



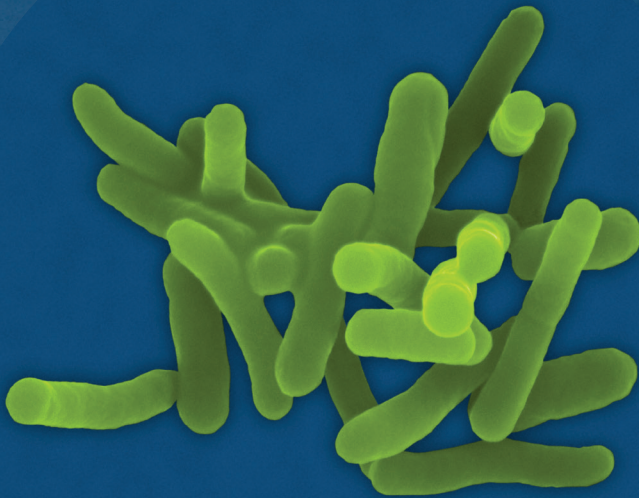
Food and Agriculture
Organization of the
United Nations



World Health
Organization

Safety and Quality of Water Used in Food Production and Processing

MEETING REPORT



33

MICROBIOLOGICAL RISK
ASSESSMENT SERIES

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Food and Agriculture Organization of the United Nations
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Declarations of interest

All participants completed a Declaration of Interests form in advance of the meeting and, based on the information provided, four experts participated as technical resource persons.

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

AMR	antimicrobial resistance
CAC	Codex Alimentarius Commission
CCFH	Codex Committee on Food Hygiene
CCP	critical control point
CFU	colony forming unit
DALYs	disability-adjusted life years
DSS	decision support systems
DT	decision tree
EC	European Commission
EFSA	European Food Safety Authority
EU	European Union
FAO	Food and Agriculture Organization of the United Nations
FDA	Food and Drug Administration
FSMS	Food Safety Management System
GAP	Good Agricultural Practices
GDWQ	Guidelines for Drinking Water Quality
GHP	Good Hygiene Practices
HACCP	Hazard Analysis and Critical Control Points
ILSI	International Life Sciences Institute
LGMA	California Leafy Green Products Handler Marketing Agreement
NACA	Network of Aquaculture Centres in the Asia-Pacific
QMRA	quantitative microbial risk assessment
RA	risk assessment
WHO	World Health Organization
WSP	water safety plan
USA	United States of America

Executive summary

Water is a major input in food, from primary production through all stages in the food value chain to consumption. Water can contact food directly or indirectly and is used in maintenance of hygiene and sanitation throughout the food chain. Water is a diminishing resource globally and not all food primary producers and processors have access to safe water sources. Water needs to be used conservatively and it is possible to reuse water if it does not present a health risk for consumers. At its 48th session in November 2016, the Codex Committee on Food Hygiene (CCFH) noted the importance of water quality in food production and 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” was indicated in Codex texts – in particular, for irrigation water and clean seawater – and on the safe reuse of processing water. In addition, guidance was sought on where it is appropriate to use “clean water”.

The first meeting of Experts was held in Bilthoven, The Netherlands, in 2017, to address this request. The Experts concluded that future work should focus on the following:

- development of a fit-for-purpose concept, taking into consideration the context of water uses along the food chain;
- focus on the priority sectors – fresh produce, fishery products and reuse of water in food operations – chosen based on their significance in health protection and global trade;
- review of existing guidance materials in food and water safety in consultation with experts with relevant expertise to exploit synergies between these areas and to ensure relevance for the food industry;
- practical guidance provided through the use of decision support system (DSS) tools, such as a decision tree (DT), incorporating assessment of risks and use of monitoring to ensure safe quality of the water;
- other end products, such as communication tools for end users.

A second meeting of Experts was held at FAO in Rome, Italy, in 2018, to address the work recommended. Working groups were formed for the three priorities for water use and safety – i.e. fresh produce sector, fishery sector and water reuse in establishments.

A summary of the 2018 meeting is provided in this report.

Reviews were prepared on current guidance and knowledge on water use and safety for the fresh produce and fishery sectors and water reuse in food establishments, and also on risk management approaches to ensure the safety of water and food supplies. These reviews provided background information for the experts to consider in development of a fit-for-purpose concept and DSS approaches.

The meeting emphasized the importance of sustainable management of global water resources, which are under stress from population growth and environmental challenges. Some farmers, food handlers and food processors do not have access to safe water, while for others, safe water access and waste discharge are incurring increasing financial and environmental costs, so minimizing water use and waste, and reusing water are highly desirable. Current guidance on water safety during primary production and further food handling and processing from Codex, international agencies and competent authorities, is inconsistent and not readily operationalized by food businesses.

There are similarities in the principles of risk management approaches taken to ensure safe drinking water and safe food. For example, they should be risk- and evidence-based, with risk reduction measures implemented within the framework of an overall water safety plan (WSP) or a structured food safety management system (FSMS) based on prerequisite hygiene and Hazard Analysis and Critical Control Points (HACCP) programmes, with verification and monitoring required to ensure the plans/systems are operating as expected. However, in food production, there are additional complexities that have to be addressed, related to the high level of diversity and variability in food products, primary production and processing systems, water/food/microbe interactions, microbial hazards and the factors influencing their presence and control at different stages along the supply chain, and the end use of food products.

The safest option in food production might be the use of water of potable or drinking water quality; however, this is often not a feasible, practical or responsible solution and other types of water could be fit for some purposes provided they do not compromise the safety of the final product for the consumer. Risk management plans addressing food safety and water use or reuse have to consider many factors in their development and implementation; additional factors to be considered could include occupational safety for workers, need for special expertise, investments, cost-benefit analyses and management of consumer perceptions.

DSS tools, such as decision trees DTs or matrices, were considered to be useful risk management tools to assist stakeholders in making decisions on the water's fitness for purpose and the required quality (potable water or other suitable quality) for use or reuse at a given step in the supply chain. Importantly, such DSS tools should be

based on an assessment of final health risks of the food at consumption and address the context for water use at a particular step and location. There is a significant amount of diversity in food production, as illustrated in the scenarios addressed at the meeting. Examples include: the food types involved; the food-water interactions; the specific water-borne food safety hazards; and their likelihood and magnitude of transmission to the consumer when present in different foods. This means it was not possible to have one DSS approach fit for all uses of water in food production and that each application of water would need to be addressed in a context-specific manner. High-level risk-based DTs with direction to further guidance were developed for fresh produce, fishery products and water reuse scenarios. This report gives a general approach for these scenarios and may be applied directly but, in most of the cases, the implementation of this system would require evaluation and refinement in specific case studies before its acceptance.

Recommendation: In Codex documents there needs to be a greater emphasis on a risk-based approach to safe water use and reuse. In Codex texts, rather than specifying use of potable water, or in some instances other water quality types, a risk-based approach and assessment of the fitness of the water for the purpose intended should be articulated.

Cross-cutting issues were identified by the three groups in addressing the scenarios.

Standardized criteria for the microbiological quality of safe water used in primary production and processing of food need to be addressed as currently there is a lack of guidance for the various types of water used in the food industry along the value chain for verification and validation, and for operational and surveillance monitoring. Where criteria are recommended, there are inconsistencies among competent authorities in different countries. Microbial indicators are most commonly enumerated as an alternative to pathogen (bacteria, viruses, parasites) detection in water; however, there is no universal agreement on the most appropriate microbial indicator species or groups and their target levels for the range of hazards in the many different contexts, and the scientific rationale for this is complex and controversial.

Key points noted include:

- microbiological criteria should be risk-based and established, taking into account Codex guidance on risk management and risk metrics and in an incremental manner;
- levels of *E. coli* alone are not an appropriate measure of water quality when assessing safe water use in food safety as it is not considered an appropriate surrogate for the diversity of bacteria, viruses and parasites that may be present and for determining their fate in the environment or during water treatment;

- the range of common criteria currently in use could be reviewed; criteria providing a high-level approach could be sought followed by more specific criteria;
- the feasibility of sector-specific criteria could be explored using the same approach as for a WSP. Some sectors have specific hazards – e.g. marine microorganisms in seafood. Tools are required for in-field and on-line use;
- limited potable water resources in many countries and lack of access to safe water and sanitation are challenges to be addressed when establishing any microbiological criteria.

Recommendation: Further work should be conducted to consider appropriate microbiological criteria.

Knowledge and data gaps limit application of risk-based approaches and introduce uncertainty. There is a lack of understanding regarding the behaviour and persistence of microbial hazards introduced via water, the interaction of water with the diverse range of products and in different environments at different steps along the supply chain, the effectiveness of risk reduction measures at these steps to improve water quality, and of unforeseen contaminations in water reuse. Qualitative, and particularly quantitative, data for use in risk assessments are very limited and, in some regions, non-existent.

Communication tools including education and training and programmes to encourage behaviour change were identified as essential requirements for effective risk management of safe water use in food chains. The concept of a fit-for-purpose approach and the implementation of guidance in the use of DSS and other tools will only be effective if food chain actors appreciate the value of this approach for their operations.

Appropriate terminology should be used when communicating safe water recycling activities in food production and processing to the food industry, customers, regulators, the public and others to reduce perceptions that water reuse will result in an unsafe product.

Recommendation: Ways to achieve behaviour change and acceptance of a fit-for-purpose concept and approach should be investigated.



Introduction

At its 48th session in November 2016, the Codex Committee on Food Hygiene (CCFH) noted the importance of water quality in food production and processing. The Committee asked the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO) to provide guidance for those scenarios in which the use of “clean water” was indicated in Codex texts – in particular, for irrigation water and clean seawater – and on the safe reuse of processing water. In addition, guidance was sought on where it is appropriate to use “clean water”.

The initial review conducted by FAO and WHO highlighted the fact that existing guidance primarily targets water and sanitation managers and identified a gap in areas relevant to food safety managers that needed to be addressed, taking into consideration some of the specific situations in which water is used along the food chain. There are a number of issues of concern in relation to water use in the food sector. Many primary producers and food processors and handlers have challenges in accessing potable or safe water; access to safe water and consistent access to water for food production and processing cannot be taken for granted by anyone. This is exacerbated by the increasing frequency of extreme weather events (drought, flooding, etc.) which impact the availability and quality of water and exert greater pressure on water resources. In addition, the food industry is facing increasing costs and challenges in managing wastewater and making optimal use of this resource. In this context it was considered timely to begin looking more closely at the quality of water used in the primary production and food processing

chain to better identify and optimize the use of available water resources without compromising the safety of the finished food product.

There are two water quality categories used in Codex: “potable” and “clean”, where clean is considered of lower quality than potable. The term “clean water”, defined by the Codex Alimentarius Commission (CAC) in CXC 53-2003 (CAC, 2003a) as “water which does not compromise the safety of the food in the context of its use”, is used in a number of Codex texts. The challenge for those competent authorities or others implementing Codex standards and guidelines is how to translate this guidance recommending the use of clean water into operational guidance/targets for primary producers and food processors, allowing them to monitor such targets as part of their food control/food safety management programmes.

PROCESS

To address the request from CCFH, FAO and WHO established a core group of multidisciplinary experts on food and water safety and quality. It was anticipated that the work plan would progress over 2-3 years. The core group of experts would provide oversight and input to the implementation of the work plan relevant to their expertise. Other experts would be invited to provide input as required.

The first meeting of this joint FAO/WHO core group of experts was held in Bilthoven, The Netherlands, from 21-23 June 2017, and served as the starting point for addressing the CCFH request on water quality guidance for primary production and processing of food.

The conclusions and areas for future work identified at this meeting were:

a. The concept of “clean water” as fit for purpose

The requirements for water quality use along the food chain must be considered in context, taking into account the purpose of the water use, potential hazards associated with the water use and whether there is any subsequent measure to decrease the potential for contamination further along the food chain. The availability of water and water quality are different in each country, region, context, setting and food establishment, and improvement in water quality should be incremental, as proposed in WHO’s approach to drinking water safety. While water quality will be different in each context, it can be fit to use for certain purposes. Deciding whether water is fit for purpose, assessment of the source water, potential hazards linked to this water source, treatment options and their efficacy, multiple barrier processes and the end use of the food product (e.g. if eaten raw) must be considered.

b. Water use and reuse in different sectors

The priority of sectors was considered by the working group from the perspectives of health protection and global trade.

Fresh produce. Many food-borne disease incidents have been attributed to contaminated fresh fruits and vegetables and contact with contaminated water on-farm and post-harvest has been a contributing factor. Water used in primary production of fresh produce was considered important as this is a major sector that uses reclaimed water for irrigation. Both irrigation and post-harvest water use will be considered.

Fishery products. The fit-for-purpose water will differ in different contexts and should consider whether fish are dead or alive, whole or filleted, and if fish is eaten raw or cooked.

Reuse of water in a food establishment. The focus will be on water reuse within an establishment and, in a broader context, wastewater use. Water reuse is considered a priority as this is becoming an emerging issue in industry due to increasing requirements for and costs of water discharge and the acceptability of the products produced for global trade.

The core group of experts also noted the following:

- Many guidance documents are already available from WHO and elsewhere; however, because they vary in terms of relevance to food production, screening is necessary. The existing sector-specific guidance documents will be reviewed, involving additional sector-specific experts and including consultation from industry to support this work;
- Approaches to food safety management have been adapted to the water safety environment highlighting the strong existing synergies between the two areas;
- In the context of food processing, an important aspect of water quality, as with food ingredients, is the nature of the relationship with the water supplier, who can sometimes be an important source of information when undertaking the steps described.

c. Risk assessment and monitoring

Risk assessment and monitoring is an overarching issue that applies to all sectors and is required for defining fit-for-purpose water. There are many guidance documents already available in this area. In view of the importance of building on existing work, review of existing documents for the purpose of extracting key points relevant to food safety managers will be conducted.

d. Decision tree approach

For practical guidance, a decision tree (DT) approach with underlying risk assessment (RA) will be considered a useful decision support systems (DSS) tool to identify opportunities for levels of log microbial reduction required for water to be considered fit for purpose. In view of the importance of building on existing work, a review will be conducted of existing documents on this approach and key points relevant to food safety managers extracted.

e. Other end products

Communication tools for end users are highly recommended and may be required.

MEETING BACKGROUND MATERIALS

A series of background reviews were prepared for the meeting. There is a large volume of information available and key points only are summarized below under the subject areas requested of the reviewers. Annex 1 provides lists of key reference materials that support the summaries in sections 2-5.



Key elements relevant for safe water use as part of a food safety management programme in food production

CAC (2003), WHO (2006b), other international organizations (e.g. ILSI, 2008), and competent authorities have provided guidance on safety requirements for use of water when handling food.

The general principles of food hygiene of Codex (CXC 1-1969 Rev.4-2003) (CAC, 2003b) include the following guidelines:

- Only potable water should be used in food handling and processing, with the following exceptions:
 - > for steam production, fire control and other similar purposes not connected with food; and
 - > in certain food processes, e.g. chilling, and in food handling areas, provided this does not constitute a hazard to the safety and suitability of food (e.g. the use of clean seawater).
- 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. The treatment process should be effectively monitored. Recirculated water that has received no further treatment and water recovered from processing of

food by evaporation or drying may be used, provided its use does not constitute a risk to the safety and suitability of food.

- As an ingredient; potable water should be used wherever necessary to avoid food contamination.
- Ice used in direct contact with food should be made from potable water. Steam used in direct contact with food or food contact surfaces should not constitute a threat to the safety and suitability of food. Ice and steam should be produced, handled and stored to protect them from contamination.
- Potable water should be as specified in the latest edition of WHO Guidelines for Drinking Water Quality, or water of a higher standard).
- An adequate supply of potable water with appropriate facilities for its storage, distribution and temperature control should be available whenever necessary to ensure the safety and suitability of food.



Water use in different sectors: Fresh produce

2.1 PRE-HARVEST

2.1.1 Map of where and how water is used

- Agriculture exerts major pressure on global renewable water resources (from 66% to 95% of global freshwater withdrawals), with 21 percent of total cultivated land under irrigation. Significant differences in water withdrawal occur between countries and in sector usage within countries.
- Potential uses of agricultural water include irrigation and fertilization as well as many other diverse foliar applications.
- Growers use a variety of water sources for field operations and irrigation. Knowledge is needed to be able to characterize risk factors and conditions associated with the survival and transport of pathogens by different water sources, pathogen concentrations, water and wastewater treatments and other conditions of water use.
- Potential sources of agricultural water are surface water, groundwater, rainwater and reused water. In arid and semi-arid areas, a significant portion of irrigation water is wastewater (treated and untreated).
- The microbiological quality of agricultural water depends mainly on the water source and distribution systems. Irrigation water sources can be ranked by increasing risk of microbial hazards as follows: potable or rainwater, deep groundwater, shallow groundwater, wells, surface water, and raw or inadequately treated wastewater.

- Growers can use several types of irrigation systems to irrigate crops, including drip, furrow and overhead irrigation. Experimentally, subsurface irrigation methods appear to lower contamination risk, compared with spray and surface irrigation methods. The rate of elimination of microorganisms in water, crops and the environment is influenced by multiple factors.
- Currently, there is not enough information on the microbiological quality of irrigation water and related risk factors, and baseline data is needed to adequately characterize the range of risks.
- Data identified for the microbiological quality of agricultural water types can depend on the specific systematic review; variations have been observed in the parameters analysed and the ranges of values varied widely within and between countries.
- Challenges in this area include:
 - > lack of conclusive and consistent correlation reported between microbial loads in irrigation water and the microbiological quality of irrigated fresh produce;
 - > lack of agreement on microbial parameters for assessing water quality fit for pre-harvest use – i.e. choice and use of indicator microorganisms can differ and thus be controversial;
 - > limited agreement among authorities on microbiological criteria, guidelines and regulations for use of these parameters in risk management;
 - > limited understanding about the fate of pathogens in water and their presence, transfer and survival on irrigated fresh produce;
 - > stringent quality assurance schemes imposed by retailers of produce that are used as a prevention strategy based on either spoilage microbes, pathogens or both and also as a marketing tool.
- Growers need to be aware of the microbiological quality of the irrigation water they use in their site-specific context. If they only have access to water sources of moderate to low quality, they should treat the water before use or reduce/eliminate contact of the fresh produce with such irrigation water.

2.1.2 Decision support systems that are relevant to food safety

- There are decision support systems (DSS) available from WHO, FAO, national competent authorities, industry groups, international organizations and academics to identify whether agricultural water is of appropriate quality for its intended use. Two approaches are common to decision trees (DTs).
 - > Minimal requirements for agricultural water either recommended or mandated based on foliar or non-foliar application of the agricultural water combined with the results of microbiological testing (United States of America, USA). This approach is under consideration by the USA Food and Drug Administration (FDA) for produce irrigation water.

- > An approach based more on the source of agricultural water – particularly if the water is coming from a vulnerable source – and whether it is contaminated or not (European Union, EU). This approach has been considered in EU areas where agricultural practices are diverse.
- Key elements of DTs identified were:
 - > characterization of water sources and the distribution and use systems to identify the risks linked to the site-specific water source;
 - > identification of the risk based on the type of application (foliar or non-foliar) and the type of crop (e.g. leafy greens versus fruit trees);
 - > testing/monitoring based on quantification of generic *E. coli*;
 - > frequency and stringency of sampling, in some cases defined according to the identified potential risks.
- Most DTs include simple yes/no answers. The most complex ones include identification of critical control points (CCPs) in water reuse systems.
- DTs can be designed with additional information to help the growers understand the risks and the potential interventions that are available; this approach is highly recommended.

2.1.3 Water quality targets

- Growers may need to be assisted in determining the risks associated with agricultural water and its use, knowing how to conduct a water sampling programme and, if needed, choosing the best mitigation option to reduce pathogens in their site-specific context.
- There is a lack of agreement among competent authorities with respect to irrigation water for fresh produce in terms of the optimum microbiological limits, definitions of quality criteria and standards, and monitoring targets and other components for assessing suitability of the water source for its use and for maintenance of consistent quality.
- Lack of available guidance for different or alternative water sources, other than potable water, limits decision-making for growers.
- Faecal indicator organisms – e.g. *E. coli* – are routinely monitored by the food industry, environmental agencies and public health organizations, as a practical and affordable alternative to pathogen testing in verification, operational and surveillance monitoring.
- The complex nature of the relationships between indicator microorganisms and food-borne pathogens makes predicting levels of pathogens through measuring indicator microorganisms a challenge, both for irrigation water and on fresh produce; simple, consistent and linear relationships cannot be relied upon for predicting pathogen levels. However, indicator microorganisms can help growers and producers to monitor and control the quality of the irrigation water.

2.1.4 Potential intervention strategies

- Treatments relevant to agricultural irrigation water include coagulation, flocculation, filtration and other physical or chemical disinfection, such as methods using chlorine-based sanitizers and ultraviolet-C (UV-C) light, among others.
- Considerations regarding the use of chemical disinfectants include appropriateness for organic production systems, and the potential accumulation of toxic disinfection by-products associated with the use of some chemical disinfectants that accumulate in the irrigation water and can be transferred to the fresh produce.
- Other actions to reduce microbial risks include: die-off of microorganisms caused by drying and UV-C light from sunlight exposure of the edible portion of the crop before harvest; using irrigation systems that avoid direct contact of the water with the edible portion of the crop; and maximizing the interval between application of irrigation water and crop harvest.
- It should be noted that evaluation of site-specific applicability of many disinfection technologies has not been performed and relevant information such as information about maintenance, costs, safety and toxicological side effects is not available.

2.1.5 Effects and challenges of water quality on end products

- The survival period of pathogens in fresh produce after application of contaminated irrigation water varies widely (1 to 56 days or potentially even longer for some pathogens), which can be attributed to many different factors but particularly to the microbial inoculum type and quantity and the prevailing seasonal conditions.
- Developing reliable metrics needed for testing agricultural water to ensure the effectiveness of food safety programmes has been difficult; evidence from studies of relationships between indicators and pathogens in water and on fresh produce vary in design, produce type, irrigation method, post-harvest processing method, geographic location, and variability in evidence for positive correlations.
- One reason for this lack of consistent correlation between the microbial load of irrigation water and fresh produce could be the variable die-off rates of faecal indicators and among individual pathogens in fresh produce, which is influenced by multiple factors and by difficulties in detecting/enumerating pathogens in these matrices.
- In quantitative microbial risk assessments (QMRAs) used to connect microbial loads with health risks in end products, the low prevalence and concentration of food-borne pathogens in water and crops and the limited availability of microbiological models for the behaviour of pathogens or indicators in agricultural settings constitute a major data gap.

- Generic *E. coli* has the potential for use in comparing mitigation strategies evaluating water sources, irrigation methods, production systems and pathogen die-off rates that affect pathogen risks in end products. However, it is an inadequate microbial indicator for the presence, behaviours and risks of all classes of pathogens, especially viruses, parasites and mycotic agents.
- As stated earlier, the complex nature of the indicator microorganisms and food-borne pathogen relationships makes predicting the levels of pathogens through measuring indicator microorganisms challenging, both for irrigation water and on fresh produce.

2.2 POST-HARVEST

2.2.1 Map of where water is used

- Water is used at the time of harvest and during post-harvest handling (e.g. washing, rinsing, fluming, chilling, cooling, and for general cleaning, sanitation and disinfection purposes), as well as fresh-cut/freeze value-added operations, distribution and end-user handling, including retail, food service and consumer uses.
- Fresh-cut produce processing and frozen fruit and vegetable manufacturing are among the most water-intensive practices, due to the large consumption of potable water.
- The identification of a single and applicable approach to water use and quality in post-harvest operations is complicated by the diverse characteristics (e.g. microbiological quality and physico-chemical properties) among different fruits and vegetables and within a single produce variety, as well as by the type of operation involved.
- Most post-harvest processors consider reuse of water to conserve water and energy (e.g. for bin dumping, hydrocooling, flume recirculation and washing). This practice means that dirt, organic matter, pathogens and chemical residues can accumulate in the process water, causing cross-contamination between different batches, and this is a major concern.
- Most current recommendations specify that post-harvest water that comes in contact with fresh produce and that is not usually subjected to an upstream microbial inactivation or reduction treatment, should be of potable quality during all post-harvest use and handling.
- The European Commission (EC) guidance document on addressing microbiological risks in fresh fruits and vegetables at primary production through good hygiene (EC, 2017) is one of the exceptions, specifying that clean water with maximum *E. coli* levels of 100 cfu/100 ml is acceptable for post-harvest cooling and post-harvest transport for non-ready-to-eat fresh fruits and vegetables, and water used for first washing of products in the case of ready-to-eat fresh produce.

- The microbiological quality of post-harvest water can be altered, although this can be complex and costly. However, to minimize microbial contamination, cross-contamination of products and microbial infiltration into products, appropriate disinfection methods should be applied and monitored.

2.2.2 Review of decision support systems that are relevant to food safety

- There are various DTs focused on the quality of post-harvest water that is in contact with edible portions of the fresh produce at harvest or after harvest in any of the post-harvest unit operations. In most of the cases, it is specified that post-harvest water shall meet the microbiological standards of potable or drinking water.
- At the processing level, the quality of the water that contacts fresh produce during cleaning, grading, cooling and surface treatment applications is widely recognized as the essential pathogen control point to avoid cross-contamination of fresh produce.
- Main points for minimizing risk include:
 - > water quality must be maintained throughout the operation; special attention is required for common wash and flume systems and reused water;
 - > washing can be done in combination with a disinfectant treatment to reduce microbial contamination; greater microbial reductions should be achievable on smooth, waxy produce than on rough-textured or porous produce;
 - > antimicrobial chemicals at appropriate levels can minimize microbial cross-contamination from reused water; levels must be routinely monitored, controlled and recorded;
 - > special attention should be paid to ice when it is in contact with products during transport and storage and ice should be used under sanitary conditions;
 - > water used to hydrovac cool produce should be free from human pathogens;
 - > first-use or one-use cooling water may be used in hydrovac cooling of lettuce/leafy greens;
 - > if hydrovac cooling water for lettuce/leafy greens is reused, water disinfectant should be present at sufficient levels and the levels monitored to reduce the potential risk of cross-contamination;
 - > product placement and storage should not facilitate cross-contamination;
 - > water storage tanks and their hygienic maintenance should be included in relevant sanitation schedules.
- Examples of DTs and matrices include:
 - > simple matrices of source of water and intended use of the water that set the analysis/values of the water for indicators of faecal contamination (indicator *E. coli*) during the use of the water;

- > DTs with the aim of helping growers and producers in the decision-making process to avoid food safety issues by including explanations and guidance at yes/no decision points and remedial actions;
- > Commodity-specific DTs (e.g. for use in rehydration and coring in the field) include microbiological standards, sampling plans and acceptance criteria;
- > Treatment decision matrices for selection of ideal treatment technologies and/or potential of water reuse.

2.2.3 Water quality targets

- See comments in pre-harvest section 2.1.3 on limitations and challenges with microbial water quality targets.
- Commonly, *E. coli* and total coliforms are used to assess the microbiological quality of post-harvest wash water even though their suitability for this role is controversial. Total coliforms are considered unreliable indicators of faecal contamination because some species (e.g., *Klebsiella* spp. and *Enterobacter* spp.) are not necessarily of faecal origin and can multiply in various plant-related environments under favourable conditions.
- Water quality is regulated in some countries (e.g. water that directly contacts edible portions of the harvested crop or that is used on food contact surfaces, such as equipment or utensils) and it has to meet a specified maximum contaminant level or “goal” or contain an approved disinfectant at sufficient concentration to prevent cross-contamination.
- There is a need for identification of new and reliable indicators and online detection methods to monitor them, to support case-by-case assessments and for implementation of RA and principles of Hazard Analysis and Critical Control Points (HACCP).
- Some of the problems that may arise or stop the greater implementation of water reuse practices to conserve water and energy are related to the types of available indicators, which in most cases are not a direct index of pathogen presence or concentration or of safety to consumers.

2.2.4 Potential intervention strategies

- To implement potential intervention strategies, it is critical to understand the process for water disinfection and for validating its efficacy for the safety of a specific produce product. Critical points and challenges to consider include:
 - > simply washing products is not an effective mechanism for removing contamination – i.e. it cannot remove or kill pathogens that naturally seek out protective surface niches on products, that adhere to surfaces and/or that may have infiltrated the product;

- > the goal of water disinfection is to prevent cross-contamination by avoiding the transfer of microorganisms from process water to fresh produce and from one produce item to another during post-harvest handling;
 - > process water in the fruit and vegetable sector is highly variable in terms of water quality parameters, such as dissolved solids, chemical oxygen demand and microbiological quality, which makes it a challenge to implement a standard treatment option fit for all;
 - > regulations may stipulate that water can be reused if the water does not present a risk of pathogen contamination. This reuse water may need to be of the same quality as potable water unless the competent authority is satisfied that the quality of the water cannot affect the wholesomeness of the foodstuff in its finished form. This is critical if the food operators do not check the quality of the reused wash water during post-harvest processing of fruits and vegetables.
- WHO *Guidelines for Drinking Water Quality* (WHO, 2017) recommend a risk-benefit approach that considers protection of public health and availability of water supplies in a site-specific context in determining requirements. These guidelines may be extrapolated and useful for water reuse in the fresh produce industry.
 - The CAC *Draft Guidelines and Principles on Hygienic Reuse of Processing Water in Food Plants* (CCFH, 2001) emphasize the use of potable water but also acknowledge the use of alternative water quality when it does not constitute a hazard to the safety and suitability of the product.
 - The specific microbial and chemical qualities of such alternative water options need to be better defined and specified to minimize microbial contamination and health risks.
 - There are many post-harvest intervention strategies to disinfect post-harvest water for reuse and disposal. They differ in technologies, modes of action, efficacy, consumer acceptability and applicability for individual produce products and processing operations. The most commonly applied disinfectants in the fresh produce industry are chlorine-based compounds.
 - Fresh produce processors may adopt several strategies to reduce freshwater consumption and wastewater generation, such as: use unit operations that use less water; optimize the water circuit within the factory; employ direct reuse and reuse following reconditioning to potable water quality. More information on water reuse can be found in Section 3 of this report.

2.2.5 Effects of water quality on end products

- Little is known about the effect of water quality on the microbial growth and survival rates of specific microorganisms in fresh produce.

- Monitoring and maintaining the quality of process water during post-harvest operations is considered important for both safety and quality of end products.
- QMRA models were used to demonstrate the importance of sanitized washes in preventing cross-contamination of leafy greens and vegetables during fresh-cut processing and for lowering the risk of pathogen presence and illness.
- Not only water quality but also the method of application and use of washing aids (e.g. mechanical brushing, spraying, dipping) and sanitary processing can contribute to the reduction of microbial populations on produce.



3

Water use in different sectors: Fishery products

3.1 MAP OF WHERE WATER IS USED

This section addresses fish storage (includes water used for onboard storage, ice, washing, etc.) and fish processing from the fishing vessel and throughout processing facilities.

- On fishing vessels, the catch can be stored in tanks with refrigerated seawater or in seawater chilled with ice or in boxes containing ice. Ice can be made from seawater (e.g. on board) or fresh-, sea- or potable water (e.g. on land).
- Processing steps that use water can be the same on board or on land and for captured or cultured fish and may include: washing and gutting, filleting, skinning, trimming and candling, glazing and mincing.
- Guidelines specific for fish and fishery products are provided by the CAC *Code of Practice for Fish and Fishery Products* (CXC 52-2003) (CAC, 2016) and are applied by the competent authorities in the fisheries sector and other agencies; however, there is no uniform definition for the type and quality of water to be used in specific steps of fish handling and processing.
- In these guidelines, categorization of quality of water used at various processing steps varies and includes potable water, with clean seawater and clean water acceptable for use depending on the step in the process.
- The potential risk of microbiological hazard exposure following the use of clean water in fish handling and processing is dependent on eventual decontamination processing steps for the fish product by the consumer.

3.2 REVIEW OF DECISION SUPPORT SYSTEMS THAT ARE RELEVANT TO FOOD SAFETY

- In the absence of sufficient data to estimate public health risks associated with various uses of clean seawater in fish harvest and processing, hazard-based criteria have been proposed to provide the required level of health protection (EFSA, 2012). Relative exposure levels associated with different uses of clean seawater were used to determine comprehensiveness of sanitary surveys required, requirements for mandatory water treatment and stringency of microbiological criteria.
- Microbiological criteria include enumeration of *E. coli*, enterococci and *Vibrio* spp.

3.3 WATER SAFETY/QUALITY TARGETS

- There are no consistent definitions of the microbiological criteria for clean water for use with fishery products.
- As noted with fresh produce, microbiological criteria for water for human consumption (potable) are defined differently (e.g. in level of stringency) by different regulatory agencies (USA and EU) and in the drinking water guidelines from WHO.
- Some fishery documents specify that clean water should meet the same microbiological criteria as potable water, whereas the *CAC Code of Practice* (CAC, 2016) adopts the definition of clean water as ‘clean water is water from any source, where harmful microbiological contamination, substances and/or toxic plankton are not present in such quantities that may affect the safety of fish, shellfish and their products intended for human consumption’.
- Choice of water quality requirements at a processing step may be supported by application of HACCP principles and assessment of the health risk.
- In 2012, the European Food Safety Authority (EFSA) report, “Scientific opinion on the minimum hygiene criteria to be applied to clean seawater and on the public health risks and hygiene criteria for bottled seawater intended for domestic use”, included an assessment of the microbiological and chemical hazards of using seawater in fish handling and processing and the formulation of microbiological criteria for clean seawater, depending on its use (EFSA, 2012).

3.4 EFFECTS OF WATER QUALITY ON END PRODUCTS

- Heterotrophic plate counts as well as *E. coli* and enterococci counts have been used to monitor hygiene and sanitary practices on board and on shore.

- *E. coli* and *L. monocytogenes* counts have also been recommended to monitor quality of water used during processing.
- Washing and washing/filleting fish that may be consumed raw in contaminated seawater has been shown experimentally to increase contamination on fish surfaces and gills while hygienic washing reduced contamination levels.

3.5 RISK REDUCTION OPTIONS (SECTOR-SPECIFIC)

- CAC *Code of Practice* (CAC, 2016) describes the use of HACCP principles for fish storage and processing in combination with good hygiene practices (GHP).
- Regardless of the source, the supply must be monitored with sufficient frequency commensurate with the level of risk to assure that the water is safe for use on fishery products and food contact surfaces, and corrective action taken when monitoring detects a problem.



4

Water use in different sectors: Reuse of water in an establishment

- In a food business operation, water can be used as an ingredient, to wash food or to clean food contact surfaces, and in many other applications where there is potential for contact between the water and the food. In addition, there are many other applications where there is no intended or expected contact of the water with food – e.g. in personal use applications and fire control.
- In all situations, water use should be part of an operation’s prerequisite hygiene and HACCP programmes.
- Water consumption and waste discharge volumes and costs are a concern for establishments.
- Increasingly, minimizing water consumption and exploiting alternative water sources (e.g. water recovered from food or a food operation that could be reused after making it fit for purpose by suitable treatments or reconditioning, if necessary) are being considered.
- Microbiological issues are considered here for reuse of water originating from drinking water or from other sources within food manufacturing establishments that are described by the CAC as “any building or area in which food is handled and the surroundings under the control of the same management” (CAC, 2003b).

4.1 WATER REUSE IN THE FOOD PROCESSING INDUSTRY

- An increasing number of companies in varying food industry sectors – e.g. dairy, poultry and pig slaughter, produce (fresh and processed), seafood, oils, meat, beverage – are now reusing different types of water for intentional food contact applications, as well as water that may come in contact with food unintentionally and water used for technical purposes in food manufacturing establishments. Reuse water is applied for various purposes, depending on the food processing operations and food types.
- Types of reuse water can include water that is reclaimed from food, recycled from food operations or recirculated in a closed loop system. Where necessary, reuse water is reconditioned to make it fit for purpose in microbiological terms.
- Compared to drinking water, there is only very limited and scattered information in the scientific literature on water reuse within food operations and it is not always apparent whether the processes described are experimental or in regular use.
- The latest official document on water reuse from the CAC dates back to 1996 and was revised in 2003 (CAC, 2003b); it states that reuse of water in food processing and handling is allowed in exceptional situations, where its use does not compromise the (microbiological) safety of the food product.
- CCFH discussed appropriate guidelines (CCFH, 1999; CCFH, 2001), and although this work was not consolidated and formally issued, the CCFH drafts have served as model guidelines in various countries worldwide.
- Other guidelines for water reuse include HACCP principles and risk-based process control programmes. HACCP principles can be applied to both potable water and water reuse. In the case of applying HACCP to water reuse, it is essential to clearly define the exact first use case of the water and its quality to aid in the identification of appropriate hazards and their suitable control points.
- All the hygienic guideline values, treatment options and process design recommendations made for drinking water distribution and storage are also important for water to be reused. Additional factors arise when water is treated and stored at the production site.
- The reuse water has to be cleaner than the food it comes into contact with, such that the food does not become more contaminated through this contact and the target level of cleanliness of the food is met after contact.
- Water can be a vector to transmit pathogens from a single food product specimen to a large number of products, thus increasing the number of people exposed and the potential health impact.
- Any RA needs to be tailored to the specific origin and quality of the water to be reused. This is because the necessary considerations with regard to micro-

biological risks may vary widely among different food operations and there is a need to consider – among other factors – the origin of the water, the specific production and recapture processes, applicable storage requirements, available treatment options and their performance characteristics and targets.

- The RA may also take into account post-processing of the food after contact with water, such as cooking.

4.2 GAPS AND CHALLENGES IN DEVELOPING GUIDANCE ON WATER REUSE

- Water reuse definitions can be ambiguous (e.g. the terms: reused, recycled, reconditioned, reclaimed, recirculated) and this may constitute a problem for regulatory compliance and the perception of water reuse applied in the food industry, both in terms of customer acceptance and food safety assurance.
- Resources and expertise are required to establish a water reuse system in a food manufacturing establishment and to manage it appropriately within an effective GHP/HACCP-based food safety management system (FSMS).
- Challenges and knowledge gaps in water reuse include a broad range of issues related to environmental impacts, economic considerations, legislative approaches, technological treatments, treatment performance targets, types and reliability of water quality assessments, consumer perceptions, food industry practices and academic/industry relationships.
- Some of the most critical data gaps with regard to microbiological hazards include the following:
 - > Limited specific understanding of the microbiological status of the different types of water reuse within a specific establishment, including the impact of storage and transport of reuse water. There is little published literature on the typical sources, initial quality and subsequent quality of the used water in the reuse water schemes of various sectors; furthermore, existing guidelines mostly do not provide an adequate level of detail.
 - > A need for better understanding of pathogen reduction efficiencies, performance variation of (single or multi-barrier) treatments, process optimization for water reconditioning under the specific conditions of the establishment and intended system performance targets. Currently, there are many descriptions of the “average” efficiency of various treatment processes for removal or inactivation of bacteria, parasites and viruses, and these have wide ranges of performance efficacy. Furthermore, differences may exist between specific types of equipment and water from different sources within establishments, which may cause very large variations in system performance and performance targets.

- > Lack of information or practical guidelines to assist various food establishments, especially small operations, for validation at the full operational scale and in daily verification of processes used for recovery and, where necessary, reconditioning of reuse water.
- > Absence of or deficiencies in suitable microbiological indicators and surrogates that can be used for validation and verification purposes – e.g. to monitor process performance in reuse scenarios and develop suitable monitoring approaches and analytical methods for their measurement during operation.
- > Lack of adequate research, guidance and tools to support establishing safe and fit-for-purpose water reuse – e.g. knowledge about significant pathogens relevant to water reuse in different sectors, QMRAs and predictive modelling applied to water reuse cases, and insight into microbial injury and survival in unfavourable conditions.

Other knowledge needs include:

- > significance of microorganisms other than pathogens – e.g. spoilage microorganisms occurring in reuse water that affect food stability, occurrence of organisms of public health significance or occupational safety concerns, such as *Legionella* spp.
- > microbial and chemical quality issues and risks of fouling, extent of recirculation of microorganisms/bacteriophages and their regrowth potential.
- > how food processing after contact with reuse water will affect potential pathogens on the food (e.g. when cooking or washing food products at home).



Risk assessment

- As the strength of the assessment for evidence-based risk management increases, the resources and expertise required also increases. RAs can include the following approaches:
 - > Descriptive assessments (least comprehensive) – e.g. sanitary inspection. Used in evaluating and managing risks from irrigation water and rapid assessment of drinking water quality;
 - > Semi-quantitative RAs – e.g. risk matrices using categories of risks from high to low that include consideration of sanitary conditions and frequencies of failure or performance degradation events. Used for planning, prioritization of water sources and rapid assessment of drinking water quality;
 - > QMRAs (most comprehensive) – e.g. for guiding potable water reuse, wastewater use in agriculture, household water treatment and community water supply systems.
- RAs can be used to set target objectives for water sources and treatments for achieving health outcomes (exposure assessments and health effects assessments to estimate burden of disease), water quality values/targets, performance (log microbial reduction), and treatment process efficacies.
- RAs and risk management approaches are considered the most effective means of consistently ensuring the safety of drinking water as well as wastewater reused for produce agriculture and these are employed in developing a Water Safety Plan (WSP).
 - > Key WSP risk management principles and concepts include a multiple barrier approach, hazard assessment, performance targets and their verifi-

cation, operational monitoring and CCPs, as in HACCP principles applied in the food industry.

- However, the microbiological status of agricultural products is often not well known, outside the control of the farmer, it can be uncertain and variable.



Decision trees: Reports from the meeting breakout groups

6.1 FRESH PRODUCE PRE- AND POST-HARVEST

6.1.1 Key gaps and challenges in current guidance

Key challenges and guidance gaps were identified that need to be considered in addressing safe water and fresh produce as follows:

- Growers and fresh produce processors are required to take adequate measures, as appropriate, and to use potable water, or clean water, whenever necessary, to minimize microbial contamination of produce via water. However, the definition of clean water is not clearly or operationally defined and there is no universal agreement regarding optimum microbiological limits, definitions of irrigation or clean water quality standards, and monitoring components that can determine if a water source is suitable for its intended use.
- For irrigation water, some guidelines refer to a specific threshold of concentration of indicator microorganisms. Such guidelines are easy to administer; however, they often lack the specificity and representativeness required for more comprehensive risk management. Newer approaches for water safety risk management recommend the implementation of a site-specific risk management plan for water use, including an RA; these require more resources but they provide an equal or better outcome compared to simple thresholds and have the ability to reduce uncertainty.
- There is a lack of guidance available to aid growers in the selection of water sources other than potable water, which limits informed decision-making for growers.

- Microbial indicators may be used in monitoring; however, their relationship with pathogen presence and concentrations in food and water is context-specific and cannot be generalized. This limits the effectiveness and representativeness of quantitative microbial target measures for water quality and their suitability as a data source for QMRAs.
- Guidance is lacking on context-specific processes to assess risks associated with water sources and to select suitable risk mitigation measures to achieve “clean water”; a general definition of the term “clean water” is not likely to be feasible, effective or practicable, except to indicate that such water be fit for purpose.
- In primary production, the quality of water sources can vary widely over both the short term and the long term, as in the case of surface water (e.g. river, canals); this variation reduces the usability of water monitoring as a risk management tool and triggers the need for fit-for-purpose risk mitigation measures that are commensurate with the variations observed.
- There is a lack of guidance, in particular for contexts that are resource-limited, with regard to conducting a comprehensive RA or for monitoring water quality.
- In post-harvest practices, guidelines and principles recommend the use of potable water; however, when used in post-harvest handling and washing operations, its quality deteriorates rapidly due to the accumulation of organic matter, microorganisms and chemical compounds. Antimicrobial agents, at appropriate levels, can minimize contamination from process water.

6.1.2 Approach to development of decision trees

Development of decision trees. A number of approaches to DTs proposed in different guidelines for water use in production and processing of fresh produce were considered. Common helpful features include: i) characterization of the water sources and distribution systems to identify the risks linked to the specific water source; ii) identification of the risk, based on the type of application (foliar or non-foliar); iii) the potential for application of agricultural water to be influenced by the type of crop (e.g. leafy greens versus fruit trees) and its intended use (e.g. raw versus cooked); iv) testing based on quantification of generic *E. coli* or other suitable microbial indicator; and v) in some cases, frequency of sampling to be employed depending on magnitude and probability of the identified potential risks.

Users of the decision trees. The experts developed examples of decision support processes (e.g. visualized as DTs, (Figure 1, Figure 2, Figure 3) and a risk mitigation measure selection table (Table 1), based on general principles and case studies (WHO, 2006a). These materials are intended to aid local regulators, risk

managers or agricultural extension agents who understand the local fresh produce primary production and processing and its context and are able to interpret FAO/WHO guidelines and instruct fresh produce farmers and processors on how to implement them.

Fresh produce supply chain. For fresh produce, typical supply chains include no or minimal post-harvest processing. Therefore, the concept of a rather simple post-harvest process has influenced the focus of the experts. The rationale for this focus is that WHO/FAO guidelines are most needed in countries and contexts that have not developed national guidelines, and in those regions fresh produce for local markets is most often sold to market without post-harvest processing. In addition, the experts decided to not focus on requirements from specific export markets, since in these cases food safety standards and practices used during primary production and processing are often determined by the importing country. Where desired, however, the principles applied in this section can be easily extended to cover a more complex supply chain.

Health-based targets. Contact between water and fresh produce can occur at various points in the fresh produce supply chain and in varying ways and quantities; this varies across the range of fresh produce types, water sources, primary production and processing systems employed, etc. The experts recognized that targets such as health outcome, water quality, specified performance and specified technology targets, are defined by WHO (2017) for drinking water quality. Based on this model, it may be recommended to improve the safety of irrigation and processing water and to monitor progress. In primary production and processing of fresh produce, risk-based targets can be established for a particular food-borne hazard in a specific product at the time of consumption. In such cases, irrigation and processing water may contribute to overall exposure to a hazard via fresh produce – though it may not be the only source of the hazard – and the presence and quantity of water-introduced hazards will vary along the fresh produce supply chain after first introduction.

The experts discussed the important role of disease surveillance in establishing health- and risk-based targets for water quality (WHO, 2017). For example, water quality categories or acceptable contamination levels can be set based on the specific context and the desired health outcome (burden of disease measures such as disability-adjusted life years (DALYs), – e.g. a 25 percent reduction in gastroenteric illnesses attributed to consuming a fresh produce type or group. Establishing health targets informed by disease surveillance requires resources and capabilities to conduct nation-wide gastroenteric disease surveillance that is relevant to a specific setting, identification of relevant etiological agents, and estimation

of disease attribution for fresh produce types based on representative and reliable data sources. Such capabilities may not be available in many regions where guidelines are needed. Therefore, while the experts recognize the importance of surveillance and the fact that it may inform the decision process described here, it was not explicitly included in the decision support tool. If this evidence base is available or can be established, it should be used. Developed countries frequently tend to set health-based targets, while specified technology targets may be more frequently applied in developing countries.

If QMRAs can be conducted, they could be used to define the quantitative level of microbial targets – usually microbial indicators – that would be required for water inputs in a fresh produce supply chain, for process verification and for comparative purposes. QMRAs can be based on pathogenic microorganisms if data are available but usually the only available data correspond to indicator microorganisms. However, as noted above, it must be borne in mind that microbial indicators are often not agreed upon and universally accepted and they have limitations in measuring pathogen presence and concentrations. Their use assumes a reliable relationship between indicators and pathogen presence which may not be possible to determine with certainty. Setting general numerical guidelines for water quality, such as a concentration threshold of an indicator bacterium, may not be appropriate for situations where a comprehensive QMRA and routine process verification are not possible, since these targets are highly context-specific. Hence, the experts decided to focus on the context-specific approach of assessing the vulnerability of a process or step related to water use for food safety risk and selecting a combination of risk reduction measures using appropriate technologies where indicated. This approach was considered comparable to the development of WSPs (WHO, 2017) and food safety management plans (CAC, 2003b).

Rationale. The rationale for recommending an empirical RA and a step-by-step selection of feasible risk reduction measures based on the specific supply chain context includes the following points:

- the entire supply chain from farm to fork should be considered;
- it should be kept in mind that the end goal is food safety, not water quality *per se*;
- an overall HACCP-based approach, focusing in this case on water inputs, should be taken to identify critical control steps and preventive measures along the produce supply chain;
- the process should leverage existing WHO/FAO/Codex guidelines where possible and operationalize them for safe water use in fresh produce primary production and processing; it is not meant to propose new frameworks/guidelines/regulations.

If national guidelines or regulations are available, and include methodologies for assessing vulnerability and risk, selecting appropriate risk mitigation measures and monitoring the process, such guidelines should be followed. The process described here is meant to be applied where such guidelines are not available or are incomplete, and in developing context-specific guidelines.

In contexts where water quality monitoring and quantitative RA capabilities are available, it is recommended to follow existing guidelines to conduct a QMRA of the local supply chains using specified risk-based microbial water quality indicators for performance control and/or to direct the choice of risk mitigation measures and process verification options, recognizing the limitations (CCFH, 1999; WHO, 2016). The DT approach presented here could still be valuable in defining the RA framework, but a risk quantification approach is advised when feasible.

6.1.3 Overview of the decision tree constructed

The experts recommended breaking down the decision process on water quality for food safety in fresh produce into two broad levels of decision-making and developed two DTs and also a risk matrix.

Step 1: Context and qualitative RA

Step 2: Selection of risk mitigation measures

Step 1 begins with fresh produce primary production and a qualitative assessment of the water-borne risks of food safety hazards associated with water sources available for primary producers. Step 2 builds on Step 1, with the starting point chosen based on the potential risk level of the water sources to which fresh produce may be exposed at production.

These decision support tools are not meant to substitute for existing national guidelines and regulations unless they are inadequate for defining water quality that is fit for purpose. One of the main decisions in Step 1 is whether national or local guidelines or regulations exist. If so, the user should refer to those, and not proceed further in the DT.

6.1.3.1 Step 1: Context and qualitative risk assessment

The first tasks in the decision processes are similar to the first steps and Principle 1 in the implementation of HACCP during food safety management (CAC, 20032b) and the initial steps in sanitation safety planning (WHO, 2015). They include some or all of the following:

- description of the fresh produce product (e.g. leafy green, root or tree crop, and extent of contact or retention of water) and its intended use (e.g. eaten raw, cooked, fermented);
- understanding the product flow from production to consumption (e.g. growing, harvest, processing, transport, marketing, consumer handling);
- identifying water use (e.g. irrigation, washing, processing, ice) and inputs (e.g. water source types, storage and delivery);
- identifying potential water-related hazards at each stage;
- analysing the hazards and considering any measures in the fresh product flow stages that may control the water-related hazards introduced in the final product.

Step 1 of the DT is shown in Figure 1. It is constructed to ask the key questions for the user so as to conduct a qualitative evaluation based on: (a) the information available on source irrigation water; and (b) the potential level of risk of the available water sources. It is a simplified assessment that aims to direct the users to the next steps in assessing the risks of their activities and should not be construed as an RA itself.

The qualitative assessment process in Step 1 (Figure 1) includes the following key considerations:

Implementation of a microbial kill step to fresh product before consumption: Is the fresh produce generally consumed raw as opposed to following some other process resulting in microbial inactivation or removal? If the answer to this question is NO, the risk directly related to consumption of the final product is significantly reduced. Good Agricultural Practices (GAPs) (see FAO, reference list) and WHO's *Five Keys to Safer Food* (WHO, 2006b) should be practised.

Degree of contact between irrigation water and fresh produce: If irrigation water is applied avoiding the direct contact with the edible parts of the plants, by means of a suitable irrigation method (e.g. by using drip irrigation), the risk associated with water quality would be significantly reduced. However, risks due to cross-contamination – e.g. soil transfer to the crop due to wind or animals, or cross-contamination via intermediate surface contact during handling and processing (e.g. containers, cutting boards washed with low-quality water and in contact with fresh produce surfaces) – still need to be accounted for and managed. In the scenario where no/limited direct contact between water and fresh produce occurs, growers should apply best practices to limit further contamination or cross-contamination (e.g. GAPs and WHO's *Five Keys to Safer Food*).

Availability of national or local guidelines or regulations on water quality for fresh produce production: If detailed local risk-based guidelines or regulations exist and include provisions for water quality used in primary production and food processing, the user is directed to refer to such guidelines. They are likely to include a higher level of detail and context-specific information than general international guidelines. The context assessment and risk mitigation decision support tools presented here are meant to include contexts where no local guidelines have been developed. The tools can also be applied to support the development of local or national guidelines.

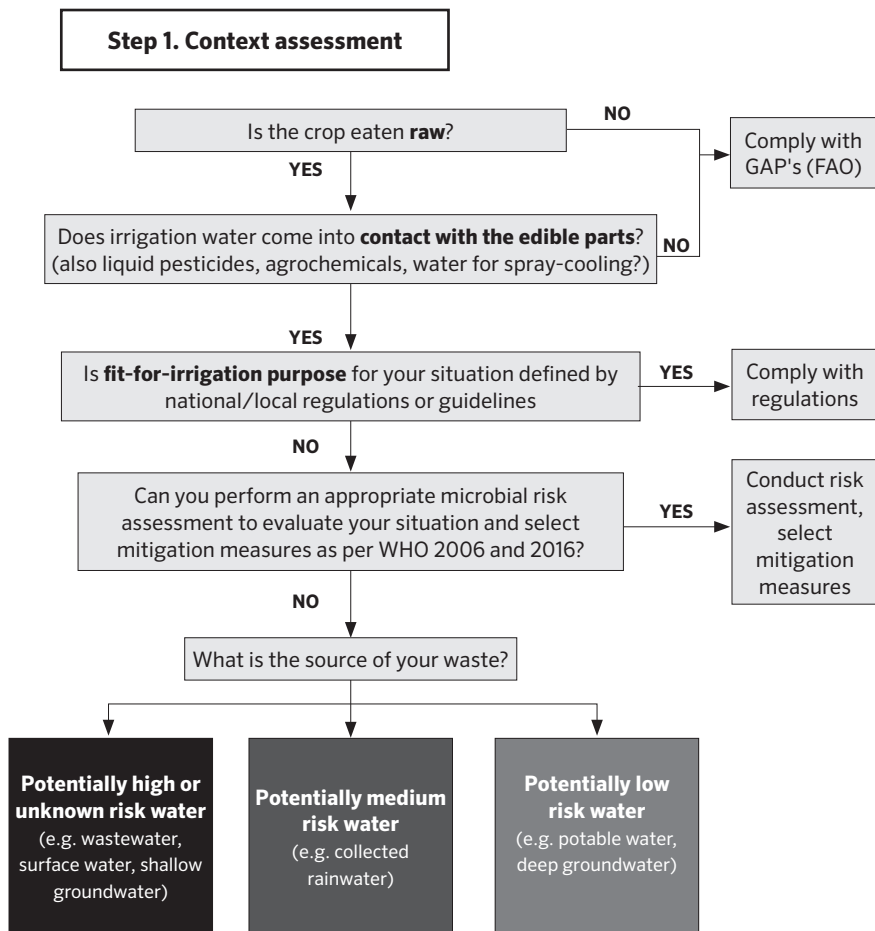


FIGURE 1. Step 1: Context assessment for fresh produce to determine the level of action necessary

Availability of data and resources to conduct a quantitative risk assessment:

The tools presented here focus on contexts where little or no quantitative data are available to formally assess risk – e.g. data on microbiological water quality parameters for water sources, relevant health data for potentially exposed populations. For situations where quantitative information is available to assess potential microbial contamination and expertise is available to conduct a QMRA or risk profile to assess context-specific risk, it is recommended that quantitative assessments be performed. This may allow risk mitigation measures to be more cost-effective and tailored to the specific needs. Such RAs could be developed at small scale – e.g. a specific processing plant – or at larger scale – e.g. the entire national production and consumption of a produce commodity.

Step 1 of the decision process includes several assumptions, such as:

- the primary producer has limited choice on the available water source(s) and their quality;
- the fresh produce production and consumer food and consumption practices are known;
- data availability on microbiological hazards throughout the fresh produce production chain is lacking.

As an outcome of the context assessment process, the user may be directed to different water resources, either because it is deemed there is low potential risk (if the answers to the first two questions are “no”), or because guidelines or data are available to support a more quantitative RA (if the answers to the last two questions are “yes”). These options lead to stopping the assessment process and using different tools – e.g. GAPs and WHO’s *Five Keys to Safer Food*. If the considered process fits the purposes of the context assessment tool (product is not always eaten after a microbial inactivation step, direct water-produce contact may occur, no national or local guidelines exist, and developing a quantitative RA is not feasible), the assessment is that the process itself could present a level of risk, and hence further decision-making is needed. The primary production process is then ranked into three qualitative potential risk categories, based on the available water source and the existing information (see Figure 1):

1. Potentially high-risk water: little data are available on water quality, and hence a worst case should be assumed. Example: river or canal water.
2. Potentially medium-risk water: while data are lacking, there is evidence that the available water source is likely to pose medium risk, based on sanitary surveys and the range of water quality observed in other comparable locations. Example: collected rainwater.
3. Potentially low-risk water: either some data are available that indicate low

or no microbial contamination in the available water source(s) or the water can likely be considered low risk based on sanitary surveys and water quality observed in similar sources in other locations. Example: deep groundwater.

The three categories in the Step 1 context assessment DT are entry points to the subsequent Step 2 risk mitigation choice DT, outlined in the next section. If possible, especially if the outcome of the DT is either the “high-risk” or “medium-risk” category due to lack of data, a sanitary survey or data collection step could be implemented to refine the assessment, potentially leading to an outcome of lower risk. For example, if the available water source is a river of unknown quality, the worst-case scenario when no data are available is to assume that the river is heavily impacted by wastewater, etc. and hence of very low quality. However, a wide range of water quality over time and geography has been observed in river water, and data collection or a qualitative sanitary survey would provide more site- specific and reliable evidence to classify the water as high- or low-risk.

6.1.3.2 Risk matrix for irrigation water

An alternative approach using a simple matrix for assessing the risk of irrigation water is presented in Figure 2. This matrix is based on risk factors including the water source, whether irrigation water would be in contact with edible plant portions and whether the product will receive a microbial kill or effective removal step before consumption.

6.1.3.3 Step 2: Decision tree approach for selection of risk mitigation measure

The approach and rationale of Step 2 is a continuation of Step 1 (Figure 3). Again, while it is aimed at simple fresh produce chains and technologies, the basic principles can be applied in more complex situations. The approach is qualitative although if a more quantitative approach is possible then that is recommended, with estimation of quantitative measures of water quality needed to result in the desired level of health protection associated with consumption of this fresh produce. Considerations listed in Step 1 apply here also.

It is anticipated that the DT could be used by extension agents, who are required to assess the points at which a food safety risk for fresh produce is presented by the introduction of water and make decisions on potential risk reduction strategies, taking into account a qualitative estimation of the level of risk reduction that could be achieved. These officers may not have ready access to a laboratory or to RA expertise. This approach builds on WHO guidelines (Mara *et al.*, 2010).

To meet these requirements the DT includes the following additional guidance.

Intended use of produce	Contact with edible plant portions	Water source				
		Wastewater	Surface and groundwater of unknown quality	Groundwater collected from protected wells	Collected rainwater	Potable water Deep groundwater
READY-TO-EAT	contact with the edible portion	HR/?	HR/?	MR	MR	LR
	not contact with the edible portion	HR/?	HR/?	LR	LR	LR
COOKED	contact with the edible portion	LR	LR	LR	LR	LR
	not contact with the edible portion	LR	LR	LR	LR	LR

FIGURE 2. Matrix to support microbiological risk assessment of irrigation water used during pre-harvest of fresh produce

1. A qualitative measure of the effectiveness of recommended control measures for improving water quality is provided, which can be used singly or in combination to cumulatively increase the overall effectiveness; these control measures are cross-referenced with the measures listed in Table 1: Qualitative effectiveness of selected control measures for produce, with focus on a small-scale production context
2. The ratings of effectiveness are context-specific and are based on suggested additions to the current WHO guidelines (Mara *et al.*, 2010).
3. Key resource material on guidelines for risk reduction to support actions is indicated at decision points. A list of key internationally recognized sources of information on risk reduction strategies, measures and their implementation is cross-referenced with the reference list provided. FAO, WHO and Codex references are supplied, in keeping with the request for this work. Other references are provided as examples, although these are not considered exclusive and other reliable reference resources may be available.

TABLE 1. Qualitative effectiveness of selected control measures for produce, with focus on a small-scale production context

Risk mitigation options	Effectiveness rating	Step 2 cross-reference
Alternative water source such as deep well or potable water	RR1
Change from raw eaten vegetables to boiled vegetables	RR2
Change from overhead irrigation (sprinklers, watering cans) to: Furrow irrigation Drip irrigation	RR3
On-farm water treatment ponds with 18+ hrs sedimentation period Water fetching without disturbing pond sediment	.	RR4
Filtering water before irrigation (e.g. fine sand, biochar)	.	RR4
Irrigation cessation for three days (no watering before harvest) Note: in hot climates, prolonged irrigation cessation is not feasible.	..	RR5
Peeling fresh produce (e.g. root crops, fruits, removal of cabbage outer leaves)	..	RR5
Washing salad with running potable water	.	RR6
Washing salad with running potable water and added sanitizer	..	RR6
TARGET FOR RISK REDUCTION (RR)	
Example: assuming a target of 6 stars, assuming reduction is additive Filtering water + Drip irrigation + Produce washing with sanitizer = . + ... + .. =		

The text boxes include risk reduction measures, a reference to qualitative estimation of the effectiveness of the risk reduction measure (e.g. RR1-RR6 in Table 1) and relevant references to guidelines (e.g. Ref. A-E)

Decision tree starting point. The starting point is one of the three irrigation water quality risk groups decided from Step 1: high, medium and low risk levels.

The first level of questions allows decisions on: direct use of low-risk water if there is no further water/manure contact; maintaining the quality of the medium-risk water through safe collection and storage; or improving the quality of high-risk or unknown quality water by seeking an alternate source of lower risk.

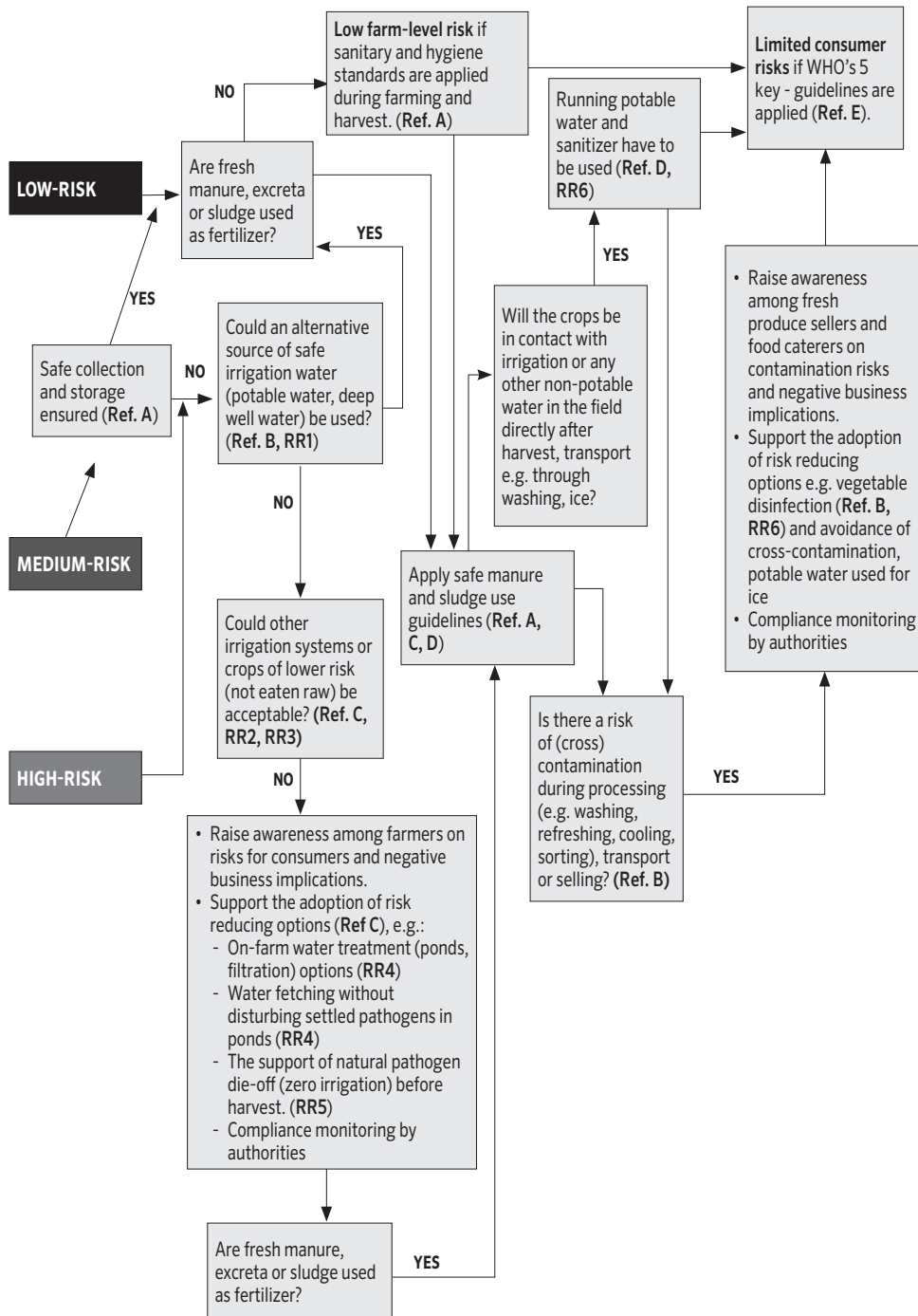


FIGURE 3. Step 2: Decision tree for selection of risk reduction measures for produce, based on the preliminary assessment in Step 1

Worst-case scenario. This is where water is of high or unknown risk and there is no water of known or improved quality available. The user can consider different approaches to risk reduction, used alone or in combination as the specific scenario allows. The risk reduction approaches (see Table 1) include several approaches, as in the following:

- if edible portions are exposed to the irrigation water, consider choosing irrigation methods that can lower the risk of fresh produce contamination (e.g. drip rather than spray, mulch);
- if the fresh produce type is generally eaten raw, consider changing to a type of crop that will receive a microbial inactivation or effective removal step before consumption (e.g. cooking, controlled fermentation);
- apply water treatment or onsite control measures appropriate for the scenario;
- advise and educate farmers and consumers of the risks and their consequences and support the adoption of risk reduction measures.

Manure, excreta, sludge. For fresh produce production, other inputs can have an influence on pathogen contamination in the field and these can also be linked with water use. Manure, human excreta/sludge and wastewater can be used as crop fertilizers. If not safely managed, these materials can be a source of food safety hazards that can directly or indirectly contaminate soil, water and potentially the produce. Guidelines for safe use of these materials are available from WHO (WHO, 2006a) or in guidelines for GAP (see FAO, reference list) or from various competent authorities and others (Refs. A, C, D). A decision step to address the need for control when using manure and other faecal waste materials is included in the pathway for each water category.

Harvest and post-harvest handling. In the fresh produce supply chain, fresh produce can be exposed to food safety hazards from multiple sources along these pathways, including irrigation and processing water. At harvest, fresh produce can be taken to market and/or further exposed to water in the field and/or exposed during post-harvest processing. The DT follows each of these pathways broadly and decisions are required if products may be at further risk of contamination with food safety hazards via water exposure. At these points a reference source is provided for guidance on risks – including risks that are water-related – options for risk reduction measures and the possible effectiveness ratings of water application and treatments (Table 1).

During harvest and post-harvest handling, crops and equipment may be exposed to water while trimming, cooling, washing products or other activities, in which case potable water is the first preference for crops where water is in contact with edible produce parts and produce is usually eaten raw. For low farm-level risk situations further control of food safety hazards along the supply chain is required

if they could occur during transport, at markets or in food preparation. Guidelines for food safety risk management are provided for these steps by Codex, WHO, FAO, competent authorities and industry associations and are listed in the reference section.

Crops can also be exposed to water during minimal processing through various processes – e.g. washing, cooling or transport – that can result not only in contamination of the fresh produce but also cross-contamination via water. During processing and handling, water or ice can contaminate surfaces and edible parts of fresh produce, or water can facilitate infiltration of pathogens into produce (e.g. during cooling) if not appropriately used. Potable or equivalent quality disinfected water is recommended when in contact with products eaten raw, to minimize contamination risks; guidelines are available on produce processing (FAO, WHO, Codex).

Qualitative estimates of effectiveness of risk reduction measures are available (see Table 1). Where potable water or water treatment is not possible, additional guidance (e.g. fresh produce disinfection) and seller and consumer education are suggested .

For information on water reuse during product processing and other non-food contact activities see also the group report on this aspect.

6.1.4 Discussion

Fresh produce is extremely diverse. This extensive diversity can include the following factors, which occur in varying combinations around the world: fresh produce types; growth characteristics; structure and topography; primary production and processing systems and volumes; food safety hazards; the range of exposure routes for water in the fresh produce supply chain; geographical and climatic variability in on-farm water quality; and whether fresh produce is subject to a microbial kill or physical removal step before consumption. Globally, the capacity to assess risks associated with water use and to implement risk reduction measures varies significantly – for example, in different geographical, social and economic settings and with different trade options (e.g. export versus domestic supplies). The variation in RA capacity is affected by the varying levels or lack of available evidence – such as health, water and food quality data, and quantitative estimates of their relationships, and/or scientific evidence for the sources, transfer, behaviour and persistence of the water-borne hazards introduced to produce along supply chains – which can be necessary for application of QMRAs. This information may not be collected, the capacity or laboratory facilities may not be available in a region or the scientific data may not yet be available.

Water and ice can be a source of hazards for fresh produce via many direct and indirect routes along the supply chain and populations of microbial hazards can be dynamic up to the point of consumption. HACCP-based principles are used in controlling hazards for both food and drinking water supplies. For fresh produce safety management – in contrast to water safety management *per se* – water is an input in the fresh produce chain flow diagram that can contribute to the final health risk of the fresh produce. The burden of disease measures estimated for a water source may be different from that for the final fresh produce.

The experts found it challenging to be able to take into account all the potential variables and the basic approaches to food and water safety management in designing a simple DT. A DT was constructed based on high-level risk-based decision-making while maintaining simplicity; however, it is possible that by doing so the DT may lack sufficiently meaningful decision-making options applicable to all potential scenarios. For the fresh produce sector, one DT may not fit all production or processing settings globally. A case-by-case analysis may be required. To assist users in using these decision support tools, they are provided with resource material at the higher-level decision points in order to make more specific choices relevant to a particular setting. In this way it is anticipated that multiple scenarios might be addressed. Evaluation and revision of the proposed DTs in real-life settings are required.

On-farm, a qualitative risk-based approach is taken to make decisions on the risk level and choice of water source in order to minimize risk of the introduction of hazards that compromise food safety. The choices are to select water from sources expected by observation and experience to have minimum levels of contamination, to use risk reduction measures to improve water quality, or to reduce the contact between the water and the crop in the absence of an alternate source with lower risk. Further levels of risk reduction may be required using options with different approaches – e.g. education and warnings for retailers and food preparers. The use of potable water (without the risk of health problems) as defined by WHO (2017) and use of sanitizers are recommended in Step 2 of the DT from the point of harvest, when the produce is eaten raw and if the water will be in contact with edible portions of the product.

Definition of water quality based on concentrations of microbial indicator organisms has not been specifically considered, although it is noted that this might be examined using QMRAs. The diversity referred to above, lack of agreement among competent authorities, controversy regarding choice of microbial parameters for assessing water quality, and lack of scientific knowledge of the behaviours and persistence of microbial hazards along produce supply chains can complicate and limit this approach currently.

The reuse of water was not addressed, and reference should be made to the water reuse section of this document.

6.1.5 Conclusion and recommendations

The diversity of fresh produce, combined with other factors (e.g. production and processing systems, production volumes, levels of social and economic development), means that the use of one DT to fit all possible scenarios globally is of limited feasibility and the approach may need to be adapted or applied on a case-by-case basis. This approach has already been considered by different organizations that focused on commodity-specific food safety guidelines for the production and harvest of different types of fresh produce, including leafy greens, tomatoes and melons. A high-level risk-based approach was developed to address this need.

Research is required to address the many knowledge gaps in understanding the behaviour (e.g. survival and persistence) of microbial hazards introduced via water, the interaction of water with the diverse range of fresh produce at different steps along the supply chain, and the effectiveness of risk reduction measures at these steps both to improve water quality and to protect fresh produce quality. Further data are required for quantitatively assessing risks in many settings globally.

There is a need for identification of new, reliable and agreed indicators for water quality that relate to safety, including practical methods for field and on-line use taking into consideration not only bacteria but also virus and protozoa.

A major gap in the existing guidelines relates to the implementation of risk mitigation measures, which require risk awareness to cause behaviour change. The provision of water treatment infrastructure appears straightforward in principle. However, behavioural change of farmers, traders and consumers still constitutes a vast research field in the context of “wastewater irrigation”, despite the fact that behaviour change concepts are largely developed and have increasingly been applied in campaigns against open defecation and promotion of hand washing. In the case of wastewater and food safety, risk awareness is often very low. A framework for supporting behaviour change (Karg and Drechsel, 2011) requires analysing:

- whether safer practices would directly pay off by either improving production or reducing production costs (push factor);
- whether safer practices would eventually pay off due to an increased willingness to pay by consumers and traders (pull factor);
- whether there are other triggers and (positive or negative) incentives that could change behaviour, including social marketing approaches.

As such an analysis will be location-specific, we are recommending case studies for application of the DT and identification of options on how to support actionable behaviour change beyond creation of risk awareness.

6.1.6 References for fresh produce decision trees

References specifically to support the DTs are provided below.

FAO GAPS

- FAO. 2010.** Good Agricultural Practices (GAP) on horticultural production for extension staff in Tanzania. (available at <http://www.fao.org/docrep/013/i1645e/i1645e00.pdf>). Accessed 27 June 2018.
- FAO. 2007.** Guidelines: Good Agricultural Practices for family agriculture. (available at <http://www.fao.org/3/a-a1193e.pdf>). Accessed 27 June 2018.
- FAO. 1996.** Environmental impact of animal manure management. 2. Manure management and effects of manure on the environment. (available at <http://www.fao.org/WAIRDOCS/LEAD/X6113E/x6113e05.htm>). Accessed 27 June 2018.
- FAO.** (no date). A scheme and training manual on Good Agricultural Practices (GAP) for fruits and vegetables. Volume 2 training manual. (available at <http://www.fao.org/3/a-i5739e.pdf>). Accessed 27 June 2018.

WHO

- WHO. 2010.** Using human waste safely for livelihoods, food production and health. Second information kit: The guidelines for the safe use of wastewater, excreta and greywater in agriculture and aquaculture. (available at http://www.who.int/water_sanitation_health/publications/human_waste/en/). Accessed 27 June 2018.
- WHO. 2009.** Water safety plan manual: step-by-step risk management for drinking water suppliers. (available at http://www.who.int/water_sanitation_health/publications/publication_9789241562638/en/)
- WHO. 2006a.** WHO guidelines for safe use of wastewater and excreta. Accessed 9 June 2018. (available at http://www.who.int/water_sanitation_health/sanitation-waste/wastewater/wastewater-guidelines/en/). Accessed 30 June 2018.
- WHO. 2006b.** Five keys to safer food manual. (available at <http://www.who.int/foodsafety/publications/5keysmanual/en/>). Accessed 27 June 2018.
- WHO. 2006c.** A guide to healthy food markets. (available at http://www.who.int/foodsafety/capacity/healthy_marketplaces/en/). Accessed 25 September 2018.
- WHO. 2010.** Guidelines for the safe use of wastewater, excreta and greywater in agriculture and aquaculture, third edition. Guidance note for national programme managers and engineers: Applying the guidelines along the sanitation ladder. (available at http://www.who.int/water_sanitation_health/wastewater/FLASH_OMS_WSHH_Guidance_note1_20100729_17092010.pdf). Accessed 9 July 2018.

Karg H. and P. Drechsel. 2011. Motivating behaviour change to reduce pathogenic risk where unsafe water is used for irrigation. *Water Internat.* 36: 476-490.

RESOURCES FOR FIGURE 3

Reference A. LGMA (Leafy Green Products Handler Marketing Agreement). 2017. Commodity-specific food safety guidelines for the production and harvest of leafy greens. (available at http://www.lgma.ca.gov/wp-content/uploads/2018/03/2017.08.10-CA-LGMA-Metrics_Numbered.pdf). Accessed 29 June 2018.

Reference B. CAC. 2003. CXC 53. Code of hygienic practice for fresh fruits and vegetables.

Reference C. US FDA. 1998. Guidance for industry: guide to minimize microbial food safety hazards for fresh fruits and vegetables. (available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm064574.htm>). Accessed 29 June 2018.

EC (European Commission). 2017. European Commission Notice No. 2017/C 163/01 Guidance document on addressing microbiological risks in fresh fruit and vegetables at primary production through good hygiene. (available at [https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XC0523\(03\)&from=LV](https://eur-lex.europa.eu/legal-content/EN/TXT/HTML/?uri=CELEX:52017XC0523(03)&from=LV)). Accessed 27 July 2018.

Amoah, P., Keraita, B., Akple, M., Drechsel, P., Abaidoo P.C. & Konradson, F. 2011. Low-cost options for reducing consumer health risks from farm to fork where crops are irrigated with polluted water in West Africa. IWMI Research Report Series 141, Colombo. (available at http://www.iwmi.cgiar.org/Publications/IWMI_Research_Reports/PDF/PUB141/RR141.pdf). Accessed 27 July 2018.

Mara, D., Hamilton, A., Sleight, A. & Karavarsamis, N. 2010. Discussion Paper: Options for updating the 2006 WHO guidelines. Second information kit: The guidelines for the safe use of wastewater, excreta and greywater in agriculture and aquaculture. WHO-FAO-IDRC-IWMI, Geneva. (available at http://www.who.int/water_sanitation_health/sanitation-waste/wastewater/guidance_note_20100917.pdf?ua=1). Accessed 9 July 2018.

Reference D. US FDA. 2008. Guidance for industry: Guide to minimize microbial food safety hazards for fresh fruits and vegetables. (available at <https://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/ucm064458.htm>). Accessed 27 July 2018.

WHO. Using human waste safely for livelihoods, food production and health. Second information kit: The guidelines for the safe use of wastewater, excreta and greywater in agriculture and aquaculture WHO-FAO-IDRC-IWMI, Geneva. (available at http://www.who.int/water_sanitation_health/publications/human_waste/en/).

Reference E. WHO. 2006c. A guide to healthy food markets. (available at http://www.who.int/foodsafety/capacity/healthy_marketplaces/en/) Accessed 27 July 2018.

6.2 FISHERY PRODUCTS

6.2.1 Approach to development of decision trees

The CAC provides a number of best hygiene practices for fish rearing and fish processing (CXC 52-2003). Current CAC guidance is mainly targeted at fish eaten cooked. The experts reviewed the literature for both cooked and uncooked fish and crustaceans (with the exception of bivalve mollusks). It was found early in the discussion process that sufficient HACCP guidance for cooked fish products already exists. The HACCP/RA-risk management plans for fish to be eaten raw or presumably undercooked still had to be delineated and this was the objective of the experts.

The variety of fish and crustaceans eaten raw is increasing. The impact of water quality used at all points in the fishery production chain from “harvest to market” for fish eaten raw or undercooked was reviewed and whether there is sufficient (and accessible) guidance for control at these points was assessed. A gap was identified in guidance for fish eaten raw or undercooked.

A DT with a binary (Yes/No) structure has been developed to assess the CCPs with regard to water quality for fish eaten raw or undercooked. Two scenarios have been used, one for wild-capture marine fish and one for pondwater fish. Identification of pathogens with most relevance to fish and fisheries and a focus on typical fish-borne pathogens have been adopted for the purpose of this work. A multi-barrier approach has been the basis for the DT constructed, which aims to:

1. identify all points where the load of pathogens could potentially be increased through the use of water of poor quality (meaning of lesser quality than at the previous step);
2. identify CCPs for food safety for the use of water in the production of fish and crustaceans eaten raw.

Both expert opinion and published literature are the basis of the decision support framework outlined. Ultimately, this DSS aims to identify CCPs for water quality in the production chain for raw fish products and to provide or refer to further (existing) guidance for achieving water of potable quality or RA planning. The structure presented in this document could be developed as it is (i.e. a binary DT) and also has the potential to be developed as a quantitative RA tool for higher-resource settings or surveillance purposes. The experts kept low-resource settings and smallholders in mind as an entry point for this particular work.

6.2.2 Fish-borne pathogens and epidemiological data

Relevant literature was reviewed. Some pathogens are of significant concern, most notably *Vibrio parahaemolyticus* in marine or estuarine environments (FAO 2011). Others – enteric pathogens, considered as a generic group – are mainly related to freshwater aquaculture. The pathogens in Table 2 were assessed in relation to fish or fish-processing (fish-associated) microbial risks associated with water quality.

TABLE 2. Fish-associated pathogens considered due to relevance in relation to water quality

Fish-associated pathogens	Relevance in relation to water quality
Parasites (trematodes) Not specifically addressed here	Relevant if product is eaten raw; mitigation is product freezing; temperature control is an important CCP; specific guidance should be consulted regarding control of fish parasites by freezing.
<i>Vibrio parahaemolyticus</i>	Very relevant; outbreak data available; FAO/WHO risk assessment studies available (FAO 2011).
<i>Listeria monocytogenes</i>	Relevant for fish consumed raw (cold smoked fish, sushi, ceviche, etc.) Existing codes of practice, hygiene codes and Codex standards would not sufficiently deal with this hazard.
<i>Vibrio cholerae</i>	Outbreak data available – example: ceviche in South America, 1990s. Often involves bivalves, crustaceans (e.g. shrimp) and fish. Risk levels are related to post-harvest handling more than directly to contaminated environmental water (which is widespread). Important risk factors post-harvest are: pathogen presence in raw fish; the status of hygiene or lack thereof during preparation; and inappropriate storage, especially time and temperature conditions.
<i>Aeromonas</i>	Pathogen present in estuarine and fish-processing environments. Based on WHO fact sheet GDWQ (2017) it appears that <i>Aeromonas</i> spp. from fish and production/processing systems is not a likely human health concern from water used for fish producing and processing, as fish-associated aeromonads are different species and strains than virulent strains of <i>A. hydrophila</i> and other species that cause human infections.
<i>Plesiomonas shigelloides</i>	Primarily a freshwater aquatic organism, although also present in estuarine water and in both fish and shellfish. Rates of isolation as well as human illness are higher in warmer months; illness has occasionally been associated with fish and shellfish (Janda <i>et al.</i> , 2016; Miller and Koburger, 1985). Cooking of fish and shellfish is a CCP. Risk of infection from raw or undercooked fish and shellfish is uncertain, although considered low based on paucity of reported outbreaks of illness.

6.2.3 Two cases - scenarios for fish and crustaceans eaten raw or undercooked

Based on the pathogen data reviewed, it was concluded that there are differences in pathogens present in freshwater fish and in marine and estuarine water fish that have to be considered. Differences between an industrial setting and a simpler harvest to market chain also have to be considered. Both the short-chain and industrial scenarios have been accounted for in the final decision support framework developed. For both scenarios it was assumed that the end product would be consumed either raw or potentially undercooked.

Scenario 1: Fresh water (tilapia/catfish/shrimp) aquaculture with short production line to market (for raw consumption)

This scenario considers a pond where either tilapia or shrimp are raised. It is assumed the pond is faecally contaminated and therefore the fish or shrimp that feed off the bottom (sediment) of the pond will show contamination in their gut and on body mucus. Main issues identified are whether the fish is eaten raw and if basic hygiene measures are applied or not – in a marketplace, in a restaurant setting or at home. Not having sufficient water of good/potable quality could be a factor for unhygienic practices, as would be awareness, or lack thereof, of hygiene measures required. These hygiene measures for food preparation are covered by the Codex *Code of Practice for Fish and Fishery Products* (CAC 2003). A concern is that the existing Codex *Code of Practice* document might not be sufficiently accessible for certain users. Also, the current Codex *Code of Practice* lacks specific guidance on water quality management. With regard to water and hygiene, the DT should make reference to existing water quality management guidance, including those management practices suitable for resource-limited market settings, such as rainwater harvesting options or point-of-use (household) water treatment guidance (WHO GDWQ, 2017).

Scenario 2: Horse mackerel for sashimi in mid- to large-scale operational setting

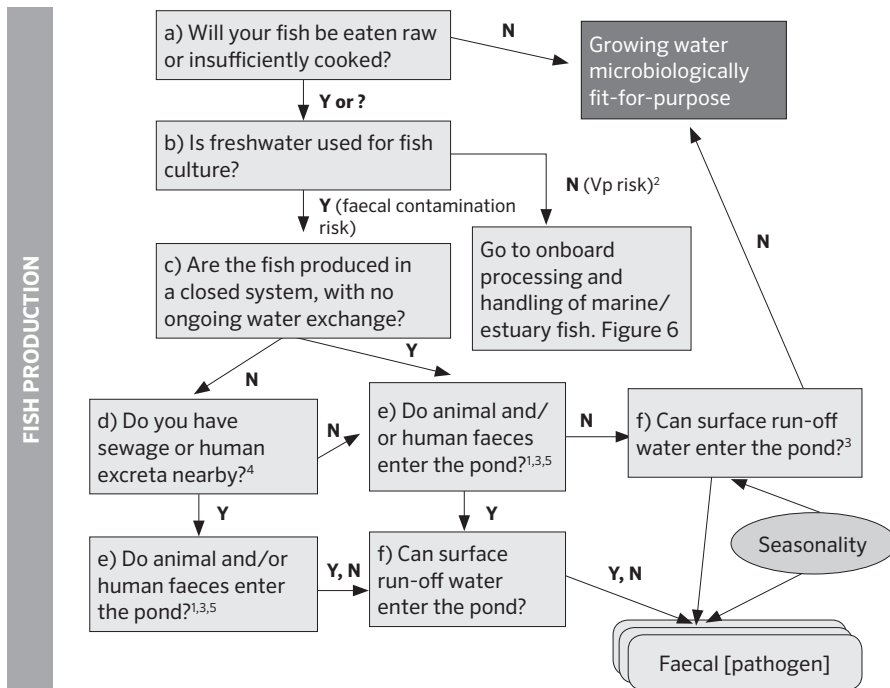
This scenario considers horse mackerel, a marine capture fish. It is assumed that the fish is gutted and washed with contaminated marine seawater onboard or in the landing site and therefore fish meat will be exposed to contamination. Main issues identified are whether the fish is eaten raw and if basic hygiene procedures are applied or not – onboard, at the landing site, in a marketplace, in a restaurant setting or at home. Not having sufficient water of good/potable quality could be a factor for unhygienic measures, as would be awareness, or lack thereof, of hygiene measures required. There are no Codex standards for fish intended to be consumed raw, nor guidance for hygiene measures in the Codex *Code of Practice for Fish and*

Fishery Products (CAC 2003). In addition, as specified in Scenario 1, the current Codex *Code of Practice* lacks specific guidance on water quality management.

6.2.4 Overview of the decision tree developed, diagram

Production (entry of the support tool, Figure 4)

The DT is generated such that answers to questions (if identified and quantified) will lead to an assessment of the expected pathogenic load around fish harvesting. This load is indicated in the following figures as multiple levels of the box labelled ‘[pathogen]’ which is the final node in each of the DTs. These boxes represent different pathogen concentrations. Additional data, such as seasonal influences (e.g. temperature, rain events), could be integrated within the DT. These data can be used in background computation of the magnitude of risk according to the magnitude of the concentration categories. Alternatively, if risks are not comput-



¹ Section 6 of the Codex Code of Practice for Fish and Fishery Products on aquaculture products, pp.54-64

² Risk assessment of *Vibrio parahaemolyticus* in seafood, WHO/FAO MRA Series 16, pp. 154-176

³ WHO Water Safety Plan. WHO/Europe 2014

⁴ WHO Sanitation Safety Plan Manual

⁵ WHO Safe Use of Wastewater, Excreta and Grey Water. Vol. 3. Aquaculture

FIGURE 4. Decision tree for production level of fish and fish products

able as intended, the DT can work as an awareness-raising tool, giving guidance to aquaculture farmers and fishers on taking preventive measures against identified sources of hazards and contamination.

a) The entry level question of the DT is whether fish will be eaten raw or insufficiently cooked. If the answer is no (N) it is assumed that the fish is eaten cooked, that there is no further microbiological hazard and that the growing water is fit for purpose [end of decision process]. If the answer is yes (Y) or the intended use is unsure (?), the DT leads to the following question (b).

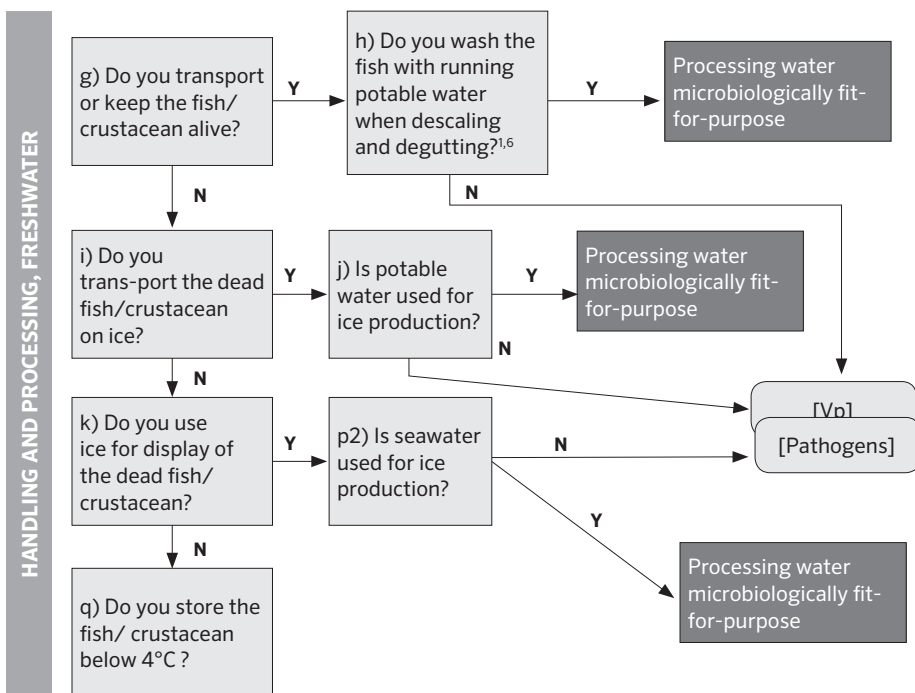
b) The next question is whether freshwater is used for fish culture. If the answer is no (N), it is seawater fish and the DT refers to Figure 6. If the answer is yes (Y) or unsure (?), there can be a risk of faecal contamination and the DT leads to the following question (c). If it is seawater fish then see Figure 6; if it is freshwater fish, the questions continue for the pond setting.

c) The next question is whether fish are produced in a closed system, with no ongoing water exchange; both replies, yes (Y) or no (N), lead to different questions, (d) and (e). Questions from (d) to (f) are designed to assess the magnitude of hazardous events related to safety and quality of pond water in contact with the fish product (both alive and after harvest) before processing.

d) If the fish is not kept in enclosed water, it is important to know if the pond water is in any other way contaminated with human or animal faeces. The use of untreated human or animal faeces as manure fertilizer or the direct disposal of human or animal excreta into the water usually results in hazards that need to be considered specifically and must be prevented and controlled as a CCP.

e) If the fish is kept in enclosed water (with no further water exchange), in principle, it will show a die-off of initial pathogen numbers, decreasing the impact of the pathogen load in the water and limiting the introduction of new pathogens to the pond and the fish. Whether or not the enclosed or open water might be indirectly affected by human excreta through sanitation facilities nearby also must be considered as a source of microbial hazards that must be managed or prevented. Reference could be made here to the *Guidelines for Safe Use of Wastewater and Excreta in Agriculture and Aquaculture* (WHO 2006) or the *Sanitation Safety Planning Manual* (WHO 2015).

f) The last question is whether or not the pond (enclosed or not) may be further contaminated by rainwater run-off from the land that may contain faecal matter. Reference could be made to the *WHO Sanitation Safety Planning Manual* (2015) or other WSP guidance targeted at source water protection. It should be noted that



¹ Codex Code of Practice for Fish and Fishery Products, Section 6. pp. 54-64
⁶ WHO Guidelines for Drinking Water Quality

FIGURE 5. Decision tree for processing and handling of freshwater fish/crustaceans which will potentially be eaten raw

there is no direct risk for food safety at this point, if the fish is not consumed before processing. To further evaluate the risk, the DT *Processing and handling of freshwater fish* will provide further guidance (Figure 5).

Processing and handling of freshwater fish

The continuing DT illustrated in Figure 5 addresses the processing of freshwater fish/crustaceans which will potentially be eaten raw.

g/h) The entry level question is whether the fish will be transported alive. If the answer is yes (Y) and the fish is kept alive during transport until processing at the marketplace the next question (h) would be if potable quality water is used when washing fish during descaling and gutting. Water of potable quality is required also for basic hygiene measures where there is contact with fish (e.g. knives, cutting boards). References are provided for guidance on how to achieve water of potable

water quality in a limited resource setting such as the marketplace [WHO GDWQ 2017; WHO 2011; WHO/EURO 2014; also see overview of WHO Water Safety Plan guidance material http://www.who.int/water_sanitation_health/publications/wsp-roadmap.pdf?ua=1]. If the answer to this last question (h) is no (N) and the fish is intended to be consumed raw, the final product is likely to contain a load of pathogens. If the answer is yes (Y) the processing water is considered microbiologically fit for purpose. If the answer to the entry level question (g) is no (N), the fish is not kept alive, the DT leads to the following question (i).

i/j) The next questions relate to whether the dead fish is transported chilled. One of the most important measures related to fish preservation and microbial pathogen die-off after death is keeping the fish at a low temperature (below 4°C). If the answer is yes (Y) the DT leads to the next question (j), about whether potable water is used for ice production. If the answer is yes (Y), the processing water is considered fit for purpose; if the answer is no (N), and the fish is intended to be consumed raw, the final product is likely to contain a load of pathogens. If the answer to the initial question (i) is no (N), and the fish is not kept on ice prior reaching the market, the DT leads to the following question (k).

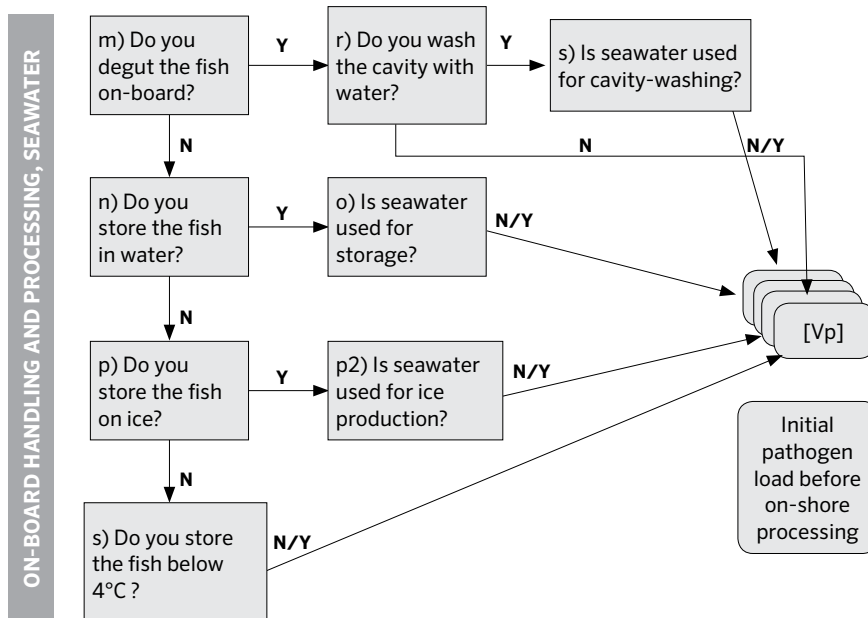


FIGURE 6 Decision tree for onboard processing and handling of marine/estuarine fish

The use of water of non-potable quality for ice-making can pose a risk for the presence of a range of potential pathogens that differ with the source of the water and its vulnerability to faecal and other contamination. Such microbial contamination poses an increased risk to fish consumption. Even if the fish has been rinsed with water of potable water quality, the fish might be recontaminated if the fish is put on microbiologically contaminated ice for display.

k/l) The next question (k) relates to whether or not fish are kept on ice for display in the marketplace or whether fish is stored below 4°C (l), in which case, the DT reverts back to question (h).

Onboard processing and handling of marine/estuarine fish

There are additional water contact events to be anticipated for marine and estuarine fish that may contribute to the order of magnitude of pathogen load of the fish before processing. For this particular DT (Figure 6) only *V. parahaemolyticus* was taken into account as a fish-borne pathogen (see case scenarios).

m) The entry level question is if the fish is gutted on board; whether or not this step has taken place can potentially influence pathogen loads and leads to the following questions:

n) If the fish is not gutted it is often kept (alive) in water in containers;

o) If seawater is used for storage of non-gutted fish, this may lead to different *V. parahaemolyticus* levels compared to other water; the answer to the question of what kind of water is used and its source may lead to an assessment of the expected *V. parahaemolyticus* load in order of magnitude.

p) If the non-gutted fish is not kept in water, the question is whether it is kept on ice. If this is the case, the next question (p2) is whether the ice is made from seawater; again, this may contribute to the expected *V. parahaemolyticus* load in order of risk magnitude (categorical) concentrations.

q) If the non-gutted fish is not kept on ice, the questions relate to whether there are other chilled storage methods. The most important control measure with regard to *V. parahaemolyticus* is to keep the fish stored on board at or below 4° C. Again, if this is not the case, then an elevated initial pathogen load is to be expected, depending on storage duration, and possibly contributing to the risk in the onshore processing environment (see Onshore processing of marine/estuarine fish).

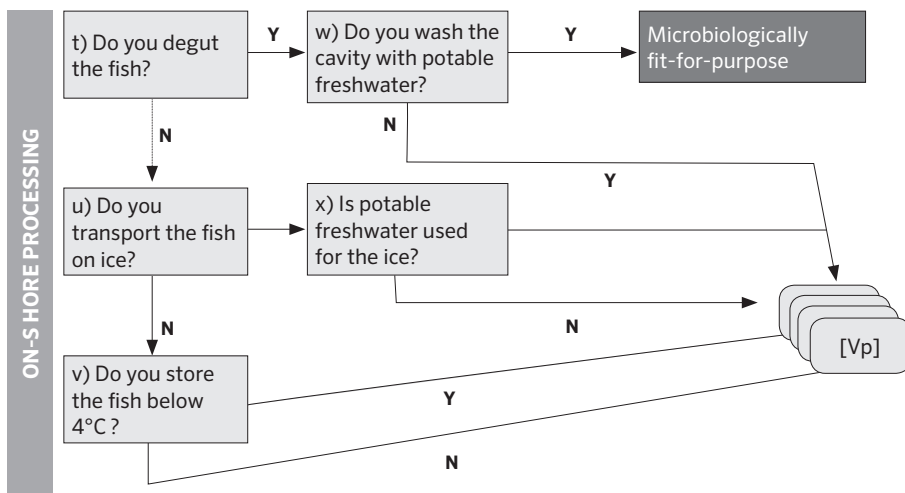


FIGURE 7. Decision tree for onshore processing of marine/estuarine fish

r) If the answer to the entry level question is yes (Y) and the fish is gutted on board, it may or may not be rinsed. No rinsing may lead to cross-contamination during subsequent handling.

s) If the answer to the question (r) is yes (Y) and if the gutted fish is rinsed with seawater, *V. parahaemolyticus* might be introduced into the cavities. A negative answer also leads to the initial appraisal of the load of *V. parahaemolyticus* before the onshore processing of marine/estuarine fish section of the DT (Figure 7).

Onshore processing of marine/estuarine fish

An industrial processing facility was envisioned for the processing of the mackerel from the case scenario.

t) The entry level question of the DT is whether the fish will normally be gutted in the processing facility; if the answer is yes (Y), the next question (w) is whether the cavity of the fish is washed with potable freshwater, in which case there would not be a further risk of *V. parahaemolyticus* at this point. If the fish cavity is not washed with potable freshwater, depending on what kind of water is used and its source, this may lead to an assessment of the expected *V. parahaemolyticus* load in order of magnitude.

The most important control measure would be to rinse the cavity with water of potable quality following the WHO *Guidelines for Drinking Water Quality* (WHO GDWQ, 2017). It is expected that the fish is then processed into fillets and packaged immediately under normal hygienic conditions (taking into account the guidance and regulations of the Codex *Code of Practice for Fish and Fishery Products*).

u/v), If the answer to the entry level question (t) about whether the fish was gutted is no (N), it is asked in the DT whether the intact fish is transported on ice to the marketplace, restaurant, etc. or kept below 4°C (question v). This would contribute to any further pathogen die-off, especially if fish would be frozen for 48 hours. See 'Identified critical control points' below.

w) Whether or not potable water is used for the production of ice may have an additional impact on the pathogenic load of *V. parahaemolyticus* in the fish. Additional washing of the fish with potable water alone, at the household for instance, can mitigate the effect of the initial pathogenic load.

6.2.5 Identified critical control points

The DTs show that the multi-barrier approach is possible with regard to water quality management in the production of fish and crustaceans consumed raw. There are however certain control points that are most important – i.e. the CCPs:

1. Washing of the fish with (running) potable water after gutting is most important. Codex does not give specific guidance on achieving running water of potable quality. It is therefore recommended there should be further reference to existing water quality management guidance (GDWQ, WSP), or to new guidance (DTs).

2. Controlling temperature to avoid pathogen growth is critical. Holding seafood at temperatures that inhibit microbial pathogen growth or restricting time above those temperatures are essential to control the level of microbial pathogens present. Freezing is an important control measure for inactivation of parasites in fish. This is already captured in the Codex *Code of Hygiene for Fish and Fishery Products* (CAC, 2016) and therefore, while recognized as important, it was not addressed in these DTs.

3. Avoiding cross-contamination by using good hygiene measures is advisable. This is already captured in the Codex *Code of Hygiene for Fish and Fishery Products* (CAC, 2016).

4. Protecting ponds from faecal contamination avoids introduction of microbial hazards. This is already described in the Codex *Code of Practice for Fish and*

Fishery Products (CAC, 2016), although the practical application could be further supported by guidance and background documentation. A link could be made to WHO water and sanitation safety planning guidance for this purpose.

Epidemiological data from fish-related outbreaks and the relevance of related pathogens for fish-processing environments were reviewed. Data from Africa and Southeast Asia were found to be largely lacking, and only limited data for the EU and North America were available. This is a research gap that could be addressed. However, it should be noted that known risk reduction strategies and mitigation measures, following the CCPs described, will still apply.

6.2.6 Conclusions and recommendations

Recommendations

- Some pathogens are of significant concern, most notably *V. parahaemolyticus* in marine or estuarine environments. Other enteric pathogens, including *V. cholerae*, *Salmonella* spp., *P. shigelloides* and *Aeromonas* spp., can be considered and addressed as a generic group, primarily related to freshwater aquaculture, although not exclusively.
- There are differences between freshwater and marine and estuarine water fish. For both scenarios, it is assumed that the end products would be consumed either raw or potentially undercooked, as they would present the greater risk compared with well-cooked fish. Access to sufficient water of clean or potable quality, and awareness about the need for and practice of rigorous hygiene measures would be crucial for the fish eaten raw.
- Based on the DTs, the CCPs, including protecting the pond from faecal contamination, washing with potable water, controlling temperature and time and avoiding cross-contamination, showed that the multi-barrier approach is possible with regard to water quality management in the production of fish and crustaceans consumed raw.

Challenges and Gaps

- Epidemiological data from fish-related outbreaks and the relevance of related pathogens for fish-processing environments for Africa and Southeast Asia are largely lacking, and only limited data for the EU and North America are available. This is a research gap that could be addressed to allow more representative assessment of appropriate risk reduction measures.
- Feasibility of implementing or creating a safe water management plan, diversity of production systems, capacity of management plan users, production volume and economic development status may require consideration on a case-by-case basis; one DT approach may not fit all fish production systems globally.

- The Codex guidance and codes of practices for fish and fishery products already cover the hygienic procedures for food preparation. However, these documents may not be sufficiently accessible enough to all users. Additional guidance resources appropriate for specific settings and users are needed and recommended.

6.2.7 References for fishery product decision trees

Reference material specifically to support the DTs

STUDIES ON FISH-BORNE PATHOGENS AND BURDEN OF DISEASE

FAO/WHO. 2003. Risk assessment of choleraenic *Vibrio cholerae* O1 and O139 in warm-water shrimp in international trade: Interpretative summary and technical report. Microbiological Risk Assessment Series 9 (available at <http://www.fao.org/tempref/docrep/fao/009/a0253e/a0253e00.pdf>). Accessed 27 July 2018.

FAO/WHO. 2011. Risk assessment of *Vibrio parahaemolyticus* in seafood: Interpretative summary and technical report. Microbiological Risk Assessment Series 16 (available at <http://www.fao.org/3/a-i2225e.pdf>). Accessed 27 July 2018.

Janda, J.M., Abbott, S.L. & McIver, C.J. 2016. *Plesiomonas shigelloides* Revisited. *Clin. Microbiol. Rev.* 29: 349-374.

Miller, M.L. & Koburger, J.A. 1985. *Plesiomonas shigelloides*: An opportunistic food and waterborne pathogen. *J. Food Prot.* 48: 449.

WHO/FERG. 2015. Estimates of the global burden of foodborne diseases. Foodborne diseases burden epidemiology reference group 2007-2015. World Health Organization, 2015. (available at http://www.who.int/foodsafety/publications/foodborne_disease/fergreport/en/). Accessed 27 July 2018.

Bad Bug Book – FDA. (available at <https://www.fda.gov/downloads/food/foodsafety/foodborneillness/foodborneillnessfoodbornepathogensnaturaltoxins/badbug-book/ucm297627.pdf>). Accessed 27 July 2018.

EFSA Food consumption database. (available at <https://www.efsa.europa.eu/en/food-consumption/comprehensive-database>). Accessed 27 July 2018.

WHO. 1999. Food safety issues associated with products from aquaculture: Report of a joint FAO/NACA/WHO Study Group, Technical report series 883. (available at <http://www.who.int/foodsafety/publications/aquaculture/en/>). Accessed 27 July 2018.

CRITICAL CONTROL POINTS AND HYGIENE MEASURES

CAC. 2013. CXC 52-2003 Codex Code of Practice for Fish and Fishery Products. FAO 2013.

WHO. 2015. Sanitation Safety Planning, Manual for safe use and disposal of wastewater, greywater and excreta. (available at http://www.who.int/water_sanitation_health/publications/ssp-manual/en/). Accessed 25 September 2018.

WHO. 2006. Guidelines for safe use of wastewater and excreta in agriculture and aquaculture. Mara, D. & Cairncross, S, eds. (available at http://www.who.int/water_sanitation_health/publications/wasteuse/en/). Accessed 27 July 2018.

GUIDANCE ON POTABLE WATER PRODUCTION AND PROTECTION

WHO. 2017. Guidelines for Drinking-Water Quality (GDWQ) (4th edition, 2017, incorporating the 1st addendum). (available at http://www.who.int/water_sanitation_health/publications/drinking-water-quality-guidelines-4-including-1st-addendum/en/). Accessed 25 September 2018.

WHO. 2011. Evaluating household water treatment options: Health-based targets and microbiological performance specification. (available at http://www.who.int/water_sanitation_health/publications/2011/household_water/en/). Accessed 27 July 2018.

WHO/Europe. 2014. Water Safety Plan: A field guide to improving drinking-water safety in small communities. (available at <http://www.euro.who.int/en/publications/abstracts/water-safety-plan-a-field-guide-to-improving-drinking-water-safety-in-small-communities>). Accessed 27 July 2018.

WHO Water Safety Planning publications. (available at http://www.who.int/water_sanitation_health/publications/wsp-roadmap.pdf?ua=1). Accessed 27 July 2018.

6.3 REUSE OF WATER IN A FOOD ESTABLISHMENT

Reuse water in food operations can be used in two broad applications: 1) where it is intended to have contact with food; and 2) where it is not intended to have contact with food. Both applications are addressed.

6.3.1 Not-for-food-contact applications

The “not-for-food-contact” applications could include technical steam, boiler feed, water needed to extinguish fires, or to wash vehicles (other than food transport vehicles), water lawns, clean external surfaces or flush toilets. While these applications may involve somewhat lower volumes of water, the use of potable water is not required from a microbiological safety point of view and reusing reclaimed or recycled water is possible (CAC, 1969).

It is a critical prerequisite that the design and infrastructure of the food operation are consistent and effective with regard to avoiding/preventing contact of the not-

for-food-application water with food or food contact materials. Where contact is controlled through logistics and staff training, active management and monitoring of required performance at timely intervals will be required to provide the food operation with the confidence that there is no breach of product safety in daily operations. When operational management effectively ensures that not-for-food-contact water is only applied for non-food-contact purposes, there is no need for additional, active management of microbiological parameters.

Not-for-food-contact applications include closed loop recirculation systems that are used to cool or heat product materials where the water does not necessarily have to be of potable or of otherwise suitable microbiological quality. The integrity of the physical barrier between the recirculating water and the food or food material is critical for avoiding cross-contamination and requires regular monitoring to ensure that the physical barrier is intact.

6.3.2 Food contact applications

Water that may come into contact, intentionally or unintentionally, with food material needs to meet microbiological requirements such that the safety of the food for consumers is not compromised.

Food contact applications include the use of water:

- as a food ingredient;
- for intentional food contact applications, such as washing and transporting, blanching, brining, soaking of food materials;
- for intentional food contact surface applications, such as cleaning and sanitation of surfaces/equipment (including clean-in-place water) that come in contact with food during operations.

Unintentional applications, for which cross-contamination of the water with food or food contact surfaces cannot fully and consistently be excluded, can include cleaning and sanitation of non-food-contact surfaces of processing equipment and lines, water spillages, cleaning of walls/ceilings, etc.

As high volumes of water can be used in both intentional and unintentional applications, substituting first-use, potable water with reuse water recovered from food or food contact sources can significantly reduce first-use water use and magnitude of water discharge.

Where reclaimed or recycled water is reused in food contact applications, the microbiological status of this reuse water must be equivalent to that of potable water (WHO, 2017) or must not contain microbiological hazards at levels that

would compromise consumer safety, given the food material concerned. The latter requires a case-by-case risk evaluation of the reuse water source, methods of recovery, storage and transport and the application of the reuse water, so the significant microbiological hazards can be identified and options for their effective and consistent mitigation determined.

Combinations of risk mitigation/management options for microbial hazards could include:

- setting limits and implementing specific control measures with appropriate validation and verification of their performance as part of the operation's FSMS (e.g. GHP and HACCP plan);
- reconditioning the reuse water to eliminate the hazards or reduce them to acceptable levels fit for the purpose;
- recovering the reuse water so it is of potable quality or water with hazards absent or at acceptable levels for the purpose;
- actively managing operations such that microbial contamination of any reuse water is reliably excluded/avoided or effectively controlled.

Reuse water can be applied where the likelihood of contamination of a food item can be significantly minimized such that there is no undue impact on consumer safety – i.e. where the risk is acceptable. For example, potable water from final rinsing operations might be recycled and reused for rinsing/washing/cleaning product materials earlier in the process (e.g. in a counter-flow process), provided cross-contamination between final and subsequent product is controlled – e.g. by an effective process water treatment measure. The final rinse still uses water from the potable water source and use of the recycled water reduces both the volume of first-use potable water used and water discharged. Also, when water is recirculated in a closed loop heating or cooling system, the risk of contamination is minimized, although the physical integrity of the system needs to be monitored and verified regularly. As long as the physical barrier is verified to be intact, the water recirculating in the closed loop system may be different from potable water and of different microbiological status.

6.3.3 Approach to development of decision trees

6.3.3.1 Risk-based framework for fit-for-purpose water reuse

The risk-based framework proposed considers the fit-for-purpose application of different types of reuse water in a food operation, differentiating among the use of water:

- a. as a food ingredient;
- b. for intentional food contact applications (contact with food or surfaces);

- c. for unintentional food contact applications (contact with food or surfaces); and
- d. for not-for-food-contact applications.

Because water reuse descriptions in the literature and guidelines are ambiguous and inconsistent, descriptions of the three types of reuse water and of first-use water are specified in Table 3.

TABLE 3. Definitions of various water types used in food operations

First-use water	Potable water from an external source that can be used in any food processing operation.
Reuse water	Water that has been recovered from a processing step within the food operation, including from the food components and/or water that, after reconditioning treatment(s) as necessary, is intended to be (re-)used in the same, prior or subsequent food processing operation. Below are three types of reuse water considered in this report.
	Reclaimed water Water that was originally a constituent of a food material, which has been removed from the food material by a process step and is intended to be subsequently reused in a food processing operation. Examples: water that was originally part of a raw material or food (e.g. tomato, sugar beet, milk, whey) and removed by a process step (e.g. sugar beet or tomato juice evaporated and condensate water collected; condensate water from milk or whey evaporate; reverse osmosis permeate water from whey).
	Recycled water Water, other than first-use or reclaimed water, which has been obtained from a food processing operation, or water that is reused in the same operation after reconditioning. Examples: brine, scalding water and water for transporting or washing of raw materials, such as vegetables and fruits, in subsequent units, for which first-use water is used initially and then reused in previous units until it is used for cleaning of product coming from the field before being discarded or reconditioned.
Recirculated water	Water reused in a closed loop for the same processing operation without replenishment. Example: a cooling or heating system in which water circulates, (e.g. condenser or pasteurizer cooling water).

Depending on the application, the reuse water may be fit for purpose with or without appropriate reconditioning. Certain applications may require a significant level of microbiological expertise regarding water recovery, reuse, storage and re-

conditioning, as well as expertise in assessing and managing consumer risks associated with water reuse and the technical and engineering aspects of implementing water reuse in the food operation along with economic and regulatory aspects.

Simple assessment of fit-for-purpose application of the different water types:

- First-use water is fit for purpose for any of the four applications in an establishment. The establishment in principle does not require specific capabilities to judge the microbiological status of the water when the potable water source is known to be reliable and meets relevant water quality guidelines (e.g. WHO GDWQ).
- All four water types are fit for purpose for not-for-food-contact applications as sourced. The establishment in principle does not require specific capabilities to judge the microbiological quality of the water when contact with food/surfaces is known to be impossible.
- All three reuse water types can also be used for all applications, provided there are no significant microbiological hazards, or that the levels of these are acceptable in terms of consumer safety. To ensure fit-for-purpose application in this case requires that the establishment has the necessary capabilities (or can access these externally) to:
 - > assess and understand the microbiological status of the reuse water, especially regarding significant pathogens and whether they could contaminate food or food contact surfaces and pose a risk to consumers (the type of pathogen present and the likelihood of contamination will determine whether risks are acceptable);
 - > effectively monitor and consistently control the relevant microorganisms during operation;
 - > apply the necessary reconditioning treatment (single or multi-barrier) to reduce relevant pathogens or appropriate microbial indicators for them in the reuse water to acceptable level before application, to validate the reconditioning at operational scale and to verify its proper functioning during operation,
 - > establish a GHP/HACCP plan to specifically manage the consumer safety aspects of reuse water applications in the FSMS of the establishment; and
 - > take into account post-processing of the product after water contact that may also be a CCP.

When the necessary capabilities are lacking, or appropriate control is not possible or variable, the reuse water should be considered not fit for purpose, i.e. unsafe.

6.3.3.2 Risk-assessment approach

The microbiological status of reuse water should be based on a sound understanding of the technology chosen to reclaim or recycle the water in the food operation,

complemented with appropriate microbiological analyses of the reuse water as it is being generated or after reconditioning. Analysis of physicochemical parameters of the reconditioning or other treatment (e.g. disinfection chemical levels) may be required as well. The reuse of water may require treatment if the microbiological status of the water as it is recovered is not suitable for a food application. The efficacy of the treatment should be validated and verified/monitored in a timely way during full-scale operations, in order to assure that it does not compromise consumer safety.

To assess whether the microbiological status of the reuse water is fit for purpose requires good technical insight in a combination of the following:

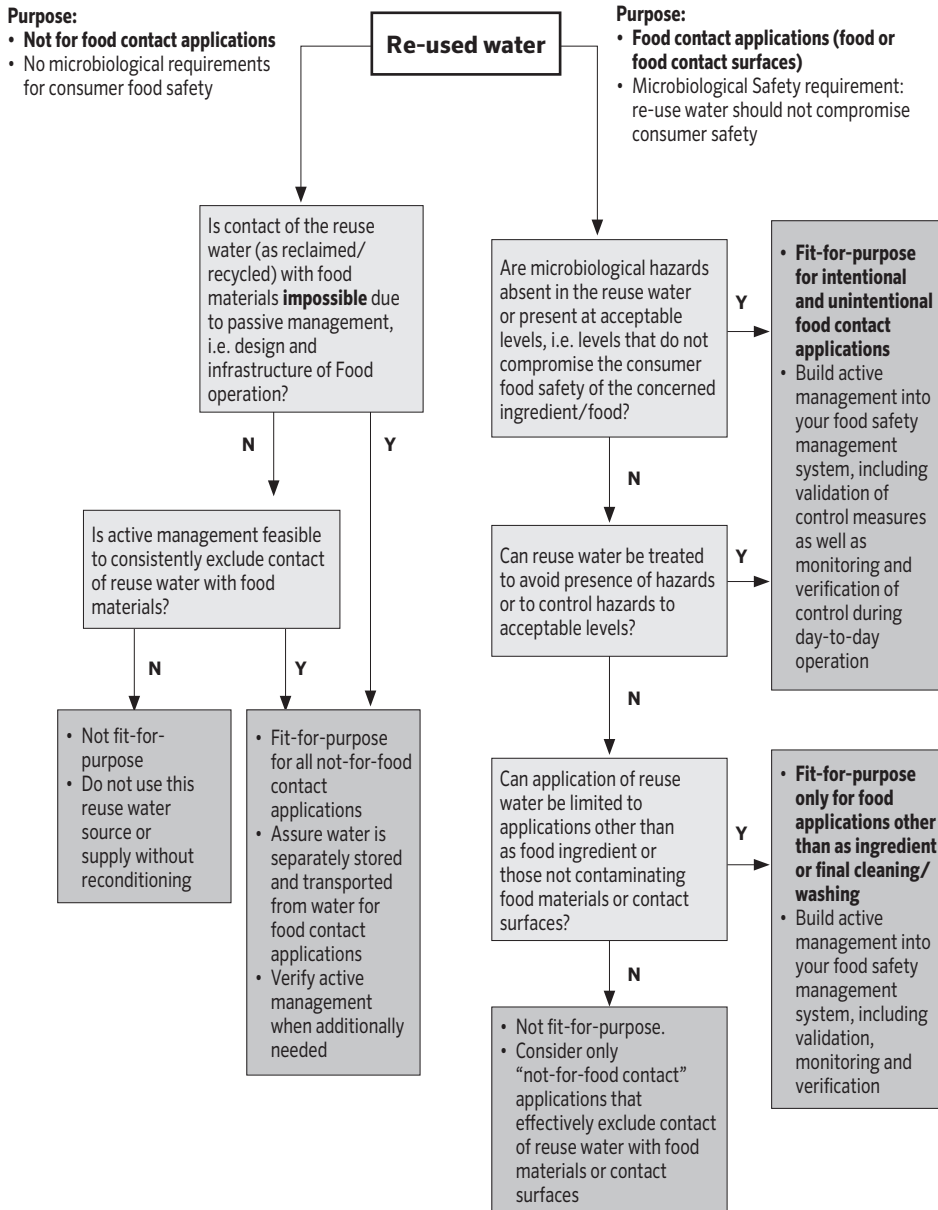
- all steps along the food chain from processing to consumption;
- the intended consumer and consumer use of the food;
- the impact of recovery, storage, transport and possible reconditioning of reuse water on its microbiological status (quality);
- the day-to-day food operation management and verification of control of water reuse applications to meet consumer microbial food safety targets.

An RA approach is recommended as a sound basis for making decisions on water reuse, including: generating reuse water; storage and/or reconditioning, when and where required; and actual use of reuse water for the specific application(s), including recirculation (Figure 8).

For example, in the case where water is reclaimed from a food material by heat evaporation and subsequent condensation, does the condensation process potentially allow for carry-over of microorganisms present in the food material (i.e. in aerosols/particles) to the condensate? If the answer is “no”, further treatment of the condensate will very likely not be relevant, and validation of the process and verification that the technology is performing as expected is required with an appropriate monitoring programme, as part of the food operation’s FSMS.

If the answer is “yes” – for instance, because of aerosol or particle formation – microbiological expertise will be required to determine:

- which microbiological hazards may be present on the food material and at what levels;
- whether these hazards survive the reuse water generation process;
- at what level the viable microbial hazards may be present in the reuse water and/or to what levels they may possibly grow during transport and/or storage before the water is used;
- the intended application of the reused water;
- other factors.



Note: only microbiological hazards are considered here, although in reality, physical and chemical hazards and quality parameters (including microbiological stability) need to be managed as well.

FIGURE 8. Risk-based framework and logic to match fit-for-purpose applications of reuse water with either a food contact application or a not-for-food-contact application

6.3.4 Treatment

Typical treatment technologies that can recover fit-for-purpose water quality or that can eliminate or inactivate microorganisms or reduce them to acceptable levels of reuse water include but are not limited to:

- pasteurization or boiling by heating;
- use of chemical disinfectant – e.g. chlorine, chlorine dioxide, ozone;
- physical treatments – e.g. UV light disinfection, membrane filtration.

All of these approaches may be used to bring the reuse water up to the quality level that allows for its use as an ingredient or for a direct or indirect food contact application, keeping in mind that a case-by-case risk evaluation and matching of water sources with fit-for-purpose applications is required. Validation is a key pre-operational requirement and verification is crucial as a post-operational requirement. In the case that such reconditioning treatments are not feasible or viable options for the food operation and the food materials concerned, it may be possible to use the reuse water supply for those applications where the consequences of water coming in contact with food are very limited regarding the safety of the consumer, such as initial (but not final) stages of washing of food materials or cleaning of food contact materials, making sure that the water used in the final stages of these operations meets the requirements for direct or indirect food contact applications.

6.3.5 Examples applying the risk-based framework for water reuse

The application of the generic framework should ideally be illustrated through specific case studies, considering different food operations that produce different food products – e.g. cheese, processed tomatoes or bottled soft drinks. This could be considered as further work.

6.3.6 Conclusions and recommendations

The reuse of water in the food industry is becoming a conventional practice. The costs of raw water or wastewater discharge and the availability of water are the main drivers that lead to water reuse/recovery practices.

- Treatments for reuse water for a fit-for-purpose use will depend on assessment of the risk of the reuse water. The RA and resulting risk management plan must meet the food operation's capacity to deal with any risks of reuse water identified and should be considered with other factors such as meeting regulatory requirements for microbiological parameters, costs and benefits. The focus here is on microbiological hazards, although it is noted that chemical hazards are also important and can involve consideration of worker occupational safety.

- Any reuse project will have associated investments and require skills development to properly conduct the risk analysis, identify CCPs, identify parameters to monitor and manage the treatment properly, while understanding the regulatory framework applicable to the reuse of water and to the quality and safety of final products.
- Consumer perceptions may be a barrier for adopting water recycling practices in food manufacturing. It is therefore strongly recommended that appropriate terminology should be used when communicating water recycling activities in food manufacturing to customers and the public. Also, regulators and other relevant government personnel may perceive concerns that should be addressed.
- Access to education and training, which could include workshops and e-learning material, is of paramount importance both for quality managers as well as for regulatory staff and inspection services.

6.3.7 References for water reuse decision trees

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WHO. 2017. Guidelines for drinking-water quality (4th edition, incorporating the 1st addendum).



Conclusions

7.1 GENERAL CONCLUSIONS AND RECOMMENDATIONS

1. Water is an essential but diminishing resource globally. Its use in food production should be managed to ensure safety while avoiding unnecessary consumption and waste and the associated costs for the community and the environment.
2. This Expert consultation provided more detailed support for the conclusion of the first Expert meeting – i.e. that the definitions of water quality and whether water is fit for purpose for a specific food application, which have been provided by Codex, international agencies and competent authorities, are inconsistent and not readily operationalized by food businesses.
3. There are similarities in the principles of risk management approaches taken to ensure safe drinking water and safe food generally that can be exploited in managing safe water use in food production and processing. RA of health risks based on scientific evidence is essential, risk reduction measures should be implemented at CCPs within an overall WSP or HACCP framework and verification is required to ensure the plans/systems are operating as expected.
4. In primary production and food processing, there are additional complexities compared with drinking water supplies; these are related to the high level of diversity and variability in food products and their contact with water in supply chains, the microbial hazards and the factors influencing their presence and control, and the end use of the food product.

5. Using water of potable or drinking water quality may be the safest option in primary production and food processing; however, requiring potable water use exclusively is not always a feasible, practical or responsible solution to safe water use in food supplies. Potable water is not always available, one-time use of potable water and the potential for unnecessary waste is unacceptable, and other types of water could be fit for some purposes provided they do not compromise the safety of the product for the consumer.
6. Risk management plans addressing food safety and water reuse have to take into account many factors – e.g. occupational safety for workers, need for special expertise, investments, cost- benefit analyses and management of consumer perceptions.
7. DTs could provide a tool for risk managers in making decisions on water's fitness for purpose and the required microbiological quality (potable water or other suitable quality) for use or reuse at a given step in the supply chain, provided they are based on assessment of final health risks at consumption and in the site context. High-level risk-based DTs with direction to further guidance were developed for fresh produce, fishery and water reuse scenarios. These would require evaluation and refinement in case studies before acceptance.
8. The meeting recommended that Codex documents need to include greater emphasis on a risk-based approach to safe water use and reuse.
9. In Codex texts, rather than specifying use of potable water or in some instances other clean (safe) water types, a risk-based approach to safe water sourcing and use that is fit for purpose should be articulated.

7.2 CROSS-CUTTING ISSUES

Criteria for microbiological quality of water used in food production

1. There is a lack of guidance on microbiological criteria for the various types of water used in the food industry for verification, operational and surveillance monitoring. Where criteria are recommended, there are inconsistencies among competent authorities in different countries.
2. Enumeration of microbial indicators is most commonly used as an alternative to pathogen (bacteria, viruses, parasites) detection in water; however, there is no universal agreement on the most appropriate microbial indicator species or groups for the range of hazards and the scientific rationale for this remains uncertain and controversial.
3. This is not a new issue and there is no simple solution available at present that can be applied to water use for food production. It is recommended that further work be conducted to consider appropriate criteria, noting the following comments:

- Emphasis has to be placed on a risk-based approach in establishing any microbiological criteria and this may need to be approached in an incremental manner.
- Microbiological criteria are one of the risk management metrics used by risk managers and the principles for their development and guidance are provided by Codex (CXG 63-2007).
- Potable water quality defined by levels of *E. coli* alone is not suitable for assessing safe water use in food safety as it is not considered an appropriate surrogate for the diversity of bacteria, viruses and parasites that may be present.
- It was proposed the criteria currently in use could be reviewed; criteria that would provide a high-level approach could be sought followed by more specific criteria.
- The feasibility of sector-specific criteria could be explored using the same approach as for a WSP. Some sectors have specific hazards – e.g. marine microorganisms in seafood.
- Accessible and appropriate analytical tools are required for in-field and on-line use.
- Potable water is a very precious resource in many countries and many people still do not have access to safe water and sanitation. This situation highlights a challenge with setting any kind of overarching microbiological criteria.

Knowledge and data gaps

- There is a lack of understanding regarding the behaviour of microbial hazards introduced via water, the interaction of water with the diverse range of products and in different environments at different steps along the supply chain, the effectiveness of risk reduction measures at these steps to improve water quality and concerns of unforeseen contaminations in water reuse.
- Qualitative and quantitative data for use in RA are very limited and, in some regions, non-existent.

Communication tools

- Education and training and programmes to encourage behaviour change were identified as essential requirements for effective risk management of safe water use in food chains. The concept of a fit-for-purpose approach and the implementation of directions in DSS will only be effective if food chain actors appreciate the value of this approach for their operations. Ways to achieve behaviour change and acceptance of a fit-for-purpose concept should be investigated and developed.

- Appropriate terminology should be used when communicating about safe water reuse activities in primary production and food processing to the food industry, regulators, customers and the public to reduce perceptions that water reuse will result in an unsafe product.

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Annexes

Resource material

Key reference materials were identified in background reviews provided for the meeting. These are listed below and include published literature, standards and guidelines and other documents. They support the background summaries in Sections 2 Produce, 3 Fishery products and 4 Reuse of water in the main report.

1. RELEVANT RISK ASSESSMENT APPROACHES AND AVAILABLE TOOLS

CAC 1999. Principles and guidelines for the conduct of microbiological risk assessment. CXG-30 (1999).

1.1 Descriptive assessments

WHO. 2017. Progress on drinking water, sanitation and hygiene. Update and SDG baselines.

WHO. 2016. Quantitative microbial risk assessment: Application to water safety management.

WHO. 2016. Safe sanitation planning.

WHO. 2012. Five keys to growing safer fruits and vegetables.

WHO/UNICEF. 2012. Rapid assessment of drinking-water quality: A handbook for implementation.

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FAO. 2014. FAO fisheries and aquaculture technical paper 574: Assessment and management of seafood safety and quality: current practices and emerging issues.

WHO. 2016. Safe sanitation planning.

WHO. 2005. Water safety plans: Managing drinking-water quality from catchment to consumer.

WHO/UNICEF. 2012. Rapid assessment of drinking-water quality: A handbook for Implementation.

1.3 QMRA

WHO. 2017. Guidelines for drinking-water quality (4th edition).

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WHO. 2011. Evaluating household water treatment options: Health-based targets and microbiological performance specifications.

WHO. 2006. WHO guidelines for the safe use of wastewater, excreta and greywater.

1.4 Decision support tree approach

ILSI. 2008. Considering water quality for use in the food industry. Report commissioned by the ILSI Europe environment and the health task force.

2. RISK REDUCING TREATMENTS

ILSI. 2013. Water recovery and reuse: Guideline for safe application of water conservation methods in beverage production and food processing.

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FAO/WHO Microbiological Risk Assessment Series

- 1 Risk assessments of *Salmonella* in eggs and broiler chickens: Interpretative Summary, 2002

- 2 Risk assessments of *Salmonella* in eggs and broiler chickens, 2002

- 3 Hazard characterization for pathogens in food and water: Guidelines, 2003

- 4 Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: Interpretative Summary, 2004

- 5 Risk assessment of *Listeria monocytogenes* in ready-to-eat foods: Technical Report, 2004

- 6 *Enterobacter sakazakii* and microorganisms in powdered infant formula: Meeting Report, 2004

- 7 Exposure assessment of microbiological hazards in food: Guidelines, 2008

- 8 Risk assessment of *Vibrio vulnificus* in raw oysters: Interpretative Summary and Technical Report, 2005

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- 11 Risk assessment of *Campylobacter* spp. in broiler chickens: Interpretative Summary, 2008

- 12 Risk assessment of *Campylobacter* spp. in broiler chickens: Technical Report, 2008

- 13 Viruses in food: Scientific Advice to Support Risk Management Activities: Meeting Report, 2008

- 14 Microbiological hazards in fresh leafy vegetables and herbs: Meeting Report, 2008

- 15 *Enterobacter sakazakii* (*Cronobacter* spp.) in powdered follow-up formula: Meeting Report, 2008

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- 22 Selection and application of methods for the detection and enumeration of human pathogenic *Vibrio* spp. in seafood: Guidance, 2016

- 23 Multicriteria-based ranking for risk management of food-borne parasites, 2014

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- 25 A risk based approach for the control of *Trichinella* in pigs and *Taenia saginata* in beef: Meeting Report, In press

- 26 Ranking of low moisture foods in support of microbiological risk management: Meeting Report and Systematic Review, In press

- 27 Microbiological hazards associated with spices and dried aromatic herbs: Meeting Report, In press

- 28 Microbial Safety of lipid based ready-to-use foods for the management of moderate acute and severe acute malnutrition: First meeting report, 2016

- 29 Microbial Safety of lipid based ready-to-use foods for the management of moderate acute and severe acute malnutrition: Second meeting report, In press

- 30 Interventions for the Control of Non-typhoidal *Salmonella* spp. in Beef and Pork: Meeting Report and Systematic Review, 2016

- 31 Shiga toxin-producing *Escherichia coli* (STEC) and food: attribution, characterization, and monitoring, 2018

- 32 Attributing illness caused by Shiga toxin-producing *Escherichia coli* (STEC) to specific foods, 2019

- 33 Safety and Quality of Water Used in Food Production and Processing, 2019

Water is a major input in food, from primary production through all stages in the food value chain to consumption. Water can contact food directly or indirectly and is used in maintenance of hygiene and sanitation throughout the food chain. Water is a diminishing resource globally and not all food primary producers and processors have access to safe water sources. Water needs to be used conservatively and it is possible to reuse water if it does not present a health risk for consumers.

The availability of water and water quality are different in each country, region, context, setting and food establishment, and improvement in water quality should be incremental. While water quality will be different in each context, it can be fit to use for certain purposes.

Deciding whether water is fit for purpose, assessment of the source water, potential hazards linked to this water source, treatment options and their efficacy, multiple barrier processes and the end use of the food product (e.g. if eaten raw) must be considered.

This report provides reviews on current guidance and knowledge on water use and safety for the fresh produce and fishery sectors and water reuse in food establishments, and also on risk management approaches to ensure the safety of water and food supplies. It also provides information on a fit-for-purpose concept and Decision support system (DSS) approaches.

There is a significant amount of diversity in food production, as illustrated in the scenarios addressed in the report. High-level risk-based Decision Trees (DTs) with direction to further guidance were developed for fresh produce, fishery products and water reuse scenarios which gives a general approach for these scenarios. The implementation of this system would require evaluation and refinement in specific case studies before its acceptance.

For further information on the joint FAO/WHO activities on microbiological risk assessment and related areas, please contact:

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