SUPPLIER CODE OF CONDUCT

The Niagara Bottling Supplier Code of Conduct is designed to ensure the products and services we receive from our Suppliers follow all laws and our commitment to ethical, responsible practices. The Supplier Code of Conduct outlines our expectations and requirements for Suppliers with respect to labor and employment, human rights, environmental sustainability, and business practices.

I. APPLICABILITY

This Code of Conduct applies to all Suppliers that provide goods or services to Niagara Bottling, LLC ("Niagara"). Niagara strives to conduct business in a responsible manner and expects its Suppliers to do the same. Each Supplier is responsible for compliance with the standards set out in this Code of Conduct throughout its operations and throughout its entire supply chain.

Niagara may audit or inspect Suppliers, directly or through use of third party auditors, at any time to determine whether they are complying with this Code of Conduct. Niagara reserves the right to suspend and/or terminate its business relationship with Suppliers violating this Code of Conduct.

II. COMPLIANCE WITH LAWS AND REGULATIONS

At a minimum, Suppliers are required abide by and act in accordance with all applicable federal, state, and local laws and regulations, in addition to all international laws and industry standards. Where this Code of Conduct requires a Supplier to meet a higher standard than that set out by law or regulation, the Supplier must meet such higher standard.

III. LABOR, EMPLOYMENT, AND WORKPLACE REQUIREMENTS

A. Human Rights and Labor: Suppliers must ensure that all labor used in services provided to Niagara Bottling and/or the procurement, manufacturing or production processes related to goods provided to Niagara complies with all local, state, and federal labor and employment laws of the United States and any laws of any country in which Supplier and/or Niagara do business. This includes, without limitation, the following:

1. Suppliers must not use slave or trafficked labor. Slave or trafficked labor includes, but is not limited to, forced labor, bonded or indentured labor, involuntary servitude, sexual exploitation, and child labor.

2. Suppliers must not use child labor: all employees must be of at least legal age, as established by local law, but in any case at least 14 years old. Employees under

the age of 18 must not perform hazardous work that may jeopardize their health, safety or morals. Hazardous work includes, but is not limited to: work at dangerous heights or in confined spaces; work with hazardous substances, dangerous machinery, equipment and/or tools; work that involves the manual handling or transport of heavy loads; and night work.

3. Suppliers must ensure that workers are not charged recruitment fees or any similar fees, or debts, or financial obligations as a condition of being hired or as a condition of employment, whether such employees are hired directly or indirectly through a recruiter or broker. Niagara expects that if any such fees are charged to workers, Supplier must repay them on behalf of its workers, even if local law authorizes imposition of such fees.

4. Employees must have freedom of movement. Suppliers and their recruiters and brokers are prohibited from retaining employees' passports, identity documents, or other valuable possessions.

5. Employees must have freedom to terminate their employment or work arrangement without restriction and without threat or imposition of discipline, penalty, retaliation, or fine or other monetary obligation.

6. Suppliers must implement and maintain a reliable system for verifying the eligibility of all workers, including age eligibility and the legal status of foreign workers, as well as keep records of such verification.

7. Suppliers must compensate all workers with wages, including overtime premiums, and benefits that at a minimum meet the higher of: (I) the minimum wage and benefits established by applicable law; (II) collective agreements; (III) industry standards; and (IV) an amount sufficient to cover basic living requirements.

B. Safe and Equitable Work Environment: Suppliers must ensure all employees are provided a safe work environment, where they are treated with dignity and respect. This includes, without limitation, the following:

1. Ensuring employees are free from physical, sexual, verbal or mental abuse, coercion or threats, corporal punishment, or any form of harassment during their hiring or employment.

2. Supplier must not discriminate in hiring, compensation, training, advancement or promotion, termination, retirement, or any other employment practice based on race, color, national origin, gender, gender identity, sexual orientation, military status, religion, age, marital or pregnancy status, disability, or any other characteristic other than the worker's ability to perform the job.

3. Providing employees with clean and sanitary facilities, safe drinking water, and appropriate procedures, safeguards, and equipment to prevent workplace and work-related accidents and injuries.

4. If providing housing for employees, such housing must be separate from production and distribution areas, provide a separate bed for each employee, and provide continuous access to safe drinking water, hot water, and toilet facilities. Employees must be able to leave facility grounds during non-working hours.

C. Policies: Suppliers must establish and maintain policies reflecting these requirements and ensure compliance in its operations and throughout its supply chain, including with its suppliers and subcontractors.

D. Fines, Fees and Penalties: Any fines, fees or penalties applied or imposed on workers by the Supplier or other parties acting on their behalf, whether at the workplace or at Supplier-operated or -affiliated housing facilities, must be clearly identified in a written policy made readily available to all workers. All such fines, fees or penalties should be properly documented, must not be excessive, and must not discriminate between local or foreign workers.

E. Grievances: Suppliers must provide all workers with an effective grievance mechanism to raise any concerns in a confidential and anonymous manner, without fear of retribution. Suppliers must investigate grievances and document the investigation. In the event a grievance is found to be valid, the Supplier must put in place a corrective action plan and monitor to ensure the underlying concern does not reoccur.

IV. ENVIRONMENTAL SUSTAINABILITY

A. Compliance: Suppliers must operate their facilities in compliance with all environmental laws, including laws and international treaties relating to waste disposal, emissions, discharges, and hazardous and toxic material handling.

B. Permitting: Suppliers must obtain and maintain any environmental permits required under international, federal, state, or local law, and maintain documentation of compliance with such permits.

C. Goods: Suppliers must ensure the goods that they manufacture (including the inputs and components incorporated into such goods) comply with all environmental laws and treaties. Suppliers must use packaging materials that comply with all environmental laws and treaties.

D. Sustainable practices: Suppliers should commit to actively work towards reducing the environmental impacts of their supply chain and operations including natural resource consumption, material sourcing, waste generation, wastewater discharges and air emissions, and prevent accidental releases of hazardous materials into the environment and adverse environmental impacts on the local community.

Suppliers should demonstrate continuous reduction of the carbon footprint and greenhouse gas (GHG) reduction of the products and services they provide via annual reports or scorecards. Such endeavors could include, but should not be limited to:

1. Measuring, tracking and investing in projects and programs to drive reduction of greenhouse gases across its manufacturing, supply chain or operational footprint.
2. Investment in technology, equipment and resources to help buildings and plants implement energy management systems and waste reduction measures.
3. Use renewable energy sources like solar, wind and biomass.
4. Programs and training to employees to reduce waste and encouraging recycling.
5. Programs that incorporate the use of post-industrial and post-consumer waste within its manufacturing and operations.

Suppliers should demonstrate continuous improvement on reducing water consumption, especially in areas threatened by water risk over the next 20 years.

V. BUSINESS PRACTICES

A. Gifts and Entertainment: While it may be customary in some companies and cultures to entertain customers and exchange gifts, such entertainment and gift exchanges may be interpreted as a conflict of interest. For this reason, Suppliers must not offer Niagara team members entertainment that could appear excessive or appear to influence a business decision. Ordinary business meals and small tokens of appreciation of nominal value (generally under $100) such as gift baskets at holiday time generally are fine, but Suppliers must avoid offering Niagara team members travel, frequent meals or expensive gifts. Niagara policy prohibits our team members from accepting any gifts of cash or cash

equivalents, including checks, gift certificates, and gift cards regardless of value. We do not allow entertainment with or gifts to government officials by Suppliers on behalf of Niagara, regardless of value.

B. Anti-Corruption: Niagara's Anti-Corruption Policy strictly prohibits all forms of corruption and bribery. Suppliers are expected to support Niagara's compliance with this Policy and all applicable anti-corruption laws and policies. Suppliers acting on behalf of Niagara are required to comply in all respects with all relevant anti-corruption laws, including without limitation the United States Foreign Corrupt Practices Act (FCPA), the United Kingdom Bribery Act, and Mexico's General Law of Administrative Responsibility. Suppliers must not engage in bribery of any kind, whether on behalf of Niagara or otherwise, including without limitation: (I) offering or paying a bribe to a government official; (II) offering, authorizing, or promising anything of value to any government official in order to secure an improper advantage, obtain or retain business, or direct business to another person or entity; or (III) offering, promising, authorizing the payment of, or paying or providing anything of value to any employee, agent, or representative of another company to induce or reward the improper performance of any function or any business-related activity.

C. Trade Laws and Sanctions: Suppliers must comply with all applicable trade laws and regulations in the country or legal subdivision in which they operate. Suppliers must not directly or indirectly provide to Niagara any materials or services from a country, person or entity that is subject to U.S. or other regional or multilateral regulations restricting transactions with specific foreign countries, entities, or persons. This includes, without limitation, compliance with all economic sanctions programs administered by the U.S. Treasury Department's Office of Foreign Assets Control, the U.S. Department of State, the United Nations, and the European Union, as well as any other sanctions programs in place in the jurisdiction(s) where Suppliers operate.

VI. REPORTING POTENTIAL MISCONDUCT

Suppliers who believe that a Niagara employee or anyone acting on behalf of Niagara, has engaged in any illegal conduct or otherwise improper conduct, including violations of this Supplier Code of Conduct, are encouraged to report the matter to Niagara. Reports can be made on a confidential basis to the Niagara Ethics Hotline via phone: 866-881-9437 or on the web: https://niagara.ethix360.com/.

Supplier Quality and Expectations Guide

Version 15

Updated: July 2025

Niagara Bottling, LLC
1440 Bridgegate Dr.
Diamond Bar, CA. 91765

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INTRODUCTION

The Niagara Bottling Supplier Quality and Expectations Guide was developed to aid our supplier partners in gaining and maintaining approved supplier status. This document outlines prevention-based supplier requirements that must be in place to ensure that we deliver consistent product safety and quality to customers in exchange for their loyalty. Embracing this document's product safety and quality principles will strengthen your quality assurance program and help support a successful long-term business relationship with Niagara Bottling.

The requirements set forth in this guide are divided into three categories: General Requirements, Product Safety Requirements, and Product Quality Requirements. Each requirement contains a section overview that summarizes the overall intent of the requirement. Each requirement that is underlined must have documentation (procedures, instructions, or records) serving as objective evidence that the requirement has been met. This Guide's Appendix contains requirements for each supplier type.

Niagara Bottling recognizes that a certain amount of variation may occur in different facilities within the same company, as well as across different processes within the same facility. For that reason, each individual facility and/or new process of potential Niagara Bottling products must pass its own qualifying audit before receiving approval to produce, store and/or ship products for Niagara Bottling. Niagara Bottling will use the requirements listed in this document to evaluate our contracted partners via audits by both internal and external parties.

Niagara Bottling may require suppliers to participate and pass periodic audits by a Niagara QA employee. Any audit findings must be corrected in a timely manner. To the extent that these guidelines are incorporated into contract obligations, failure to comply with these guidelines may result in consequences including monetary damages, the rejection or destruction of product and/or termination of contract. To the extent that non-compliance may result in a violation of law, including laws prohibiting adulteration of foodstuffs, non-compliance may indirectly result in civil and criminal penalties. Compliance will be determined as mutually agreed. Audits or other inspections may reveal compliance and/or deficiencies.

Qualification audit results and facility status are based on a non-numerical scoring system, with emphasis on the finding(s) identified during an audit rather than an overall score. Niagara Bottling is not able to audit all suppliers, thus will rely on third party audits when unable to conduct its own second party audits. Second party audits will be completed to evaluate the supplier and do not have an expiration date. Any audit by Niagara will be conducted by individuals with certified audit training. Niagara Bottling has developed a rating program for supplier facilities that defines facility status as follows:

- **Approved** – All Niagara Bottling Product Safety & Quality Standard requirements are satisfied. The facility or process is approved to produce product or provide service for Niagara Bottling.

- **Probationary** – Not all Niagara Bottling Product Safety & Quality Standard requirements are satisfied; however, the facility may continue to provide products or services for Niagara Bottling. Corrective action(s) must be implemented that addresses the root cause of any finding(s).

- **Not Approved** – Not all Niagara Bottling Product Safety & Quality Standard requirements are satisfied, and the facility or process is not approved to produce product or provide service for Niagara Bottling until corrective action(s) have been implemented that address the root cause of audit finding(s) or product quality issues.

We hope that you find the Niagara Bottling Supplier Quality Guide useful in your efforts to achieve and maintain approved status. Commitment to these requirements is a tangible expression of your dedication to product safety and quality. If you have any questions, please contact Niagara Bottling for more information:

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GENERAL REQUIREMENTS

1. Social Responsibility

SECTION OVERVIEW
Niagara Bottling strives to conduct business in a responsible manner and expects its suppliers to do the same.

REQUIREMENTS

Suppliers are required to:

1. Abide by the Niagara Supplier Code of Conduct Policy.
   https://www.niagarawater.com/Resources/Documents/NBLCodeExpGuide.pdf

2. Executive Accountability for Product Safety & Quality

SECTION OVERVIEW
Senior-level management must create an effective quality management environment and provide the resources necessary to develop and maintain prevention-based product safety and quality programs. Management is accountable for establishing a reactionary process for handling storage and handling incidents, customer and regulatory complaints.

REQUIREMENTS

Suppliers are required to:

1. Provide the resources necessary to manage all product safety and quality activities. This includes, but is not limited to, staffing, training and certification, financial resources, facilities and equipment.
2. Develop, implement and maintain prevention-based product safety and product quality programs.
3. Designate a qualified employee(s) to manage the product safety and product quality programs.
4. Conduct root cause investigations for all major or repetitive incidents to assess safety and quality impact and to reduce or eliminate likelihood of recurrence.
   a. CAPA's should be addressed right away and completed within 30 days of the incident discovery. If more time is needed this explanation must be provided to and approved by Niagara Bottling. Urgent issues should be investigated right away and CAPA's should be completed as soon as possible.
   b. Status memos are highly recommended to let our teams know the problem is being addressed.
   c. Preventative measures should have substance and be sustainable.
5. Establish a procedure to track and address customer and/or regulatory complaints. The procedure shall outline the roles and responsibilities for investigating causes, taking corrective and preventive actions, determining resolution, and providing the appropriate follow-up communication back to the customer or regulatory agency.
6. Designate an employee(s) responsible for managing a customer/regulatory complaint process.

7. Perform a routine analysis of complaints received for trends to identify and correct opportunities in the prevention-based product safety and quality systems.
8. Have a system in place to inform staff on problems that occurred.
9. Maintain records of complaints, investigations, and trending analysis for at least two years and make them available for review.
10. Document the organizational structure of the personnel involved in all product safety and quality activities to include roles, responsibilities, authorities and their interrelationships.
11. Develop a training program for all employees and activities that affect product safety and quality. The program shall include a master training schedule and contractor/visitor policies.
12. Conduct a senior-level management review of the organizational structure, resources, training, and product safety and quality programs to evaluate for adequacy and effectiveness at least annually, or after any significant product safety or quality failure (ex. product recalls, GMP failures, trends in customer complaints).

3. Information & Facility Access

SECTION OVERVIEW
All potential and existing suppliers are asked to provide Niagara Bottling with information for the purpose of preparing confidentiality agreements, pre-screening prior to auditing, conducting desk audits, conducting facility audits, writing product specifications and reviewing all records related to the manufacturing, storage, handling, and repack of Niagara Bottling products. All information received is treated as confidential and secured in facility-specific files.

REQUIREMENTS

Suppliers are required to:
1. Sign a confidentiality agreement prior to entering into any business conversations related to Niagara Bottling products and/or processes.
2. Allow Niagara Bottling and third-party auditor's access to audit facilities that produce, handle, or store products for Niagara Bottling. Access shall extend to all areas of the facility associated with the production and warehousing of product for Niagara Bottling.
3. Allow Niagara Bottling and third-party auditors access to inspect and test products destined for Niagara Bottling or Niagara Bottling customers.
4. Allow Niagara Bottling and third-party auditor's access to all production, warehouse, safety, and quality records pertaining to products for Niagara Bottling.
5. Complete all request(s) by Niagara Bottling for information relating to facility/industry changes or needs.

4. Training

SECTION OVERVIEW
All potential and existing suppliers are required to develop a documented training program that ensures personnel carry out their duties in a way that is consistent with the objectives of the product safety and quality system. This training shall be conducted by qualified personnel.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain procedures and instructions that identify training and certification needs of personnel.
2. Provide training to personnel performing tasks affecting product safety and quality.
3. Maintain individual records of all training for each employee.
4. Training to include a general training matrix, the type of training, date of training, names of employees who attend the training, and content of training materials.
5. All training documents must be signed by the employee and trainer.
6. Training should be completed at onboarding, any time a document is revised and at least annually thereafter.

5. Certification

SECTION OVERVIEW
Facilities shall be registered and have all proper licensing and permits as required by local, state, and federal governments including any off-site storage, and manufacturing.

1. Maintain records of all required certifications, to include type of certification, date of certification, names of employees who obtained the certification and expiration dates.
2. Provide proof of registration with the appropriate local, state, and federal licensing where required.

6. Change Management

SECTION OVERVIEW
This section requires suppliers to notify Niagara Bottling prior to making any significant changes to the facility, storage and handling procedures, product repack, or key staff as specified below.

REQUIREMENTS

Suppliers are required to:

1. Provide Niagara Bottling with a minimum of 30 days advance written notice of any proposed changes to the list below or before executing any change that is significant enough to affect the safety or quality of Niagara Bottling products.
    a. Equipment Change
    b. Storage, Handling, Formula and Process Change
    c. Facility Renovations
    d. Facility Location Change
    e. Specification Change
    f. Major Supplier Change
    g. Other changes affecting raw materials or process

2. Obtain Niagara Bottling Quality Assurance written approval prior to implementation of changes (Requirement 1a. – 1g.).

3. Notify immediately Niagara Bottling on changes in management, ownership, and/or facility renovations; these do not require Niagara Bottling approval (unless otherwise specified in supplier's contract with Niagara Bottling).
4. Ensure all quality plans, GMP plans, finished product specifications, and organizational outlines have been updated to reflect changes.

7. Internal Audits

SECTION OVERVIEW
This section requires suppliers to implement an Internal Audit Program, which is a vital part of the accountability for prevention-based programs. The internal audit program is necessary to assess the effectiveness of the product safety, GMP, GWP, and quality programs. It exposes weaknesses and provides a basis for continuous improvement.

Suppliers are required to:
1. Designate a qualified employee(s) to manage the internal audit program.
2. Define the scope of the overall internal audit program to assess the following product safety and quality systems:

   Product Safety
   h. Outbound / Inbound Trailer Inspections
   i. Maintenance of Facility and Equipment
   j. Good Manufacturing or Warehouse Practices
   k. Pest Control
   l. Housekeeping Standards
   m. Traceability
   n. FIFO / FEFO
   o. Calibration Records for Critical Equipment
   p. Storage and Transportation
   q. Food Security **If handling food grade products**
   r. Building Security
   s. Sanitation Standard Operating Procedures
   t. Glass and Brittle Plastic inspections

   Quality Systems
   a. Control of Non-Conforming Items
   b. Corrective Actions
   c. Documents and Records
   d. Storage and Handling of Product
   e. Incoming Product Integrity
   f. Manufacturing Process Controls
   g. Control of Purchased Materials
   h. Raw Material Supplier Selection and Approval
   i. Critical to Quality and general control points in their process.
3. Develop, implement and maintain an internal audit procedure that includes:
   a. Identification of the person(s) responsible for planning, scheduling and conducting internal audits
   b. How audits are conducted and corrective actions are assigned
   c. Follow-up activities to verify the implementation and effectiveness of corrective actions

4. Develop a master audit schedule defining the frequency at which all product safety and quality programs shall be audited.
5. Ensure all internal auditors are trained in the areas necessary to conduct internal audits.
6. Maintain records of all internal audits with complete audit reports and resulting corrective actions. Corrective actions shall eliminate the cause and prevent the recurrence of the nonconformance. All audits and corrective action reports shall be available to Niagara upon request.

PRODUCT SAFETY REQUIREMENTS

8. Good Manufacturing Practices

SECTION OVERVIEW

This section requires suppliers to develop, deploy, and sustain Good Manufacturing Practices (GMPs). GMPs cover the entire facility including, but not limited to outside grounds, driveways, docks, parking, facilities walls, roof, and floors. GMPs also include fire safety, pest control, FEFO/FIFO, training, audits, employee practices and PPE. In distribution or storage warehouses, this may be referred to as Good Distribution Practices or Good Warehouse Practices (GDP/GWP).

REQUIREMENTS

Suppliers are required to:

1. Comply with the GMPs as applied to storage, handling and sanitation of food products and food contact equipment.
2. GMPs shall clearly apply to contractors and visitors and a documented procedure on file for this action.
3. Designate qualified employee(s) to manage GMP programs and ensure compliance.
4. Perform regular internal inspections/audits.
5. Establish and implement corrective actions to eliminate the cause(s) and prevent future noncompliance.
6. Provide training to all employees responsible for complying with GMPs upon employment, annually thereafter, and when any change is made to the GMP program.
7. Comply with the GMPs in the U.S. Code of Federal Regulations (CFR), Good Agricultural Practices (GAPs) and other guidance documents appropriate to their industry including but not limited to the following: 21 CFR Part 117 – Current Good Manufacturing Practice in Manufacturing, Packing or Holding of Human Food; 21 CFR Part 129 – Processing and Bottling of Bottled Drinking Water. NOTE: U.S.CFR website can be found at:

https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-129
https://www.ecfr.gov/current/title-21/chapter-I/subchapter-B/part-117

9. Sanitation Program

SECTION OVERVIEW

This section requires suppliers to have a prevention-based Facility Sanitation and Housekeeping Program. This applies to the facility's interior / exterior including tankers / silos used to haul or store product used by Niagara Bottling.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage the Facility Sanitation Program.
2. Develop, implement and maintain a Facility Sanitation Program and Master Sanitation Schedule for the entire facility. This program shall include the facility and equipment maintenance schedules and verification records.
3. Provide training to all maintenance employees at a minimum annually as it relates to sanitation activities and maintenance work instructions.
4. When working in food production or food contact areas, develop, implement and maintain sanitation procedures and instructions that are equipment and facility specific. Procedures and instructions shall include equipment breakdown, chemical usage, chemical concentration, water temperature, cleaning utensils and appropriate frequencies. Perform pre-operational inspections of the processing facility and adjacent areas to verify the cleaning and sanitation program.
5. Develop, implement, and maintain a Chemical Control Program to identify, segregate and control chemicals per regulatory requirements. The program shall include an approved chemical list with appropriate Safety Data Sheet (SDS) paperwork.

10. Pest Management

SECTION OVERVIEW

This section requires supplier facilities to have a detailed, documented and fully maintained pest management program. The program should describe all required procedures that ensure the planned activities conducted are executed properly. A licensed Pest Control Operator (PCO) must manage the application of chemicals, baits and traps. The PCO shall use their knowledge and experience to proactively inspect and treat the premises to deter and eliminate infestation. Destruction facilities must follow pest control guidelines as outlined in appendix I.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement and maintain a facility specific pest management program that effectively prevents the infestation of the facility and grounds. The pest management program manual must include:
    a. A contract for the services of a third party PCO or designated licensed employee, for the regular inspection and treatment of premises.
    b. Establish a frequency of pest inspections.
    c. Have a map detailing the location of bait stations, traps, and bug lights.
    d. A pest sighting log.
    e. List all chemicals/baits used and the targeted pests and have associated SDSs.
    f. Corrective actions shall be taken whenever there is a finding from the PCO.
    g. A copy of the current pest control operator and technician's license.
2. Designate a qualified employee(s) to manage and maintain the pest management program.
    a. The designated employee must:
        i. Verify that services provided by the PCO are properly carried out according to the contract and facility pest management program.
        ii. Provide pest management training to all employees.
        iii. Verify and track that all findings are corrected and closed.

3. Maintain inspection reports for a period of at least one year.
4. Maintain records of corrective actions taken when pest activity is observed. Corrective actions shall eliminate the cause and prevent the reoccurrence of the non-conformances.
5. In the event “Fogging” or “Fumigation” of pesticide is used, all Niagara products and equipment must be removed from the facility. This should be approved by Niagara Supplier Quality prior to any fogging.

PRODUCT QUALITY REQUIREMENTS

11. Corrective Actions

SECTION OVERVIEW
This section requires suppliers to have a program for identifying and addressing problems by finding the root cause, taking corrective action, implementing preventive measures, and monitoring results to ensure the actions are effective.
REQUIREMENTS

Suppliers are required to:

1. Investigate the cause of all non-conformances, rejections, recalls, and customer complaints originating from their facility.
2. Implement corrective actions to eliminate the cause and prevent the recurrence of non-conformances.
3. Implement preventative actions.
4. Perform verification of the effectiveness of corrective actions.

12. Documents and Records

SECTION OVERVIEW
This section requires suppliers to have a documented system for creating, identifying, distributing, using, revising, storing, and disposing of all documents and records.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain a document control program. The program shall include procedures for creating, identifying, distributing, using, revising, storing, and disposing of documents and records, as well as defining the responsibilities and authorities of employees involved in each function of the document and record control program.
2. Ensure documents in use are current, valid, and available at all locations where they are used.
3. Review and approve new documents or changes to documents prior to use. Only employees designated in the document control program shall be authorized to create or revise documents.
4. Promptly remove obsolete documents from all points of use. Obsolete documents retained for legal or other purposes shall be identified and stored in a manner to prevent unintended use.
5. Maintain a master list of current documents and revisions to documents. Information for each document shall include the status of the document, revision number, revision date reviewer and changes made. Documents should be reviewed at least annually.

6. Develop, implement, and maintain a procedure for completing, verifying, and maintaining records. The procedure shall outline how documents are to be completed, the proper method of correcting entries to documents, and where completed records are maintained or stored.
7. Ensure all safety and quality records are complete, legible, titled, dated, and signed by the employee monitoring and recording the data, as well as the employee verifying the safety and quality record.
8. Properly maintain documents and records for a period as specified by Niagara Bottling or legal/regulatory requirements, whichever is greater.
9. Provide training to all employees on the control of documents and records, and how to properly complete necessary documentation.

APPENDIX

Appendix A – Ingredients

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GENERAL REQUIREMENTS

Supplier Selection and Approval Process

All Niagara approved ingredient suppliers must have a current GFSI certificate and FDA registration for each manufacturing facility or gain executive approval as part of the qualification and approval process.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
Suppliers are required to use a HACCP based system to identify and control all hazards associated with the product and the manufacturing process, from receipt of purchased materials through distribution of finished product.

REQUIREMENTS

Suppliers are required to:

1. Designate qualified employee(s) to develop, implement, and maintain product safety plan(s) for all products and processes.
2. Establish and implement written corrective action procedures for potential contamination. The corrective action procedures shall define how the potentially affected product is controlled, how root cause is identified, and how to prevent reoccurrence. All corrective actions shall be documented.
3. Conduct verification of the product safety plan(s) to ensure that the planned activities are execute properly. A pre-shipment review must be conducted prior to shipping product to Niagara Bottling.
4. Conduct validation of the product safety plan(s) annually and whenever significant changes to storage, handling, or packaging occur, or when product safety issues (system failures) or other industry related incidents occur.
5. Establish record-keeping and documentation procedure(s) that are in accordance with appropriate regulatory requirements.
6. Provide a Certificate of Analysis (COA) for every lot of product shipped to Niagara Bottling, which includes test results and specification range of critical parameters.
7. All ingredients should have, at a minimum, 50% of the shelf life upon receipt at Niagara facilities.
8. Provide training to employees in the requirements of the product safety plan(s) as it relates to their specific work area.

Product Security

SECTION OVERVIEW
This section requires suppliers of ingredients to have an effective system to prevent an intentional threat to the facility or to the materials produced at the facility. The product defense and facility security

plan shall be developed in accordance with all local, state, federal and/or international regulatory requirements.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage a product defense and facility security program.
2. Conduct and document a risk assessment to identify product defense and security vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping and receiving, and personnel.
3. Develop and implement a Food Security and Defense Plan, utilizing the FDA Food Security Preventive Measures Guidance documents, that addresses all identified vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping and receiving, and personnel. The plan should include procedures for handling threats and actual cases of product tampering in an effort to protect materials from intentional adulteration from biological, chemical, physical or radiological agents.
4. Establish and implement corrective action procedures to be taken in all cases of product tampering to ensure that adulterated or potentially injurious products do not enter commerce. Corrective actions shall eliminate the cause and prevent the reoccurrence of the non-conformances.
5. Review the product defense and facility security plan at a minimum annually, and whenever changes to the facility or process occur, or in the event of a system failure, and revise as necessary.
6. Provide training to all facility employees in the requirements of the product defense and facility security plan.

Maintenance of Facility and Equipment

SECTION OVERVIEW
This section requires suppliers to have a prevention-based Facility and Equipment Maintenance program.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage the Facility and Equipment Maintenance Program.
2. Develop, implement, and maintain a Preventive Maintenance Program for the entire facility. This program shall include the facility and equipment maintenance schedules and verification records.
3. Develop, implement and maintain an equipment design standard for each area of the facility. The standard shall outline equipment criteria prior to purchase of new equipment or refurbishing previously used equipment as it relates to ease of cleaning, sanitizing and maintaining.
4. Develop, implement and maintain a Maintenance Sanitation Program that supports the cleaning of maintenance supplies, new and used equipment, parts, and hand tools.
5. Develop, implement and maintain procedures and instructions for both planned and unplanned maintenance. Procedures and instructions shall be equipment and facility specific, address use of temporary repairs, and identify measures to prevent physical, chemical, and biological cross contamination.

6. Provide training to all maintenance employees at a minimum annually as it relates to product safety, personal safety, GMP and maintenance work instructions.

Storage and Transportation

SECTION OVERVIEW
This section requires suppliers of ingredients to develop, implement, and maintain a system for ensuring incoming raw components are stored and shipped in a manner that protects product safety and integrity, and meets minimum regulatory requirements as set forth in the Code of Federal Regulations (CFR), including but not limited to Sanitary Transportation (21 CFR Part 1, Subpart O), GMPs (21 CFR Part 110) and Preventive Controls (21 CFR Part 117). Requirements apply to offsite storage facilities as well as on-site product storage.

REQUIREMENTS

Suppliers are required to:

1. Handle, store and distribute purchased materials, work-in-process and finished products in a manner that prevents damage, deterioration, and contamination. Storage areas and transportation vehicles must be capable of achieving appropriate conditions (temperature, humidity, and atmosphere) to ensure finished product safety, quality, and integrity.
2. Monitor storage conditions to ensure finished product integrity.
3. Develop, implement and maintain a system to properly rotate finished product inventory. All materials must be identified in a manner to allow proper stock rotation and usage. This shall include, but not be limited to description, date of receipt/production, lot number, and status.
4. Develop, implement and maintain a storage and transportation container inspection system that ensures transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution.
    a. Maintain records of outgoing trailer inspection prior to loading on a truck-by-truck basis. Inspections shall include at a minimum:
        i. Smell/Odor issues
        ii. Evidence of Pest activity
        iii. No extraneous material or potential contaminant
5. Conduct container inspections upon receipt of materials and upon loading of finished goods.
    a. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.
6. Ensure all incoming and outgoing loads have a secure trailer seal with a number that matches and is verified on the Bill of Lading (BOL) and Certificate of Analysis (COA).
7. Develop, implement and maintain a system to ensure the integrity of all goods stored off-site.
8. Provide training to employees responsible for receiving, storing, and shipping goods.
9. All bulk ingredients (tanker, rail cars, ect...) must follow and comply with current International Society of Beverage Technologists (ISBT) Guidelines.

Product Identification & Traceability

SECTION OVERVIEW

This section requires suppliers to have an effective system in place to identify and trace product from receipt of materials through distribution of finished product to allow for effective product recalls or withdrawals.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement and maintain a system for tracing finished product within twenty four (24) hours of request. This system must ensure identification of the product to allow for proper stock rotation and effective recalls, lot withdrawals, and problem investigation.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
3. Ensure system can produce written or electronic confirmation of ship to locations for all individual pallets or bulk delivery by truck/BOL/PO, within four (4) hours of initial request.
4. Provide training to employees responsible for documenting lot information.
5. Develop, implement, and maintain a documented system for timely and effective withdrawal or recall of product. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls. The system shall include an investigation that is conducted during the recall to determine if there are other affected products or lots.
6. Document all product recalls and withdrawals. Documented recalls/withdrawals must include percent recovery, amount of time taken to conduct the recall/withdrawal, and any associated corrective actions.
7. Conduct a minimum of two mock product recalls/withdrawals annually. Documented mock recalls/withdrawals must include percent recovery, amount of time taken to conduct the call/withdrawal and any corrective actions.

Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall implicating product sold to Niagara Bottling. This notification must occur within twenty four (24) hours of supplier determining whether the product should be recalled or withdrawn from the market.

Foreign Supplier Verification Program (FSVP)

SECTION OVERVIEW

This section requires all foreign suppliers to be compliant with the FSVP rule as part of the Food Safety Modernization Act (FSMA). The FSVP rule is to ensure that all imported foods (including food ingredients and packaging materials) meet the same food safety standards that are required of foods produced in the United States. The US importer has the responsibility of ensuring that its foreign suppliers are in compliance and meet the requirements of FSMA.

REQUIREMENTS

Suppliers are required to:

1. Meet requirements of FSMA including a Process Control Qualified Individual (PCQI).
2. Register with the FDA as a food facility and renew their biannual registration and maintain a DUNS#.

3. Submit samples for testing if Niagara's food safety plan or food adulteration assessment reveals a high degree of risk. These products will be randomly tested at least annually to determine compliance of known hazard that needs a control applied by the supplier or supply chain.
4. Verify that any food safety hazards identified from Niagara's food safety plan are controlled and verified before shipping.
5. Submit Letter of Guarantee that product meets FDA regulations and is not adulterated or misbranded. This must be signed by a person of significance from the company on letterhead.
6. Pass a GSFI audit as specified in FDA 21 CFR Part 117.
7. Domestic brokers are required to have a FSVP in place to evaluate all manufacturing facilities and products before importing from foreign manufacturers.

PRODUCT QUALITY REQUIREMENTS

Finished Product Specifications

SECTION OVERVIEW
This section requires suppliers to maintain comprehensive specifications that define criteria for workmanship, product attributes, and/or characteristics for materials as agreed upon by the supplier and Niagara Bottling.

REQUIREMENTS

Suppliers are required to:
1. Maintain and provide documented specifications for finished products.
2. Review finished product specifications at a minimum annually, or when any change occurs that could result in a change in the finished product, to ensure finished product specifications are accurate.
3. Adhere to all Niagara Bottling internal specifications as recorded for each individual product specification as necessary.
4. Treat Niagara Bottling specifications as confidential. Note: Once the finished product specification is agreed upon and authorized by Niagara Bottling, changes to product and/or packaging specifications cannot be made without prior written approval of Niagara Bottling.
5. Standard Labeling
    a. Company Name
    b. Manufacturing Site Address
    c. Product Name -
    d. Supplier ID/Product Code -
    e. NIA Item Code – If possible, may not be
    f. Lot # -
    g. MFG Date -
    h. Exp. Date –
    i. Allergen ID, if applicable
    j. Certifications –
    k. Kosher
    l. Organic
    m. GMO certified

n. *Specialty

Control of Non-Conforming Product

SECTION OVERVIEW
This section requires suppliers to develop and implement procedures outlining how non-conforming product is identified and controlled. The objective is to ensure that non-conforming product does not reach Niagara Bottling.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure non-conforming product is not used or shipped to Niagara. Procedures shall include identification and segregation of non-conforming product, and determination of product disposition. Any non-conforming products shipped to a Niagara facility will be returned for full credit via the Non-Conforming Raw Material (NCRM) program.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the product hold program. This shall include designation of employees responsible for placing product on hold and those determining disposition.
3. Do not receive in any non-conforming materials. Any materials deemed non-conforming due to tampering or damage shall be rejected and returned.
4. Identify and document all process and product deviations from receiving, storing, and shipping of finished product.

Topics of Interest and Related Websites

CFR (GMP's, cGMP's, etc.): https://www.ecfr.gov/

International Bottled Water Association: www.bottledwater.org

International HACCP Alliance: www.haccpalliance.org

Food Allergies: www.foodallergy.org. www.farrp.org

Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986):
https://oehha.ca.gov/proposition-65/about-proposition-65

Food Safety Modernization Act (FSMA)
https://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247548.htmResource Guide | ISBT

Guidelines, Best Practices, and White Papers | ISBT

Appendix B – Packaging Materials
GENERAL REQUIREMENTS

Product/Supplier Risk Factors

SECTION OVERVIEW
Niagara Bottling has categorized all incoming raw materials into two categories: low risk and high risk. High risk materials are defined as those that come into direct contact with product, are an ingredient in the finished product or used in the direct processing of the product. More stringent requirements have been established for suppliers of high-risk materials. Low risk materials are defined as a secondary material that does not directly come into contact with the product. Resin is listed as a "low risk" because it goes through a high heat and high-pressure process to form the usable finished product.

Packaging Currently Defined as High Risk are:

1. Caps
2. Bottles

Raw Materials Currently Defined as Low Risk are:

1. Shrink Film
2. Labels
3. Corrugate
4. Raw Resin
5. Cardboard
6. Carriers and handles
7. Other secondary packaging materials

REQUIREMENTS

1. High risk suppliers must meet all applicable legal/regulatory food safety and have a quality system in place to meet Niagara's quality requirements.
2. Low risk suppliers must have quality system in place to meet Niagara quality requirements and must meet all applicable legal/regulatory requirements.
3. Both high and low risk suppliers must have evidence of a completed third-party audit. Without this evidence a supplier may be disqualified or subject to a second-party audit.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
All suppliers must maintain a system to control hazards associated with the manufacturing, storage, and handling of products.

REQUIREMENTS

Suppliers are required to:

1. High-risk suppliers are required to have a HACCP-based system to identify and control hazards.
2. Designate qualified employee(s) to develop, implement, and maintain a Quality Management System (QMS) for all products and processes.
3. Establish and implement written corrective and preventative action (CAPA) for reported or potential out of spec conditions. The CAPA should define how the potentially affected product is controlled, what root cause was identified, and how to prevent recurrence. All CAPAs shall be documented and provided on request.
4. Conduct verification of the QMS to ensure that the planned activities are executed properly. A finished goods inspection must be conducted prior to shipping the product to Niagara Bottling.
5. Conduct validation of the QMS annually and whenever significant changes to storage, handling, or packaging occur, or when product safety issues (system failures) or other industry related incidents occur.
6. Establish record-keeping and documentation procedure(s) that are in accordance with appropriate regulatory and Niagara Bottling requirements.
7. Provide a Certificate of Analysis (COA) for every lot of products shipped to Niagara Bottling, which includes test results and specification range of critical parameters.
8. Provide training to employees in the requirements of the product safety plan(s) as it relates to their specific work area.

Product Security

SECTION OVERVIEW
This section requires suppliers of high-risk materials to have an effective system to prevent an intentional threat to the facility or to the materials produced at the facility. The product defense and facility security plan shall be developed in accordance with all local, state, federal and/or international regulatory requirements.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage a product defense and facility security program.
2. Conduct and document a risk assessment to identify product defense and facility security vulnerabilities in the following areas: facility exterior & interior, storage, shipping and receiving, and personnel service areas.
3. Develop and implement a Food Security and Defense Plan, utilizing the FDA Food Security Preventive Measures Guidance documents, that addresses all identified vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping and receiving, and personnel. The plan should include procedures for handling threats and actual cases of product tampering in an effort to protect materials from intentional adulteration from biological, chemical, physical or radiological agents.
4. Establish and implement corrective action procedures to be taken in all cases of product tampering to ensure that adulterated or potentially injurious products do not enter commerce. Corrective actions shall eliminate the cause and prevent the reoccurrence of the non-conformances.

5. Review the product defense and facility security plan at a minimum annually, and whenever changes to the facility or process occur, or in the event of a system failure, and revise as necessary.
6. Provide training to all facility employees in the requirements of the product defense and facility security plan.

Maintenance of Facility and Equipment

SECTION OVERVIEW
This section requires suppliers to have a prevention-based Facility and Equipment Maintenance Program.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage the Facility and Equipment Maintenance Program.
2. Develop, implement, and maintain a Preventive Maintenance Program for the facility and all major equipment. This program should include documented facility and equipment maintenance performance tasks, schedules, listed jobs completed, and verification records.
3. Develop, implement and maintain an equipment design standard for each area of the facility. The standard shall outline equipment criteria prior to purchase of new equipment or refurbishing previously used equipment as it relates to ease of cleaning, sanitizing and maintaining.
4. Develop, implement and maintain a Maintenance Sanitation Program that supports the cleaning of maintenance supplies, new and used equipment, parts, and hand tools.
5. Develop, implement and maintain procedures and instructions for both planned and unplanned maintenance. Procedures and instructions shall be equipment and facility specific, address use of temporary repairs, and identify measures to prevent physical, chemical, and biological cross contamination.
6. Provide training to all maintenance employees at a minimum annually as it relates to product safety, personal safety, GMP and maintenance work instructions.

Storage and Transportation

SECTION OVERVIEW
This section requires suppliers to develop, implement, and maintain a system for ensuring incoming raw components or finished products are handled, stored, and shipped in a manner that protects safety and integrity. Requirements apply to offsite storage facilities as well as on site product storage.

REQUIREMENTS

Suppliers are required to:

1. Handle, store and distribute purchased materials, work-in-process and finished products in a manner that prevents damage, deterioration, and contamination. Storage areas and transportation vehicles must be capable of achieving appropriate conditions (temperature, humidity, and atmosphere) to ensure finished product safety, quality, and integrity.

2. Monitor storage conditions to ensure relevant temperatures, product integrity, cleanliness, and organized for ease of storage and retrieval.
3. Develop, implement and maintain a system to properly rotate raw material and finished goods inventory (FIFO / FEFO). All materials must be identified in a manner to allow proper stock rotation and usage. This shall include, but not be limited to description, date of receipt / production date, lot number, and status.
4. Develop, implement and maintain a storage and transportation container inspection system that ensures incoming and outgoing transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.
5. Ensure all incoming and outgoing loads have a secure trailer seal with a number that matches and is verified by receiving/shipping personnel on the Bill of Lading (BOL). Provide proof of outgoing trailer inspection prior to loading on a truck-by-truck basis. Inspections shall include at a minimum:
    a. Smell/Odor issues
    b. Evidence of Pest activity
    c. No extraneous material or potential contaminant
    d. Temperature requirements are met
6. Develop, implement and maintain a system to ensure the integrity of all goods stored off-site.
7. Provide training to employees responsible for receiving, storing, and shipping goods.

Product Identification & Traceability

SECTION OVERVIEW
This section requires suppliers to have an effective system in place to identify and trace products from receipt of materials through distribution of finished product to allow for effective product recalls or withdrawals.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement and maintain a system for tracing finished product within twenty-four (24) hours of request. This system must ensure identification of the product to allow for proper stock rotation and effective recalls, lot withdrawals, and problem investigation.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
3. Ensure system is able to provide written or electronic confirmation of ship to locations for all individual pallets by truck/BOL/PO, within four (4) hours of initial request.
4. Provide training to employees responsible for documenting lot information.
5. Conduct a minimum of one mock product trace annually. Documented mock trace must include percent recovery, amount of time taken to conduct the call/withdrawal and any corrective actions.
6. Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall implicating product sold to Niagara Bottling. This notification must occur within twenty-four (24) hours of supplier determining whether the product should be recalled or withdrawn from the market.

PRODUCT QUALITY REQUIREMENTS

Finished Product Specifications

SECTION OVERVIEW
This section requires suppliers to maintain comprehensive specifications that define criteria for workmanship, product attributes, and/or characteristics for materials as agreed upon by the supplier and Niagara Bottling.

REQUIREMENTS

Suppliers are required to:

1. Maintain and provide documented specifications for finished products type including full description of relevant raw materials inputs.
2. Review finished product specifications at a minimum annually, or when any change occurs that could result in a change in the finished product, to ensure finished product specifications are accurate.
3. Adhere to all Niagara Bottling internal specifications or requirements as recorded for each individual product specification.
4. Treat Niagara Bottling specifications as confidential. Note: Once the finished product specification is agreed upon and authorized by Niagara Bottling, changes to product and/or packaging specifications cannot be made without prior approval of Niagara Bottling.
5. Niagara Bottling must be notified before any changes to the raw material specifications occur.

Control of Non-Conforming Product

SECTION OVERVIEW
This section requires suppliers to develop and implement procedures outlining how non-conforming products are identified and controlled.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure non-conforming products are not shipped to Niagara Botling. Procedures shall include identification, segregation, and quarantine of non-conforming product and determination of product disposition. Supplier will be responsible for removing and crediting any non-conforming products shipped to a Niagara Bottling facility via the NCRM program.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the product hold program. This shall include designation of employees responsible for placing product on hold and those determining disposition.
3. Maintain a log of non-conforming materials including when put on hold, reason, disposition, and date removed from hold.

4. If samples are required for the investigation, provide a clear description of what is needed, a shipper account number, to whose attention, and address to ship to. Upon evaluation of this sample, provide a report and a disposition statement within 10 days of receipt.

Topics of Interest and Related Websites

CFR (GMP's, cGMP's, etc.): www.gpoaccess.gov/cfr/index.html

International Bottled Water Association: www.bottledwater.org

Proposition 65 (Safe Drinking Water and Toxic Enforcement Act of 1986): https://oehha.ca.gov/proposition-65/about-proposition-65

ISBT: https://www.bevtech.org/resources-manuals-guidelines.asp

Appendix C – Contracted Manufacturing

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General Requirements

Supplier Selection and Approval Process

All new suppliers must complete the Pre-Audit Questionnaire to ensure that minimum systems are in place to assure the quality and integrity of raw materials and/or finished products/services are established.

Certifications

1. The facility shall be registered with the FDA and have a current certificate with expiration date. All Niagara Bottling suppliers are required to be registered with the FDA and comply with all local, state, and federal laws and regulations including those pertaining to lot traceability and record retention.
2. The facility shall be registered with the appropriate State licensing authority and obtain a current food handling license or permit, as well as any applicable bottled water or beverage licenses or permits.
3. The facility shall obtain an annual third-party food safety and quality certificate in good standing by a food safety auditing body recognized by the Global Food Safety Initiative (GFSI), preferably SQF.

Product Safety

Control of Hazards

Section Overview
This section requires contracted manufacturers to use a HACCP approach to identify and control all hazards and potential food safety issues associated with the product and the storage and handling process, from receipt through distribution of the finished product.
REQUIREMENTS

Suppliers are required to:
1. Designate qualified employee(s) to develop, implement, and maintain food safety plan(s) for all products and processes, in compliance with 21 CFR Part 117.
2. Establish and implement written corrective action procedures for potential contamination. The corrective action procedures shall define how the potentially affected product is controlled, how root cause is identified, and how to prevent recurrence. All corrective actions shall be documented and completed in no more than 30 days; critical items should be completed within 7 days of finding.
3. Conduct verification of the food safety plan(s) to ensure that the planned activities are executed properly. A pre-shipment review must be conducted prior to shipping product to Niagara Bottling.
4. Conduct validation of the food safety plan(s) annually and whenever significant changes to storage, handling, or packaging occur, or when product safety issues (system failures) or other industry related incidents occur.
5. Establish record-keeping and documentation procedure(s) that are in accordance with appropriate regulatory requirements.
6. Provide documented training to employees in the requirements of the food safety plan(s) as it relates to their specific work area.

Product Security

Section Overview
This section requires contracted manufacturers to have an effective system to prevent an intentional threat to the facility or the materials produced at the facility. The product defense and facility security plan shall be developed in accordance with all local, state, federal and/or international regulatory requirements, including without limitation FDA's Intentional Adulteration rule (21 CFR Part 121).

REQUIREMENTS

Suppliers are required to:
1. Designate a qualified individual(s) to manage a product defense and facility security program.
2. Conduct and document a risk assessment to identify product defense and security vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping, receiving, and personnel.
3. Develop and implement a Food Security and Defense Plan, utilizing the FDA Food Security Preventive Measures Guidance documents, that addresses all identified vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping, receiving, and personnel. The plan should include procedures for handling threats and actual cases of product tampering in an effort to protect materials from intentional adulteration from biological, chemical, physical or radiological agents.
4. Establish and implement corrective action procedures to be utilized in all cases of product tampering to ensure that adulterated or potentially injurious products do not enter commerce. Corrective actions shall eliminate the cause and prevent the reoccurrence of the non-conformances.
5. At minimum, a documented annual review of the product defense and facility security plan should be conducted, as well as whenever changes to the facility or process occur or in the event of a system failure. Revisions should be conducted as necessary.
6. Provide training to all employees in the requirements of the product defense and facility security plan.

Storage and Transportation

Section Overview
This section requires contracted manufacturers to develop, implement, and maintain a system for ensuring incoming raw components, work in process (WIP) and finished products are stored and shipped in a manner that protects product safety and integrity, and meets minimum regulatory requirements as set forth in the Code of Federal Regulations (CFR), including but not limited to Sanitary Transportation (21 CFR Part 1, Subpart O), GMPs (21 CFR Part 110) and Preventive Controls (21 CFR Part 117). Requirements apply to offsite storage facilities as well as on-site product storage. Any storage locations must be approved by Niagara Supplier Quality.

REQUIREMENTS

Suppliers are required to:
1. Handle, store and distribute purchased materials, work-in-process and finished products in a manner that prevents damage, deterioration, and contamination. Storage areas and transportation vehicles must be capable of achieving appropriate conditions (temperature, humidity, and atmosphere) to ensure finished product safety, quality, and integrity.

2. Monitor storage conditions to ensure finished product integrity. Products that are considered hazardous or omit an odor may not be stored with our products. Notification should be provided to Niagara Supplier Quality in the event of any storage of hazardous or odorous products.
3. Develop, implement and maintain a system to properly rotate finished product inventory. All materials must be identified in a manner to allow proper stock rotation and usage. This shall include, but not limited to description, date of receipt, date of production, lot number, and shipping status. Product shall not be shipped from the facility before older (3 months or more) product on site with the same SKU.
4. Develop and document a system that prevents the storage of Niagara Bottling products in any area adjacent to chemicals, products with noticeable odors, and allergens.
5. Organic Product Storage must follow these requirements. This is only if the warehouse is storing organic products.
    a. Organic certification is not required as long as these products remain in the same package and label in which they are received.
    b. Must maintain the identity and integrity of organic products in your custody.
    c. Ensure that organic products do not come in contact with prohibited substances such as cleaners, sanitizers, pest control materials or non-organic products.
6. Develop, implement and maintain a storage and transportation container inspection system that ensures transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution.
7. Conduct container inspections upon receipt of materials and upon loading of finished goods.
8. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.
9. All incoming and outgoing loads shall have a secure trailer seal with a number that matches and is verified on BOL by a company employee.
10. 9. Ensure that product pallet configurations are self-supporting, interlocking and secured (e.g. banded, stretch wrapped) in accordance with Niagara Bottling requirements to minimize product shifting and damage.
11. Provide proof of inbound and outbound trailer inspections prior to unloading or loading, on a truck-by-truck basis.
    Inspections shall include at a minimum:
    a. Date
    b. Trailer Number
    c. Employee Signature
    d. Smell/Odor issues
    e. Evidence of Pest activity
    f. No extraneous material or potential contaminants
    g. Condition of trailer walls, floors, ceiling and any moisture.
12. Develop, implement and maintain a system to ensure the integrity of all goods stored offsite. Any offsite locations must be approved by Niagara Supplier QA.
13. Provide documented training to employees responsible for receiving, storing, and shipping goods.
14. All doors and openings must be closed and locked or screened when not actively used. All doors must remain secured when not actively in use.

Product Identification & Traceability

Section Overview
This section requires suppliers to have an effective system in place to identify and trace product from receipt of materials through distribution of finished product to allow for effective product recalls or withdrawals.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement and maintain a system for tracing finished products within two (2) hours of request. This system must ensure identification of the product to allow for proper stock rotation and effective recalls, lot withdrawals, and investigations.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
3. System shall be able to produce written or electronic confirmation of ship to locations for all individual pallets by truck/BOL/PO, within two (2) hours of initial request.
4. Provide training to employees responsible for documenting lot information.
5. Clearly code all product containers and shipping cases according to Niagara Bottling Production Date Code Format and all regulatory identification requirements. Lot code format shall not be changed without prior approval from Niagara Bottling Quality Assurance.
    a. All bottles must have a code to identify line number, date and time of manufacturing, best by date, and four-digit plant code (will be given separately to each co-manufacturer).
    b. Each case shall have printed the four-digit plant code, best by date, time of manufacturing, and production line. The code format may change depending on Niagara customer requirements.
6. Develop, implement and maintain a documented system for timely and effective withdrawal or recall of product. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls. The system shall include an investigation that is conducted during the recall to determine if there are other affected products or lots.
7. Document all product recalls and withdrawals. This must include product recalled, reason for recall, start and stop time, total recall/withdrawal time, quantity, percent recovery and any associated corrective actions.
8. Conduct a minimum of two mock product recalls/withdrawals annually with 100% recovery in under 2 hours.
9. Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall implicating product sold to Niagara Bottling. This notification must occur within twenty-four (24) hours of supplier determining the product should be recalled or withdrawn from the market.

Product Quality

Finished Product Specifications

SECTION OVERVIEW
This section requires suppliers to maintain comprehensive specifications that define criteria for workmanship, product attributes and/or characteristics for materials, work-in-process (WIP), and finished products as agreed upon by the supplier and Niagara Bottling.

REQUIREMENTS

Suppliers are required to:
1. Maintain documented specifications for finished products. These specifications shall include, but are not limited to pallet quality, stretch wrap, stack patterns, loading patterns, and quality standards.
2. Review finished product specifications at a minimum annually, or when any change occurs that could result in a change in the finished product, to ensure finished product specifications are accurate.
3. Treat Niagara Bottling specifications as confidential. Note: Once the finished product specification is agreed upon and authorized by Niagara Bottling, changes to product and/or packaging specifications cannot be made without prior approval of Niagara Bottling. Please see the section titled “Change Management” for more information.

Control of Non-Conforming Product

Section Overview

This section requires suppliers to develop and implement procedures outlining how non-conforming product is identified and controlled. The objective is to ensure that non-conforming product does not reach Niagara Bottling or their customers.

REQUIREMENTS

Suppliers are required to:
1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming product cannot be inadvertently used or shipped. Procedures shall include identification and segregation of non-conforming product, and determination of product disposition.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the product hold program. This shall include designation of employees responsible for placing product on hold and those determining disposition.
3. Do not receive any non-conforming materials. Any materials deemed non-conforming due to tampering or damage shall be rejected and returned.
4. Identify and document all process and product deviations from receiving, storing, and shipping of finished product.
5. Develop, implement and maintain a way to physically identify hold product.
6. Conduct re-inspection of product designated for repack in accordance with documented procedures and specifications prior to shipping.

7. Develop, implement and maintain a documented tracking system that identifies all product on QA Hold and resulting disposition.
8. Develop, implement and maintain corrective actions to eliminate the cause and prevent the reoccurrence of non-conformances. All corrective actions should be closed within 30 days; critical items should be completed within 7 days of finding.
9. Repackage non-conforming product so that any reference to Niagara Bottling is removed before donation or sale of any kind. Exceptions to this requirement must be obtained in writing from the appropriate Executive approval of Niagara Bottling Quality Assurance.
10. Provide documented training to employees on instructions for controlling non-conforming product.
11. Destruction must be done by an approved facility with a closely monitored and documented process. Niagara Quality Team must approve any destruction prior to any disposal.

Topics of Interest and Related Web Sites

CFR (GMP's, cGMP's, etc.) eCFR — Code of Federal Regulations

International Bottled Water Association www.bottledwater.org

Food Defense Plan Builder
http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm

Referenced Documents

NIA-305-16-0004 Production Date Code Format

FDA Food Security Preventive Measures Guidance documents

Appendix D – Warehouse

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GENERAL REQUIREMENTS

SECTION OVERVIEW
The following is designed to provide consistent service of warehousing, third party storage and/or distribution locations for Niagara Bottling. This policy applies to all contracted off site storage facilities.

REQUIREMENTS

1. Register with the U.S. Food and Drug Administration (FDA) and have a certificate with a registration number. Registration should include expiration date.
2. Register with the appropriate State licensing authority and obtain a current food handling and/or warehousing license where required.
3. Pass a third party GMP Warehousing audit and submit audit report, audit certificate and corrective actions to Niagara Bottling for review. This should be completed annually and all corrective actions must be submitted and closed within 30 days; critical items should be completed within 7 days of finding.
4. At minimum the person onsite in charge of Food Safety and Quality should completed AIB Food Protection for Warehouses and Distribution Centers Webinar 5 series training or equivalent and provide completed certificate to Niagara Bottling.

Facility and Grounds

SECTION OVERVIEW
The grounds around a food storage warehouse shall be free from conditions that may result in the contamination of food. Facilities shall be so designed, fabricated, and finished as to minimize the entrance of insects, birds, rodents, and other pests.

REQUIREMENTS

1. Roads, yard, and parking areas around the facility must be maintained or treated to prevent the generation of dust, or the facility must be a construction with a design that prevents the generation of dust.
2. Grounds around the facility must be well drained. There should be no evidence of standing water that may attract rodents or breed insects.
3. Grounds shall be free of litter and refuse.
4. Grounds shall be free from improperly or unnecessarily stored equipment and/or materials that could harbor pests or rodents.
5. Exterior walls and roofs shall be free from holes and cracks that could harbor vermin or allow entrance of pests or rainwater.
6. Warehouse facility shall provide 18” perimeter around outside of building and this includes shrubs, trees and tall grass. There should be no access points for pests to the roof or other areas of the building.
7. Dumpsters containing decayable waste shall be properly covered with tight fitting covers.
8. Dock doors shall have exterior trailer seals that are in good operable condition.

9. Dock doors and levelers shall have seals or brushes that prevent the intrusion of dust, pests, or visible light.
10. All necessary ventilation doors, windows, louvers, or other openings shall be effectively screened against insects, rodents, and birds.
    a. All filters should be regularly changed, and this process should be documented.
11. Lights should be shatter proof or covered in a manner to prevent glass or plastic fragments from entering product or packaging.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
This section requires contracted warehouses to use a Good Manufacturing Practices (GMP) approach to identify and control all hazards and potential food safety issues associated with the product and the storage and handling process, from receipt through distribution of the finished product. Food Safety Modernization Act (FSMA) requires that any warehouse storing foods have a current Hazard Analysis and Risk Based Preventive Controls (HARPC) plan in place.

REQUIREMENTS

Suppliers are required to:

1. Designate qualified employee(s) to develop, implement, and maintain food safety plan(s) for all products and processes.
2. Any facility that is not exempt from the FDA – FSMA requirement must have a food safety plan in place.
3. This plan must have a Team Leader who has a current preventive controls (PCQI) certification and conducts regular team meetings to discuss this plan.
4. Establish and implement written corrective action procedures for non-conformances, audit findings and customer complaints. The corrective action procedures shall define how the potentially affected product is controlled, how root cause is identified, and how to prevent recurrence. All corrective actions shall be documented and closed within 30 days, critical items should be completed within 7 days of finding.
5. Conduct verification of the food safety plan(s) to ensure that the planned activities are execute properly.
6. A pre-shipment review must be conducted prior to shipping product to Niagara Bottling or a customer.
7. Conduct validation of the food safety plan(s) annually and whenever significant changes to storage, handling, or packaging occur, or when product safety issues (system failures) or other industry related incidents occur.
8. Create a food safety team, meeting minutes should be kept on file with attendees, dates and topics discussed.
9. Establish record-keeping and documentation procedure(s) that are in accordance with appropriate regulatory requirements.
10. Provide training to employees in the requirements of the food safety plan(s) as it relates to their specific work area.
11. Glass objects or similar materials in storage and handling areas must be listed on a glass register with location detailed. Glass should only be used where other materials are not

available. Regular inspections should be conducted to ensure no cracks, chips, breakage or changes of objects listed on the glass register. A glass clean-up procedure must be in place.

Product Security

SECTION OVERVIEW
This section requires suppliers to have an effective system to prevent an intentional threat to the facility or the materials stored at the facility. The product defense and facility security plan shall be developed in accordance with all local, state, federal and/or international regulatory requirements.

REQUIREMENTS

Suppliers are required to:

1. Designate a qualified individual(s) to manage a product defense and facility security program.
2. Conduct and document a risk assessment to identify product defense and security vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping, receiving, and personnel.
3. Develop and implement a Food Security and Defense Plan, utilizing the FSMA Final Rule for Mitigation Strategies documents, that addresses all identified vulnerabilities in the following areas: facility exterior, facility interior, storage, shipping and receiving, and personnel. The plan should include procedures for handling threats and actual cases of product tampering in an effort to protect materials from intentional adulteration from biological, chemical, physical or radiological agents.
4. Establish and implement corrective action procedures to be taken in all cases of product tampering to ensure that adulterated or potentially injurious products do not enter commerce. Corrective actions shall eliminate the cause and prevent the reoccurrence of the non-conformances.
5. Review the product defense and facility security plan at a minimum annually, and whenever changes to the facility or process occur, or in the event of a system failure, and revise as necessary.
6. Provide training to all employees in the requirements of the product defense and facility security plan.

Storage and Transportation

SECTION OVERVIEW
This section requires contracted warehouses to develop, implement, and maintain a system for ensuring incoming raw components, work in process (WIP) and finished products are stored and shipped in a manner that protects product safety and integrity, and meets minimum Code of Federal Regulations (CFR) requirements. Requirements apply to offsite storage facilities as well as on site product storage.

REQUIREMENTS

Suppliers are required to:

1. Handle, store and distribute purchased materials, work-in-process and finished products in a manner that prevents damage, deterioration, and contamination. Storage areas and

transportation vehicles must be capable of achieving appropriate conditions (temperature, humidity, and atmosphere) to ensure finished product safety, quality, and integrity.

2. Monitor storage conditions to ensure finished product integrity through documented audit inspections. Products that are considered hazardous or omit an odor must not be stored with our finished product.
3. Have ventilation fans that are capable of turning the air within the warehouse at least two (2) times per hour or a proven means of circulating the air to prevent mold growth. Ventilation fans should not be turned on if outside humidity is >60%; instead internal fans should be used for air flow. If the warehouse is in a region that experiences high humidity, air turns should be calculated only with the internal fans.
4. Develop, implement and maintain a system to properly rotate finished product inventory. All materials must be identified in a manner to allow proper stock rotation and usage. This shall include, but not be limited to description, product sku, date of receipt, date of production, best by date, lot number, and status. Suppliers shall ship water products in a First Expiration First Out (FEFO) manner with no products to exceed 3 months in age before shipping new product.
5. Beverage product shall be shipped within FEFO without exception and product shall be put on hold status after half its shelf life. Product cannot be released from hold until inspected and approved by Niagara management.
6. Maintain finished goods row spacing of at least 12” between sets of double pallets.
7. Develop and document a system that prevents the storage of Niagara Bottling products in any area near hazardous materials or other products with noticeable odors.
8. Develop, implement, document, and maintain a storage and transportation container inspection system that ensures transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution.
9. Conduct documented container inspections upon receipt of materials and upon loading of finished goods.
10. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.
11. Have a secure trailer seal on all incoming and outgoing loads that are verified as intact by a company employee with a number that matches and is verified on BOL. Only a company employee can apply and remove the seals. All seal verifications must be documented.
12. Ensure that product tie & tier configurations are self-supporting, interlocking and secured (e.g. banded, stretch wrapped) in accordance with Niagara Bottling requirements to minimize product shifting and damage.
13. Ensure that any drop trailers are sealed and unloaded or shipped within 24 hours.
14. Provide proof of outgoing trailer inspection prior to loading on a truck-by-truck basis. Inspections shall include at a minimum:
    a. Smell/odor issues.
    b. Evidence of pest activity.
    c. No extraneous material or potential contaminant.
    d. Damage to the trailer.
    e. Moisture in the trailer or evidence of leaks.

15. Provide training to employees responsible for receiving, storing, and shipping goods.
16. Organic Product Storage must follow these requirements. This is only if the warehouse is storing organic products.
    a. Organic certification is not required as long as these products remain in the same package and label in which they are received.

b. Must maintain the identity and integrity of organic products in your custody.
c. Ensure that organic products do not come in contact with prohibited substances such as cleaners, sanitizers, pest control materials or non-organic products.

18. All doors and openings must be closed or screened when not actively used.

Product Identification & Traceability

SECTION OVERVIEW
This section requires suppliers to have an effective system in place to identify and trace product from receipt of materials through distribution of product to allow for effective product recalls or withdrawals.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement and maintain an electronic system for tracing finished products and raw materials within two (2) hours of request. This system must ensure identification of the product to allow for proper stock rotation and effective recalls, lot withdrawals, and problem investigation.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
3. System shall be able to produce written or electronic confirmation of ship to locations for all individual pallets by truck/BOL/PO, within 2 hours of initial request.
4. Any pallets that are broken down for repack or repacking must have the Lot Number of each pallet (LPN) recorded and the facility must have the ability to trace the locations where all parts of the pallet were shipped.
5. Any new pallets created with mixed lots must be recorded as a mixed lot pallet and have the ability to trace these through the distribution chain.
6. All new pallets must generate a new pallet lot number (LPN) and be traceable by the original lot number as received.
7. Provide training to employees responsible for documenting lot information.
8. Clearly code all product containers and shipping cases according to Niagara Bottling product specifications and all regulatory identification requirements. Lot code format shall not be changed without prior approval from Niagara Bottling Quality Assurance. SOP for case coding is available upon request.
9. Develop, implement and maintain a documented system for timely and effective withdrawal or recall of product. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls. The system shall include an investigation that is conducted during the recall to determine if there are other affected products or lots.
10. Document all product recalls and withdrawals. Documented recalls/withdrawals must include percent recovery, start time, stop time, amount of time taken to conduct the recall/withdrawal, and any associated corrective actions.
11. Conduct a minimum of two mock product recalls annually. Documented mock recalls must include percent recovery, start time, stop time, amount of time taken to conduct the recall, ship to locations, and any associated learnings and corrective actions.

12. Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall. This notification must occur within twenty four (24) hours of supplier determining the product should be recalled or withdrawn from the market

PRODUCT QUALITY REQUIREMENTS

Finished Product Specifications

SECTION OVERVIEW
This section requires suppliers to maintain comprehensive specifications that define criteria for workmanship, product attributes and/or characteristics for materials, work-in-process (WIP), and finished products as agreed upon by the supplier and Niagara Bottling.

REQUIREMENTS

Suppliers are required to:

1. Maintain documented specifications for finished products. These specifications shall include, but are not limited to pallet quality, stretch wrap, stack patterns, loading patterns, and quality standards.
2. Review finished product specifications at a minimum annually, or when any change occurs that could result in a change in the finished product, to ensure finished product specifications are accurate.
3. Treat Niagara Bottling specifications as confidential. Note: Once the finished product specification is agreed upon and authorized by Niagara Bottling, changes to product, equipment and/or packaging specifications cannot be made without prior approval of Niagara Bottling. Please see the section titled “Change Management” for more information.

Control of Non-Conforming Product

SECTION OVERVIEW
This section requires suppliers to develop and implement procedures outlining how non-conforming product is identified and controlled. The objective is to ensure that non-conforming product does not reach Niagara Bottling or their customers. All non-conforming materials must not be released unless signed off by a Niagara QA Manager, DC Manager, Plant Director, Corporate QA, or Regional Logistics Manager.

REQUIREMENTS

Contracted warehouses are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming product cannot be inadvertently used or shipped. Procedures shall include identification and segregation of non-conforming product, and determination of product disposition.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the product hold program. This shall include designation of employees responsible for placing product on hold and those determining disposition.

3. If product is received already on hold from plant, a hold must be immediately placed at the receiving warehouse. Must ensure hold tags are on each pallet received. Any non-conforming materials must be recorded on the BOL.
4. Identify and document all process and product deviations from receiving, storing, and shipping of finished product.
5. Develop, implement and maintain a hold log and hold tag that physically identifies the affected product. Information on the hold tag and log shall include product description, batch/lot information, date of hold, reason for hold, amount of product involved, and person responsible for placing product on hold and disposition.
6. Conduct re-inspection of product designated for repack in accordance with documented procedures and specifications prior to shipping.
7. Develop, implement and maintain a documented tracking system that identifies all product on hold and resulting disposition.
8. Develop, implement and maintain corrective actions to eliminate the cause and prevent the reoccurrence of non-conformances.
9. Repackage non-conforming product so that any reference to Niagara Bottling is removed before donation or sale of any kind. Exceptions to this requirement must be obtained in writing from the appropriate Director of Niagara Bottling Quality Assurance.
10. Any products destroyed must be approved by Niagara Bottling and destruction must be coordinated by Niagara bottling facility who shipped the product. All destruction must be performed at a Niagara approved destruction facility and follow all Niagara destruction procedures and paperwork.
11. Provide training to employees on instructions for controlling non-conforming product.

Product Handling & Storage Guidelines

SECTION OVERVIEW
Niagara Bottling recommends the following guidelines are followed by all warehousing and distribution locations in order to maintain safety and uphold quality for our customers and consumers. If for any reason the pallet integrity is compromised where product needs to be down stacked the supplier shall immediately notify the Niagara facility of the issue. This guideline is only applicable for Niagara manufactured product (herein after “Product”).

PRODUCT HANDLING REQUIREMENTS

Trailer Unloading:
1. Shall be unloaded and transported for storage at a maximum of two pallets per trip.
2. Shall not be used to push other product and/or should not be stacked and pushed to storage location.
3. Shall be carried with enough clearance is such a manner that the pallet is not pushed or dragged on the floor.

Trailer Loading:
1. Shall be carefully un-stacked and transported at a maximum of two pallets per trip.
2. Shall not be used to push other product and/or should not be stacked and pushed into trailer.
3. Shall be carried with enough clearance in such a manner that the pallet is not pushed or dragged on the floor.

4. Shall be loaded in such a manner that will minimize movement during transit. Additional use of items such as, but not limited to, airbags and loading bars shall be used when necessary.
5. Use Niagara approved loading patterns for all outbound loads.

Case loading for product that is removed from pallet in distribution centers for purposes of mix loads:

1. Shall avoid the use of gravity, roller, or wheel conveyors when possible. Use of transport materials, such as a sled, shall be used to transport product on these types of conveyors.
2. Shall avoid conveyors with large gaps and broken parts which can cause damage to product.
3. Shall place product onto conveyors. Tossing, dropping, or sliding product is not allowed.
4. Shall lift product from the bottom of the pack. Product shall not be lifted by the side openings (bullseye).

PRODUCT STORAGE REQUIREMENTS

Niagara does not allow the continual use of a trailer as a method of storage due to the nature of the product and its sensitivity with different environments.

Double Stacking:

1. Pallets shall be in good condition.
2. Cases shall be evenly centered on pallet and remain upright and not leaning.
3. Pallets shall consist of identical product type (24-pack on 24-pack, 32-pack on 32-pack, etc…) double stacking 24-pack on 32-pack or any other product combination is not permitted. Contact Niagara for a list of approved product for double stacking.
4. Ensure that pallet supporting product be free of defects such as loose, broken, or missing boards.
5. Ensure that pallets are stored on a flat, level ground surface only.
6. Bottom pallet shall not be permitted to move while bearing any weight until such weight is removed.

Rack Storage:

1. Shall be in good condition.
2. Cases shall be evenly centered on pallet and remain upright.
3. Ensure that pallet supporting product be free of defects such as loose, broken, or missing boards.
4. Ensure that double slotted racks with wire mesh be used to store product
5. Ensure that all racking systems are approved by your designated Niagara Quality Assurance contact before use is permitted.

Mold Control and Prevention

SECTION OVERVIEW

Niagara Bottling requires the following guidelines be followed to help ensure the warehouse space and the product remain mold free. The objective is to prevent mold from entering the building, monitor environmental conditions inside the warehouse that support mold growth, quickly identify mold, remove mold from the warehouse safely and efficiently and prevent affected product from reaching Niagara Bottling or their customers.

Risk Level of 3PL:

1. Each 3PL will be given a risk level (high or low) for mold growth based on regional location, environmental conditions and history of mold issues. Contact your Regional Logistics Manager or Supplier Quality for your 3PL's risk level, they are subject to change based on environment.

High Risk	High Risk	High Risk	Low Risk
Alabama	Maryland	Tennessee	Alaska
Arkansas	Massachusetts	Texas	Arizona
Connecticut	Michigan	Vermont	California
Delaware	Minnesota	Virginia	Colorado
Florida	Mississippi	West Virginia	Montana
Georgia	Missouri	Wisconsin	Mexico
Hawaii	New Hampshire		Nebraska
Idaho	New Jersey		Nevada
Illinois	New York		New Mexico
Indiana	North Carolina		North Dakota
Iowa	Ohio		Oregon
Kansas	Oklahoma		South Dakota
Kentucky	Pennsylvania		Utah
Louisiana	Rhode Island		Washington
Maine	South Carolina		Wyoming

MOLD IDENTIFICATION AND TRAINING:

1. All staff shall be trained on mold identification and prevention. Training should be completed at minimum upon hire and annually thereafter. Training guide can be found under Referenced Documents section below – *Mold Prevention and Management*.

INSPECTION REQUIREMNTS:

1. All incoming shipments shall be inspected to ensure pallets, finished goods and raw materials are mold free.
    a. If any mold is observed, the trailer should be rejected or product segregated in a hold area to prevent mold from entering and spreading in the warehouse.
2. Once temperatures reach 70F and relative humidity reaches 60%, high risk 3PL's need to inspect current inventory daily for mold. Low risk regions should inspect weekly at minimum. Logs can be found in Referenced Documents section below.
3. All outbound pallets should be inspected for mold prior to loading trailer.
4. Any mold observed on product needs to be placed on hold and segregated from all other product and notify the local Niagara Management Team of the hold immediately. Holds may not be removed without written instruction from Niagara.

PRODUCT STORAGE:

1. Maintain 12" spacing between double rows of pallets.

2. Product should be rotated in First Expiration First Out (FEFO) manner, with no products to exceed 3 months in age before shipping new product. Beverage product shall be shipped within FEFO without exception.

MONITORING ENVIRONMENTAL CONDITIONS:

1. Temperature and Humidity – Monitoring devices should be monitored and recorded. Any conditions that support mold growth or any signs of mold should be reported to the local Niagara Management Team, as well as Corporate Supplier Quality immediately.
    a. An adequate amount of hygrometers should be placed throughout the warehouse depending on size and region risk level. Corners of the warehouse and areas that have lowest airflow should be monitored.
    b. The warehouse should remain below 70°F and less than 60% relative humidity (RH).
    c. If temperatures and RH exceed 70°F and 60% RH, actions must be taken and documented, to help reduce these levels. All efforts need to be made to increase airflow to all areas of the warehouse. If this threshold is reached the 3PL Humidity and Mold Monitoring Log must be completed. See Referenced Documents section below for log templates.
        i. High risk 3PL's will complete the daily log and low risk 3PL's will complete a weekly log.
        ii. If low risk 3PL's have two consecutive weeks of temperatures greater than 70F and RH > 60%, a daily log must be completed until two consecutive week remain below this threshold.
2. Air flow – There should be at least 2 air turns per hour throughout all areas of the warehouse 24/7. Air movement should be felt throughout the warehouse including corners and areas furthest away from dock doors and other sources of external air.
    a. Air turns may need to exceed 2 turns per hour in high risk 3PL's during warm months. Ventilation fans should not be used to calculate air turns in these regions, only internal fans should be calculated.
    b. Ventilation fans should not be used if outside humidity is greater than internal humidity.
    c. Water leaks – All buildings should be monitored for leaks and when possible, should be completed after rain so any water leaks are better identified. Windows, walls, doors, ceilings, floors and product are all areas that should be closely monitored for water leaks. Any standing water needs to be cleaned up right away.

CLEANING AND REMOVAL OF MOLD

1. Once mold is observed, it will need to be controlled and removed right away. Mold spores grow and spread very fast as the spores can travel easily through the air, water, or a host like forklifts and foot traffic. Contaminated areas need to be handled in a manner to minimize the spread of the mold spores.
2. Mold can penetrate surfaces up to 1.5mm deep and will germinate within 24-48 hours.
3. Contaminated areas like the floors, walls and forklift forks should be cleaned with 1:10 bleach solution and let sit for about 15 minutes. Once the area is cleaned, avoid reintroducing the mold to the cleaned area via foot and forklift traffic.
4. All pallets and products contaminated with mold should be removed from the warehouse as quickly as possible. Contact your local Niagara Management Team to schedule destruction loads and return of contaminated pallets so the vendor may treat these pallets.

a. There is a method for cleaning pallets with Potassium Bicarbonate but must be approved by the plant QA team or Supplier Quality. They will provide the directions for mixing and use of this.

Topics of Interest and Related Web Sites

21-CFR (GMP's, cGMP's, etc.):
eCFR: 21 CFR Part 117 -- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

International Bottled Water Association: www.bottledwater.org

Food Defense Plan Builder:
http://www.fda.gov/Food/FoodDefense/ToolsEducationalMaterials/ucm349888.htm

Food Safety Modernization Act: http://www.foodsafety.gov/news/fsma.html

AIB Food Protection for Warehouses and Distribution Centers Webinar Series: Food Protection for Warehouses and Distribution Centers Webinar Series - AIB International, Inc.

Referenced Documents

NIA-305-15-0026 3PL Humidity and Mold Monitoring Log – Daily
NIA-305-15-0027 3PL Humidity and Mold Monitoring Log – Weekly
NIA-305-15-0028 3PL Mold Prevention and Management Training
NIA-305-15-0002-15-0008 MRB Product Rotation Policy

Appendix E – Spring Water Tanker Haulers

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GENERAL REQUIREMENTS

SECTION REVIEW
The following is designed to provide consistent method for the transportation of spring water.

REQUIREMENTS

1. Registered with the appropriate State licensing authority.
2. Be in compliance with all local, state, and Federal laws and regulations.
3. Have documented training that covers –the Sanitary Transportation Rule.
4. For the approval of each new tanker, the Questionnaire must be provided with the supporting documents listed on the form. A desk audit will be completed and approval status will be provided by Supplier Quality. Additional steps and testing may be requested by Niagara based on the age, condition of tanker, previously hauled products, etc.
5. All tankers must be dedicated to spring water and this must be identified with a decal on the tanker.
6. Only Niagara approved spring sites are to be used.
7. Only Niagara approved tankers are to be used.
8. Only Niagara approved tanker washes are to be used.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
This section requires Hauler to control all hazards and potential food safety issues.

REQUIREMENTS

Suppliers are required to:

1. Review wash tickets to ensure all wash requirements are met and documented. This is the responsibility of the driver after the wash is complete and prior to loading any spring water.
2. Be constructed and operated in a manner as to prevent contamination and to operate in compliance with the Federal regulations, including 21 CFR Part 117.
3. Incorporated into their process a Food Safety plan based on Hazard Analysis Critical Control Point (HACCP) principles.
4. Have prerequisite programs implemented that include employee training protocols. This needs to be completed upon hire, re-trained at a minimum annually, and anytime there are revisions within the policy. These prerequisite programs include:
    a. GMP, tanker security, food safety, sanitary transportation and quality systems in place.
5. Must ensure the tanker is fully drained from previous load. Stagnant water allows microorganisms to grow.

6. If tanker shows signs of rust or discoloration, the tanker must be taken out of service and rust/discoloration must be removed. Any pitting in the tanker needs to be repaired as soon as it is observed to help prevent microbial contamination.
7. Tanker openings and hose compartments must be sealed at all times and seal number must be clearly documented.

Additional requirements may be necessary upon approval:

1. Collect microbiological sample from a test load. This test load would need to be dumped and placed on hold until results are confirmed.
2. Allergen testing.
3. Odor test.
4. Training for Drivers at Spring Site.
5. Tanker conversion process.

NOTE: Before first load, please make sure that Tankers have been approved and confirmed by Corporate Quality Assurance. The plant will not receive tankers that are not on the list of Approved tankers.

Tanker Requirements

SECTION OVERVIEW
This section requires suppliers to control the tankers used for hauling water for Niagara Bottling. This covers the construction and condition of all tankers used to ensure the product safety of the water delivered to Niagara Bottling plant locations.

REQUIREMENTS

Suppliers are required to:

1. Use only food grade tankers that are permanently dedicated and clearly identified as such.
2. Be dedicated to hauling only potable water. Other potable water sources hauled must be approved by Niagara. *No other food product may be hauled in the tankers so long as they are servicing Niagara water plants.*
3. Hauling history must only have approved food products.
    a. All hauling histories must include the contents of what was hauled and dates. Hazardous materials must not have been previously hauled.
4. All haulers need to show records of last passivation.
5. Tanker must not contain baffles or other interior obstructions that would prevent thorough cleaning, must be a single compartment with smooth bore.
6. Tanker interior, caps, fittings, and valves that are composed of food grade stainless steel and are in good condition. If a tanker has been damaged to the extent that its function and integrity are compromised, then it should not be used and Niagara shall be notified of any repairs. Supplier Quality will need to give approval before returning to service.
7. Use only tankers (including valve systems) that are cleanable, sealable, and constructed of either 304, 316 or higher quality stainless steel.

8. Seal tanker openings using tamper evident seals at all times including when empty. Any unsealed vessels should never be left unattended. All seal numbers and locks must be documented.
9. All gaskets will be appropriately sized, will be intact with no visible tears breaks or rips and be capable of being cleaned and sanitized. All gaskets must be food grade material.
10. Carry or have installed air vent screen that remains in place during un-loading. The screens must be approved to "prevent contamination" of the potable water.
    a. These screens need to be maintained to ensure cleanliness.
11. Obtain written approval from Niagara if the carrier's hoses, pumps, or fittings are to be used for loading or un-loading.
12. Receive a Niagara approved wash at a minimum of every 30 days by a Niagara approved wash station; approved wash station list is available upon request. This frequency may be increased if requested by Niagara Bottling.
    a. If a wash facility no longer meets Niagara requirements, these facilities will be removed from the approved list and the hauler must assist in finding another feasible option.
13. If a tanker sits empty for more than 72 hours, then the tanker must at a minimum be sanitized and documentation of this must be presented to Niagara Quality Assurance.
14. Sanitize a tanker upon request from a Niagara approved wash station.
15. Niagara may adjust the requested wash type based on the hauling history of the tanker in question.
16. All water products must be delivered within 24 hours of loading the tanker at the spring site or it will need to be dumped.

Seals

SECTION OVERVIEW
This section requires suppliers to develop a seal procedure to ensure that all tankers are clean and sanitized prior to use and gives the assurance that it has not been tampered with.

REQUIREMENTS

1. Only tamper evident seals shall be used to secure tanker openings. The seal shall be constructed in such a way that it can be used only once, not re-sealable, can be easily noticed if tampered with and fabricated from non-toxic, non-corrosive, and appropriate materials.
2. Each seal must be legibly and uniquely identified and documented.
3. Spring water tankers must be sealed at all times.
4. Broken Seals: In any case where a seal has been breached or broken, except by reason of loading or unloading product, the breach must be reported, noted on records and appropriate corrective actions taken.
    a. Corrective action for a breached seal on a washed but empty tank would include notification to Niagara Supplier Quality and rewashing of the tanker.
    b. A breached seal on a filled tanker will be rejected and dumped.
    c. Resealing alone is never adequate as a corrective action.
    d. Draining of a rejected water load must occur at the rejecting plant, and the Niagara personnel must ensure the tanker is completely empty before it leaves the property. If

draining at Niagara property is not feasible then arrangements must be made by Niagara to empty the trailer at an approved location.

e. A CAPA for the broken seal must be completed and sent to Niagara Supplier Quality for approval.

Product Identification & Traceability

SECTION OVERVIEW
This section requires facilities to have an effective system in place to identify and trace washes and transportation of product throughout the entire process. This will allow for effective product recalls and traceability.
REQUIREMENTS

Suppliers are required to:

1. Document detailed haul history to ensure adequate traceability throughout the process, from washing to spring water loading, through final distribution.
2. Provide training to employees responsible for documenting traceability.
3. Develop, implement, and maintain a documented system for timely and effective withdrawal or recall of product. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls. The system shall include an investigation that is conducted during the recall to determine if there are other affected products or lots.
4. Document all product recalls and withdrawals.
5. Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall implicating product delivered to Niagara Bottling. This notification must occur within twenty-four (24) hours of supplier determining whether the product should be recalled or withdrawn from the market.
6. Notify Niagara Bottling Quality Assurance at the Plant and Supplier Quality at Corporate, of any positive microbiological testing. Tankers should be removed from service until Niagara Bottling has approved for continued use.
    a. Niagara Bottling may request the tanker to be re-washed, re-tested, inspected, etc., before the tanker may be allowed back in service.

PRODUCT QUALITY REQUIREMENTS

Control of Non-Conforming Tankers and Product Water

SECTION OVERVIEW
This section requires tanker wash facilities to develop and implement procedures outlining how non-conforming tankers are identified and controlled. The objective is to ensure that non-conforming tankers do not reach Niagara Bottling facilities. A non-conforming tanker could be a tanker not intended for food grade usage or a food grade tanker constructed with non-food grade parts, materials, or welds. A non-conforming tanker could also be a food grade tanker that has been damaged in a way to affect the cleaning and sanitization process.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming tankers cannot be inadvertently used to haul product for Niagara Bottling. Procedures shall include identification and segregation of non-conforming tankers, and determination of tanker disposition.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the tanker inspection program. This shall include designation of employees responsible for placing tankers on hold and those determining disposition.
3. Provide training to employees on instructions for controlling non-conforming tankers.
4. Haulers are responsible for maintaining the quality of their tankers.
5. Loads may be tested upon receipt, if a positive microbiological test is observed than the tanker may be requested to get washed before returning to service.
6. Any tanker testing positive for E.coli will be removed from service until it is cleaned and approved by Niagara Corporate QA. Please refer to your spring hauler contract for reject loads and payment agreement.

Topics of Interest and Related Web Sites

FSMA section 111 Sanitary Transportation of Human and Animal Food Training
https://collaboration.fda.gov/sanitary_transportation_carrier_training/

eCFR :: 21 CFR Part 117 -- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Referenced Documents

NIA-305-18-0017 – Sanitary Tanker Inspection Form
NIA-305-18-0015 - Spring Water Hauler Pre-Screening and Approval Questionnaire

Appendix F – Spring Water Tanker Wash Facilities (Back to Table of Contents)

GENERAL REQUIREMENTS

SECTION REVIEW
The following is designed to provide consistent method for the washing of spring water tanker haulers and the transportation of the spring water.

REQUIREMENTS

1. Registered with the appropriate State licensing authority.
2. Be in compliance with all local, state, and Federal laws and regulations.
3. For the approval of each new wash facility, the Questionnaire must be provided with the supporting documents listed on the form. A desk audit will be completed, and approval status will be provided by Niagara Bottling Supplier Quality.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
This section requires Tanker Wash Facilities to control all hazards and potential food safety issues associated with the wash and sanitization process.

REQUIREMENTS

Suppliers are required to:

8. When washing tanker, use potable water from a source certified annually. Certification must be available upon request.
9. Declare type of wash performed on wash tickets.
10. Be able to document chemical (detergent, degreaser, and sanitizer) concentration, wash time, and wash/rinse temperatures for each step performed. This documentation must be available upon request.
11. Be constructed and operated in a manner to prevent contamination and to operate in compliance with the Federal regulations, including 21 CFR Part 117.
12. Food grade and non-food grade tankers must be washed using separate equipment in segregated wash bays. Drainage from other non-food grade wash bays must be constructed in a manner that does not flow into the food-grade bay.
    a. Food-grade bay must be identified with signs.
13. Incorporated into their process a Food Safety plan based on Hazard Analysis Critical Control Point (HACCP) principles.

14. Have prerequisite programs implemented that include employee training protocols. This needs to be completed upon hire, re-trained at a minimum annually, and anytime there are revisions within the policy. These prerequisite programs include:
    a. GMP, security, food safety, pest control, safety, and quality systems for all employees.

Tanker Wash Types

SECTION OVERVIEW
This section requires suppliers to use a Niagara Bottling approved wash as described below. Niagara Bottling approved wash for tankers previously hauling potable water must complete the following tanker wash procedures every 30 days. Please be aware, this is not monthly, but every 30 days.

REQUIREMENTS

Suppliers are required to:

1. Drain all previous products from tanker interior. Tanker interior scraping or spraying with high-pressure potable water as necessary. Drain thoroughly.
2. Perform visual inspection from top hatch to assure effective removal of product from tanker and no visible damage, corrosion, or pitting on inner surface.
3. Rinse tanker thoroughly with warm (75 – 110˚ F) potable water. Drain thoroughly.
4. Remove, hand wash and sanitize all vents and vent tubes. Hand-wash and sanitize rear valve assembly and top hatch. If present, air vents located at the top of the tanker must also be hand washed and sanitized, regardless if vent was previously used.
5. Apply to the tanker a hot cleaning caustic-based solution consisting of a cleaner (at prescribed level) or equivalent food grade cleanser under pressure through CIP system for a minimum of 15 continuous minutes or per manufacturers' recommendation.
6. Ensure the cleaner meets applicable food contact requirements for the intended use as established by a government agency or third-party.
7. The period of 15 minutes should commence only when the effluent at the outlet reaches a temperature of 140˚F. A minimum effluent temperature of 140°F should be sustained for the duration of the caustic wash. Temperatures below 140°F at drain outlet are never acceptable, unless cleaner is being used at the concentration, the temperature and times recommended by the manufacturer, cleaners can be "circulated" during this 15-minute cycle.
8. Drain thoroughly.
9. Ensure that cleansers used in this cleaning cycle are single use cleansers and not recycled cleansers.
10. Rinse tanker with potable water at 185˚ F for 15 minutes or until no residual cleaning solution is detected. Do not use recycled rinse water. Drain thoroughly.
11. As appropriate, perform visual inspection of tanker interior in a manner providing for safe and sanitary evaluation, without entering tanker. When tanker entry by a person takes place or is required, the cleaning process described in subparagraph (v), (vi) and (vii) must be repeated. If tanker entry is necessary, comply with confined space entry requirements.

Tanker Accessory Cleaning

SECTION OVERVIEW

This section requires suppliers to clean and sanitize all accessory items used to load and unload the tankers including pumps, hoses, and fittings.

REQUIREMENTS

1. Perform accessory cleaning on every food contact surface for every component used for unloading.
2. Cleaning protocol for these components must mimic those of the tanker and are based on the food commodity previously hauled.
3. Pumps, hoses, and fittings can be cleaned in place (CIP) provided a separate drive capable of turning the pump fast enough to completely fill the size of the hose and fittings used and provide a velocity of at least 5 feet per second.
4. Hoses should be supported off the ground to avoid damage and prevent the introduction of contaminants. Hoses should be stored off the ground and capped when not in use. Any damaged hoses should be immediately removed from service. Unattended hoses should be locked or capped and sealed with tamper evident seals. The ends of the hose should never touch the ground or other unsanitary surface.
5. If a CIP drive is not available that meets the minimum flow requirements, all parts must be physically removed and washed in a “COP” (clean out of place) tank. Every step used for the tanker wash protocol based on wash type must be used on these parts. This includes all parameters for temperature, chemical concentration, duration etc. Each parameter will need to be recorded and documented using test kits, temperature-recording devices, and etc.
6. All parts after complete cleaning must be closely inspected to insure proper cleaning. Parts should be reassembled and re-sanitized after assembly.
7. Pumps and hoses must be capped and sealed using tamper evident seals. All seal numbers used on these components must be documented on the wash ticket or accompanying paperwork.

Seals

SECTION OVERVIEW
This section requires suppliers to develop a seal procedure to ensure that all tankers are clean and sanitized prior to use and gives the assurance that it has not been tampered with.

REQUIREMENTS

5. Only tamper evident seals shall be used to secure tanker openings. The seal shall be constructed in such a way that it can be used only once, not re-sealable, can be easily noticed if tampered with and fabricated from non-toxic, non-corrosive, and appropriate materials.
6. Each seal must be legibly and uniquely identified.
7. After Wash: Suitable seals for use after a tanker is washed but not loaded with food shall be constructed to preserve the cleanliness and security of the clean tanker. The seals used for this purpose may be characterized as temporary and may consist of plastic material.
8. After loading: Seals used to secure openings after a tanker is filled with food must be secure and durable enough to withstand the stresses of handling and transportation. Each seal must be uniquely identified using a coding system, permanently affixed to the seal that can be easily recorded on wash tickets.

9. Broken Seals: In any case where a seal has been breached or broken, except by reason of loading or unloading product, the breach must be reported, noted on records and appropriate corrective actions taken.
    f. Corrective action for a breached seal on a washed but empty tank would include rewashing.
    g. Corrective action for a breached seal on a filled tanker would be rejection and destruction of the load.
    h. Resealing alone is never adequate as a corrective action.
    i. Draining of a rejected water load must occur at the rejecting plant, and the Niagara Bottling personnel must ensure the tanker is completely empty before it leaves the property. If draining at Niagara Bottling property is not feasible then arrangements must be made by Niagara Bottling to empty the trailer at an approved location.

Wash Ticket Documentation

SECTION OVERVIEW
This section requires suppliers to record all critical wash and sanitization process information so that any persons loading or unloading the tanker can have the assurance that the tanker has been properly cleaned and sanitized within the allotted time periods prior to use.

REQUIREMENTS

1. All tankers used to transfer food ingredients must present their Wash Ticket(s) to the designated department of the receiving company upon arrival at the receiving facility.
2. Every time a tanker is received at a Niagara Bottling Water Plant the driver of the tanker must be able to produce a current wash ticket if requested.
    a. The wash ticket at a minimum must have the following information.
        i. Date.
        ii. Time.
        iii. Name of Wash Station and location.
        iv. Wash type (i.e., “Niagara, Passivation, Kosher Type, Sanitization”) or any combination as described herein and whether any additional wash or treatment that was applied.
        v. Including the temperature of the cleaning solution during the wash.
        vi. Concentration of cleaning solution during the wash.
        vii. Final rinse pH.
    b. Original signature certifying information on wash ticket from authorized agent of wash facility.
    c. Seal identifiers.
3. The Wash Ticket(s) must be presented prior to sampling and unloading.
4. Tanker driver is to obtain or confirm the presence of the tankers’ Wash Ticket(s) prior to leaving the tanker wash site or accepting the shipment. This includes vendors who transport their own products.
5. If the Wash Ticket(s) are lost during shipment, the destination site will provide a FAX number so the missing information can be sent; however, it is the responsibility of the tanker driver to have the Wash Ticket(s) sent.

6. Tankers are to be filled within 72 hours of the cleaning time stamped on the Wash Ticket. If the 72-hour time period has elapsed before the tanker loading commences, then the tanker must at a minimum be sanitized and documentation of this must be present.

**The signature of the On Duty Dispatcher or Supervisor of the tanker carrier company must be included on all corrected documents that are transmitted to a site designated by the product owner. This procedure is required to confirm the authenticity of the information being provided.

Chemical usage and Storage

SECTION OVERVIEW
This section requires tanker wash facilities to develop, implement, and maintain a system for ensuring that all chemicals are used and stored in a manner that protects product safety and integrity, and meets minimum regulatory requirements as set forth in the Code of Federal Regulations (CFR), including but not limited to Sanitary Transportation (21 CFR Part 1, Subpart O), GMPs (21 CFR Part 110) and Preventive Controls (21 CFR Part 117).

REQUIREMENTS

Suppliers are required to:
1. Ensure chemicals used to clean food contact surfaces meet applicable food contact requirements for the intended use as established by a government agency or third party (e.g., USDA, FDA, NSF International, United States Pharmacopeia (USP_, 3-A Sanitary Standards).
2. Use and rotate chemicals, detergents, and sanitizers according to a FEFO basis.
    a. If no expiration date is listed, the designated chemical representative should be contacted to determine the chemical shelf life. This should be documented on the chemical container as well as with the chemical lot records.
3. Monitor and record chemical concentrations according to supplier recommendations.
4. Monitor chemicals for long term usage to ensure proper levels are being consumed.
5. Record lot numbers and expiration dates for all washes to ensure traceability.
6. Store all chemicals, detergents, and sanitizers in such a manner as to prevent contamination, and degradation.
7. Label and store chemicals, detergents, and sanitizers in a locked and secured location.
8. Store food grade and non-food grade chemicals, detergents, and sanitizers separately as to prevent any cross contamination.
9. Maintain a list of all chemicals (detergents, sanitizers, etc.), SDS, and technical data sheets.
10. Provide training to employees responsible for chemical control and usage.

PRODUCT QUALITY REQUIREMENTS

Control of Non-Conforming Tankers and Product Water

SECTION OVERVIEW
This section requires tanker wash facilities to develop and implement procedures outlining how non-conforming tankers are identified and controlled. The objective is to ensure that non-conforming tankers

do not reach Niagara Bottling facilities. A non-conforming tanker could be a tanker not intended for food grade usage or a food grade tanker constructed with non-food grade parts, materials, or welds. A non-conforming tanker could also be a food grade tanker that has been damaged in a way to affect the cleaning and sanitization process.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming tankers cannot be inadvertently released to the customer without proper notification of issue.
    a. Procedures shall include identification and segregation of non-conforming tankers, and determination of tanker disposition.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the tanker inspection program. This shall include designation of employees responsible for placing tankers on hold and those determining disposition.
3. Provide training to employees on instructions for controlling non-conforming tankers.

Compliance with Tanker Wash Guidelines, Audit and Approvals

SECTION OVERVIEW
This section requires suppliers to participate and pass periodic audits by a Niagara QA employee. Tanker wash facilities will be listed as an approved tanker wash facility once they have passed this audit inspection.

REQUIREMENTS

Any audit findings shall be corrected in a timely manner. Critical items should be corrected within 7 days and no other washes should be performed until this is corrected and approved by Niagara Bottling. Any non-critical findings should be corrected within 30 days of identification.

1. Auditing of Tanker Wash Stations
    a. All tanker wash stations must be audited and approved by Niagara QA before they may be used to wash tankers hauling for a Niagara Bottling Plant.
    b. Audit Checklists are available upon request.
    c. Periodically, a Niagara representative or approved substitute will re-inspect each wash station being used to clean Niagara dedicated tankers.
    d. All wash stations must be Kosher certified and present current certification letter when requested.

Topics of Interest and Related Web Sites

21-CFR (GMP's, cGMP's, etc.)
eCFR :: 21 CFR Part 117 -- Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Human Food

Referenced Documents

NIA-305-18-0016 - Tank Wash Facility Questionnaire

Appendix G – Resin Storage

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GENERAL REQUIREMENTS

Product/Supplier Risk Factors

SECTION OVERVIEW
The following is designed to provide consistent method for resin storage and handling for Niagara Bottling facilities. This policy applies to all off site resin storage locations.

REQUIREMENTS

For the approval of each new storage warehouse, a Questionnaire must be completed and sent to Supplier Quality for review and approval, along with the listed documents within the Questionnaire.

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
This section requires resin storage facilities to control all hazards and potential food safety issues associated with the storage and handling of resin.

REQUIREMENTS

Suppliers are required to:

1. Facility must be constructed and operated in a manner to prevent contamination and to operate in compliance with applicable regulations.
2. There should be no external openings within the building. If air vents are in place, they should have filters that are capable of blocking dust particles and insects. All filters must be monitored and cleaned as needed.
3. All doors and openings must be closed or screened when not actively used.
4. If multiple grades of plastic resins are being handled, there must be a documented procedure in place that ensures mixing of different types of resin does not occur. Removal and cleaning of the hopper screen, filter, magnet, piping, and hose is important in this process.
5. Cleaning chemicals should not be needed on a regular basis but if any cleaning chemicals are used on processing equipment, they must be food grade. Cleaning documentation must be performed and available upon request.
6. Hoppers must be dedicated to loading only resin and must be clearly identified this way. No other product may be used in the hoppers.
7. Any hopper used to load bulk trucks must have screens and magnets to catch metal and foreign material from entering bulk trucks. Screen and magnets must be cleaned after each truck load.
8. When transferring resin, hoses should be supported off the ground during loading and unloading to avoid damage and prevent the introduction of contaminants. Hoses should be stored off the

ground and capped when not in use. Any damaged hoses should be immediately removed from service. If potential contamination occurs, this must be reported to Niagara Bottling Supplier Quality.

9. Any damaged or missing parts, gloves, tools, seals, etc. must be documented and reported to Niagara Bottling Supplier Quality.
10. External openings on hoppers should have filters in place that are capable of blocking any dust and foreign materials from entering. These filters must be monitored and cleaned as needed
11. Seal tanker openings using tamper evident seals. Seals should be kept in a controlled location and only warehouse employees should remove or place the seals. Seal numbers need to be documented and verified.
12. Avoid excessive air velocity and loading rate in the system and minimize the number of bends in the piping to reduce the amount of angel hair in product.
13. Use food grade hose, gaskets and seal materials. All seals and gaskets will be appropriately sized, will be intact with no visible tears, breaks or rips and be capable of being cleaned and sanitized as needed.
    a. If any gaskets are missing or broken there needs to be an investigation performed immediately to locate missing parts or notify Niagara of a potential contamination.
14. Ensure good housekeeping in resin storage and processing areas.
15. Have prerequisite programs implemented including employee training protocols.
16. Lights should be shatter proof or covered in a manner to prevent glass or plastic fragments from entering product or packaging.

Storage and Transportation

SECTION OVERVIEW
This section requires storage facilities to develop, implement, and maintain a system for ensuring incoming raw components are stored and shipped in a manner that protects product safety and integrity, and meets minimum Code of Federal Regulations (CFR) requirements.

REQUIREMENTS

Suppliers are required to:

1. Store resin in a way to not create any hazards. Resin storage areas should be kept clean and dry location, and the warehouse must:
    a. Operate under GMP requirements as outlined in 21 CFR Part 110 and 21 CFR Part 117.
    b. Have a pest control program in place with employees trained in pest control awareness.
    c. Product should be placed in orderly fashion where locators can identify product lot numbers to effectively ship in FIFO and be quickly identified for traceability.
    d. Product super sacks need to be sealed and kept clean to prevent any contamination and exposure to hazards.
2. Develop, implement and maintain a storage and transportation container inspection system that ensures transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution.
3. Conduct container inspections upon receipt of materials and upon loading of resin.
    a. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.

b. All containers received should be verified against the COA to ensure proper lot/container information is present. Any containers received that are not listed on the COA, must be placed on hold until the correct COA is received.

4. Ensure all incoming and outgoing loads have a tamper evident seal with a number that matches and is verified on the BOL. The BOL should contain lot number, quantities and corresponding seal numbers.
5. Outgoing tanker inspection should be conducted prior to loading as well as hose and hoppers for wear and contamination. Inspections shall include at a minimum:
   a. No extraneous material or potential contaminant
      i. This needs to be completed by verifying tanker blow out documentation from hauler or by observing the blow out procedure and the outcome. This must be documented and available for Niagara when requested.
6. Develop, implement and maintain a system to ensure the integrity of all goods stored on-site. Provide training to employees responsible for receiving, storing, and shipping resin. When bulk loading super sacks into tankers ensure that all super sacks are cleaned, especially the bottom of the super sack, prior to moving over hopper. All super sacks shall be untied at bottom to release resin into hopper, however if super sacks must be cut extreme care shall be taken to prevent any foreign material from entering the hopper. Any tools used, need to be accounted for.
   a. Immediately notify management and Niagara Supplier Quality and halt loading or delivery of tankers if potential contamination is discovered.
   b. Any hopper used to load bulk trucks must have screens and magnets to catch metal and foreign material from entering bulk trucks. Screen and magnets must be cleaned after each load, this must be documented and available to Niagara upon request.
7. Ensure the warehouse/storage area is dust-free and dry with adequate ventilation and absence of direct sunlight. Keep storage temperatures within ambient conditions.
8. All doors and openings must be closed and locked when not actively used. Secured screen doors may be used to allow airflow into the warehouse.
9. All resin loads must be accompanied with a COA that matches the container/lot number. This needs to be provided to the driver once lot/container number is verified by warehouse.

Chemical Usage and Storage

SECTION OVERVIEW
This section requires resin-handling suppliers to develop, implement, and maintain a system to ensure that all chemicals are used and stored in a manner that protects product safety and integrity, and meets minimum regulatory requirements as set forth in the Code of Federal Regulations (CFR), including but not limited to Sanitary Transportation (21 CFR Part 1, Subpart O), GMPs (21 CFR Part 110) and Preventive Controls (21 CFR Part 117).

REQUIREMENTS

Suppliers are required to:

1. Develop an SOP for approving chemicals, handling, storing, labeling etc.
2. Ensure chemicals used are approved and listed on the approved chemical list.
3. Use and rotate chemicals, detergents, and sanitizers according to a FIFO basis.
4. Store all chemicals in such a manner as to prevent contamination of foreign substances.
5. Label and store chemicals in a locked and secured location.

6. Store food grade and non-food grade chemicals.
7. Maintain a list of all chemicals and SDS for each.
8. Provide training to all employees.

Product Identification & Traceability

SECTION OVERVIEW
This section requires resin handling suppliers to have an effective system in place to identify and trace products from receipt of materials through distribution of resin to allow for effective product recalls and traceability.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain a system for tracing all resin. This system must ensure identification of the product to allow for proper stock rotation and effective recalls, lot withdrawals, and problem investigation. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
    a. Lots will be identified by container number.
3. Provide training to employees responsible for documenting lot/container information.
4. Suppliers must challenge the system for tracing resin by conducting a mock recall at least twice per year. All paperwork must be maintained and kept on file including BOLs, ship to locations or locations within the warehouse if product is still in possession of the warehouse.
5. Document all product recalls and withdrawals.
6. Notify Niagara Bottling Quality Assurance in the event of a product withdrawal or recall implicating product sold to Niagara Bottling. This notification must occur within twenty-four (24) hours of supplier determining the product should be recalled or withdrawn from the market, this pertains to resin suppliers that also store resin for Niagara.

PRODUCT QUALITY REQUIREMENTS

Control of Non-Conforming Resin

SECTION OVERVIEW
This section requires suppliers to develop and implement procedures outlining how non-conforming products are identified and controlled. The objective is to ensure that non-conforming products do not reach Niagara Bottling.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming products cannot be inadvertently used or shipped. Procedures shall include identification and segregation of non-conforming product, and determination of product disposition.

2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the product hold program. This shall include designation of employees responsible for placing product on hold and those determining disposition.
3. Any materials deemed non-conforming due to tampering or damage shall be received on hold.
4. Identify and document all process and product deviations from receiving, storing, and shipping of resin.

Appendix H – Resin Hauling

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GENERAL REQUIREMENTS

Product/Supplier Risk Factors

SECTION OVERVIEW
The following is designed to provide consistent method for resin delivery to the Niagara Bottling facilities. This policy applies to all resin containers, bulk storage tanks, storage, and deliveries to all facilities.

REQUIREMENTS

For the approval of each new hauler, a Questionnaire must be completed and sent to Supplier Quality for review and approval along with the list documents within the form. The tanker may not haul any resin until the written approval has been given by Supplier Quality

PRODUCT SAFETY REQUIREMENTS

Control of Hazards

SECTION OVERVIEW
This section requires resin haulers to control all hazards and potential food safety issues associated with the handling of resin.

REQUIREMENTS

Suppliers are required to:

1. Maintain a list of approved tankers hauling to Niagara Bottling. This list should include at minimum tanker number and VIN.
2. Declare procedure used to clean tankers on a regular basis. This process must be approved by Niagara Bottling. Tankers should be cleaned at least every 3 months.
3. If multiple grades of plastic resins are being handled, there must be a documented procedure in place that ensures mixing of different types of resin does not occur. Removal and cleaning of the filters is important in this process. All particles or pellets of the previous grade, must be removed including, coating on the walls, piping, filters, filter bags, valves and other equipment.
4. If any cleaning chemicals are used, they must be able to document chemicals used (detergent, degreaser and sanitizer) concentration, wash time and wash/rinse temperatures (according to manufacturer recommendation) for each step taken and this documentation must be available upon request.
5. Tankers must be dedicated to hauling only resin and must be clearly identified this way. No other product may be hauled in the tankers so long as they are servicing Niagara Bottling plants. If this must occur, the cleaning process must first be approved by Niagara Bottling Supplier Quality Department.

6. Tankers must be constructed and operated in a manner as to prevent contamination and to operate in compliance with applicable regulations.
7. When transferring resin, hoses should be supported off the ground during loading and unloading to avoid damage and prevent the introduction of contaminants. Hoses should be stored off the ground and capped when not in use. Any damaged hoses should be immediately removed from service. If potential contamination occurs, this must be reported to the warehouse and Niagara Bottling Supplier Quality. The tanker should not be offloaded until direction is given by Niagara Bottling Supplier Quality Department.
8. External openings on truck and rail cars should have filters in place that are capable of blocking any dust particles or insects. These filters must be monitored and cleaned as needed.
9. Seal tanker openings and hose compartments using tamper evident seals and this must be applied and documented by the warehouse team, the driver should verify this for accuracy.
10. When off-loading the resin, do not exceed 10 psi to help minimize “angel hairs”. A lower psi may be requested by the manufacturing plant and should be verified prior to any deliveries and be able to adjust as requested.
11. Use appropriate gasket and seal materials. All seals and gaskets will be appropriately sized, will be intact with no visible tears, breaks or rips and be capable of being cleaned and sanitized as needed. Any missing or damaged seals that may have resulted in contamination, must be reported to the Warehouse Management and Niagara Bottling Quality Department.
12. Have prerequisite programs implemented including employee training protocols.

Transportation

SECTION OVERVIEW
This section requires resin haulers to develop, implement, and maintain a system for ensuring resin is shipped in a manner that protects product safety and integrity, and meets minimum Code of Federal Regulations (CFR) requirements.

REQUIREMENTS

Haulers are required to:

1. Operate under GMP requirements as outlined in 21 CFR Part 110 and 21 CFR Part 117.
2. Develop, implement and maintain a transportation container inspection system that ensures transportation containers meet all regulatory requirements and maintain product integrity throughout product distribution.
3. Conduct container inspections upon receipt of materials and upon loading of resin.
    a. Inspections shall include actions taken for those containers not meeting requirements for ensuring product safety and integrity.
4. Ensure all incoming and outgoing loads have a tamper evident seal with a number that matches and is verified on BOL. The BOL should contain lot number, quantities and corresponding seal numbers.
5. Outgoing tanker inspection should be conducted and documented prior to loading as well as hose, seals and gaskets for wear and contamination. Inspections shall include at a minimum:
    a. Blow down of tanker to remove any foreign materials or potential contaminant.
    b. Inspection of all seals, gaskets, connections and hoses
6. Develop, implement and maintain a system to ensure the integrity of the resin and tanker throughout the entire process.

7. Provide documented training to employees responsible for hauling and transferring resin to the silos at the manufacturing plants.

Product Identification & Traceability

SECTION OVERVIEW
This section requires resin handling suppliers to have an effective system in place to identify and trace products from receipt of materials through distribution of resin to allow for effective product recalls and traceability.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain a system for tracing all resin deliveries. This system must ensure identification of the product to allow for effective recalls, lot withdrawals, and problem investigation. The system shall establish clear lines of authority and responsibility concerning handling of product withdrawals and recalls.
2. Document detailed lot information to ensure adequate traceability throughout the process, from receipt through final distribution.
3. Provide training to employees responsible for documenting or verifying lot information.

PRODUCT QUALITY REQUIREMENTS

Control of Non-Conforming Resin Deliveries and Out of Service Tankers

SECTION OVERVIEW
This section requires suppliers to develop and implement procedures outlining how non-conforming tankers are identified and controlled. This section also includes the documentation required for any haulers that deliver non-conforming resin to Niagara Bottling. The objective is to ensure that non-conforming tankers are not placed in rotation for delivering resin to Niagara Bottling and that non-conforming resin deliveries are documented and prevented.

REQUIREMENTS

Suppliers are required to:

1. Develop, implement, and maintain documented procedures and instructions to ensure nonconforming tankers and resin, cannot be inadvertently used. Procedures shall include identification and segregation of non-conforming tankers and resin.
2. Create a Standard Operating Procedure that clearly defines and documents the responsibilities and authorities of employees managing the tanker and resin hold program. This shall include designation of employees responsible for placing tankers and resin on hold and those determining disposition.
3. Identify and document all process and product deviations from receiving through shipping of resin.

Appendix I – Destruction Facility

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GENERAL REQUIREMENTS

Supplier Risk Factors

SECTION OVERVIEW
The following is designed to provide a consistent method for unsellable finished good destruction, its transportation/ transfer, destruction, and appropriate/corresponding disposal. This policy applies to all offsite destruction service suppliers and/or facilities to set a clear understanding between the parties and to ensure Niagara Bottling products that require destruction are not used for their original intended purpose.

This Appendix is not intended for scrap removal or recycling companies.

REQUIREMENTS

1. Business license or valid registration with local authority.
2. Documentation of assured product destruction (Certificate of Destruction).

PRODUCT SAFETY AND SECURITY REQUIREMENTS

Product Security

SECTION OVERVIEW
This section requires destruction service suppliers and facilities to have an effective control system to prevent any threats to the unsellable finished goods stored at the facility. Additionally, this section requires destruction service suppliers to assure product destruction for incoming unusable products.

REQUIREMENTS

Suppliers are expected to:

1. Document the procedure(s) used to:
    a. Transport
    b. Handle
    c. Store
    d. Destroy
    e. Dispose, and/or Recycle
2. Ensure all incoming and outgoing loads have a secure trailer seal with a number that matches and is verified on BOL.
    a. If the seal is missing or the seal does not match the paperwork the trailer must be rejected or placed on hold in a secured location until the plant is contacted for further instructions.
3. The BOL should contain:
    a. Date Shipped

   b. BOL Number
   c. Hauling Company
   d. Trailer Number
   e. Shipping to/from Addresses
   f. Product Description
   g. Lot Number
   h. Quantities
   i. Seal Number
   j. Driver Signature
   k. Facility Checkout Information
4. If any information is missing on the BOL the seal should not be broken and the trailer should not be unloaded, please contact the Niagara Bottling manufacturing plant to obtain the information before proceeding.
5. A Destruction Verification Form (NIA-305-09-0014) should be sent with each destruction load.
6. If destroying ingredients, SDS should be sent with the load.
7. All dock doors and facility access points should be monitored and controlled to ensure products are not removed from the premises.
8. Inform and control that employees do not consume, take, or resell products that should be destroyed.
9. Provide a Certificate of Destruction for each load destroyed, as well as proof of destruction, including photos (if requested) of product being destroyed.
   a. If the product can not be destroyed within 24 hours, a letter should be provided stating the product is in a secure location until it can be destroyed.

Referenced Documents

NIA-305-09-0014 Destruction Verification Form

Appendix J – Print Quality Management
GENERAL REQUIREMENTS

Product/Supplier Risk Factors

SECTION OVERVIEW

The purpose of this document is to define expectations of print quality for all flexible packaging suppliers. The goal of the print quality management program is consistent print quality across the packaging supply chain, regardless of substrate, print process, or any other variables in the creation of printed packaging. Compliance with all program requirements is mandatory and each supplier will be scored on adherence to the Print Quality Management program by the Supplier Quality team on a quarterly basis.

Referenced Documents

MM00175 Print Quality Management