

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

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

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 anti-microbial 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 anti-microbial 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.

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https://www.canr.msu.edu/news/turbidity_in_post_harvest_wash_water_monitor_and_change_when_needed

<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	Parameters¹	Requirements	Reference
Hypochlorite	<ul style="list-style-type: none"> • 50-200 ppm total chlorine; ≥ 10 ppm free chlorine • Optimal pH 6.0-7.0 	<ul style="list-style-type: none"> • Monitor pH in reused water systems • Sensitive to organic matter load • Follow label regarding potable water rinse 	21 CFR 173.315 (a)(2)(5)(c)
Chlorine Dioxide	<ul style="list-style-type: none"> • Processed ≤ 3 ppm residual; Raw agricultural commodities 3-5 ppm residual • Optimal pH 4.0-10.0 	<ul style="list-style-type: none"> • Sample point for residual testing • On-site generation • pH monitoring not required • Follow label regarding potable water rinse 	21 CFR 173.300
Peroxyacetic Acid	<ul style="list-style-type: none"> • Processed ≤ 80 ppm • Raw agricultural commodities ≤100 ppm • Optimal pH 3.0-7.5 	<ul style="list-style-type: none"> • Sample point for residual testing • pH monitoring not required • Follow label regarding potable water rinse 	21 CFR 173.315 (5)(a) 40 CFR 180.1196
Ozone	<ul style="list-style-type: none"> • 0.5-3.0 ppm • Optimal pH 6.0-8.5 	<ul style="list-style-type: none"> • On-site generation • Sensitive to organic matter load 	21 CFR 173.368
UV-C	<ul style="list-style-type: none"> • 200-280 nm (optimal 264 nm) • Optimal pH 6.5-9.5 	<ul style="list-style-type: none"> • Unit located as close as possible to point of use • Sensitive to organic matter load 	21 CFR 179.39
Acidic Electrolyzed Water	<ul style="list-style-type: none"> • 50-200 ppm total chlorine; ≥ 10 ppm free chlorine • 800-1,000 mV • Optimal pH 2.0-5.0 	<ul style="list-style-type: none"> • On-site generation • Sensitive to organic matter load • Follow label regarding potable water rinse 	FCN No. 1811

¹This 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 checked hourly by measuring the "free anti-microbial" as opposed to bound microbial (e.g., testing for free

chlorine as opposed to total chlorine). **Re-circulated/ batch water systems using sodium/calcium hypochlorite should have records showing the pH is controlled.** 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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Suslow, T. Directors Update. 2017 Revisiting Practical Considerations in the Application of Oxidation Reduction Potential (ORP) as a Water Quality Metric. <https://postharvest.ucdavis.edu/files/260798.pdf>

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 anti-microbial 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 anti-microbial 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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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.

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Anti-microbial	Parameters ¹	Requirements	Reference
Hypochlorite	<ul style="list-style-type: none"> • 50-200 ppm total chlorine; ≥ 10 ppm free chlorine • Optimal pH 6.0-7.0 	<ul style="list-style-type: none"> • Monitor pH in reused water systems • Sensitive to organic matter load • Follow label regarding potable water rinse 	21 CFR 173.315 (a)(2)(5)(c)
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Peroxyacetic Acid	<ul style="list-style-type: none"> • Processed ≤ 80 ppm • Raw agricultural commodities ≤100 ppm • Optimal pH 3.0-7.5 	<ul style="list-style-type: none"> • Sample point for residual testing • pH monitoring not required • Follow label regarding potable water rinse 	21 CFR 173.315 (5)(a) 40 CFR 180.1196
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¹This 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 anti-microbial. 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 ≤ 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.

Non-compliance (0 points) if:

- 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.**