### **Supplementary Guidance for v3.2**

This document provides supplemental text to clarify the intent of the requirement and should be used in conjunction with PrimusGFS v3.2 Normative Documents and Interpretation Guidelines

Summary	of	Changes	Table
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Section	Question #	Change to Question	Change to Interpretation Text	Change to Scoring Criteria Text
Irrigation/Water Use	2.09.01f	No	Yes	No
Harvest Practices	4.05.14a	Yes	Yes	Yes
Harvest Practices	4.05.14b	Yes	Yes	Yes
Site	5.10.04	No	Yes	No
Chemical Files	5.11.03	No	Yes	Yes
Operation Monitoring Records	5.13.04	Yes	Yes	Yes
Field Worker Hygiene (applies to on-the- farm workers, not the harvesting workers)	2.07.04	Yes	Yes	No
Field Worker Hygiene (applies to on-the- farm workers, not the harvesting workers)	2.07.04a	Yes	Yes	No
Field Worker Hygiene (applies to on-the- farm workers, not the harvesting workers)	2.07.04b	Yes	Yes	No
Field Worker Hygiene (applies to on-the- farm workers, not the harvesting workers)	2.07.04c	Yes	Yes	No

Green text indicates new updates, red text indicates updates original to v3.2

**2.09.01f:** Are records kept for periodic visual inspection of the water source available for review? Total compliance (5 points): "Records" may include calendar books with commentary regarding what was checked, the condition, unusual occurrences, (e.g., issues regarding access to shut-off valve not impaired, any leakage from holes/cracks in line, well cap, well casing, seals, piping tanks, treatment equipment, cross connections, trash, animal presence, pooled water, etc.), and any action taken. The appropriate documentation should be available for review.

#### 4.05.14a: Are there specific Standard Operating Procedures (SOPs) for the monitoring of antimicrobial parameters in single-pass and/or recirculated/batch water systems, changing of recirculated and batch water systems (e.g., dump tanks), and for monitoring pH and water temperature (if applicable)?

Total compliance (10 points): The addition of an anti-microbial is expected for product contact water and/or ice. This includes single-pass, recirculated and batch water systems. In addition, for recirculated and batch water systems there is an expectation to monitor organic and soil build-up (turbidity). There should be specific written SOPs that describe the process of performing and recording antimicrobial concentration testing in water systems (including parameters, testing frequency, methodology and corrective action requirements), methods and monitoring procedures for measuring build-up of organic material (turbidity) in recirculated and batch water systems, monitoring pH (when using sodium/calcium hypochlorite in reused water systems) and water temperature (if applicable). The water temperature should be appropriate for the products and processes being performed. Water should be changed when it is dirty or when switching products. There should be documentation that validates the water changing frequency. Minimum frequency for water changing is at least daily; records of changes are kept. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used.

The "Common Anti-microbial Treatments for Product Contact Water &/or Ice" table (below) provides information regarding common anti-microbial treatments and resources relative to those treatments. Actual concentrations used should be properly justified with supporting documents, rationale and evidence. If utilizing and maintaining anti-microbial concentrations different than those indicated in the chart, justification supported by validation will be required.

Note, US (NOP) regulations allow for chlorine use in wash water at levels sufficient to control microbial contaminants and higher than 4 ppm free chlorine, where there is a final rinse with potable water to meet their ≤4 ppm free chlorine product contact requirement. Other anti-microbials include peracetic acid, chlorine dioxide, etc.

Lopez-Galvez, F., Allende, A., Gil, M. 2021. Recent progress on the management of the industrial washing of fresh produce with a focus on microbiological risks. Current Opinions in Food Science 38, 46-51.

Luo, Y. *et al.*, 2011. Determination of Free Chlorine Concentrations Needed to Prevent *Escherichia* coli O157:H7 Cross-Contamination During Fresh-Cut Produce Wash. J. Food Protection 74, 352–358. Luo, Y. *et al.*, 2018. Association between bacterial survival and free chlorine concentration during commercial fresh-cut produce wash operation. Food Microbiology 70, 120-128.

Gombas, D. *et al.*, 2017. Guidelines to Validate Control of Cross-Contamination During Washing of Fresh-Cut Leafy Vegetables. J. Food Protection 80, 312-330.

Suslow, T. Directors Update. 2017 Revisiting Practical Considerations in the Application of Oxidation Reduction Potential (ORP) as a Water Quality Metric. <u>https://postharvest.ucdavis.edu/files/260798.pdf</u> <u>https://www.canr.msu.edu/news/turbidity\_in\_post\_harvest\_wash\_water\_monitor\_and\_change\_when\_nee\_ded</u>

https://www.ams.usda.gov/rules-regulations/organic/handbook/5026

#### Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions within the SOPs for water monitoring or changing.
- Single/isolated instance(s) of errors or omissions in the validation documentation for water monitoring or changing.

Major deficiency (3 points) if:

- Numerous instances of errors or omissions within the SOPs for water monitoring or changing.
- Numerous instances of errors or omissions in the validation documentation for water monitoring or changing.

Non-compliance (0 points) if:

- SOPs for water monitoring or changing do not exist.
- SOPs do not address the frequency of water monitoring or changing.
- SOP requires changing less than daily and there is not a validated regeneration system used.
- Validation documentation does not support the parameters used.
- There is no validation documentation for water monitoring or changing frequency.

#### Common Anti-microbial Treatments for Product Contact Water &/or Ice

Anti- microbial	Parameters <sup>1</sup>	Requirements	Reference
Hypochlorite	<ul> <li>50-200 ppm total chlorine; ≥ 10 ppm free chlorine</li> <li>Optimal pH 6.0-7.0</li> </ul>	<ul> <li>Monitor pH in reused water systems.</li> <li>Sensitive to organic matter load</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.315 (a)(2)(5)(c)
Chlorine Dioxide	<ul> <li>Processed ≤ 3 ppm residual; Raw agricultural commodities 3-5 ppm residual.</li> <li>Optimal pH 4.0-10.0</li> </ul>	<ul> <li>Sample point for residual testing</li> <li>On-site generation</li> <li>pH monitoring not required.</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.300
Peroxyacetic Acid	<ul> <li>Processed ≤ 80 ppm.</li> <li>Raw agricultural commodities ≤100 ppm</li> <li>Optimal pH 3.0-7.5</li> </ul>	<ul> <li>Sample point for residual testing</li> <li>pH monitoring not required.</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.315 (5)(a) 40 CFR 180.1196
Ozone	<ul><li>0.5-3.0 ppm</li><li>Optimal pH 6.0-8.5</li></ul>	<ul> <li>On-site generation</li> <li>Sensitive to organic matter load</li> </ul>	21 CFR 173.368
UV-C	<ul> <li>200-280 nm (optimal 264 nm)</li> <li>Optimal pH 6.5-9.5</li> </ul>	<ul> <li>Unit located as close as possible to point of use</li> <li>Sensitive to organic matter load</li> </ul>	21 CFR 179.39
Acidic Electrolyzed Water	<ul> <li>50-200 ppm total chlorine; ≥ 10 ppm free chlorine</li> <li>800-1,000 mV</li> <li>Optimal pH 2.0-5.0</li> </ul>	<ul> <li>On-site generation</li> <li>Sensitive to organic matter load</li> <li>Follow label regarding potable water rinse</li> </ul>	FCN No. 1811

<sup>1</sup>This chart is intended for guidance only. Consult with research and industry guidelines for appropriate product, process and intended use.

# **4.05.14b**: Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, peroxyacetic acid) concentration testing of product contact water and ice solutions prior to start up and throughout the run?

Total compliance (10 points): Water systems using anti-microbial agents should have records showing that the concentration of the solution is within stated parameters. For "single pass" systems, this should be every batch of anti-microbial solution that is mixed. Recirculated/batch water systems should be

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Gombas, D. *et al.*, 2017. Guidelines to Validate Control of Cross-Contamination During Washing of Fresh-Cut Leafy Vegetables. J. Food Protection 80, 312-330.

Suslow, T. Directors Update. 2017 Revisiting Practical Considerations in the Application of Oxidation Reduction Potential (ORP) as a Water Quality Metric. <u>https://postharvest.ucdavis.edu/files/260798.pdf</u>

Minor deficiency (7 points) if:

- Single/isolated instance(s) of records showing solution strength out of parameters without adequate documented corrective actions.
- Single/isolated instance(s) of errors or omission in the records.
- Single/isolated instance(s) of total chlorine being recorded when free chlorine should have been used e.g., in chlorinated reused water systems.
- Single/isolated instance(s) of checks not carried out at the required frequencies.

Major deficiency (3 points) if:

- Numerous instances of records showing solution strength out of parameters without adequate documented corrective actions.
- Numerous instances of errors or omission in the records.
- Numerous instances of total chlorine being recorded when free chlorine should have been used e.g., in chlorinated reused water systems.
- Numerous instances of checks not carried out at the required frequencies.

Non-compliance (0 points) if:

- Water testing is not being recorded.
- Recorded solution strengths consistently out of parameters i.e., an unstable system (even if documented corrective actions exist).
- Widespread errors and omissions in the records.
- Total chlorine has been recorded throughout the system, when free chlorine should have been recorded e.g., in chlorinated reused water systems.
- Frequencies of checks consistently do not meet requirements of prior to start up and throughout the production runs.
- Single pass water system is in use without anti-microbial being used. The auditor should consider whether to apply 4.05.09 and score an automatic failure in view of the risk of cross contamination.
- Reused water system is in use without an anti-microbial being used. The auditor should consider whether to apply 4.05.09 and score an automatic failure in view of the risk of cross contamination.

### **5.10.04**: Is there a current certificate of inspection (or similar record) for backflow prevention assemblies on water lines into the facility?

Total compliance (3 points): There should be a backflow prevention device on main water lines entering the facility and backflow prevention devices or air gaps on individual water lines within production areas. Examples of backflow prevention include backflow preventer valves, air gaps, check valves, vacuum breakers. A trained inspector (e.g., appropriately certified plumber) should verify the principal backflow prevention system annually (unless there is a stated expiration on the certificate). Certificate should

indicate name of tester, their certificate number, location information for assembly, type of assembly, pressure across check valve(s), relief valve pressure, and whether unit passed or failed the test. Wells are also required to have backflow prevention devices to prevent cross connection or backflow during pump priming or maintenance. This question is still applicable even if local and/or national legislation does not require this type of inspection/testing. This question is not applicable if the facility does not use water. If the backflow prevention assembly type is one that cannot be inspected or tested, then the auditee should have documentation supporting this on–site e.g., backflow assembly manufacturer's documentation.

#### 5.11.03: Are there specific Standard Operating Procedures (SOPs) for the monitoring of antimicrobial parameters in single-pass and/or recirculated/batch water systems, changing of recirculated/batch water systems (e.g., dump tanks, flumes, hydrovacuums, hydrocoolers, etc.) and for monitoring pH and water temperature (if applicable)?

Total compliance (10 points): The addition of an anti-microbial is expected for product contact water and/or ice. This includes single-pass, recirculated and batch water systems. In addition, for recirculated and batch water systems there is an expectation to monitor organic and soil build-up (turbidity). There should be specific written SOPs that describe the process of performing and recording antimicrobial concentration testing in water systems (including parameters, testing frequency, methodology and corrective action requirements), methods and monitoring procedures for measuring build-up of organic material (turbidity) in recirculated and batch water systems, monitoring pH (when using sodium/calcium hypochlorite in reused water systems) and water temperature (if applicable). The water temperature should be appropriate for the products and processes being performed. Water should be changed when it is dirty and ideally when switching products. There should be documentation that validates the water changing frequency and water testing frequency. Minimum frequency for water changing is at least daily; records of changes are kept. Water may be used for longer if a validated regeneration system (e.g., a water pasteurization/filtration system) is being used.

The "Common Anti-microbial Treatments for Product Contact Water &/or Ice" table (below) provides information regarding common anti-microbial treatments and resources relative to those treatments. Actual concentrations used should be properly justified with supporting documents, rationale and evidence. If utilizing and maintaining anti-microbial concentrations different than those indicated in the chart, justification supported by validation will be required.

Note, US (NOP) regulations allow for chlorine use in wash water at levels sufficient to control microbial contaminants and higher than 4 ppm free chlorine, where there is a final rinse with potable water to meet their ≤4 ppm free chlorine product contact requirement. See 5.13.03, 5.13.04 and 5.13.05 for record keeping expectations. This question is not applicable in operations without product contact water/ice systems.

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https://www.ams.usda.gov/rules-regulations/organic/handbook/5026

Minor deficiency (7 points) if:

- Single/isolated instance(s) of errors or omissions within the SOPs for water monitoring or changing.
- Single/isolated instance(s) of errors or omissions in the validation documentation for water monitoring or changing.

Major deficiency (3 points) if:

- Numerous instances of errors or omissions within the SOPs for water monitoring or changing.
- Numerous instances of errors or omissions in the validation documentation for water monitoring or changing.

Non-compliance (0 points) if:

- SOPs for water monitoring and changing do not exist.
- SOPs do not address the frequency of water monitoring or changing.
- SOP requires changing less than daily and there is not a validated regeneration system used.
- Validation documentation does not support the parameters used.
- There is no validation documentation for water monitoring or changing frequency.

#### Common Anti-microbial Treatments for Product Contact Water &/or Ice

Anti- microbial	Parameters <sup>1</sup>	Requirements	Reference
Hypochlorite	<ul> <li>50-200 ppm total chlorine; ≥ 10 ppm free chlorine</li> <li>Optimal pH 6.0-7.0</li> </ul>	<ul> <li>Monitor pH in reused water systems.</li> <li>Sensitive to organic matter load</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.315 (a)(2)(5)(c)
Chlorine Dioxide	<ul> <li>Processed ≤ 3 ppm residual; Raw agricultural commodities 3-5 ppm residual.</li> <li>Optimal pH 4.0-10.0</li> </ul>	<ul> <li>Sample point for residual testing</li> <li>On-site generation</li> <li>pH monitoring not required.</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.300
Peroxyacetic Acid	<ul> <li>Processed ≤ 80 ppm.</li> <li>Raw agricultural commodities ≤100 ppm</li> <li>Optimal pH 3.0-7.5</li> </ul>	<ul> <li>Sample point for residual testing</li> <li>pH monitoring not required.</li> <li>Follow label regarding potable water rinse</li> </ul>	21 CFR 173.315 (5)(a) 40 CFR 180.1196
Ozone	<ul><li>0.5-3.0 ppm</li><li>Optimal pH 6.0-8.5</li></ul>	<ul> <li>On-site generation</li> <li>Sensitive to organic matter load</li> </ul>	21 CFR 173.368
UV-C	<ul> <li>200-280 nm (optimal 264 nm)</li> <li>Optimal pH 6.5-9.5</li> </ul>	<ul> <li>Unit located as close as possible to point of use.</li> <li>Sensitive to organic matter load</li> </ul>	21 CFR 179.39
Acidic Electrolyzed Water	<ul> <li>50-200 ppm total chlorine; ≥ 10 ppm free chlorine</li> <li>800-1,000 mV</li> <li>Optimal pH 2.0-5.0</li> </ul>	<ul> <li>On-site generation</li> <li>Sensitive to organic matter load</li> <li>Follow label regarding potable water rinse</li> </ul>	FCN No. 1811

<sup>1</sup>This chart is intended for guidance only. Consult with research and industry guidelines for appropriate product, process and intended use.

# 5.13.04: Are there records (with corrective actions) that show anti-microbial (e.g., free chlorine, peroxyacetic acid) concentration testing of product contact water and ice solutions prior to start up and throughout the production runs?

Total compliance (10 points): Product contact water and ice production systems using anti-microbial agents e.g., hypochlorite (chlorine), aqueous chlorine dioxide, peroxyacetic acid (PAA), ozone, etc., should have records showing that the concentrations of the solutions are within

parameters. Recirculated/batch water systems (e.g., flumes, wash/dump tanks, ice injectors, hydrovacuums, etc.) and single pass systems (e.g., spray bars) should be using an approved antimicrobial. Recirculated/batch water systems should be checked by measuring the "free anti-microbial" as opposed to bound microbial (e.g., testing for free chlorine as opposed to total chlorine); pH should be measured (5.13.03) when using sodium/calcium hypochlorite in reused water systems. In single pass systems it is acceptable to measure total chlorine (as per legislation). Water systems must have a stated anti-microbial level. For hypochlorite, the criteria should be ≥10 ppm free chlorine. Different concentrations should be properly justified with supporting documents, rationale and evidence. Note, US (NOP) regulations allow for chlorine use in wash water at levels sufficient to control microbial contaminants and higher than 4 ppm free chlorine, where there is a final rinse with potable water to meet their  $\leq 4$  ppm free chlorine product contact requirement. Other anti-microbials e.g., chlorine dioxide, ozone, electrolyzed water, etc., should also meet manufacturer label recommendations (auditee should have proof of parameter derivation) and be approved for use in wash water (refer to 5.01.02). Frequency of checks should be relative to the stability of the system, but at least pre-start, then at a frequency that ensures the availability of the anti-microbial is adequate while the system is running. As a minimum guide, a processing facility should be checked every 30 minutes, whereas whole washed product water anti-microbial levels should be checked hourly. These steps may be covered in a HACCP plan (e.g., sanitizing of flume water). Operations should not rely solely on ORP readings to manage chlorine levels and should verify free chlorine levels by another method (e.g., colorimeter/photometer, titration, appropriate test strips). Any water treatment (e.g., chlorine, reverse osmosis, UV light, active carbon) at the source (e.g., well, canal) should be monitored and records available. Where out of specification results are recorded, there should be corrective action records, including root cause analysis and preventive actions (where relevant).

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Minor deficiency (7 points) if:

- Single/isolated instance(s) of records showing solution strength out of parameters without adequate documented corrective actions.
- Single/isolated instance(s) of errors or omission in the records.
- Single/isolated instance(s) of total chlorine being recorded when free chlorine should have been used e.g., in chlorinated reused water systems.
- Single/isolated instance(s) of checks not carried out at the required frequencies.

Major deficiency (3 points) if:

- Numerous instances of records showing solution strength out of parameters without adequate documented corrective actions.
- Numerous instances of errors or omission in the records.
- Numerous instances of total chlorine being recorded when free chlorine should have been used e.g., in chlorinated reused water systems.
- Numerous instances of incorrect parameters being stated.
- Numerous instances of checks not carried out at the required frequencies.

- Water/ice testing is not being recorded.
- Recorded solution strengths consistently out of parameters i.e., an unstable system (even if documented corrective actions exist).
- Fundamental errors and omissions in the records.
- Total chlorine has been recorded throughout the system, when free chlorine should have been recorded e.g., in chlorinated reused water systems.
- Frequencies of checks consistently do not meet requirements of prior to start up and throughout the production runs.
- No evidence of water anti-microbial parameters has been stated/ incorrect parameters being used.
- Single pass water system is in use without anti-microbial being used. The auditor should consider whether to apply Q 5.03.04 and score an automatic failure in view of the risk of cross contamination.
- Recycled/reused water system is in use without an anti-microbial being used. The auditor should consider whether to apply Q 5.03.04 and score an automatic failure in view of the risk of cross contamination.

2.07.04: Is the water used for hand washing in compliance with potable water microbiological standards? The water used for hand washing shall meet the microbial standards for potable water at all times. The water used for hand washing should be tested and/or treated according to the assessment of the water source(s), distribution system, storage, and associated risks. If there are multiple sources for hand wash water risk assessments shall also account for each used source. Total compliance (15 points): Risk assessment of water source(s), distribution, and storage system, as well as implementation of measures such as water testing, water treatments or others based on the assessment should occur prior to use. A risk assessment shall be documented with required measures defined (water testing, water treatment or others). If the risk assessment concludes that water testing is necessary, water samples should be taken from as close to the point of use as is practical e.g., hand wash spigot/faucet. If there are multiple hand wash units, then samples should be taken from a different location for each test (randomize or rotate locations). If there are multiple sources for hand wash water, testing should also account for each source used. Frequency of testing shall depend on the risk assessment, or at least annually. If water treatment is deemed necessary based on the conducted risk assessment, documented justification for the effectiveness of the treatment, treatment procedure (including frequency), parameters of treatment efficacy, corrective actions, and monitoring records should be available for review.

Reference:

https://extension.psu.edu/coliform-bacteria

https://www.govinfo.gov/content/pkg/CFR-2011-title40-vol23/pdf/CFR-2011-title40-vol23-part141.pdf https://www.epa.gov/dwstandardsregulations

Minor deficiency (10 points) if:

- Water testing based on the risk assessment is conducted and a single instance of water testing not occurring at the right frequency.
- Water testing based on the risk assessment is conducted and sample(s) was not taken from the closest practical point of use.
- Water testing based on the risk assessment is conducted and a single water source (where there is more than one) has not been tested.
- Water treatment based on the risk assessment is conducted and a single instance of water treatment is not occurring according to the defined procedure (e.g., monitoring frequency, results, corrective actions, etc.).

Major deficiency (5 points) if:

- Water testing based on the risk assessment is conducted and more than one instance of water testing not occurring at the right frequency.
- Water testing based on the risk assessment is conducted and more than one water source (where there are more than two) has not been tested.
- Water treatment based on the risk assessment is conducted and more than one instance of water treatment is not occurring according to the defined procedure (e.g., monitoring frequency, results, corrective actions, etc.).

Non-compliance (0 points):

- No documented risk assessment of water source(s), distribution, and storage system available for review.
- If water testing based on the risk assessment is defined to be conducted and no microbiological test results are available or last test was done over 12 months ago.
- If water treatment based on the risk assessment is defined to be conducted and no records are available for review (monitoring of frequency, parameter affecting the treatment, corrective actions, etc.).

2.07.04a: If water testing based on the risk assessment is conducted, do written procedures (SOPs) exist covering proper sampling protocols, which include where samples should be taken and how samples should be identified? Total compliance (10 points): There should be a documented procedure in place detailing how water samples are to be taken, including stating how samples should be identified i.e., clearly naming the location that the sample was taken, identifying the hand wash station, the water source, and the date.

Minor Deficiency (7 points) if:

• Single/isolated instance(s) of incomplete or missing details in the procedure.

Major Deficiency (3 points) if:

• Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:

• There is no documented procedure.

NA:

• Based on the risk assessment water testing is not conducted,

**2.07.04b: If water testing based on the risk assessment is conducted, do written procedures (SOPs) exist covering corrective measures for unsuitable or abnormal water testing results?** Total compliance (10 points): Written procedures (SOPs) should exist covering corrective measures, not only for the discovery of unsuitable or abnormal water testing results, but also as a preparation on how to handle such findings.

Minor Deficiency (7 points) if:

• Single/isolated instance(s) of incomplete or missing details in the procedure.

#### Major Deficiency (3 points) if:

• Numerous instances of incomplete or missing details in the procedure.

Non-compliance (0 points) if:

• There is no documented procedure.

#### NA:

• Based on the risk assessment water testing is not conducted.

## 2.07.04c: If water testing based on the risk assessment is conducted and unsuitable or abnormal results have been detected, have documented corrective measures been performed?

Total compliance (15 points): For total coliforms (TC) and generic E. coli, there should be negative or < detection limit (MPN or CFU/100mL). Where thresholds have been exceeded, there should be recorded corrective actions, including investigations and water retests.

Minor Deficiency (10 points) if:

• Single/isolated instance(s) of records showing unsuitable or abnormal test results for total coliforms without adequate documented corrective actions.

#### Major Deficiency (5 points) if:

• Numerous instances of records showing unsuitable or abnormal test results for total coliforms without adequate documented corrective actions.

Non-compliance (0 points) if:

• No corrective actions have been performed. • A single out of specification result for generic E. coli without proper corrective actions.

NA:

• Based on the risk assessment water testing is not conducted,