some dissolved organic matter.
- **Ion exchange.** A chemical process that effectively removes dissolved inorganic salts (e.g. phosphates, nitrate, sulphates, carbonates) but not organic material, which may result in the microbial contamination of the water.
- **Reverse osmosis (RO).** The extra RO filtration ensures against fluctuations and delivers a very uniform and efficient purification.
- **Distillation.**

The degrees of purification achievable with MBR technology are described in **Table A14** and **Table A15**. Based on these descriptions, MBR permeate can be recycled for use as technical water, whereas MBR water can be used for indirect and direct contact with food in manufacturing.

Note that the MBR permeate is somewhat corrosive (pH 4–6) with low alkalinity, which necessitates the use of alkali to adjust to a neutral pH and an alkalinity corresponding to that of drinking water.

**TABLE A14** Differences in purification efficiencies of various technologies on some chemicals and microorganisms possibly occurring in water supplies

SUBSTANCE	RO	ION EXCHANGE	DISTILLATION	ACTIVATED CARBON
Chlorine	98–99%	0%	partly	98–99%
Alkaline fumes	98–99%	96–99%	98–99%	0%
Dioxin	98–99%	0%	98–99%	partly
Organic substances	98–99%	0%	partly	98–99%
Arsenic	96–99%	96–99%	96–99%	0%
Calcium	96–99%	96–99%	96–99%	0%
Cadmium	96–99%	96–99%	96–99%	0%
Lead	96–99%	96–99%	98–99%	0%
Organic phosphorous	96–99%	96–99%	98–99%	0%
Sulphur	96–99%	96–99%	98–99%	0%
Magnesium	96–99%	96–99%	98–99%	98–99%
Bacteria	98–99%	0%	98–99%	partly
Virus	98–99%	0%	98–99%	0%

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.

**TABLE A15** MBR technology purification. Sample characteristics of MBR permeate and MBR water

PARAMETER	MBR PERMEATE (BEFORE RO)	MBR WATER (AFTER RO)
COD (mg O <sub>2</sub> /l)	30	5
Conductivity (mS/cm)	3 011	48
Alkalinity (mg/l)	1 690	25
pH	7.6	7.2
Hardness (Dh, g)	5.1	< 0.28
Total N (mg/l)	5.5	0.7
Ammonium-N (mg/l)	1.5	0.15
Nitrate N (mg/l)	2.2	0.19
Total P (mg/l)	0.21	< 0.1
Chloride (mg/l)	71	< 10
Calcium (mg/l)	26.8	< 0.2
Total dry matter (mg/l)	1 993	47

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.

## Shelf-life assessment

*Note: The shelf life is understood in this context as the time period between each emptying and cleaning of the system.*

The shelf-life MBE water is equivalent to that of UV-treated RO water.

These shelf lives are recommended default shelf lives of RO water based on worst-case scenarios in nutrient composition and microbial characterization. This shelf life should be validated locally at each plant and may be adjusted as experience and an archive of monitoring and verification results are obtained to warrant re-evaluation.

## Occurrence of hazards

The purified MBR effluent water is almost completely free of particles and bacteria.

The occurrence of biohazards related to the recovery and the use of MBR water is typically due to factors such as those noted in **Table A16**.

**TABLE A16** Possible hazards of concern, likely associated risks and possible control options for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS	
Bioreactor	Residues of organic material	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Adjust air supply for aerobic fermentation.</li> <li>Adjust treatment time and temperature.</li> <li>Denitrification, controlled pH adjustment to &gt;6.5 (6.7-7.0).</li> </ul>
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
	Minor				✗				
	(Residues of) chemical substances, such as indicated under hazard analysis above	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
Moderate									
Minor				✗					
Microfiltration of activated sludge	Carry over of substance from activated sludge	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	<ul style="list-style-type: none"> <li>Adjust dosage of alum to the level of phosphate present to precipitate phosphorus.</li> <li>Monitor membrane density, e.g. by flux control.</li> <li>Do not use that supply of MBR water when substances that are foreign to milk persists in the water.</li> </ul>
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
			Moderate						
	Minor			✗					
	(Residues of) chemical substances foreign to milk	LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE		Unlikely	Seldom	Sometimes	Frequent	Always	
		RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe						
Moderate									
Minor				✗					

**TABLE A16** Possible hazards of concern, likely associated risks and possible control options for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	
Carry over of substance from leaks in RO membranes	Carry over of nutrients	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate			○		
			Minor					
	Carry over of micro-organisms	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate		○			
			Minor					
	Carry over of residues of substances foreign to milk	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate					
			Minor	○				
Contamination from biofilm on the permeate side in RO plants, tanks and pipes	Undesirable micro-organisms	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate					
			Minor		✘			

- Monitor that no leaks occurred.
- Visual check of water for light transmittance (RO membrane systems usually have a clear part of the tube for visual inspection of the flow).

Determination of maximum operating time between cleaning and possible disinfection.

UV treatment of MBR water for food contact purposes.

**TABLE A16** Possible hazards of concern, likely associated risks and possible control options for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>						CONTROL OPTIONS
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	
Insufficient UV exposure	Survival of micro-organisms	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate					○
			Minor					
Low liquid level in UV reactor	Reduced UV effect	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					
			Moderate					
			Minor			✗		
Breakage of equipment in UV systems	Glass splinters	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe	✗				
			Moderate					
			Minor					
	Mercury (LMP lamps)	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe	✗				
			Moderate					
			Minor					
LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE								
Unlikely      Seldom      Sometimes      Frequent      Always								
Alarms and automatic flow diversion valve for bypass or in case of lock-down. Disposal of affected water.								
Alarms and automatic flow diversion valve for bypass. Disposal of affected water.								

**TABLE A16** Possible hazards of concern, likely associated risks and possible control options for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

EVENT	HAZARD	RISK/HAZARD MATRIX <sup>a</sup>					CONTROL OPTIONS	
		LIKELIHOOD OF HAZARD OCCURRENCE IN THE REUSABLE WATER SOURCE	Unlikely	Seldom	Sometimes	Frequent	Always	
Microbial growth in MBR water	Undesirable micro-organisms	RISK TO CONSUMER IN THE ABSENCE OF ADEQUATE CONTROL	Severe					Control the shelf-life of the MBR water.
			Moderate			✘		
			Minor					

<sup>a</sup> The above is illustrated using the following symbols:

○ = transfer of the hazard from previous steps.

✘ = the hazard originates in this step.

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.

## Validation<sup>11</sup>

The MBR system should be validated during start-up to demonstrate that the setup will produce intended water quality and to determine the required cleaning frequency and verification parameters. The following validation procedure is recommended, but alternatives that can achieve the same goal can also be used:

- 1) During a test period of up to 3 times the default shelf-life,<sup>12</sup> review the monitoring results of the measures recorded in the hazard control plan. When the data on the process parameters show stable operation and are compliant with the limits, proceed to Step 2.
- 2) Daily sampling of the MBR water (RO permeate) for analysis for COD, conductivity, nitrogen, and ammonium-N. If all samples show compliance with respect to quality parameters, proceed to Step 3. If not, adjust the control measures (lower the limits) and repeat Step 1.

<sup>11</sup> Some elements of “Validation” may be done at laboratory or pilot plant scale, but operational validation ultimately has to be performed at full scale.

<sup>12</sup> For UV treatment before use, and storage without temperature control, the pre-determined shelf life is 4 days (i.e. test period 12 days); For UV treatment before use, storage refrigerated, the default shelf life is 5 days (i.e. test period 15 days); When circulating over UV systems, and storage without temperature controls the default shelf life is 6 days (i.e. test period 18 days); When circulating over UV systems, and storage refrigerated, the default shelf life is 10 days (i.e. test period 30 days).

- 3) (Can possibly be combined with Step 2). Daily sampling from the storage tank or the use site for analysis for coliforms, plant-specific indicators, TPC 22 °C, *Enterobacteriaceae*, psychotropic counts, and *Pseudomonas*. The indicator first exceeding the specified limit is selected as the verification parameter. If no indicator has exceeded the limit at the end of the 3<sup>rd</sup> week, the indicator that came closest to the specified limit is selected as the verification parameter – see Verification plan. Proceed to Step 4.
- 4) The plant is stopped and allowed to stand for 24 hours, after which, 5 samples are taken for a microbiological analysis for *B. cereus*. If the detected levels exceed the specified limits, the relevant process control parameters are adjusted, and Step 1 is repeated.
- 5) Normal operation can be restarted if the results of the analyses in Step 3 showed that the quality requirements have been met.

The system should be re-validated in a timely manner and depending on the specific operational conditions (e.g. the frequency and volume of reuse water supplies being generated and the risk related to hazards not being controlled) but no later than once a year or when significant changes are introduced (e.g. changes in the plan for hazard control, change of cleaning agents used and the possibility of new substances in the dairy wastewater, major maintenance, etc.).

## Hazard Control Plan

**TABLE A17** Details of a hazard control plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
Bioreactor (measured e.g. at inlet to RO plant)	Denitrification is not effective	pH-neutral environment	pH measurement	Ongoing	pH >6.5	Adjust the denitrification process (e.g. dosing of air, pH, temperature, treatment time).
MF/UF (measured e.g. at inlet to RO system)	Insufficient decomposition of organic material	Measurement of indicator of organic material in feed water	Phosphorus measurement	Ongoing	< 1 mg/L	Cause analysis: <ul style="list-style-type: none"> <li>• Assessment of e.g. the course of the fermentation (time, temperature, pH),</li> <li>• The microfiltration</li> <li>• Dosing of alum.</li> </ul>



**TABLE A17** Details of a hazard control plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
RO plants (outlet)	Leakage in the plant (organic materials and microorganisms)	Measurement of permeate	Monitoring that no leaks occur, e.g.: • Conductivity • Turbidity • TOC	Ongoing	Determined by the dairy establishment, adapted to the plant and chosen management strategy.	<ul style="list-style-type: none"> <li>• Causal analysis: <ul style="list-style-type: none"> <li>◦ Inspect membranes and gaskets for leaks</li> <li>◦ Replace leaky parts.</li> </ul> </li> </ul>
	Fouling and building up of biofilm on membranes	Control of fouling on the retentate side and scaling in membranes	Determined by the dairy establishment, adapted to the plant, and chosen management strategy, e.g.: • Pressure control (Feed pressure till normal flux) • Permeate flux • Degree of concentration, e.g. Brix. etc.	Ongoing	Determined by the dairy establishment, adapted to the plant, and chosen management strategy	<ul style="list-style-type: none"> <li>• Emptying (e.g. with compressed air) and CIP of the systems.</li> <li>• Affected MBR water is not used, but can be reworked.</li> <li>• Verification that corrective action is effective; emptying (e.g. with compressed air) and CIP of the systems.</li> <li>• Affected MBR water is not used but can be reworked.</li> <li>• Verification that corrective action was effective.</li> </ul>
			Operating time before cleaning	Determined locally, adapted to the plant and according to validation.	-	-

**TABLE A17** Details of a hazard control plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
UV treatment	Biofilm and microbial growth	UV-dose	Irradiance, pre-set maximum flow rates and UVT ensures an operational minimum dose of 40 mJ/cm <sup>2</sup> ; if necessary, use higher dose	Ongoing (sensor in plant)	Determined locally, depending on UV lamp type	<ul style="list-style-type: none"> <li>Alarm and automatic activation of flow diversion valve when irradiance is low.</li> <li>Rework.</li> </ul>
			Flow rate (if not pre-set to maximum)	Ongoing	> Maximum flow set for the plant as determined by the dairy company in collaboration with the equipment supplier	<ul style="list-style-type: none"> <li>Alarm and automatic activation of flow diversion valve when flow is at too high.</li> <li>Rework.</li> </ul>
			Flow diversion valve	Before start-up	Doesn't work	<ul style="list-style-type: none"> <li>Alarm.</li> <li>No start-up.</li> <li>Service on valve and/or sensor.</li> </ul>
	Low liquid level in UV reactor	Degree of filling	Automatic recording	Ongoing	Determined by the dairy establishment in collaboration with the equipment supplier	<ul style="list-style-type: none"> <li>Alarm in case of low liquid level.</li> <li>Refill.</li> <li>In case of damage, replacement of lamp.</li> </ul>
	Decrease in effect	Measurement by activating the flow diversion	Conductivity or UVT with by flow diversion	Ongoing	<b>Conductivity</b> $\leq 100 \text{ mS/cm}^b$ or <b>UVT:</b> $\leq 95 \text{ percent}$	<ul style="list-style-type: none"> <li>Alarm and automatic activation of flow diversion valve in case of too high conductivity/too low UVT.</li> <li>Rework.</li> </ul>

**TABLE A17** Details of a hazard control plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO (cont.)

CONTROL POINT	HAZARD	RECOMMENDED CONTROL MEASURE	MONITORING PROCEDURE <sup>a</sup>			
			Parameter	Recommended frequency	Recommended limit	Corrective action(s)
UV treatment	Glass splinters	Protect against contamination of the water	Intact glass tubes	Ongoing	Damaged glass	Alarm and automatic activation of flow diversion valve. For UV systems that is within a closed system, stop the line in case of glass breakage, before glass debris reaches products. Emptying and CIP of the affected parts of the system before restart. If there is a risk of mercury in the used CIP liquid, it must be disposed. Assess whether the product may be contaminated. If so, affected product contaminated with glass or mercury must be disposed.
	Mercury					Emptying and CIP of the affected parts of the system before restart. If there is a risk of mercury in the used CIP liquid, it must be disposed.
<b>System (piping, UV system and tanks)</b>						
Storage without temperature control	Contamination from biofilm (e.g. B. cereus)	Cleaning	Operating time (shelf-life)	To be determined locally, per validation	<b>UV treatment before use:</b> Default limit: 4 days <b>Circulation over an UV plant:</b> Default limit: 6 days	Emptying and CIP before restart.
Refrigerated storage	Contamination from biofilm (e.g. B. cereus)	Cleaning	Operating time (shelf-life)	To be determined locally, Per validation	<b>UV treatment before use:</b> Default limit: 5 days <b>UV treatment before use:</b> Default limit: 10 days	Emptying and CIP before restart.

<sup>a</sup> When reference is made to monitoring limits or frequencies being “determined locally” or “determined by the dairy establishment”, the selected values must appear in the Hazard Control Plan.

<sup>b</sup> Can be replaced by turbidity with a limit of 3 FTU or by UVT with a limit of 95%.

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.

## Verification Plan

**TABLE A18** Details of a verification plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Records of monitoring of measures</b>	Check that the data was recorded automatically	Control of documentation	Determined by the dairy establishment	Recording has been done	The measuring and recording equipment are inspected. Any defects are repaired, or relevant parts replaced.
<b>Equipment</b>					
<b>Flow diversion valve for UV system</b>	Contaminated water	Per the instructions of the supplier	Determined locally by the dairy establishment	Working Flow diversion valve	The sensor is replaced or repaired. The UV system is emptied and cleaned before restarting. Drainage water is discarded into drains.
<b>Calibration</b>	Ensure that measurements of temperature, conductivity etc. are accurate	According to local procedure as determined by the dairy establishment			In the event of an off reading, the meter is adjusted/repared or replaced.
<b>Water quality – Chemical analyses (MBR water)</b>					
<b>Total phosphorus</b>	Verification of phosphorus precipitation (separation in the UF plant)	Determined locally by the dairy establishment	In-line with frequency as determined locally by the dairy establishment	<1 mg/L	The dosage of alum is adjusted in the Bioreactor process.
<b>Total nitrogen</b>	Verification of denitrification	Kjeldahl	Monthly	< 5 mg/L	The bioreactor process is adjusted for optimization of the fermentation.
<b>COD in MBR water outlet</b>	Membrane tightness (leaks)	ISO 15705	Monthly	≤12 mg O <sub>2</sub> /L	If level is exceeded, test 3 more samples and if the results are confirmed, do a causal analysis, including an inspection of membranes for leaks and replace the defective parts. Monitoring results are reviewed to find any variations and assess the need for changes in monitoring. The effectiveness of the above is documented by testing 3 new samples.
<b>Conductivity in MBR water outlet</b>	Membrane tightness (leaks)	Suitable conductivity meter	Weekly	≤ 100 mS/cm <sup>a</sup>	If level is exceeded, test 3 more samples and if the results are confirmed, do a causal analysis including an inspection of membranes for leaks and replace the defective parts. Monitoring results are reviewed to find any variations and assess the need for changes in monitoring. The effectiveness of the above is documented by testing 3 new samples.

**TABLE A18** Details of a verification plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Substances identified in the dairy effluents, cf. the hazard analysis</b>	Total purification effect of bioreactor and RO plant	To be determined locally	Monthly	To be established on the basis of hazard analysis	The system is improved. The affected water is not used for food contact surfaces (indirectly or directly).
<b>Water quality – Microbiological analyses (storage tank or site of use)</b>					
<b>Coliforms in MBR water</b>	Indicator of microbiological contamination	Detection (n=1) ISO 9308-1 or ISO 2255	Once every two weeks	Not detected in 100 ml	If detected, a sample is taken from the same batch for <i>E. coli</i> analysis.
<b><i>E. coli</i> in MBR water</b>	Indirect indicator for pathogens	Detection (n=1) ISO 9308-1 or SO 2255	If coliforms are detected	Not detected in 100 ml	If detected, test 3 more samples and if results are confirmed: <ul style="list-style-type: none"> <li>• Search for the cause,</li> <li>• the cleaning procedure is reviewed, and the system is emptied and cleaned,</li> <li>• temporarily intensify verification and increase sampling frequency for coliforms (e.g. sample the first and the last batch in the process).</li> </ul> If results are negative, no further action is needed. The effectiveness of the above is documented by testing 3 new samples.
<b><i>B. cereus</i> (vegetative cells and spores) in MBR water stored</b>	Indicator of biofilm	Detection (n=1) ISO 7932 or ISO 21871	Monthly	≤ 1 cfu/ml	If detected, test 3 more samples and if results are confirmed, search for the cause, including assessment for the need to: <ul style="list-style-type: none"> <li>• Change separation values in conductivity-controlled valves.</li> <li>• Effectiveness of the MBR system.</li> </ul> The effectiveness of the above is documented by testing 3 new samples.

**TABLE A18** Details of a verification plan for the recovery and reuse water supplies obtained from dairy effluents using MBR and RO

PARAMETER	PURPOSE	METHOD	RECOMMENDED FREQUENCY	ACCEPTABLE RESULT	FOLLOW-UP
<b>Hygiene indicator selected by validation</b> (The indicator that determined the cleaning frequency during the validation is selected as the verification parameter)	Accumulation of microorganisms	Enumeration (split sampling) ( $n=1$ )	Once every two weeks	$\leq M$	If $M$ is exceeded, test 3 more samples and if the result are confirmed, do a causal analysis and the effect of the system (e.g. greater flux) is reassessed. If the exceedance is very large (e.g. $5 \times M$ ), the system is emptied and cleaned. The effectiveness of the above is documented by testing 3 new samples.
		“Moving window” on weekly results	The recent 5 analysis results are compiled continuously	Out of 5 (= $n$ ) consecutive results, a maximum of 2 (= $c$ ) may be between $m$ and $M$ .	If “ $c$ ” is exceeded (over the last 5 tests), search for the cause, and appropriate corrective actions are taken (e.g. extra cleaning). If limits are exceeded repeatedly, consider reducing the shelf life.
		Trend analysis	Quarterly review of recent year’s results	No patterns of high numbers or changes in the frequency of violations.	Patterns can give a clue as to the cause so that targeted action can be taken. In the event of a negative trend, corrective actions shall be taken (e.g. thorough cleaning) and temporary intensify verification by increasing the sampling frequency (e.g. sample the first and the last batch in the process).

<sup>a</sup> mS = milli Siemens.

<sup>b</sup> The use of moving windows to verify compliance with microbiological criteria has been described (ICMSF, 2018. Microorganisms in Foods 7. Microbiological Testing in Food Safety Management. Second Edition. Springer, Cham, Switzerland. **FAO & WHO**. 2013a. Codex Alimentarius. Principles and guidelines for the establishment and application of microbiological criteria related to foods. CAC/GL 21 - 1997. Rome, FAO. Accessed 24 July 2022. [https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fstandards%252FCXG%2B21-1997%252FCXG\\_021e.pdf](https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fstandards%252FCXG%2B21-1997%252FCXG_021e.pdf)). It appears from this that moving windows are used for continuous verification of the entire system and not for the approval of specific lots. The follow-up of results included in moving windows is thus targeted at the system and not at the specific batches from which the sample was taken. If there is a need to assess a specific batch, sampling is performed without the sample being split.

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.

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- 43 Prevention and control of microbiological hazards in fresh fruits and vegetables - Part 3: sprouts: meeting report, 2023

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Water is used for a wide range of activities in the dairy sector, which consumes a substantial volume of first-use drinking water for production processes, cleaning and disinfection. There is a great potential to exploit possible sources of reusable water in the dairy sector.

In 2020, the 43rd session of the Codex Alimentarius Commission approved the new work entitled “Development of Guidelines for the Safe Use and Reuse of Water in Food Production” proposed by the 51st session of the Codex Committee on Food Hygiene. To support this work, the Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) was asked to provide scientific advice regarding safe use and reuse of water in the dairy sector. JEMRA convened an online meeting from 14 June to 2 July 2021 to provide clear and practical guidance on risk-based approaches to assess and manage fit-for-purpose water sourcing, use and reuse in the dairy sector. This report describes the output of this meeting to support the decision-making when applying the concept of fit-for-purpose water for use in the production and processing of dairy products.

Food Systems and Food Safety - Economic and Social Development

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