Food and Agriculture Organization of the United Nations

World Health Organization

Joint FAO/WHO Expert Meeting on Microbiological Risk Assessment (JEMRA) on the Safety and Quality of Water Used in the Production of Dairy Products

Virtual Meeting

14 June – 2 July, and 8 July 2021

SUMMARY

Issued on 8 November 2021

The Codex Committee on Food Hygiene (CCFH) has recognized the importance of providing science-based guidance on assuring consumer food safety related to use and reuse of water in food production and processing since 2016. To address the CCFH's request for scientific advice on determining appropriate, sector-specific, fit-for-purpose advice on water sourcing, use and reuse, FAO and WHO convened a JEMRA meeting on the safety and quality of water use and reuse in the dairy sector (note: a JEMRA meeting on the Safety and Quality of Water Used in the Production of Fishery Products was convened concomitantly).

If conditions had permitted, this meeting would have been held at WHO headquarters in Geneva, Switzerland. Because of the travel restrictions and lockdowns due to the COVID-19 pandemic in many countries, the joint FAO/WHO secretariat was unable to convene a physical meeting. Therefore, the meeting was held as a videoconference using a virtual online platform.

Dr Leon Gorris served as Chairperson.

Dr Claus Heggum served as rapporteur.

This document summarizes the situation analysis and recommendations concerning water use and reuse in dairy production and processing. The full report of the meeting will be published as part of the FAO and WHO Microbiological Risk Assessment (MRA) Series. The meeting participants are listed in Annex 1 of this summary report.

More information on this work is available at:

http://www.fao.org/food-safety/en/

and

https://www.who.int/foodsafety/en/

Background and objectives

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, 2020). To support this work, JEMRA was asked to provide scientific advice on sector-specific applications and case studies for determining appropriate and fit-for-purpose microbiological criteria for water sourcing, use and reuse in:

- fresh produce,
- fish and fishery products from primary production to retail, and
- in the dairy sector from milk harvest to manufacturing.

The purpose of the meeting was to provide clear and practical guidance on the criteria and parameters that can be used to determine if water is fit-for-purpose for sourcing, use and reuse in the dairy sector.

Situation analysis concerning water use and reuse in the dairy sector from the expert meeting

Water is used for a wide range of activities in dairy operations, and the sector 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 could be reused that:

- is part of a dairy product (e.g. in milk powder or cheese manufacturing);
- has come into an operation as drinking water and is recirculated until not suitable anymore;
- has been used for cleaning of the food processing operation or other parts of a facility; and
- is part of an effluent of a dairy operation.

The application for which water is intended to be reused, will determine whether that water is fit-for-purpose as it has been recovered, or whether a particular reconditioning (e.g. purification, treatment) is required before it can be used.

Controlling the reuse water generation process as part of the dairy operation has to be within the operators' capabilities. The operator needs to control all potential hazards (including chemical, biological and physical) associated with the source of reusable water exploited considering the intended application of the reuse water.

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

- the microbiological status of the potential reusable water source;
- the microbiological requirements associated with the reuse water application to ensure the safety of the finished product;
- the microbiological suitability of the reuse water generation processes (i.e., the combinations of technologies, equipment and infrastructure for water recovery, reconditioning, and storage);
- Also critical are the need to control the reuse water generation process and application and the role of microbiological testing for validation and verification; and
- the expertise available to ensure day-to-day control of reuse water generation processes and water reuse at the facility's scale.

An assessment of potential microbiological hazards and a risk management approach for achieving effective control should support the design of the process 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:

- to consider both microbiological hazards present in the source of reuse water as well as hazards associated with other parts of the operation (e.g. factory environment; storage and distribution system) that could contaminate the reuse water supply once generated;
- to account for nutrients present in the reuse water supply after recovery and (possible) reconditioning which may foster growth of spoilage organisms (limiting shelf-life) or of microbiological hazards (possibly related to consumer risk, depending on the reuse water application);
- to determine that when reuse water is recycled or recirculated multiple times in a specific process operation, there is a possibility of biofilm formation;
- to establish whether any specific measure for the preservation or control of microbial growth is required over the set shelf-life of the reuse water supply; and
- to consider the need for a back-up fit-for-purpose water supply, such as drinking water, that can be used in case the reuse water generation process is not under control or fails.

Once a reuse water generation process and the fit-for-purpose reuse water application have been decided on, these need to be implemented and controlled ensuring the safety of the final food produced in cases when reuse water may come in contact with food or food contact surfaces.

There are clear similarities in the way a food operation controls food safety and the supply of reuse water. In both cases, a risk- and evidence-based approach is followed at the stage of designing the overall operation and operationalizing the required control at full-scale. For the food operation, control measures to ensure that water reuse is fit-for-purpose when used in direct contact with food or food contact surfaces will be necessary. Such measures would include provisions that not fit-for-purpose water would come in contact with food or food contact surfaces.

Operational control of reuse water supplies consists of basic prerequisite programs (including water distribution logistics and marking to minimize errors) and validated hazard control plans to control the generation and storage process, including monitoring and verification procedures to manage the day-by-day operation.

Hazard control plans for a reuse water generation process should be based on several steps of hazard analysis:

- identifying the known or potential hazards that the water to be reused might have acquired through its earlier application;
- identifying hazards possibly contaminating the reuse water in the course of the reuse water generation process, storage and use; and
- assessing the potential risk that the above identified hazards pose, based on the likelihood of their occurrence and concentration in the reuse water. The latter depends on the recovery or reconditioning process, storage conditions and the measures applied to reduce the hazards to acceptable levels.

Given that the microflora differs from operation to operation, it is recommended to validate the reuse water generation process, including the shelf-life of the water, and choose locally specific hygiene indicators for verifying process control.

The validation provides evidence that the reuse water generation process delivers a fit-for-purpose water supply containing no significant hazards when intended for an application involving exposure to food or food contact surfaces. Validation ultimately needs to cover the full-scale operation to generate and store reuse water supplies (where relevant, for each scenario of water reuse operated) and typically conducted under actual dairy processing conditions of the particular operation.

During operation, the reuse water generation process should be monitored in day-to-day operation, including timely verification of its microbiological status, in order to prove the ongoing control of the process and thus the suitability of the reuse water supply, or to be able to take timely action should the process performance require this.

For monitoring, physical or chemical parameters may typically provide timely results concerning ongoing process control or for identifying trends and taking prompt action when needed.

For verification purposes, microbiological testing and analysis based on utility organisms (e.g. total viable counts) or hygiene indicators (e.g. coliforms) have proven useful. Given that the microflora relevant for the reuse of water is plant and operation specific, it is generally not appropriate to rely solely on testing microbiological parameters that typically apply to drinking water, such as levels of coliforms, when these are not relevant in the context of the particular dairy operation. It is more appropriate to conduct an operation-specific study to determine what indicator(s) could be used for signalling control of the reuse water generation process or the need to take action.

Technical expertise and knowledge of the microbiological profile of reusable water sources, the food safety requirements of the finished food product associated with the fit-for-purpose application(s) and the technologies to generate the appropriate reuse water(s) are all vital for safe reuse of water in food operations. Suppliers and solution providers may provide such expertise and knowledge. However, this does not take away the responsibility of the management of the food business operation for the safety and suitability of its food products.

This report focuses on microorganisms that may pose health risks to consumers through the final product when not adequately controlled. Limited guidance is provided for other microorganisms, such as those that potentially affect worker health (e.g. *Legionella*), that impact on food quality/stability or that may cause animal health disease when spread through reuse water generation or use (e.g. Foot-and-mouth-disease virus), as well as concerning chemical or physical hazards. However, effective operational control measures will have to be put in place by the food business operator to prevent or control these hazards and ensure product safety, stability and quality as well as occupational safety.

Notably, when designing a water reuse operation, regulatory requirements and advice of competent authorities need to be carefully considered.

General recommendations concerning the implementation of water reuse in dairy operations

A water reuse scenario needs to be tailored to the specific conditions of the particular food operation that it is applied to, taking into account its specific source(s) of water to generate reuse water from, its potential application purposes, available recovery and (when necessary) reconditioning technologies, and the capabilities of the operator.

For each possible water reuse scenario, it is recommended to consider the following specific points in assessing and managing microorganisms:

- assess the relevant hazards and associated risks of a reuse water supply for the particular fit-for-purpose application(s), which can be done at the design stage and/or at full-scale implementation of the reuse water generation process;

- based on the assessment of hazards and risks, evaluate options available to the operator to manage the generation of the reuse water such that there is adequate control of the reuse water supply or that back-up water supplies can be utilized, when needed;
- that the operator validates the reuse water generation process in view of the intended purpose of the reuse water; where it is intended for direct or indirect food applications, microbiological requirements are to be met for the finished food product;
- establish adequate monitoring and verification procedures, allowing evidence of control of the reuse water generation process and enabling timely action to trigger back-up water supplies; and
- to consider conditions or factors that are conducive for microbial growth and persistence, such as nutrients present in reuse water after recovery and reconditioning; biofilm formation due to multiple subsequent uses of a reuse water source (in recirculation or recycling applications); and the need for additional measures to control shelf-life during storage of reuse water.

For each water reuse scenario that is to be implemented in a particular dairy production or processing operation, it is recommended to:

- validate at full-scale that the reuse water generation process and the storage of the reuse water, where relevant, deliver a fit-for-purpose supply of reuse water for the intended purpose;
- put in place the necessary monitoring procedures to enable ongoing control over the process and storage operation and to trigger timely action when required;
- establish timely verification of the microbiological control over the reuse water generation process and storage operation using relevant microbiological parameters;
- assure that the logistics of distribution of different water types/qualities in the food minimize operator errors; and
- put in place contingency plans and procedures to deploy suitable alternative water supplies (e.g. first-use drinking water) when needed.

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

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

However, microbiological sampling and testing are appropriate for validating the reuse water generation process and may be useful for operational control trend analysis.

Importantly, microbiological parameters (utility organisms; hygiene indicators; pathogens and their reference levels) chosen should be relevant for validation or for verification in the specific context of the particular dairy operation.

To plan the most suitable approach of verification, including trend analysis for each water reuse scenario of a particular dairy operation, it is recommended to conduct a validation (ultimately during start-up) to identify the level of specific, relevant microbiological indicators and to select one of these for routine verification purposes.

The appropriateness of using microbiological testing against particular microbiological parameters depends on the purpose of testing and needs to be fit-for-purpose too.

Considering a reuse water to be the end product of a reuse water generation process and storage operation, it is recommended to give consideration to microbiological testing for the following four types of water application/purpose:

- Reuse water intended for use without any food contact (e.g. water for gardening; extinguishing fire; cleaning non-food transport vehicles):
    - These do not need microbiological testing for food safety but may need monitoring of microbiological hazards relevant for occupational safety.

- Scenarios with reuse water not intended for contact with food or food contact surfaces, for instance water used for rinsing/flushing and cleaning steps of the CIP (excluding final rinse), make-up water for non-food contact cooling and steam applications, water used for cleaning of the exterior of processing equipment not in contact with food materials, etc.:
    - If the operational design ensures that such waters do not contact food, there is no need for microbiological testing related to the safety of the final food product. (Still, monitoring for occupational safety may be required).
    - If the operational design does not exclude possible food contact, microbiological testing in the context of validation of the design and verification of control during operation is relevant to the safety of the final food product.

- Scenarios with reuse water in direct (intentional) contact with food or food-contact surfaces, such as water used for rinsing steps of the CIP (including final rinse), water used for cleaning of food processing and transport equipment, diafiltration, brine for cheese making, ice and steam in contact with food materials:
    - Microbiological testing of the reuse water supply in the context of validation of the design and verification of control during operation is relevant for the safety of the final food product.
    - When such water is at temperatures between 25 and 55°C and personnel is exposed to aerosols, occupational safety monitoring may also be relevant.

- Water used as a food ingredient that, in dairy operations, typically include water used for rinsing steps of the CIP (including final rinse), process and curd washing water, ingredients in dairy products, ice and steam, water removed during washing of casein/whey protein, water for direct cooling of cheese, cleaning of membrane filtration systems, diafiltration of milk products, etc.:
    - Microbiological testing in the context of validation of the design and verification of control during operation is relevant to the safety of the final product.

Microbiological criteria concerning relevant microorganisms of concern (for safety/spoilage) and indicators of operational control may be useful for validation of the design (including measures of control for reuse water generation and storage/shelf-life) and for out-of-control situation analysis and management.

Microbiological limits/thresholds may be useful for verification of operational control and to document that the reuse water quality is adequate for its intended use and does not deteriorate with time over the established shelf-life.

The appropriate microbiological limits/thresholds or microbiological criteria in quantitative terms and the recommended microorganism or group of microorganisms should be established on a case-by-case basis as specifics of the reusable water source, recovery/reconditioning approach and fit-for-purpose application need to be considered.

It is obvious that reuse water that may come into contact with food shall be free of pathogens that could cause a risk to consumers of the product from the dairy operation. Pathogen testing may be most relevant in the context of validating the reuse water generation process and establishing a suitable shelf-life in storage. Verification by routine testing for pathogens in dairy reuse waters is not practical, as the likelihood of any such hazards being present typically is very low.

Microbiological indicators (e.g. total counts, *Pseudomonas* spp.) would more likely be present at levels that can be quantified and can signal whether operational control is adequate or whether it may be not adequate or trending in that direction.

When an operation fails, pathogen testing may be relevant; for instance to assess the out-of-control situation and measures to regain control. Examples of operational failure could, for instance, include leakages of membranes in purification systems, inadequate antimicrobial treatment impact, as well as post-process contamination of the reuse water. Hazard analysis and assessment of risks should demonstrate the need for pathogen testing for validation, verification and out-of-control situations.

It should be considered that, while testing for indicators of operational failures may be useful, chemical parameters (such as TOC, COD, turbidity or conductivity) can be used as alternative signals of control or failure. The benefit of using chemical parameters is that results will be available quickly (immediately in case of on-line measuring) and that they often are less costly.

References

FAO and WHO. 2020. *Codex Alimentarius Commission*. Report of the 51st Session of the Codex Committee on Food Hygiene. Guidelines for the Safe Use and Reuse of Water in Food Production. http://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FMeetings%252FCX-712-51%252FReport%252FREP20_FHe.pdf.

Annex 1: List of participants

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